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

Joseph E. Kernan
Governor

Lori F. Kaplan
Commissioner

100 North Senate Avenue
P.O. Box 6015
Indianapolis, Indiana 46206-6015
(317) 232-8603
(800) 451-6027
www.IN.gov/idem

PART 70 OPERATING PERMIT
AND
PREVENTION OF SIGNIFICANT DETERIORATION (PSD) FLEXIBLE PERMIT
OFFICE OF AIR QUALITY

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

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

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

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

Operation Permit No.: T157-6879-00006	
Issued by: Original signed by Janet G. McCabe, Assistant Commissioner Office of Air Quality	Issuance Date: February 27, 2004 Expiration Date: February 27, 2009

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.

Responsible Official:	Mr. Lawrence J. McShane, General Manager
Source Address:	1650 Lilly Road, Lafayette, Indiana, 47909
Mailing Address:	1650 Lilly Road, Lafayette, Indiana, 47909
Source Phone Number:	(765) 477-4226
SIC Code:	2833, 2879
County Location:	Tippecanoe County
Source Location Status:	Attainment for all criteria pollutants
Source Status:	Part 70 Permit Program; Major Source under PSD; 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.1 Utilities Operations: The utilities operations consist of three coal-fired boilers 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. The detailed equipment list is located in Section D.1 of this permit.

(b) D.2 Utilities Support Operations: 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 detailed equipment list is located in Section D.2 of this permit.

(c) D.3 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, T2B, T2C) and product storage area (T63). The detailed equipment list is located in Section D.3 of this permit.

(d) D.4 Fermented Products - Purification Operations: 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, T40, and T94), solvent recovery (T4), raw and recovered material storage (T147), and product storage (T39). The detailed equipment list is located in Section D.4 of this permit.

(e) D.5 Fermented Products - Support Operations: The support operations for the Fermented Products (FP) area consist of the FP wastewater treatment plant and FP wastewater sludge storage operations. The detailed equipment list is located in Section D.5 of this permit.

(f) 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.

(g) 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.

(h) 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.

(i) 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.

(j) 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.

(k) 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/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/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.

(l) 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.

(m) D.13 BPM Control Systems – T149 Solids-Liquid Waste Incinerator: The T149 solids-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 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.

(n) 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.

(o) D.15 BPM Control Systems – T79 Fume Incinerator 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.

(p) D.18 BPM – Chemical Wastewater Treatment Plant: The wastewater generated from the BPM operations is collected in wastewater holding tanks, transferred through a clarification process, followed by the biological treatment facility. The detailed equipment list is located in Section D.18 of this permit.

A.3 Insignificant Activities [326 IAC 2-7-1(21)] [326 IAC 2-7-4(c)] [326 IAC 2-7-5(15)]

(a) This stationary source consists of the following insignificant activities, which are specifically regulated, as defined in 326 IAC 2-7-1(21):

(1) D.3 Fermented Products - Fermentation Operations: Various mixers, bump tanks and fermenter tanks in the fermentation operations each emitting less than 5 pounds PM10 per hour or 25 pounds PM10 per day. [326 IAC 6-3]

(2) D.8 BPM Individual Drain Systems (IDSs): Individual drain systems (sumps) in the BPM operating areas each emitting less than less than 3 pounds VOC per hour or 15 pounds VOC per day. [40 CFR 63.1256(e), 40 CFR 63.689(b), and 326 IAC 2-2]

(3) D.10 BPM Support – Waste Storage Tank Operations: Various BPM waste tanks and knock out pots in the BPM operating areas each emitting less than 3 pounds VOC per hour or 15 pounds VOC per day. [40 CFR 63.1256(b), 40 CFR 63.685, 40 CFR 60.110b, 326 IAC 2-2, and 326 IAC 8-5-3]

(4) D.11 BPM Waste Containers: Small and large waste containers in the BPM operating areas each emitting less than less than 3 pounds VOC per hour or 15 pounds VOC per day. [40 CFR 63.1256(d), 40 CFR 63.688, 326 IAC 2-2]

(5) D.6 BPM Production Operations: Heat exchange systems in the BPM operating areas are classified as insignificant activities under the closed loop heating and cooling system clause pursuant to 326 IAC 2-7-1(21)(FF). [40 CFR 63.1252(c)]

(6) D.16 Research and Development Operations: The T71 equipment components from process piping systems, including pumps, valves, and piping connections [flanges] are classified as insignificant activities under the research and development facility clause pursuant to 326 IAC 2-7-1(21)(E). [40 CFR 63.1255 and 40 CFR 61, Subpart V]

(b) This stationary source consists of the following types of insignificant activities, as defined in 326 IAC 2-7-1 (21), that do not have applicable requirements:

(1) Natural gas-fired combustion sources with heat input equal to or less than 10 MMBtu per hour;

(2) Propane or liquefied petroleum gas, or butane-fired combustion sources with heat input equal to or less than 6 MMBtu per hour;

(3) Equipment powered by internal combustion engines of capacity equal to or less than 0.5 MMBtu per hour, except where total capacity of equipment operated by one stationary source exceeds 2 MMBtu per hour;

(4) A gasoline fuel transfer and dispensing operation handling less than or equal to 1300 gallons per day, such as filling of tanks, locomotives, automobiles, having a storage capacity less than or equal to 10,500 gallons;

(5) 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;

(6) VOC/HAP storage tanks with capacity less than or equal to 1,000 gallons and annual throughputs less than 12,000 gallons;

(7) VOC/HAP vessels storing lubricating oils, hydraulic oils, machining oils, and machining fluids;

(8) Refractory storage not requiring air pollution control equipment;

(9) Machining where an aqueous cutting coolant continuously floods the machining interface;

(10) Degreasing operations that do not exceed 145 gallons of solvent usage per 12 months, except if subject to 326 IAC 20-6;

(11) Cleaners and solvents having a vapor pressure equal to or less than 2kPa measured at 38°C or having a vapor pressure equal to or less than 0.7kPa measured at 20°C and not exceeding a combined usage rate of 145 gallons per 12 months;

(12) Closed loop heating and cooling systems; [See Section D.2]

(13) Structural or fabrication cutting 200,000 linear feet or less of one inch plate or equivalent or using 80 tons or less of welding consumables;

(14) Activities associated with the treatment of wastewater streams with an oil and grease content less than or equal to 1% by volume;

(15) 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;

(16) Any operation using aqueous solutions containing less than 1% by weight of VOCs excluding HAPs;

(17) Forced and induced draft noncontact cooling tower systems not regulated under a NESHAP;

(18) Replacement or repair of electrostatic precipitators, bags in baghouses and filters in other air filtration equipment;

(19) Heat exchanger cleaning and repair;

(20) Process vessel degassing and cleaning to prepare for internal repairs;

(21) Stockpiled soils from soil remediation activities that are covered and waiting transport for disposal;

(22) Paved and unpaved roads and parking lots with public access;

(23) Covered conveyors for coal or coke conveying of less than or equal to 360 tons per day; [See Section D.1]

(24) Coal bunker and coal scale exhausts and associated dust collector vents;

(25) Asbestos abatement projects regulated by 326 IAC 14-10;

(26) 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;

(27) 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;

(28) Blowdown from sight glasses; boilers; compressors; pumps; and cooling towers;

(29) On-site fire and emergency response training approved by the department;

(30) Gasoline emergency generators not exceeding 110 horsepower;

(31) Diesel emergency generators not exceeding 1600 horsepower; [See Section D.2]

(32) Natural gas emergency turbines or reciprocating engines not exceeding 16,000 horsepower;

(33) Other emergency equipment such as stationary fire pumps; [See Section D.2]

(34) 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 deburring,

buffing, polishing, abrasive blasting, pneumatic conveying, and woodworking operations;

(35) Purge double block and bleed valves;

(36) Filter or coalescer media changeout;

(37) Vents from ash transport systems not operated at positive pressures;

(38) A laboratory as defined in 326 IAC 2-7-1(21)(D);

(39) Research and development facility as defined in 326 AIC 2-7-1(E); [See Section D.21]

(40) Farm operations; and

(41) Other activities below insignificant threshold levels:

(A) Portable cleaning and collection tanks less than 3 pounds VOC per hour or 15 pounds VOC per day;

(B) T4 sulfuric acid tank less than 5 pounds PM10 per day or 25 pounds PM10 per day;

(C) T47 trash transfer less than 5 pounds PM10 per day or 25 pounds PM10 per day;

(D) Sump tanks less than 3 pounds VOC per hour or 15 pounds VOC per day;

(E) T116 hydrochloric acid tank less than 5 pounds single HAP per day or 1 ton single HAP per year;

(F) T14 Ranney Well less than 5 pounds single HAP per day or 1 ton single HAP per year;

(G) T99 ethylene glycol expansion tanks/system less than 12.5 pounds combined HAP per day or 2.5 tons combined HAP per year;

(H) T100 MACE tanks/system less than 12.5 pounds per day or 2.5 tons combined HAP per year;

(I) T100 Unit 1 drumming operations less than 5 pounds PM10 per day or 25 pounds PM10 per day;

(J) T99/T100 solids particle sizing equipment (mills and delumpers) less than 5 pounds PM10 per day or 25 pounds PM10 per day; and

(K) Various fermentation and purification operations less than 3 pounds VOC per hour or 15 pounds VOC per day, less than 12.5 pounds per day or 2.5 tons combined HAP per year; and less than 5 pounds PM10 per day or 25 pounds PM10 per day. [See Section D.3 and D.4]

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); and

(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]

This permit 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.

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 the "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.

(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. The initial certification shall cover the time period from the date of final permit issuance through December 31 of the same year. All subsequent certifications shall cover the time period from January 1 to December 31 of the previous year, and shall be submitted in letter form no later than July 1 of each year to:

Indiana Department of Environmental Management
Compliance Branch, Office of Air Quality
100 North Senate Avenue, P. O. Box 6015
Indianapolis, Indiana 46206-6015

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 the "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 prepare and maintain Preventive Maintenance Plans (PMPs) within ninety (90) days after issuance of this permit, 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.

If, due to circumstances beyond the Permittee's control, the PMPs cannot be prepared and maintained within the above timeframe, the Permittee may extend the date an additional ninety (90) days provided the Permittee notifies:

Indiana Department of Environmental Management
Compliance Branch, Office of Air Quality
100 North Senate Avenue, P. O. Box 6015
Indianapolis, Indiana 46206-6015

The PMP extension notification does not require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

(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 PMP does not require the certification by the "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 and, otherwise, such Plan is deemed to satisfy the applicable PMP requirements 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: 317-233-5674 (ask for Compliance Section)
Facsimile Number: 317-233-5967

(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 Branch, Office of Air Quality
100 North Senate Avenue, P. O. Box 6015
Indianapolis, Indiana 46206-6015

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 the “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) 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 determinations set forth in Sections D of this permit, the IDEM, OAQ has made the following determination regarding this source:

(1) **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)]

(2) **40 CFR 60, Subpart Db – Industrial-Commercial-Institutional steam generating units:** This source is not subject to 40 CFR Part 60, Subpart Db because none of the boilers at plant site were constructed, reconstructed, or modified after June 19, 1984. [40 CFR 60.40b(a)]

(3) **40 CFR 60, Subpart Dc – Industrial-Commercial-Institutional steam generating units:** This source is not subject to 40 CFR Part 60, Subpart Dc because none of the boilers at plant site were constructed, reconstructed, or modified after June 9, 1989. [40 CFR 60.40c(a)]

(4) **40 CFR 60, Subpart E – Incinerators:** This source is not subject to 40 CFR Part 60, Subpart E because none of the incinerators at plant site exceed a charging rate of 50 metric tons per day. [40 CFR 60.50(a)]

(5) **40 CFR 60, Subparts Ec and CCCC – Hospital/Medical/Infectious waste incinerators and Commercial-Industrial solid waste incinerators:** 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)]

(6) **40 CFR 60, Subparts VV, 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], 40 CFR 60.617 [Subpart III], 40 CFR 60.667 [Subpart NNN], or 40 CFR 60.707 [Subpart RRR].

(7) **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)]

(8) **40 CFR 61, Subpart C – 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)]

(9) **40 CFR 61, Subpart E – 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.

(10) **40 CFR 61, Subpart FF – 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.

(11) **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)]

(12) **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]

(13) **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]

(14) **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]

(15) **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]

(16) **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]

(17) **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.

(18) **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.

(19) **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.

(20) **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.

(21) **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.

(22) **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.

(23) **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.

(24) **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.

(25) **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.

(26) **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]

(a) Terms and conditions of previous permits issued pursuant to permitting programs approved into the state implementation plan have been either

(1) incorporated as originally stated,

(2) revised, or

(3) deleted

by this permit.

(b) All previous registrations and permits are superseded by this 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, P.O. Box 6015
Indianapolis, Indiana 46206-6015

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 the “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 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 the “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 2-7-4]

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

Request for renewal shall be submitted to:

Indiana Department of Environmental Management
Permits Branch, Office of Air Quality
100 North Senate Avenue, P.O. Box 6015
Indianapolis, Indiana 46206-6015

(b) Timely Submittal of Permit Renewal [326 IAC 2-7-4(a)(1)(D)]

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

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

(B) 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.

(2) If IDEM, OAQ, upon receiving a timely and complete 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.

(c) Right to Operate After Application for Renewal [326 IAC 2-7-3]
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.

(d) United States Environmental Protection Agency Authority [326 IAC 2-7-8(e)]
If IDEM, OAQ, fails to act in a timely way on a Part 70 permit renewal, the U.S. EPA may invoke its authority under Section 505(e) of the Clean Air Act to terminate or revoke and reissue a Part 70 permit.

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

(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 Branch, Office of Air Quality
100 North Senate Avenue, P.O. Box 6015

Indianapolis, Indiana 46206-6015

Any such application shall be certified by the "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 have been obtained;

(3) The changes do not result in emissions which exceed the emissions allowable under 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 Branch, Office of Air Quality
100 North Senate Avenue, P. O. Box 6015
Indianapolis, Indiana 46206-6015

and

United States Environmental Protection Agency, Region V
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 which document, on a rolling five (5) year basis, all such changes and emissions trading that are subject to 326 IAC 2-7-20(b), (c), or (e) and makes 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 the “responsible official” as defined by 326 IAC 2-7-1(34).

(c) Emission Trades [326 IAC 2-7-20(c)]
The Permittee may trade increases and decreases in emissions in 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.

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, 326 IAC 2-7-10.5.

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 Branch, Office of Air Quality
100 North Senate Avenue, P.O. Box 6015
Indianapolis, Indiana 46206-6015

The application which shall be submitted by the Permittee does require the certification by the "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, I/M & Billing 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.

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 [40 CFR 52 Subpart P][326 IAC 6-3-2]

(a) Pursuant to 40 CFR 52 Subpart P, particulate matter emissions from any manufacturing process not already regulated by 326 IAC 6-1 or any New Source Performance Standard, and which has a maximum process weight rate less than 100 pounds per hour shall not exceed 0.551 pounds per hour.

(b) 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. This condition becomes federally enforceable upon approval by EPA of 326 IAC 6-3-2 as part of the federally approved State Implementation Plan (SIP); until then, this term is only state-enforceable.

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. 326 IAC 4-1-3 (a)(2)(A) and (B) are not federally enforceable.

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 Operation of Equipment [326 IAC 2-7-6(6)]

Except as otherwise provided by statute or rule, or in this permit, all air pollution control equipment listed in this permit and used to comply with an applicable requirement shall be operated at all times that the emission units vented to the control equipment is in operation.

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 1-7-2, 326 IAC 1-7-3(c) and (d), 326 IAC 1-7-4(d), (e), and (f), and 326 IAC 1-7-5(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, P. O. Box 6015
Indianapolis, Indiana 46206-6015

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

(c) 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 source 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 [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)] [326 IAC 3-5]

(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 Branch, Office of Air Quality
100 North Senate Avenue, P. O. Box 6015
Indianapolis, Indiana 46206-6015

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 the “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 supercedes the monitoring provisions in 40 CFR Part 60 or 40 CFR Part 63.

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 Branch, Office of Air Quality
100 North Senate Avenue, P. O. Box 6015
Indianapolis, Indiana 46206-6015

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 the “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 supercedes the monitoring provisions in 40 CFR Part 60 or 40 CFR Part 63.

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

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

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

(a) The Permittee prepared and submitted written emergency reduction plans (ERPs) consistent with safe operating procedures on December 13, 2000.

(b) Upon direct notification by IDEM, OAQ, that a specific air pollution episode level is in effect, the Permittee shall immediately put into effect the actions stipulated in the approved ERP for the appropriate episode level. [326 IAC 1-5-3]

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

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

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

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

(1) Reasonable response steps that may be implemented in the event that a response step is needed pursuant to the requirements of Section D of this permit; and an expected timeframe for taking reasonable response steps.

(2) If, at any time, the Permittee takes reasonable response steps that are not set forth in the Permittee's current Compliance Response Plan or Operation, Maintenance and Monitoring (OMM) Plan (or Parametric Monitoring Plan and Start-up, Shutdown, and Malfunction (SSM) Plan) and the Permittee documents such response in accordance with subsection (e) below, the Permittee shall amend its Compliance Response Plan or Operation, Maintenance and Monitoring (OMM) Plan (or Parametric Monitoring Plan and Start-up, Shutdown, and Malfunction (SSM) Plan) to include such response steps taken.

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

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

(1) Reasonable response steps shall be taken as set forth in the Permittee's current Compliance Response Plan or Operation, Maintenance and Monitoring (OMM) Plan (or Parametric Monitoring Plan and Start-up, Shutdown, and Malfunction (SSM) Plan); or

(2) If none of the reasonable response steps listed in the Compliance Response Plan or Operation, Maintenance and Monitoring (OMM) Plan (or Parametric Monitoring Plan and Start-up, Shutdown, and Malfunction (SSM) Plan) is applicable or responsive to the excursion, the Permittee shall devise and implement additional response steps as expeditiously as practical. Taking such additional response steps shall not be considered a deviation from this permit so long as the Permittee documents such response steps in accordance with this condition.

(3) If the Permittee determines that additional response steps would necessitate that the emissions unit or control device be shut down, and it will be ten (10) days or more until the unit or device will be shut down, then the Permittee shall promptly notify the IDEM, OAQ of the expected date of the shut down. The notification shall also include the status of the applicable compliance monitoring parameter with respect to normal, and the results of the response actions taken up to the time of notification.

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

(c) The Permittee is not required to take any further response steps for any of the following reasons:

(1) A false reading occurs due to the malfunction of the monitoring equipment and prompt action was taken to correct the monitoring equipment.

(2) The Permittee has determined that the monitoring parameters established in the permit conditions are technically inappropriate, has previously submitted a request for a minor permit modification to the permit, and such request has not been denied.

(3) An automatic measurement was taken when the process was not operating.

(4) The process has already returned or is returning to operating within "normal" parameters and no response steps are required.

(d) When implementing reasonable steps in response to a monitoring condition, if the Permittee determines that an exceedance of an emission limitation has occurred, the Permittee shall report such deviations pursuant to Section B-Deviations from Permit Requirements and Conditions.

(e) The Permittee shall record all instances when, in accordance with Section D, response steps are taken. In the event of an emergency, the provisions of 326 IAC 2-7-16 (Emergency Provisions) requiring prompt corrective action to mitigate emissions shall prevail.

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 and 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 the "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) The Permittee shall submit an annual emission statement certified pursuant to the requirements of 326 IAC 2-6, that must be received by July 1 of each year and must comply with the minimum requirements specified in 326 IAC 2-6-4. The annual emission statement shall meet the following requirements:

(1) Indicate estimated actual emissions of criteria pollutants from the source, in compliance with 326 IAC 2-6 (Emission Reporting);

(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 purposes of Part 70 fee assessment.

(b) The annual emission statement covers the twelve (12) consecutive month time period starting January 1 and ending December 31. The annual emission statement must be submitted to:

Indiana Department of Environmental Management
Technical Support and Modeling Section, Office of Air Quality
100 North Senate Avenue, P. O. Box 6015
Indianapolis, Indiana 46206-6015

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

(c) The annual 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]

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

(a) The source 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 the "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, P. O. Box 6015
Indianapolis, Indiana 46206-6015

(c) Unless otherwise specified in this permit, any notice, report, or other submission required by this permit shall be considered timely if the date postmarked on the envelope or certified mail receipt, or affixed by the shipper on the private shipping receipt, is on or before the date it is due. If the document is submitted by any other means, it shall be considered timely if received by IDEM, OAQ, on or before the date it is due.

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

(e) The first report shall cover the period commencing on the date of issuance of this permit and ending on the last day of the reporting period. Reporting periods are based on calendar years.

Stratospheric Ozone Protection

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

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

Part 2 MACT Application Submittal Requirement

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

(a) The Permittee shall submit a Part 2 MACT Application in accordance with 40 CFR 63.52(e)(1). The Part 2 MACT Application shall meet the requirements of 40 CFR 63.53(b).

(b) Notwithstanding paragraph (a), the Permittee is not required to submit a Part 2 MACT Application if the Permittee no longer meets the applicability criteria of 40 CFR 63.50 by the application deadline in 40 CFR 63.52(e)(1). For example, the Permittee would not have to submit a Part 2 MACT Application if, by the application deadline:

(1) The source is no longer a major source of hazardous air pollutants, as defined in 40 CFR 63.2;

(2) The source no longer includes one or more units in an affected source category for which the U.S. EPA failed to promulgate an emission standard by May 15, 2002; or

(3) The MACT standard or standards for the affected source categories included at the source are promulgated.

(c) Notwithstanding paragraph (a), pursuant to 40 CFR 63.56(a), the Permittee shall comply with an applicable promulgated MACT standard in accordance with the schedule provided in the MACT standard if the MACT standard is promulgated prior to the Part 2 MACT Application deadline or prior to the issuance of permit with a case-by-case Section 112(j) MACT determination. The MACT requirements include the applicable General Provisions requirements of 40 CFR 63, Subpart A. Pursuant to 40 CFR 63.9(b), the Permittee shall submit an initial notification not later than 120 days after the effective date of the MACT, unless the MACT specifies otherwise. The initial notification shall be submitted to:

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

and

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

SECTION D.1 UTILITIES OPERATION CONDITIONS

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

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

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

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	UOM	Control Device
Building T6:					
BLR001	Coal Boiler	S-T6-BLR001	92	MMBtu/hr	Multiclone001
BLR002	Coal Boiler	S-T6-BLR002	92	MMBtu/hr	Multiclone002
BLR003	Coal Boiler	S-T6-BLR003	92	MMBtu/hr	Multiclone003
BLR004	Natural Gas/Fuel Oil Boiler	S-T6-BLR004	142	MMBtu/hr	None
BLR005	Natural Gas/Fuel Oil Boiler	S-T6-BLR005	97	MMBtu/hr	None
CONASH	Ash Handling System	PV-T6-CONASH	1805	lbs/hr	Baghouse

(b) The following emission units are not subject to applicable requirements described in this D section and are listed only for informational purposes:

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	UOM	Control Device
Outside Building T6:					
OILTK001*	Fuel Oil Storage Tank	PV-T6-OILTK001	250,000	gallons	None
COAL	Coal Pile	N/A	N/A	N/A	N/A
CNV001-CNV005	Covered Coal Conveyor System	N/A	N/A	N/A	N/A

* Emission units marked with a single asterisk are insignificant activities as defined in 326 IAC 2-7-1(21). Specifically, the fuel oil storage tank is an insignificant activity pursuant to 326 IAC 2-7-1(21)(A)-(C).

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

D.1.1 Particulate Matter (PM) Limitations [326 IAC 6-2-3, 326 IAC 6-3, and PC (79) 1510 Issued March 22, 1982 (Revised by this permit)]

(a) Pursuant to 326 IAC 6-2-3(b) (Particulate Matter Emission Limitations for Sources of Indirect Heating), 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.

(b) Pursuant to 326 IAC 6-2-3(c) (Particulate Matter Emission Limitations for Sources of Indirect Heating), particulate emissions from Boiler 4 shall not exceed 0.39 pounds per MMBtu heat input.

(c) Pursuant to 326 IAC 6-2-3(c) (Particulate Matter Emission Limitations for Sources of Indirect Heating), particulate emissions from Boiler 5 shall not exceed 0.31 pounds per MMBtu heat input.

(d) Pursuant to 326 IAC 6-3-2 and 40 CFR 52 Subpart P, particulate matter emissions from the ash handling system shall not exceed 3.83 pounds per hour based on a maximum throughput of 0.902 tons of ash per hour.

D.1.2 Sulfur Dioxide (SO_2) Limitations [326 IAC 2-2, 326 IAC 7-1.1-2, and PC (79) 1510 Issued March 22, 1982 (Revised by this permit)]

(a) Pursuant to 326 IAC 7-1.1-2 (Sulfur Dioxide Emission Limitations), the SO_2 emissions from each of the coal-fired boilers (Boilers 1, 2 and 3) shall not exceed 6.0 pounds per MMBtu heat input.

(b) Pursuant to 326 IAC 7-1.1-2 (Sulfur Dioxide Emission Limitations), the SO_2 emissions from Boiler 4 shall be limited to 0.5 pounds per MMBtu heat input, when burning No. 2 fuel oil. Pursuant to 326 IAC 7-2-1, compliance with this standard is based on a calendar month average. This emission limit correlates to a maximum fuel oil sulfur content of 0.49 percent by weight.

(c) Pursuant to 326 IAC 7-1.1-2 (Sulfur Dioxide Emission Limitations), the SO2 emissions from Boiler 5 shall not exceed 0.5 pounds per MMBtu heat input, when burning No. 2 fuel oil. This emission limit correlates to a maximum fuel oil sulfur content of 0.49 percent by weight.

(d) The SO_2 emissions from Boiler 5 shall not equal or exceed 40 tons per year to avoid the requirements of 326 IAC 2-2 (Prevention of Significant Deterioration). This emission limit correlates to a maximum fuel oil usage of 1,120,000 gallons per 12 consecutive month period based on a maximum sulfur content of 0.49 percent.

D.1.3 Nitrogen Oxides (NO_x) Limitations [326 IAC 2-2] [PC (79) 1510 Issued March 22, 1982 (Revised by this permit)]

The NOx emissions from Boiler 5 shall not equal or exceed 40 tons per year to avoid the requirements of 326 IAC 2-2 (Prevention of Significant Deterioration). This emission limit correlates to a maximum natural gas usage of 780 MMCF per 12 consecutive month period. To account for fuel oil usage, the following equivalency shall be used:

1 MMCF of Natural Gas = 5000 gallons of Fuel Oil

D.1.4 Temporary Alternative Opacity Limitations [326 IAC 5-1-3]

Pursuant to 326 IAC 5-1-3 (Temporary Alternative Opacity Limitations), the following conditions apply as an alternative to the opacity limitations in Section C – Opacity:

(a) When building a new fire in a boiler, or shutting down a boiler, opacity may exceed the applicable limit established in 326 IAC 5-1-2 and stated in Section C - Opacity. 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.

(b) When removing ashes from the fuel bed or furnace in a boiler or blowing tubes, opacity may exceed the applicable limit established in 326 IAC 5-1-2 and stated in Section C - Opacity. However, opacity levels shall not exceed sixty percent (60%) for any six (6)-minute averaging period and opacity in excess of the applicable limit shall not continue for more than one (1) six (6)-minute averaging periods in any sixty (60) minute period. The averaging periods shall not be permitted for more than three (3) six (6)-minute averaging periods in a twelve (12) hour period.

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

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

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

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

(a) The Permittee shall perform particulate matter performance tests for Boilers 1, 2 and 3 utilizing Methods 5 or 17 (40 CFR 60, Appendix A) for PM or other methods as approved by the Commissioner. These tests shall be repeated every third calendar year from the calendar year of the most recently completed compliance stack test. Tests shall be conducted in accordance with Section C – Performance Testing.

(b) No emissions testing is required for the boilers for compliance with particulate matter for boilers 4, and 5, or sulfur dioxide or nitrogen oxides emission limits established in Conditions D.1.1, D.1.2 and D.1.3, respectively, at this time. However, IDEM may require performance testing when necessary to determine compliance. Any testing shall be conducted in accordance with Section C – Performance Testing.

D.1.7 Coal Sampling and Analysis for SO_2 [326 IAC 3-7 and 326 IAC 7-2]

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

(a) Coal sampling and analysis shall be performed using one of the following procedures:

(1) Sampling and analyzing the coal according to the Permittee's Coal Sampling and Assay Plan, submitted pursuant to 326 IAC 3-7-5(a). The following minimum sampling and analysis requirements shall be met:

(A) The coal sample acquisition point shall be at a location where representative samples of the total coal flow to be combusted by the facility or facilities may be obtained. A single as-bunkered or as-burned sampling station may be used to represent the coal to be combusted by multiple facilities using the same stockpile feed system;

(B) Coal shall be sampled at least two (2) times per day and at least one (1) time per twelve (12) hour period unless no coal is bunkered during the preceding twelve (12) hour period. This permit condition satisfies the requirements of 326 IAC 3-7-2(b)(3)(B);

(C) Minimum sample size shall be five hundred (500) grams;

(D) Samples shall be composited and analyzed at the end of each calendar month;

(E) Preparation of the coal sample, heat content analysis, and sulfur content analysis shall be determined pursuant to 326 IAC 3-7-2(c), (d), (e); or

(2) Sample and analyze the coal pursuant to 326 IAC 3-7-2(b).

(b) Upon written notification to IDEM by a facility owner or operator, continuous emission monitoring data collected and reported pursuant to 326 IAC 3-5-1 may be used as the means for determining compliance with the emission limitations in 326 IAC 7-1.1-2. Upon such notification, the other requirements of 326 IAC 7-2 shall not apply. [326 IAC 7-2-1(g)]

D.1.8 Fuel Oil Sampling and Analysis for SO_2 [326 IAC 7-2]

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

(a) Provide vendor analysis of quantity, heat content and sulfur content of fuel delivered, if accompanied by a certification;

(b) Analyze the oil sample to determine the sulfur content of the oil via the procedures in 326 IAC 3-7-4.

(1) Oil samples may be collected from the fuel tank immediately after the fuel tank is filled and before any oil is combusted; and

(2) If a partially empty fuel tank is refilled, a new sample and analysis would be required upon filling; or

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

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

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

D.1.10 Control Equipment Operation

(a) The Permittee shall operate the baghouse at all times the ash handling system is in operation.

(b) The Permittee shall operate the multiclones at all times its associated coal-fired boiler is in operation.

D.1.11 Visible Emission Notations

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

(b) For processes operated continuously, “normal” means those conditions prevailing, or expected to prevail, eighty percent (80%) of the time the process is in operation, not counting startup or shutdown time.

(c) In the case of batch or discontinuous operations, readings shall be taken during that part of the operation that would normally be expected to cause the greatest emissions.

(d) A trained employee is an employee who has worked at the plant at least one (1) month and has been trained in the appearance and characteristics of normal visible emissions for that specific process.

(e) The Compliance Response Plan for the boilers shall contain troubleshooting contingency and response steps for when an abnormal emission is observed.

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

D.1.12 Coal Characteristics and Consumption Records

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

(a) The amount (expressed in tons) of coal burned;

(b) The average sulfur content (expressed in percentage) of coal burned;

(c) The average heat content (expressed in Btu per pound) of the coal burned; and

(d) The average sulfur dioxide emission rate (expressed in pounds per MMBtu).

D.1.13 Fuel Oil Characteristics and Consumption Records

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

(a) The amount (expressed in thousands of gallons (Mgal)) of No. 2 fuel oil burned in Boilers 4 and 5;

(b) The average sulfur content (expressed in percentage by weight) of the No. 2 fuel oil burned in Boilers 4 and 5;

(c) The average higher heating value (expressed in Btu per gallon) of the No. 2 fuel oil burned in Boilers 4 and 5; and

(d) The average sulfur dioxide emission rate (expressed in pounds per MMBtu) of the No. 2 fuel oil for Boilers 4 and 5.

D.1.14 Natural Gas Consumption Records

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

D.1.15 Standard Operating Procedures

Pursuant to 326 IAC 3-7-5(a), the Permittee shall maintain and implement a standard operating procedure (SOP) for coal sampling, handling, analysis, quality control, quality assurance, and data reporting of the information collected pursuant to 326 IAC 3-7-2. In addition, any revision to the SOP shall be submitted to IDEM, OAM.

D.1.16 Visible Emissions Notations

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

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

D.1.17 Recordkeeping Requirement

All records shall be maintained in accordance with Section C - General Recordkeeping Requirements, of this permit.

D.1.18 Reporting Requirements

(a) The Permittee shall submit quarterly summary reports of the monthly coal characteristic and consumption records required by Condition D.1.12 for Boilers 1, 2 and 3.

(b) The Permittee shall submit quarterly summary reports of the monthly fuel oil characteristic and consumption records required by Condition D.1.13 for Boilers 4 and 5.

(c) The Permittee shall submit quarterly summary reports of the monthly natural gas and fuel oil consumption records required by Condition D.1.14 for Boiler 5.

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

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

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

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

SECTION D.2 UTILITIES SUPPORT OPERATION CONDITIONS

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

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

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

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	UOM	Control Device
Building T6:					
T121	Diesel Generator	N/A	1250	KW	None

(b) The following emission units are not subject to applicable requirements described in this D section and are listed only for informational purposes:

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	UOM	Control Device
Building T5:					
T5*	Diesel Generator	N/A	380	HP	None
Portable Units:					
T62*	Diesel Generator	N/A	1100	KW	None
T135*	Diesel Generator	N/A	390	HP	None
T78*	Diesel Compressor	N/A	58	KW	None
T89-1*	Diesel Compressor	N/A	58	KW	None
T89-2*	Diesel Compressor	N/A	58	KW	None
Building T97/T98:					
T97/T98*	Glycol System	N/A	45,000	gallon	None
Building T9/T23:					
T9/T23*	Lime Storage Silo	N/A	79.5	lb/hr	None

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

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

D.2.1 Nitrogen Oxide (NOx) Emission Limitations [326 IAC 2-2 and CP 157-3319 Issued February 21, 1995]

Generator T121 shall not exceed 900 hours of operation per 12 consecutive month period rolled on a monthly basis. This operational limitation limits NOx emissions to less than 40 tons per year; therefore, the Prevention of Significant Deterioration (PSD) rules pursuant to 326 IAC 2-2 does not apply.

D.2.2 Preventive Maintenance Plan [326 IAC 2-7-5(13)]

A Preventive Maintenance Plan, in accordance with Section B - Preventive Maintenance Plan, of this permit, is not required for the facility described in this Section.

Testing and Monitoring Requirements

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

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

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

D.2.4 Generator Hours of Operation

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

D.2.5 Reporting Requirements

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

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

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

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

SECTION D.3 FERMENTATION OPERATION CONDITIONS

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

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

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

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	UOM	Control Device
Building T1 – Raw Material Prep Area:					
MIX001*	Dry Raw Material Mixer	PV-T1-T52348	N/A	N/A	Dust Collector T52348**
MIX002*	Dry Raw Material Mixer	PV-T1-T52348	N/A	N/A	
MCNV001	Conveyor of Raw Material Mixers	PV-T1-T52348	N/A	N/A	
Building T2 – Fermentation Production Area:					
T001*	Bump Tank	S-T2-FERM	5000	liters	None
T002*	Bump Tank	S-T2-FERM	5000	liters	None
T003*	Bump Tank	S-T2-FERM	5000	liters	None
T004*	Bump Tank	S-T2-FERM	5000	liters	None
T011*	Bump Tank	S-T2-FERM	5000	liters	None
T012*	Bump Tank	S-T2-FERM	5000	liters	None
T013*	Bump Tank	S-T2-FERM	5000	liters	None
T014*	Bump Tank	S-T2-FERM	5000	liters	None
T005*	Fermentor Tank	S-T2-FERM	60000	liters	Cyclone T67457**
T006*	Fermentor Tank	S-T2-FERM	60000	liters	
T007*	Fermentor Tank	S-T2-FERM	60000	liters	
T008*	Fermentor Tank	S-T2-FERM	60000	liters	Cyclone T67458**
T009*	Fermentor Tank	S-T2-FERM	60000	liters	
T010*	Fermentor Tank	S-T2-FERM	60000	liters	
T015*	Fermentor Tank	S-T2-FERM	60000	liters	Cyclone T67462**
T016*	Fermentor Tank	S-T2-FERM	60000	liters	Cyclone T67463**
T017*	Fermentor Tank	S-T2-FERM	60000	liters	Cyclone T67464**
T018*	Fermentor Tank	S-T2-FERM	60000	liters	Cyclone T65689**
T019*	Fermentor Tank	S-T2-FERM	60000	liters	Cyclone T52221**
T020*	Fermentor Tank	S-T2-FERM	60000	liters	Cyclone T52228**

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	UOM	Control Device
Building T2A – Fermentation Production Area:					
T021*	Bump Tank	S-T2-FERM	10000	liters	None
T022*	Bump Tank	S-T2-FERM	10000	liters	None
T023*	Bump Tank	S-T2-FERM	10000	liters	None
T024*	Bump Tank	S-T2-FERM	10000	liters	None
T025*	Fermentor Tank	S-T2-FERM	120000	liters	Cyclone T67459**
T026*	Fermentor Tank	S-T2-FERM	120000	liters	
T027*	Fermentor Tank	S-T2-FERM	120000	liters	
T028*	Fermentor Tank	S-T2-FERM	120000	liters	Cyclone T67696**
T029*	Fermentor Tank	S-T2-FERM	120000	liters	Cyclone T67697**
T030*	Fermentor Tank	S-T2-FERM	120000	liters	Cyclone T67698**
Building T2C – Fermentation Production Area:					
T043*	Bump Tank	S-T2-FERM	37625	liters	Cyclone T65363**
T044*	Bump Tank	S-T2-FERM	37625	liters	Cyclone T65364**
T048*	Fermentor Tank	S-T2-FERM	254000	liters	Cyclone T65367**
T049*	Fermentor Tank	S-T2-FERM	254000	liters	Cyclone T65359**
T050*	Fermentor Tank	S-T2-FERM	254000	liters	Cyclone T65360**

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

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

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

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	UOM	Control Device
BIN008	Dry Raw Material Storage Bin	PV-T46-T67455	23000	liters	
BIN009	Dry Raw Material Storage Bin	PV-T46-T67659	23000	liters	Baghouse T67659**
BIN010	Dry Raw Material Storage Bin	PV-T46-T67659	23000	liters	
BIN011	Dry Raw Material Storage Bin	PV-T46-T67456	23000	liters	Baghouse T67456**
BIN012	Dry Raw Material Storage Bin	PV-T46-T67456	23000	liters	
Building T1 – Raw Material Prep Area:					
BLO001	Railcar Pneumatic Conveyor	N/A	N/A	liters	None
DISP001	Automated Dispensing Station	PV-T1-T44984	N/A	liters	Dust Collector T44984**
DISSC001	Dispensing Scale	PV-T1-T44984	N/A	liters	
T121	Make Up Tank	PV-T1-314512	10150	liters	Rotoclone 314512**
T122	Make Up Tank	PV-T1-314512	10150	liters	
T123	Make Up Tank	PV-T1-314512	2100	liters	
T123A	Make Up Area Tank	N/A	380	liters	None
T124	Make Up Tank	PV-T1-314512	2100	liters	Rotoclone 314512**
TSLU	Slurry Tank	N/A	3600	liters	None
T125	Make Up Tank	PV-T1-T67489	24600	liters	Rotoclone T67489**
T126	Make Up Tank	PV-T1-T67492	24600	liters	Rotoclone T67492**
SC001	Liquid Weigh Scale Tank	N/A	N/A	liters	None
Building T1 – Liquid Storage Area:					
T231	Liquid Storage Tank	N/A	20000	liters	None
T232	Waste Holding Tank	N/A	200000	liters	None
T233	Whole Broth Storage Tank	N/A	200000	liters	None
T234	Liquid Storage Tank	N/A	200000	liters	None
T235	Liquid Storage Tank	N/A	200000	liters	None
T236	Waste Holding Tank	N/A	200000	liters	None
T237	Liquid Storage Tank	N/A	200000	liters	None
T241	Liquid Storage Tank	N/A	100000	liters	None
T242	Liquid Storage Tank	N/A	100000	liters	None
T243	Liquid Storage Tank	N/A	100000	liters	None
T244	Liquid Storage Tank	N/A	100000	liters	None
T245	Liquid Storage Tank	N/A	100000	liters	None
T246	Liquid Storage Tank	N/A	100000	liters	None
T247	Liquid Storage Tank	N/A	100000	liters	None
T248	Liquid Storage Tank	N/A	30400	liters	None

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	UOM	Control Device
T249	Liquid Storage Tank	N/A	45300	liters	None
Building T1 – Filter Room:					
T813	Lime Tank	PV-T1-316488	8600	liters	Rotoclone 316488**
T814	Filter Room Tank (Tank 8.5)	PV-T1-316488	9600	liters	
T143	Slurry Tank	N/A	3800	liters	None
T144	Slurry Tank	N/A	3800	liters	None
Building T2 – Fermentation Production Area:					
T116	Liquid Feed Tank	N/A	4000	liters	None
T117	Liquid Feed Tank	N/A	4000	liters	None
Building T63 – Product Storage Area:					
TK252	Whole Broth Tank	N/A	189400	liters	None
TK255	Whole Broth Tank	N/A	94700	liters	None

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

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

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

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

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

(a) The emission units associated with the fermentation operations do not manufacture pharmaceutical products by chemical synthesis. Therefore, the emission units associated with the fermentation operations are not subject to the requirements of 326 IAC 8-5-3 (VOC Emission Limitations for Synthesized Pharmaceutical Manufacturing Operations).

(b) The emission units associated with the fermentation operations are not subject to the requirements of 326 IAC 8-1-6 (Best Available Control Technologies for VOC Emissions) because the VOC emissions associated with each emission unit or emission project are less than 25 tons per year.

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

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

Emission Unit Description	Emission Unit ID	Maximum Process Weight Rate (ton/hr)	Allowable PM Emission Rate (lb/hr)
Building T1 – Raw Material Prep Area:			
Dry Raw Material Mixers + Conveyor for Mixers	MIX001, MIX002, MCNV001	0.881	3.77, combined
Building T2 – Fermentation Production Area:			
Bump Tanks	T001 – T004	18.3	28.7, combined
Fermentor Tanks	T005 – T010		
Bump Tanks	T011 – T014		
Fermentor Tanks	T015 – T020		
Building T2A – Fermentation Production Area:			
Bump Tanks	T021 – T024	18.3	28.7, combined
Fermentor Tanks	T025 – T027, T029 – T030		
Fermentor Tank	T028		
Building 2C – Fermentation Production Area:			
Bump Tanks	T043 – T044	31.6	5.5, combined
Fermentor Tanks	T048 – T050		

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

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

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

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

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

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

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

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

SECTION D.4 FERMENTED PRODUCTS - PURIFICATION OPERATION CONDITIONS

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

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

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

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	UOM	Control Device
Building T3 – Purification Production Area:					
T3-RVD040	Rotary Vacuum Dryer	Vent	500	gallons	Dust Collector**
Building T147 – Storage Tank Module:					
T147-T001	Storage Tank	Vent	19000	gallons	Vent Condenser**
T147-T002	Storage Tank	Vent	19000	gallons	Vent Condenser**
T147-T003	Storage Tank	Vent	19000	gallons	Vent Condenser**
T147-T004	Storage Tank	Vent	19000	gallons	Vent Condenser**
T147-T005	Storage Tank	Vent	19000	gallons	Vent Condenser**
T147-T006	Storage Tank	Vent	19000	gallons	Vent Condenser**
T147-T007	Storage Tank	Vent	19000	gallons	Vent Condenser**
T147-T008	Storage Tank	Vent	19000	gallons	Vent Condenser**
T147-T009	Storage Tank	Vent	19000	gallons	Vent Condenser**
T147-T010	Storage Tank	Vent	19000	gallons	Vent Condenser**
T147-T011	Storage Tank	Vent	19000	gallons	Vent Condenser**
T147-T012	Storage Tank	Vent	19000	gallons	Vent Condenser**

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

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

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	UOM	Control Device
Building T3 – Purification Production Area:					
T3-T47718*	Azo Receiver Tank	Vent	1000	gallons	None
T3-T56*	Vent Condensate Tank	Vent	30	gallons	None
T3-CENT001*	Stacked Plate Centrifuge	Vent	20	gallons	None
T3-CENT002*	Stacked Plate Centrifuge	Vent	20	gallons	None
T3-CENT003*	Stacked Plate Centrifuge	Vent	20	gallons	None
T3-CENT004*	Stacked Plate Centrifuge	Vent	20	gallons	None

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	UOM	Control Device
T3-COL001*	East Carbon Column	Vent	200	gallons	None
T3-T261*	Process Tank	Vent	500	gallons	None
T3-T327-1T*	Process Tank	Vent	500	gallons	None
T3-T330*	Process Tank	Vent	4000	gallons	None
T3-T332-3T*	Process Tank	Vent	3000	gallons	None
T3-T337-1T*	Process Tank - Acid tank	Vent	500	gallons	None
T3-T338-1T*	Process Tank	Vent	500	gallons	None
T3-T338-2T*	Process Tank	Vent	500	gallons	None
T3-T341-1T*	Process Tank	Vent	500	gallons	None
T3-T346-1T*	Amyl Acetate Tank	Vent	500	gallons	None
T3-T353-1T*	Receive Amyl Acetate from EVAP305	Vent	1000	gallons	None
T3-T355-1T*	Process Tank	Vent	1000	gallons	None
T3-T357-1T*	Process Tank	Vent	1000	gallons	None
T3-T376-1T*	Process Tank	Vent	2000	gallons	None
T3-T376-2T*	Process Tank	Vent	2000	gallons	None
T3-T376-3T*	Process Tank	Vent	2000	gallons	None
T3-T378-1T*	Process Tank	Vent	500	gallons	None
T3-T394*	Chemical Waste Tank	Vent	2000	gallons	None
T3-T397-1T*	Spent Aqueous Tank	Vent	2000	gallons	None
T3-T399*	Acid Wash Tank	Vent	500	gallons	None
T3-EVAP300*	Swenson Evaporator	Vent	400	gallons	None
T3-EVAP305	Evaporator	Vent	800	gallons	None
T3-COL002*	West Carbon Column	Vent	200	gallons	None
Building T40 – Purification Production Area:					
T40-T050*	Holding Tank	Vent	750	gallons	None
T40-T051*	Tank	Vent	2000	gallons	None
T40-T052*	Tank	Vent	2000	gallons	None
T40-T053*	Holding Tank	Vent	2000	gallons	None
T40-T055	Tank	Vent	500	gallons	None
T40-T060*	Still	Vent	2000	gallons	None
Building T4 – Solvent Recovery:					
T4-COL001	Distilling Column	Vent	269	cf	None
T4-T001*	Process Tank	Vent	1985	gallons	None
T4*	Tylosin System	Vent	N/A	N/A	None
T4-T101*	Process Tank	Condenser	25000	gallons	Vent Condenser**

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	UOM	Control Device
Building T39 – Product Storage:					
T39-T021*	Storage Tank	Vent	2000	gallons	None
T39-T022*	Storage Tank	Vent	2000	gallons	None
T39-T023*	Storage Tank	Vent	2000	gallons	None
T39-T030*	Storage Tank	Vent	5000	gallons	None
T39-T031*	Storage Tank	Vent	5000	gallons	None
T39-T036*	Storage Tank	Vent	5000	gallons	None
Outside Storage Tanks:					
T420-1T*	Hydrochloric Acid Tank	Scrubber Vent	12000	gallons	Acid Scrubber**
T434-1T*	Sulfuric Acid Tank		15000	gallons	None

* Emission units marked with an asterisk are insignificant activities as defined by 326 IAC 2-7-1(21)(A)-(C).
** Control devices marked with a double asterisk are voluntary control units and are not required to demonstrate compliance with any regulations.

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

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

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

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

(a) Except for the T3 rotary vacuum dryer, the emission units associated with the purification operations do not manufacture pharmaceutical products by chemical synthesis. Therefore, except for the T3 rotary vacuum dryer, these emission units are not subject to the requirements of 326 IAC 8-5-3 (VOC Emission Limitations for Synthesized Pharmaceutical Manufacturing Operations).

(b) The T3 rotary vacuum dryer does not dry pharmaceutical products by chemical synthesis with a potential to emit equal to or greater than 15 pounds per day. Therefore, this dryer is not subject to the requirements of 326 IAC 8-5-3.

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

Pursuant to 40 CFR 63 Subpart GGG (Pharmaceutical MACT Standard), undiluted and uncontrolled process vent streams equal to or greater than 50 ppmv HAP from the T3 rotary vacuum dryer shall be limited to an annual mass limit of 900 kilograms (kg) per 365-day period to comply with the individual process-based mass limit standards under 40 CFR 63.1254(a)(2)(i). The sum of process vent emissions from all uncontrolled processes generated during the manufacturing of pharmaceutical products shall not exceed an annual mass limit of 1800 kg HAP per 365-day period pursuant to 40 CFR 63.1254(a)(2)(ii).

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

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

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

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

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

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

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

(a) The Permittee shall maintain in the following records of the T3 rotary vacuum dryer:

(1) Daily rolling annual total HAP emissions from process vent streams equal to or greater than 50 ppmv from the T3 rotary vacuum dryer;

(2) Number of batches per year for each batch process;

(3) Standard batch uncontrolled and controlled emissions for each process;

(4) Actual uncontrolled and controlled emissions for each nonstandard batch,; and

(5) Record whether each batch operated was considered a standard batch.

(b) Pursuant to 40 CFR 60.116b(b) [New Source Performance Standard for Solvent Storage Tanks], the Permittee shall maintain records of the dimensions and capacity of each storage tank associated with the T147 tank module for the life of the source.

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

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

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

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

SECTION D.5 FERMENTED PRODUCTS – SUPPORT OPERATION CONDITIONS

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

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

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

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	UOM	Control Device
Fermented Products Wastewater Sludge Management Operations:					
T110-TKA	Bio-solids Storage Tank	T110	300,000	gallons	T110 Iron Sponge Reactor
T110-TKB	Bio-solids Storage Tank	T110	300,000	gallons	T110 Iron Sponge Reactor
T110-TKC	Bio-solids Storage Tank	T110	300,000	gallons	T110 Iron Sponge Reactor
T110-TKD	Bio-solids Storage Tank	T110	300,000	gallons	T110 Iron Sponge Reactor

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

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	UOM	Control Device
Fermented Products Wastewater Treatment (100 Series Tanks):					
T174*	Thermal Research Incinerator	T174	17	MMBtu/hr	N/A
T10-TK101	Aeration Tank*	T174	110,000	gallons	None
T10-TK102	Aeration Tank*	T174	123,000	gallons	None
T10-TK103	Aeration Tank*	T174	123,000	gallons	None
T10-TK104	Aeration Tank*	T174	123,000	gallons	None
T10-TK120	Aeration Tank	T174	270,000	gallons	T174** Incinerator
T10-TK121	Clarifier*	T174	122,000	gallons	
T10-TK122	Clarifier*	T174	122,000	gallons	
T10-TK123	Lift Station*	T174	27,000	gallons	
T10-TK124	Nitrification Tank*	Atmosphere	1,700,000	gallons	None
T10-TK125	Nitrification Tank*	Atmosphere	1,700,000	gallons	None
T10-TK126	Nitrification Tank*	Atmosphere	1,700,000	gallons	None
T10-TK127	Nitrification Clarifier*	Atmosphere	90,000	gallons	None
T10-TK128	Nitrification Clarifier*	Atmosphere	90,000	gallons	None
T10-TK132	Final Clarifier*	Atmosphere	155,000	gallons	None

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	UOM	Control Device
T10-TK142	Final Clarifier*	Atmosphere	155,000	gallons	None
T79-TK401	Wastewater Tank	Atmosphere	21,588	gallons	None
T79-TK402	Wastewater Tank	Atmosphere	21,588	gallons	None
Fermented Products Wastewater Sludge Management Operations:					
T42	Centrifuge*	T174	300	gal/min	T174 Incinerator**
T42-A	Sludge Centrifuge*	T174	100	gal/min	
T42-B	Sludge Centrifuge*	T174	150	gal/min	

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

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

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

D.5.1 Non-Applicability Determination of Pharmaceutical MACT Standards [40 CFR 63, Subpart GGG]

The fermented products support operations are not subject to the requirements of 40 CFR 63, Subpart GGG (Pharmaceutical MACT Standards) because:

(a) The emission units associated with the fermented products wastewater sludge management operations 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); and

(b) The wastewater associated with the fermented products wastewater treatment plant do not contain HAP emissions in excess of 5 ppmw pursuant to 40 CFR 63.1251 (Wastewater Stream Definition).

D.5.2 Non-Applicability Determination of State VOC Emission Standards [326 IAC 8-5-3]

The emission units associated with the fermented products support operations do not manufacture pharmaceutical products by chemical synthesis. Therefore, these emission units are not subject to the requirements of 326 IAC 8-5-3 (VOC Emission Limitations for Synthesized Pharmaceutical Manufacturing Operations).

D.5.3 Emission Limitations and Standards [326 IAC 2-2, CP 157-4363 Issued August 28, 1996, and Amendment 157-8953 Issued November 12, 1997 (Revised by this permit)]

To avoid the requirements of 326 IAC 2-2 (Prevention of Significant Deterioration), the Permittee shall comply with the following:

(a) The total reduced sulfur (TRS) emissions from the iron sponge reactor shall not equal or exceed 2.28 pounds per hour, which is equivalent to 762 micrograms per liter (ug/l). This emission limitation also satisfies the emission limitations for reduced sulfur compounds and hydrogen sulfide; and

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

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

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

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

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

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

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

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

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

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

(a) The Permittee shall maintain the following records:

(1) daily pressure drop readings across the iron sponge reactor annubar; and

(2) weekly analysis of the TRS outlet concentration from the iron sponge reactor.

(b) Pursuant to 40 CFR 60.116b(b), Subpart Kb (New Source Performance Standard for Volatile Organic Liquid Storage Vessels) and CP157-4363, issued August 28, 1996, the Permittee shall keep readily accessible records of the dimensions and capacity for each bio-solids storage tank. These records shall be kept for the life of the source.

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

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

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

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

SECTION D.6 BULK PHARMACEUTICAL MANUFACTURING (BPM) PRODUCTION OPERATIONS

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

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

(a) The emission units listed below are 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-TK32-6	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-TK33-6	Process Tank	RTO	1000 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-TK35-10B	Process Tank	RTO	1000 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-TK40-31	Process Tank	RTO	500 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-TK41-6	Process Tank	RTO	300 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-TK45-3	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-TK47-2	Process Tank	RTO	550 gal	RTO
T27-TK47-3	Process Tank	RTO	1000 gal	RTO
T27-TK47-5	Process Tank	RTO	300 gal	RTO
T27-TK48-1	Process Tank	RTO	300 gal	RTO
T27-TK48-1A	Process Tank	RTO	1000 gal	RTO
T27-TK48-2A	Process Tank	RTO	100 gal	RTO
T27-TK48-3A	Process Tank	RTO	500 gal	RTO
T27-TK49-1	Process Tank	RTO	200 gal	RTO
T27-TK49-5	Process Tank	RTO	50 gal	RTO
T27-TK49-6	Process Tank	RTO	75 gal	RTO
T27-TK50-1	Process Tank	RTO	650 gal	RTO
T27-TK50-2	Process Tank	RTO	150 gal	RTO
T27-TK50-3	Process Tank	RTO	150 gal	RTO
T27-TK50-4	Process Tank	RTO	500 gal	RTO
T27-TK372-A	Process Tank	RTO	500 gal	RTO
T27-CENT9	Centrifuge	RTO	NA	RTO
T27-CENT16	Centrifuge	RTO	NA	RTO
T27-CENT19	Centrifuge	RTO	NA	RTO
T27-CENT30	Centrifuge	RTO	NA	RTO
T27-CENT37	Centrifuge	RTO	NA	RTO
T27-CENT38	Centrifuge	RTO	NA	RTO
T27-CENT40	Centrifuge	RTO	NA	RTO
T27-DT46-1	Process Tank	RTO		RTO
T27-RVD53-1	Process Dryer	RTO	NA	RTO
T27-RVD53-2	Process Dryer	RTO	NA	RTO
T27-SCR30-4	Process Scrubber	RTO	NA	RTO
T27-SCR33-7	Process Scrubber	RTO	NA	RTO
T27-SCR34-9	Process Scrubber	RTO	NA	RTO
T27-SCR35-10A	Process Scrubber	RTO	NA	RTO
T27-SCR35-10B	Process Scrubber	RTO	NA	RTO
T27-VC31-1	Process Condenser	RTO	NA	RTO
T27-VC32-1	Process Condenser	RTO	NA	RTO
T27-VC32-2	Process Condenser	RTO	NA	RTO
T27-VC32-3	Process Condenser	RTO	NA	RTO
T27-VC33-1	Process Condenser	RTO	NA	RTO
T27-VC33-2	Process Condenser	RTO	NA	RTO
T27-VC33-3	Process Condenser	RTO	NA	RTO
T27-VC33-4	Process Condenser	RTO	NA	RTO
T27-VC35-1	Process Condenser	RTO	NA	RTO
T27-VC35-2	Process Condenser	RTO	NA	RTO
T27-VC35-4	Process Condenser	RTO	NA	RTO
T27-VC36-1	Process Condenser	RTO	NA	RTO
T27-VC36-2	Process Condenser	RTO	NA	RTO
T27-VC36-3	Process Condenser	RTO	NA	RTO
T27-VC40	Process Condenser	RTO	NA	RTO
T27-VC40-2	Process Condenser	RTO	NA	RTO
T27-VC40-5	Process Condenser	RTO	NA	RTO

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

T28-TK28-21	Process Tank	RTO	2000 gal	RTO
T28-TK28-22	Process Tank	RTO	2000 gal	RTO
T28-TK28-23	Process Tank	RTO	2000 gal	RTO
T28-TK28-24	Process Tank	RTO	2000 gal	RTO
T28-TK28-25	Process Tank	RTO	1500 gal	RTO
T28-TK28-26	Process Tank	RTO	1500 gal	RTO
T28-TK28-27	Process Tank	RTO	140 gal	RTO
T28-TK28-29	Process Tank	RTO	1000 gal	RTO
T28-TK28-30	Process Tank	RTO	500 gal	RTO
T28-TK28-31	Process Tank	RTO	2000 gal	RTO
T28-TK28-32	Process Tank	RTO	2000 gal	RTO
T28-PTK1	Portable Charge Tank	RTO	300 gal	RTO
T28-PTK2	Portable Charge Tank	RTO	300 gal	RTO
T28-PTK3	Portable Charge Tank	RTO	300 gal	RTO
T28-SCR1	Process Scrubber	RTO	NA	RTO
T28-SCR2	Process Scrubber	RTO	NA	RTO
T28-SCR3	Process Scrubber	RTO	NA	RTO
T28-SCR4	Process Scrubber	RTO	NA	RTO
T28-SCR6	Process Scrubber	RTO	NA	RTO
T28-SCR64	Process Scrubber	RTO	NA	RTO
T28-SCRTK1	Scrubber Tank	RTO	300 gal	RTO
T28-SCRTK2	Scrubber Tank	RTO	500 gal	RTO
T28-SCRTK4	Scrubber Tank	RTO	500 gal	RTO
T28-VC28-1	Process Condenser	RTO	NA	RTO
T28-VC28-3	Process Condenser	RTO	NA	RTO
T28-VC28-4	Process Condenser	RTO	NA	RTO
T28-VC28-5	Process Condenser	RTO	NA	RTO
T28-VC28-6	Process Condenser	RTO	NA	RTO
T28-VC28-8	Process Condenser	RTO	NA	RTO
T28-VC28-10	Process Condenser	RTO	NA	RTO
T28-VC28-11	Process Condenser	RTO	NA	RTO
T28-VC28-12	Process Condenser	RTO	NA	RTO
Building T29:				
T29-CENT1401	Heinkel Centrifuge	RTO	70 gal	RTO
T29-CENT2401	Heinkel Centrifuge	RTO	70 gal	RTO
T29-CENT3401	Heinkel Centrifuge	RTO	70 gal	RTO
T29-DRY1501	Cone Dryer	RTO	580 gal	RTO
T29-DRY2402	Filter Dryer	RTO	863 gal	RTO
T29-DRY2502	Filter Dryer	RTO	863 gal	RTO
T29-DRY3501	Cone Dryer	RTO	580 gal	RTO
T29-IBC8201	Process Tank	RTO	100 gal	RTO
T29-IBC8202	Process Tank	RTO	150 gal	RTO
T29-IBC8203	Process Tank	RTO	150 gal	RTO
T29-IBC8204	Process Tank	RTO	150 gal	RTO
T29-IBC8205	Process Tank	RTO	150 gal	RTO
T29-IBC8206	Process Tank	RTO	150 gal	RTO
T29-IBC8207	Process Tank	RTO	150 gal	RTO

T29-IBC8208	Process Tank	RTO	150 gal	RTO
T29-IBC8209	Process Tank	RTO	150 gal	RTO
T29-IBC8210	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-IBC8252	Process Tank	RTO	150 gal	RTO
T29-IBC8253	Process Tank	RTO	150 gal	RTO
T29-IBC8254	Process Tank	RTO	150 gal	RTO
T29-IBC8255	Process Tank	RTO	150 gal	RTO
T29-IBC8256	Process Tank	RTO	150 gal	RTO
T29-IBC8257	Process Tank	RTO	150 gal	RTO
T29-IBC8258	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-TK1201	Process Tank	RTO	2000 gal	RTO
T29-TK1202	Process Tank	RTO	2000 gal	RTO
T29-TK1203	Process Tank	RTO	2000 gal	RTO
T29-TK1204	Process Tank	RTO	2000 gal	RTO
T29-TK1205	Process Tank	RTO	2000 gal	RTO
T29-TK2201	Process Tank	RTO	1600 gal	RTO
T29-TK2202	Process Tank	RTO	2000 gal	RTO
T29-TK2203	Process Tank	RTO	2000 gal	RTO
T29-TK2204	Process Tank	RTO	2000 gal	RTO
T29-TK2205	Process Tank	RTO	2000 gal	RTO
T29-TK3201	Process Tank	RTO	2000 gal	RTO
T29-TK3202	Process Tank	RTO	2000 gal	RTO
T29-TK3203	Process Tank	RTO	2000 gal	RTO
T29-TK3204	Process Tank	RTO	2000 gal	RTO
T29-TK3205	Process Tank	RTO	2000 gal	RTO
T29-TK4201	Process Tank	RTO	1600 gal	RTO
T29-TK4203	Process Tank	RTO	2000 gal	RTO
T29-TK7920	Process Tank	RTO	200 gal	RTO
T29-TK7921	Process Tank	RTO	80 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-TK8218	Process Tank	RTO	50 gal	RTO
T29-TK8220	Process Tank	RTO	50 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

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-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-TK1203A	Accumulator Tank	RTO	70 gal	RTO
T29-TK1204A	Accumulator Tank	RTO	70 gal	RTO
T29-TK1401A	Accumulator Tank	RTO	70 gal	RTO
T29-TK2401A	Accumulator Tank	RTO	70 gal	RTO
T29-TK3401A	Accumulator Tank	RTO	70 gal	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-CENT	Centrifuge	RTO	13 cf	RTO
T31-CENT504	Centrifuge	RTO	13 gal	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	RTO	100 gal	RTO
T31-HE501	Process Condenser	RTO	N/A	RTO
T31-HE503	Process Condenser	RTO	N/A	RTO
T31-HE511	Process Condenser	RTO	N/A	RTO
T31-HE512	Process Condenser	RTO	N/A	RTO
T31-HE531	Process Condenser	RTO	N/A	RTO
T31-HE541	Process Condenser	RTO	N/A	RTO
T31-SCR-OZ	Process Scrubber (Ozone)	RTO	N/A	RTO
T31-SCR701	Process Scrubber	RTO	1000 gal	RTO

T31-SCR721	Process Scrubber	RTO	200 gal	RTO
Building T31A:				
T31A-CENT981	Centrifuge	RTO	N/A	RTO
T31A-FD861	Filter Dryer	RTO	0.6 m2	RTO
T31A-FD874	Filter Dryer	RTO	0.6 m2	RTO
T31A-RVD881	Dryer	RTO	100 cf	RTO
T31A-RVD891	Dryer	RTO	100 cf	RTO
T31A-DT683	Drowning Tank 001	RTO	NA	RTO
T31A-TK621	Process Tank	RTO	300 gal	RTO
T31A-TK622	Process Tank	RTO	800 gal	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-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
T31A-TK861K	Process Tank	RTO	50 gal	RTO
T31A-HE481	Process Condenser	RTO	N/A	RTO
T31A-HE482	Process Condenser	RTO	N/A	RTO
T31A-HE491	Process Condenser	RTO	N/A	RTO
T31A-HE492	Process Condenser	RTO	N/A	RTO
T31A-HE521	Process Condenser	RTO	N/A	RTO
T31A-HE551	Process Condenser	RTO	N/A	RTO
T31A-HE561	Process Condenser	RTO	N/A	RTO
T31A-HE581	Process Condenser	RTO	N/A	RTO
T31A-HE583	Process Condenser	RTO	N/A	RTO
T31A-HE591	Process Condenser	RTO	N/A	RTO
T31A-HE593	Process Condenser	RTO	N/A	RTO
T31A-HE781	Process Condenser	RTO	N/A	RTO
T31A-HE791	Process Condenser	RTO	N/A	RTO
T31A-SCR261	Process Scrubber	RTO	N/A	RTO
T31A-SCR262	Process Scrubber	RTO	N/A	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-CENT	Heinkel Centrifuge	RTO	NA	RTO

T99-PD43	Pan Dryer	RTO	528 gal	RTO
T99-PD44	Pan Dryer	RTO	528 gal	RTO
T99-RVD1	Rotary Vacuum Dryer	RTO	1200 gal	RTO
T99-RVD2	Rotary Vacuum Dryer	RTO	1200 gal	RTO
T99-RVD3	Rotary Vacuum Dryer	RTO	1200 gal	RTO
T99-RVD5	Rotary Vacuum Dryer	RTO	1200 gal	RTO
T99-RVD6	Rotary Vacuum Dryer	RTO	1200 gal	RTO
T99-RVD7	Rotary Vacuum Dryer	RTO	1200 gal	RTO
T99-RVD8	Rotary Vacuum Dryer	RTO	1200 gal	RTO
T99-TK-D41	Process Tank	RTO	300 gal	RTO
T99-TK-D42	Process Tank	RTO	150 gal	RTO
T99-HE43	Process Condenser	RTO	NA	RTO
T99-HE44	Process Condenser	RTO	NA	RTO
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-TK1C	Process Tank	RTO	N/A	RTO
T100-TK2	Process Tank	RTO	4000 gal	RTO
T100-TK3	Process Tank	RTO	2000 gal	RTO
T100-TK4	Process Tank	RTO	2000 gal	RTO
T100-TK5	Process Tank	RTO	2000 gal	RTO
T100-TK6	Process Tank	RTO	2000 gal	RTO
T100-TK7	Process Tank	RTO	4000 gal	RTO
T100-TK8	Process Tank	RTO	4000 gal	RTO
T100-TK8C	Process Tank	RTO	30 gal	RTO
T100-TK9	Process Tank	RTO	4000 gal	RTO
T100-TK10	Process Tank	RTO	4000 gal	RTO
T100-TK11	Process Tank	RTO	4000 gal	RTO
T100-TK11C	Process Tank	RTO	70 gal	RTO
T100-TK12	Process Tank	RTO	4000 gal	RTO
T100-TK13	Process Tank	RTO	3300 Gal	RTO
T100-TK14	Process Tank	RTO	4000 gal	RTO
T100-TK15	Process Tank	RTO	2000 gal	RTO
T100-TK16	Process Tank	RTO	2000 gal	RTO
T100-TK17	Process Tank	RTO	2000 gal	RTO
T100-TK18	Process Tank	RTO	2000 gal	RTO
T100-TK20	Process Tank	RTO	4000 gal	RTO

T100-TK21	Process Tank	RTO	4000 gal	RTO
T100-TK22	Process Tank	RTO	2000 gal	RTO
T100-TK24	Process Tank	RTO	4000 gal	RTO
T100-TK25	Process Tank	RTO	4000 gal	RTO
T100-TK26	Process Tank	RTO	4000 gal	RTO
T100-TK27	Process Tank	RTO	4000 gal	RTO
T100-TK28	Process Tank	RTO	4000 gal	RTO
T100-TK29	Process Tank	RTO	4000 gal	RTO
T100-TK30	Process Tank	RTO	4000 gal	RTO
T100-TK31	Process Tank	RTO	4000 gal	RTO
T100-TK32	Process Tank	RTO	4000 gal	RTO
T100-TK33	Process Tank	RTO	1000 gal	RTO
T100-TK34	Process Tank	RTO	1000 gal	RTO
T100-TK35	Process Tank	RTO	1000 gal	RTO
T100-TK36	Process Tank	RTO	1000 gal	RTO
T100-TK37	Process Tank	RTO	1000 gal	RTO
T100-TK38	Process Tank	RTO	1000 gal	RTO
T100	Portable Process Tank	RTO	N/A	RTO
T100	Portable Process Tank	RTO	N/A	RTO
T100-PTK1	Portable Cleaning Tank	RTO	150 gal	RTO
T100-HE1	Process Condenser	RTO	N/A	RTO
T100-HE1C	Process Condenser		N/A	
T100-HE2	Process Condenser	RTO	N/A	RTO
T100-HE4	Process Condenser	RTO	N/A	RTO
T100-HE6	Process Condenser	RTO	N/A	RTO
T100-HE7	Process Condenser	RTO	N/A	RTO
T100-HE8	Process Condenser	RTO	N/A	RTO
T100-HE11	Process Condenser	RTO	N/A	RTO
T100-HE12	Process Condenser	RTO	N/A	RTO
T100-HE13	Process Condenser	RTO	N/A	RTO
T100-HE14	Process Condenser	RTO	N/A	RTO
T100-HE14B	Process Condenser	RTO	N/A	RTO
T100-HE16	Process Condenser	RTO	N/A	RTO
T100-HE21A	Process Condenser	RTO	N/A	RTO
T100-HE21B	Process Condenser	RTO	N/A	RTO
T100-HE26	Process Condenser	RTO	N/A	RTO
T100-HE28	Process Condenser	RTO	N/A	RTO
T100-HE31	Process Condenser	RTO	N/A	RTO
T100-TK14A	Accumulator Tank	RTO	50 gal	RTO
T100-TK21A	Accumulator Tank	RTO	50 gal	RTO
T100-TK53A	Accumulator Tank	RTO	200 gal	RTO
T100-TK55A	Accumulator Tank	RTO	200 gal	RTO
T100-TK39	CIP Tank	RTO	500 gal	RTO
T100-SCR80	Process Scrubber	RTO	N/A	RTO
T100-SCR80	Process Scrubber	RTO	N/A	RTO
T100-SCR80	Process Scrubber	RTO	N/A	RTO
T100-SCR80	Process Scrubber	RTO	N/A	RTO
T100-SCR80	Process Scrubber	RTO	N/A	RTO

T100-SCR80	Process Scrubber	RTO	N/A	RTO
T100-TK82	Scrubber Holding Tank	RTO	1000 gal	RTO
T100-TK83	Scrubber Holding Tank	RTO	1000 gal	RTO
T100-TK84	Scrubber Holding Tank	RTO	1000 gal	RTO
T100-TK85	Scrubber Holding Tank	RTO	1000 gal	RTO

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

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

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

(a) With the exception of Conditions D.6.1(c) and D.6.2, the Permittee shall route the vapors from each operating BPM process vent containing undiluted and uncontrolled process vent streams equal to or greater than 50 ppmv HAP, 50 ppmv VOC, or 15 pounds per day VOC through a closed-vent system to the RTO control system. The operation, inspection and maintenance requirements for the RTO control system, and its closed-vent system, used to control emissions from these emission units are described in Section D.14 of this permit.

(b) The Permittee shall cover all in-process tanks, having an exposed liquid surface containing VOC greater than 15 pounds per day unless production, sampling, maintenance, or inspection procedures require operator access.

(c) The Permittee is not required to control emissions from BPM process vents in accordance with (a) of this section, if it would result in a safety hazard, as long as the sum of the uncontrolled BPM process vent streams within an individual BPM process does not exceed an annual mass limit of 900 kilograms (2000 pounds) of HAP per 365-day period and the sum of all uncontrolled process vent emissions generated during the manufacturing of pharmaceutical products do not exceed an annual mass limit of 1800 kilograms (4000 pounds) of HAP per 365-day period.

(d) The Permittee shall enclose all centrifuges, rotary vacuum filters, and other filters having an exposed liquid surface, where the liquid contains VOC and exerts a total vapor pressure of 0.5 pounds per square inch or more at 20^0C.

D.6.2 Control Strategy for VOC BPM Process Vents [326 IAC 2-2-3]

To satisfy the BACT requirements for the following BPM process activity types operating in VOC service only, the Permittee shall apply the control standards required by Condition D.6.1 (a) within 365 days after this permit becomes effective:

(a) open manway operations;

(b) charging a liquid from a drum to a tank;

(c) centrifuge emptying operations;

(d) drum filling and drum cleaning operations; or

(e) loading wetcake into driers.

Following this 365-day period, all new operations utilizing the activity types described above shall comply with the control standards required by Condition D.6.1 (a) upon startup.

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

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

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

(a) The Permittee shall inspect the physical integrity of heat exchange systems that use water to cool process equipment or materials used in pharmaceutical manufacturing operations in accordance with the following current good manufacturing practice (CGMP) requirements of 21 CFR 211 to satisfy the streamlined standards of the Pharmaceutical MACT for heat exchange systems [40 CFR 63.1252(c)(2)] and the PSD BACT requirements [326 IAC 2-2-3]:

(1) Assignment of responsibility for maintaining equipment;

(2) Maintenance schedules; and

(3) Description in sufficient detail of the methods, equipment, and materials used in maintenance operations, and the methods of disassembling and reassembling equipment as necessary to assure proper maintenance.

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

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

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

(1) Detailed plans and/or procedures for operating and maintaining the process during periods of SSM; and

(2) Corrective action program for malfunctioning processes.

(b) The startup, shutdown and malfunction (SSM) requirements for the RTO control system, and associated closed-vent system, are described in Section D.14 of this permit.

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

D.6.6 Requirements

With the exception of Condition D.6.1(c), the Permittee shall operate the RTO control system, and associated closed-vent system, at all times a process vent is in operation. The requirements for the RTO control system, and its associated closed-vent system, used to control emissions from the emission units listed in this section are described in Section D.14 of this permit.

D.6.7 Monitoring Requirements

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

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

D.6.8 Record Keeping and Reporting Requirements

(a) Record Keeping Requirements

(1) RTO Control System Records - The record keeping and reporting requirements for the RTO control system, and associated closed-vent systems, used to control emissions from the emission units listed in this section are described in Section D.14 of this permit.

(2) Process Records - The Permittee shall maintain the following records:

(A) Daily rolling annual total HAP emissions;

(B) Number of batches per year for each batch process;

(C) Standard batch uncontrolled and controlled emissions for each process;

(D) Actual uncontrolled and controlled emissions for each nonstandard batch; and

(E) Record whether each batch operated was considered a standard batch.

(3) Heat Exchange System Records - Maintenance records, including the date, time, and sign off or initials of the individual who completed the task, of all heat exchange systems that use water to cool process equipment or materials used in pharmaceutical manufacturing operations. The Permittee shall track the heat exchange systems that use water to cool process equipment or materials used in pharmaceutical manufacturing operations in an operating scenario maintained in the On-Site Implementation Log (OSIL).

(4) LDAR Records - The record keeping and reporting requirements for the LDAR standards are described in Sections E.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.

(6) 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)] and the PSD BACT requirements [326 IAC 2-1.1-11]:

(A) SSM summary reports for the processes.

(2) 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.

(3) The reporting requirements for the LDAR standards are described in Sections E.1 and E.2 of this permit.

(4) All reports shall be submitted to the address listed in Section C – General Reporting Requirements, of this permit, using the reporting form located at the end of this permit, or its equivalent, within thirty (30) days after the end of the quarter being reported. The report does require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

(c) Immediate Reporting Requirements

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

(1) Any time an action taken by the Permittee during an SSM event of a process is not consistent with the procedures specified in the SSM Plan, the Permittee shall report the actions taken for that event. The immediate report shall be submitted to the agency via a telephone call or facsimile within 2 working days after commencing actions inconsistent with the plan.

(2) Within 7 working days after the end of an SSM event of a process where an action taken by the Permittee is not consistent with the procedures specified in the SSM Plan, the Permittee shall submit a letter containing the following information in accordance with 40 CFR 63.10(d)(5):

(A) Name, title and signature of responsible official certifying accuracy;

(B) Explanation of the circumstances for the event;

(C) Reason for not following the SSM Plan; and

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

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 OPERATIONS – SOLVENT RECOVERY OPERATIONS

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

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

(a) The emission units listed below are 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*	500 gal	T79 or RTO*
T19-REC7	Receiver	T79 or RTO*	500 gal	T79 or RTO*
T19-REC8	Receiver	T79 or RTO*	500 gal	T79 or RTO*
T19-REC9	Receiver	T79	500 gal	T79
Building T52:				
T52-REC52-3	Receiver	T79	2000 gal	T79
T52-REC52-4	Receiver	T79	2000 gal	T79
T52-REC52-1	Stainless Receiver	T79 or RTO*	2000 gal	T79 or RTO*
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*
T52-REC52-2	Stainless Receiver	T79 or RTO*	2000 gal	T79 or RTO*
T52-ACC10	Accumulator	T79 or RTO*	NA	T79 or RTO*
T52-ACC5	Accumulator	T79 or RTO*	NA	T79 or RTO*
T52-ACC6	Accumulator	T79 or RTO*	NA	T79 or RTO*
T52-COL52-8	Wash Column	T79 or RTO*	NA	T79 or RTO*
T52-EVAP10	Evaporator	T79 or RTO*	2000 gal	T79 or RTO*
T52-EVAP5	Evaporator	T79 or RTO*	2000 gal	T79 or RTO*
T52-EVAP6	Evaporator	T79 or RTO*	2000 gal	T79 or RTO*
T52-STPR52-14	Steam Stripper	T79 or RTO*	250 gal	T79 or RTO*
T52-ACC14	Accumulator	T79 or RTO*	NA	T79 or RTO*

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	Control Device
Building T61:				
T61-COL61-1	Column	T79	NA	T79
T61-COL61-2	Column	T79	NA	T79
T61-COL61-3	Column	T79	NA	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

* 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.

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

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) The Permittee shall route the vapors from each operating BPM process vent containing undiluted and uncontrolled process vent streams equal to or greater than 50 ppmv VOHAP and/or 50 ppmv VOC through a closed-vent system to either the RTO control system or T79 fume incinerator control system. The operation, inspection and maintenance requirements for the RTO control system and T79 fume incinerator control system, and associated closed-vent systems, used to control emissions from these emission units are described in Sections D.14 and D.15 of this permit, respectively.

(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 20^0C.

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), 40 CFR 63.697(b)(3), and 40 CFR 63.6(e)(3) and 63.8(c)]

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

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

(1) Detailed plans and/or procedures for operating and maintaining the process during periods of SSM; and

(2) Corrective action program for malfunctioning processes.

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

(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:

(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.

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

(3) The reporting requirements for the LDAR standards are described in Sections E.1 and E.2 of this permit.

(4) All reports shall be submitted to the address listed in Section C – General Reporting Requirements, of this permit, using the reporting form located at the end of this permit, or its equivalent, within thirty (30) days after the end of the quarter being reported. The report requires certification by the “responsible official” as defined by 326 IAC 2-7-1(34).

(c) Immediate Reporting Requirements

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

(1) Any time an action taken by the Permittee during an SSM event of a process is not consistent with the procedures specified in the SSM Plan, the Permittee shall report the actions taken for that event. The immediate report shall be submitted to the agency via a telephone call or facsimile within 2 working days after commencing actions inconsistent with the plan.

(2) Within 7 working days after the end of an SSM event of a process where an action taken by the Permittee is not consistent with the procedures specified in the SSM Plan, the Permittee shall submit a letter containing the following information in accordance with 40 CFR 63.10(d)(5):

(A) Name, title and signature of responsible official certifying accuracy;

(B) Explanation of the circumstances of the event;

(C) Reason for not following the SSM Plan; and

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

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

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

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

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 CONDITIONS

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

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

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.

Unit ID	Unit Description	Stack/Vent	Nominal Capacity	Control Device
Building T27:				
T27-Sump*	Sump Tank/Lift Station	RTO	2000 gal	RTO
Building T28:				
T28-Sump*	Sump	RTO	1300 gal	RTO
Building T31:				
T31-Sump*	Sump	RTO	5900 gal	RTO
Building T31A:				
T31A-Sump*	Sump	RTO	300 gal	RTO
Building T19:				
T19-1-Sump*	Sump	None		None

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

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) The Permittee shall route the vapors from each operating BPM IDS containing waste equal to or greater than 500 ppmw HAP and/or 500 ppmw VOC through a closed-vent system to either the RTO control system or T79 fume incinerator control system. The operation, inspection and maintenance requirements for the RTO control system and T79 fume incinerator control system, and associated closed-vent systems, used to control emissions from these emission units are described in Sections D.14 and D.15 of this permit, respectively; 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), 326 IAC 2-2-3, 40 CFR 63.6(e) and 40 CFR 63.8(c)]

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

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

(1) Detailed plans and/or procedures for operating and maintaining the process during periods of SSM; and

(2) Corrective action program for malfunctioning processes.

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

(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:

(i) Records of the current and superseded versions of SSM Plan.

(ii) Occurrence/duration records of each process malfunction.

(iii) Information to demonstrate conformance with each SSM are consistent wit the procedures in the SSM Plan.

(iv) Records of actions taken during each SSM when different from SSM Plan.

(4) IDS Waste Stream Records - The Permittee shall identify each IDS not controlled by the RTO or T79 control system and maintain documentation to support the average waste stream constituents of VOHAP and/or VOC concentration are less than 500 ppmw.

(5) 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)] 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.

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

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

(c) Immediate Reporting Requirements

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

(1) Any time an action taken by the Permittee during an SSM event of a process is not consistent with the procedures specified in the SSM Plan, the Permittee shall report the actions taken for that event. The immediate report shall be submitted to the agency via a telephone call or facsimile within 2 working days after commencing actions inconsistent with the plan.

(2) Within 7 working days after the end of an SSM event of a process where an action taken by the Permittee is not consistent with the procedures specified in the SSM Plan, the Permittee shall submit a letter containing the following information in accordance with 40 CFR 63.10(d)(5):

(A) Name, title and signature of responsible official certifying accuracy;

(B) Explanation of the circumstances for the event;

(C) Reason for not following the SSM Plan; and

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

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

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

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

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

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

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	Control Device
Building T143 – Tank Module:				
T143-TK01	Solvent Tank	T79 Incinerator	38,245 gal	T79 Incinerator
T143-TK03	Solvent Tank	T79 Incinerator	38,245 gal	T79 Incinerator
T143-TK05	Solvent Tank	T79 Incinerator	38,245 gal	T79 Incinerator
T143-TK07	Solvent Tank	T79 Incinerator	38,245 gal	T79 Incinerator
T143-TK09	Solvent Tank	T79 Incinerator	38,245 gal	T79 Incinerator
T143-TK11	Solvent Tank	T79 Incinerator	38,245 gal	T79 Incinerator
T143-TK12	Solvent Tank	T79 Incinerator	19,500 gal	T79 Incinerator
T143-TK13	Solvent Tank	T79 Incinerator	19,500 gal	T79 Incinerator
T143-TK14	Solvent Tank	T79 Incinerator	19,500 gal	T79 Incinerator
T143-TK16	Solvent Tank	T79 Incinerator	19,500 gal	T79 Incinerator
T143-TK17	Solvent Tank	T79 Incinerator	19,500 gal	T79 Incinerator
T143-TK18	Solvent Tank	T79 Incinerator	19,500 gal	T79 Incinerator
T143-TK19	Solvent Tank	T79 Incinerator	19,500 gal	T79 Incinerator
T143-TK20	Solvent Tank	T79 Incinerator	19,500 gal	T79 Incinerator
T143-TK21	Solvent Tank	T79 Incinerator	19,500 gal	T79 Incinerator
T143-TK22	Solvent Tank	T79 Incinerator	19,500 gal	T79 Incinerator
T143-TK23	Solvent Tank	T79 Incinerator	19,500 gal	T79 Incinerator
T143-TK24	Solvent Tank	T79 Incinerator	19,500 gal	T79 Incinerator
Building T145 – Tank Module:				
T145-TK25	Solvent Tank	T79 Incinerator	18,900 gal	T79 Incinerator
T145-TK26	Solvent Tank	T79 Incinerator	18,900 gal	T79 Incinerator
T145-TK27	Solvent Tank	T79 Incinerator	18,900 gal	T79 Incinerator
T145-TK28	Solvent Tank	T79 Incinerator	18,900 gal	T79 Incinerator
T145-TK29	Solvent Tank	T79 Incinerator	18,900 gal	T79 Incinerator
T145-TK30	Solvent Tank	T79 Incinerator	18,900 gal	T79 Incinerator
T145-TK31	Solvent Tank	T79 Incinerator	18,900 gal	T79 Incinerator
T145-TK32	Solvent Tank	T79 Incinerator	18,900 gal	T79 Incinerator
T145-TK33	Solvent Tank	T79 Incinerator	18,900 gal	T79 Incinerator

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	Control Device
T145-TK34	Solvent Tank	T79 Incinerator	18,900 gal	T79 Incinerator
T145-TK35	Solvent Tank	T79 Incinerator	18,900 gal	T79 Incinerator
T145-TK36	Solvent Tank	T79 Incinerator	18,900 gal	T79 Incinerator
T145-TK37	Solvent Tank	T79 Incinerator	18,900 gal	T79 Incinerator
T145-TK38	Solvent Tank	T79 Incinerator	18,900 gal	T79 Incinerator
T145-TK39	Solvent Tank	T79 Incinerator	18,900 gal	T79 Incinerator
T145-TK40	Solvent Tank	T79 Incinerator	18,900 gal	T79 Incinerator
T145-TK41	Solvent Tank	T79 Incinerator	18,900 gal	T79 Incinerator
T145-TK42	Solvent Tank	T79 Incinerator	18,900 gal	T79 Incinerator
T145-TK43	Solvent Tank	T79 Incinerator	18,900 gal	T79 Incinerator
T145-TK44	Solvent Tank	T79 Incinerator	18,900 gal	T79 Incinerator
T145-TK45	Solvent Tank	T79 Incinerator	18,900 gal	T79 Incinerator
T145-TK46	Solvent Tank	T79 Incinerator	18,900 gal	T79 Incinerator
T145-TK47	Solvent Tank	T79 Incinerator	18,900 gal	T79 Incinerator
T145-TK48	Solvent Tank	T79 Incinerator	18,900 gal	T79 Incinerator
T145-TK49	Solvent Tank	T79 Incinerator	18,900 gal	T79 Incinerator
T145-TK50	Solvent Tank	T79 Incinerator	10,000 gal	T79 Incinerator
T145-TK51	Solvent Tank	T79 Incinerator	10,000 gal	T79 Incinerator
T145-TK52	Solvent Tank	T79 Incinerator	10,000 gal	T79 Incinerator
T145-TK53	Solvent Tank	T79 Incinerator	10,000 gal	T79 Incinerator
T145-TK54	Solvent Tank	T79 Incinerator	10,000 gal	T79 Incinerator
T145-TK55	Solvent Tank	T79 Incinerator	10,000 gal	T79 Incinerator
T145-TK56	Solvent Tank	T79 Incinerator	10,000 gal	T79 Incinerator
T145-TK57	Solvent Tank	T79 Incinerator	10,000 gal	T79 Incinerator
T145-TK58	Solvent Tank	T79 Incinerator	10,000 gal	T79 Incinerator
T145-TK59	Solvent Tank	T79 Incinerator	10,000 gal	T79 Incinerator
Building T146 – Tank Module:				
T146-TK01	Solvent Tank	RTO	19,500 gal	RTO
T146-TK02	Solvent Tank	RTO	19,500 gal	RTO
T146-TK03	Solvent Tank	RTO	19,500 gal	RTO
T146-TK04	Solvent Tank	RTO	19,500 gal	RTO
T146-TK05	Solvent Tank	RTO	19,500 gal	RTO
T146-TK06	Solvent Tank	RTO	19,500 gal	RTO
T146-TK07	Solvent Tank	RTO	19,500 gal	RTO
T146-TK08	Solvent Tank	RTO	19,500 gal	RTO
T146-TK09	Solvent Tank	RTO	19,500 gal	RTO

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	Control Device
T146-TK10	Solvent Tank	RTO	19,500 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
Building T64:				
T64-TK2	Phenol Storage Tank	RTO	10,000 gal	RTO

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) The Permittee shall route the vapors from each operating BPM solvent storage tank through a closed-vent system to either the RTO control system or the T79 fume incinerator control system. The operation, inspection and maintenance requirements for the RTO control system and T79 fume incinerator control system, and associated closed-vent systems, used to control emissions from these emission units are described in Sections D.14 and D.15 of this permit, respectively.

(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 year.

(b) BPM solvent storage tanks storing VOC/VOHAP with a vapor pressure less than 3.5 kPa are not subject to the requirements of D.9.1 (b)(1) and (c).

(c) BPM solvent storage tanks that are unsafe or difficult to inspect are not subject to the requirements of D.9.1(c).

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

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

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

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

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

(4) Detailed plans and/or procedures for operating and maintaining the process during periods of SSM; and

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

D.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 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 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.

(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)] and the PSD BACT requirements [326 IAC 2-1.1-11]:

(A) Semiannual visual inspections conducted during which a leak was detected;

(B) Periods of planned routine maintenance; and

(C) SSM summary reports for the processes.

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

(3) The reporting requirements for the LDAR standards are described in Section E of this permit.

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

(c) Immediate Reporting Requirements

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

(1) Any time an action taken by the Permittee during an SSM event of the process is not consistent with the procedures specified in the SSM Plan, the Permittee shall report the actions taken for that event. The immediate report shall be submitted to the agency via a telephone call or facsimile within 2 working days after commencing actions inconsistent with the plan.

(2) Within 7 working days after the end of an SSM event of the process where an action taken by the Permittee is not consistent with the procedures specified in the SSM Plan, the Permittee shall submit a letter containing the following information in accordance with 40 CFR 63.10(d)(5):

(A) Name, title and signature of responsible official certifying accuracy;

(B) Explanation of the circumstances for the event;

(C) Reason for not following the SSM Plan; and

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

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

D.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.

SECTION D.10 BPM SUPPORT OPERATIONS – WASTE TANK CONDITIONS

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

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

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	Control Device
Building T27:				
T27-TK53-10*	Waste Tank	RTO	500 gal	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 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-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
Tank Module Building T140:				
T140-TK3122	Waste Tank	T79 Incinerator	38,425 gal	T79 Incinerator
T140-TK3123	Waste Tank	T79 Incinerator	38,425 gal	T79 Incinerator
T140-TK3124	Waste Tank	T79 Incinerator	38,425 gal	T79 Incinerator
T140-TK3125	Waste Tank	T79 Incinerator	38,425 gal	T79 Incinerator
T140-TK3126	Waste Tank	T79 Incinerator	38,425 gal	T79 Incinerator
T140-TK3227*	Waste Tank	T79 -324 stream	18,130 gal	T79 Incinerator
T140-TK3228*	Waste Tank	T79 - 324 stream	18,130 gal	T79 Incinerator
T140-TK3229*	Waste Tank	T79 - 324 stream	500 gal	T79 Incinerator
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

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	Control Device
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
Tank Module Building T143:				
T143-TK02*	Waste Tank	T79 - 325 stream	19,500 gal	T79 Incinerator
T143-TK06*	Waste Tank	T79 - 325 stream	19,500 gal	T79 Incinerator
T143-TK08	Waste Tank	T79 Incinerator	19,500 gal	T79 Incinerator
T143-TK10*	Waste Tank	T79 - 325 stream	19,500 gal	T79 Incinerator
T143-TK15*	Waste Tank	T79 - 325 stream	19,500 gal	T79 Incinerator
T143-TK56*	Knock Out Pot	T79 Incinerator	45 gal	T79 Incinerator
Tank Module Building T145:				
T145-TK76*	Knock Out Pot	T79 Incinerator	45 gal	T79 Incinerator
T145-TK77*	Knock Out Pot	T79 Incinerator	45 gal	T79 Incinerator
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	18,644 gal	RTO
T146-TK20*	Waste Tank	RTO	18,644 gal	RTO
T146-TK21*	Waste Tank	RTO	18,644 gal	RTO
T146-TK12	Solvent Tank	RTO	19,500 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 Incinerator
T48-TK3208*	Waste Tank	T79 - 324 stream	102,759 gal	T79 Incinerator
T48-TK3209*	Waste Tank	T79 - 324 stream	102,759 gal	T79 Incinerator
T48-TK3211*	Waste Tank	T79 - 324 stream	260,650 gal	T79 Incinerator
T48-TK3212*	Waste Tank	T79 - 324 stream	260,650 gal	T79 Incinerator

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

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) The Permittee shall route the vapors from each operating BPM waste storage tank through a closed-vent system to either the RTO control system or the T79 fume incinerator control system. The operation, inspection and maintenance requirements for the RTO control system and T79 fume incinerator control system, and associated closed-vent systems, used to control emissions from these emission units are described in Sections D.14 and D.15 of this permit, respectively.

(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, and 326 IAC 2-2-3]

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

(b) BPM waste storage tanks storing VOC/VOHAP with a vapor pressure less than 3.5 kPa are not subject to the requirements of D.10.1 (b)(1) and (c).

(c) BPM waste storage tanks that are unsafe or difficult to inspect are not subject to the requirements of D.10.1(c).

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

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

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

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

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

(1) Detailed plans and/or procedures for operating and maintaining the process during periods of SSM; and

(2) Corrective action program for malfunctioning processes.

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

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

D.10.5 Requirements

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

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 ~~to~~:

(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.

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

(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.

(2) 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.

(3) The reporting requirements for the LDAR standards are described in Section E of this permit.

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

(c) Immediate Reporting Requirements

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

(1) Any time an action taken by the Permittee during an SSM event of a process is not consistent with the procedures specified in the SSM Plan, the Permittee shall report the actions taken for that event. The immediate report shall be submitted to the agency via a telephone call or facsimile within 2 working days after commencing actions inconsistent with the plan.

(2) Within 7 working days after the end of an SSM event of a process where an action taken by the Permittee is not consistent with the procedures specified in the SSM Plan, the Permittee shall submit a letter containing the following information in accordance with 40 CFR 63.10(d)(5):

(A) Name, title and signature of responsible official certifying accuracy;

(B) Explanation of the circumstances for the event;

(C) Reason for not following the SSM Plan; and

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

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

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

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

(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.11 BPM SUPPORT OPERATIONS – WASTE CONTAINER CONDITIONS

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

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

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	Control Device
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).

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.

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.

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

(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.

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

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

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

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

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

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

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 63.1203 and 40 CFR 52, Subpart P]

(a) In order to satisfy the HWC MACT standards [40 CFR 63.1203(a)(7)] and the approved Indiana State Implementation Plan (SIP) applicable to incinerators [40 CFR 52, Subpart P], the particulate matter (PM) emissions from the T49 liquid waste incinerator stack exhaust shall not exceed 34 milligrams per dry standard cubic meter (mg/dscm) (0.015 grains per dry standard cubic feet (gr/dscf)), corrected to 7 percent oxygen.

(b) In order to satisfy the approved SIP applicable to incinerators [40 CFR Part 52, Subpart P], the T49 liquid waste incinerator shall:

(1) Consist of primary and secondary chambers or the equivalent. The design and operation of this incinerator in accordance with the requirements of this section of the permit is equivalent to the design and operation of a primary and secondary chamber,

(2) Be equipped with a primary burner unless burning wood products,

(3) Comply with 326 IAC 5-1 and 326 IAC 2,

(4) Be maintained properly as specified by the manufacturer and approved by the commissioner. The issuance of this permit shall be considered approval by the commissioner,

(5) Be operated according to the manufacturer's recommendations and only burn waste approved by the commissioner. The issuance of this permit shall be considered approval by the commissioner,

(6) Comply with other state and/or local rules or ordinances regarding installation and operation of incinerators,

(7) Be operated so that emissions of hazardous material including, but not limited to, viable pathogenic bacteria, dangerous chemicals or gases, or noxious odors are prevented,

(8) Not emit particulate matter in excess of three-tenths (0.3) pounds of particulate matter per one thousand (1,000) pounds of dry exhaust gas at standard conditions corrected to fifty percent (50%) excess air, and

(9) Not create a nuisance or a fire hazard.

If any of the above result, the burning shall be terminated immediately.

The terms of Condition D.12.2 (b) will no longer apply upon USEPA approval of the revised requirements of 326 IAC 4-2 (26 Ind. Reg. 1071) into the SIP because the T49 liquid waste incinerator is subject to 40 CFR 63, Subpart EEE.

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 – In order to satisfy the HWC MACT standards [40 CFR 63.1203(a)(2)], the mercury emissions from the T49 liquid waste incinerator stack exhaust shall not exceed 130 ug/dscm, corrected to 7% oxygen.

(b) Lead and Cadmium – In order to satisfy the HWC MACT standards [40 CFR 63.1203(a)(3)], the total semi-volatile metals (lead and cadmium) emissions from the T49 liquid waste incinerator stack exhaust shall not exceed 240 ug/dscm, corrected to 7% oxygen.

(c) Arsenic, Beryllium, and Chromium – In order to satisfy the HWC MACT standards [40 CFR 63.1203(a)(4)], the total low volatile metals (arsenic, beryllium, and chromium) emissions from the T49 liquid waste incinerator stack exhaust shall not exceed 97 ug/dscm, corrected to 7 percent oxygen.

(d) Hydrochloric Acid/Chlorine Gas (HCl/Cl_2) and Fluorides – In order to satisfy the HWC MACT standards [40 CFR 63.1203(a)(6)], the HCl/Cl_2 emissions from the T49 liquid waste incinerator stack exhaust shall not exceed 77 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 a HCl control efficiency of 98% or greater.

(e) Dioxin/Furans – In order to satisfy HWC MACT standards [40 CFR 63.1203(a)(1)], 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 63.1203(c)(1) and (2)], the Permittee shall comply with the following requirements:

(1) The destruction and removal efficiency (DRE) for each principle organic hazardous constituent (POHC), excluding dioxin-listed hazardous wastes F020, F021, F022, F023, F026, or F027 shall be at least 99.99 percent.

(2) Dioxin-listed hazardous wastes F020, F021, F022, F023, F026, or F027 shall not be burned in the T49 liquid waste incinerator.

D.12.6 Carbon Monoxide (CO) Emission Standards [326 IAC 2-2-3, 40 CFR Part 52, Subpart P, and 40 CFR 63.1203]

(a) In order to satisfy the HWC MACT standards [40 CFR 63.1203(a)(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.

(b) In order to satisfy the carbon monoxide emission limitations in the approved SIP [40 CFR Part 52, Subpart P], the Permittee shall control carbon monoxide emissions in a direct flame afterburner or other controls approved by the Commissioner. Compliance with the emission limits described in D.12.6 (a) constitutes an approved control methodology. The terms of Condition D.12.6 (b) will no longer apply upon USEPA approval of the revised requirements of 326 IAC 9-1-2 into the SIP because the T49 liquid waste incinerator is subject to 40 CFR 63, Subpart EEE.

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 for HC [40 CFR 63.1203(a)(5)(i)] and the PSD BACT requirements for VOC [326 IAC 2-2-3], the hourly rolling average hydrocarbon emissions, as monitored with a CEMS during the POHC DRE test, shall not exceed 10 ppmv dry corrected to 7% oxygen or 99.99 percent, reported as propane.

(b) During the POHC DRE test, 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) In order to satisfy 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). SSM Plan shall be developed and implemented in accordance with 40 CFR 63.1206(c)(2), 40 CFR 63.6(e)(3), and 40 CFR 63.8(c), to ensure that the T49 liquid waste incinerator, including associated air emission control equipment and CEMS and CMS, is operated and maintained in a manner which satisfies the general duty to minimize emissions established by 40 CFR 63.6(e)(1)(i), and that all malfunctions are corrected as soon as practicable after their occurrence in order to minimize excess emissions. The SSM Plan shall contain the following information:

(1) Detailed procedures for operating and maintaining the T49 liquid waste incinerator system, including associated CEMS and CMS equipment, during periods of startup, shutdown, and malfunction; and

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

(c) Feedstream Analysis Plan -The Feedstream Analysis Plan shall be developed and implemented in accordance with 40 CFR 63.1209(c)(2) for those parameters with feed rate limits defined in Condition D.12.15.

(d) Continuous Emissions Monitoring System (CEMS) Standard Operating Procedures (SOP) – The Permittee shall prepare and implement a SOP that provides step-by-step procedures and operations of the CEMS in accordance with 326 IAC 3-5-4(a)(9) – Preventive maintenance procedures and corrective maintenance procedures that include those procedures taken to ensure continuous operation and to minimize malfunctions.

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

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

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

(a) Initial Comprehensive Performance Test Requirements:

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

(2) The Permittee shall perform initial comprehensive performance tests within 6 months after the HWC MACT compliance date unless an exemption is granted pursuant to 40 CFR 63.1207(e)(3).

(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 initial comprehensive performance tests shall be conducted under operating conditions representative of the extreme range of normal conditions as specified in 40 CFR 63.6(f)(2)(iii)(B) 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) Subsequent Comprehensive Performance Tests

(1) Pursuant to 40 CFR 63.1207(d)(4)(i), no subsequent comprehensive performance tests (including DRE tests) shall be required until the U.S. EPA promulgates permanent replacement standards pursuant to the Settlement Agreement noticed in the Federal Register on November 16, 2001, unless the Permittee modifies or otherwise alters operations such that compliance with the emission standards of Conditions D.12.2, D.12.5, and D.12.7 cannot be achieved.

(2) Upon promulgation of the permanent replacement standards, the Permittee shall comply with the subsequent comprehensive testing requirements established.

(c) Confirmatory Performance Tests

(1) Pursuant to 40 CFR 63.1207(d)(4)(ii), no confirmatory performance tests shall be required until the U.S. EPA promulgates permanent replacement standards pursuant to the Settlement Agreement noticed in the Federal Register on November 16, 2001.

(2) Upon promulgation of the permanent replacement standards, the Permittee shall comply with the subsequent comprehensive testing requirements established.

D.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 operation is defined as the collection of at least one measurement for each successive 15-second period.

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

□□□ 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™ scrubber 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 following CMS in accordance with the quality assurance requirements specified in 40 CFR 63.1209(d) at all times the T49 incinerator is burning waste. To satisfy the HWC MACT standards [40 CFR 63.1209(b), (d), (e), (f), and (h)] and the requirements for PSD sources [326 IAC 2-1.1-11] the following parameters shall be monitored when burning waste:

(1) Dioxin/Furan CMS Requirements – Pursuant to the HWC MACT standards [40 CFR 63.1209(k)], the Permittee shall install and operate CMS monitors for the following parameters:

(A) Combustion Chamber Temperature - Minimum rolling hourly average combustion chamber temperature established from the average temperature measured during the three DRE test runs;

(B) Combustion Air Flow Rate - Maximum hourly rolling average combustion air flow rate established from the average of the maximum hourly rolling average for each performance test run; and

(C) Primary Waste Feed Rate – Maximum hourly rolling average primary waste feed rate as established from the average of the maximum hourly rolling averages for each performance test run.

(D) Secondary Waste Feed Rate - Maximum hourly rolling average secondary waste feed rate as established from the average of the maximum hourly rolling averages for each performance test run.

(2) DRE Standard CMS Requirements – Pursuant to the HWC MACT standards [40 CFR 63.1209(j)], the Permittee shall install and operate CMS monitors for those parameters identified in Condition D.12.15 (a)(1).

(3) Metals CMS Requirements – Pursuant to the HWC MACT standards [40 CFR 63.1209(l) and (n)], the Permittee shall install and operate CMS monitors for the following parameters:

(A) Waste Feed Rate - Maximum 12-hour rolling average feed rates for total Hg, semi-volatile metals (cadmium and lead) and low volatile metals (arsenic, beryllium, and chromium) in all waste feedstreams established from the average of the hourly rolling averages for each performance test run and approved extrapolation techniques;

(B) Scrubber Liquids Solid Content - Maximum 12-hour rolling average solids content of the scrubber liquid using a continuous monitoring system established from the average of the performance test run averages. This parameter does not apply to mercury;

(C) Hydro-Sonic™ Scrubber Pressure Drop - Minimum hourly rolling average pressure drop across the Hydro-Sonic™ scrubber established from the average of the performance test run averages;

(D) Scrubber Liquid Flow Rate - Minimum hourly rolling average scrubber liquid flow rate established from the average of the performance test run averages; and

(E) Flue Gas Flow Rate - Maximum hourly rolling average flue gas flow rate, the maximum production rate, or another surrogate parameter for gas residence time, established from the average of the maximum hourly rolling averages for each test run.

(4) PM CMS Requirements – Pursuant to the HWC MACT standards [40 CFR 63.1209(m)], the Permittee shall install and operate CMS monitors for the following parameters:

(A) Those parameters identified in Condition D.12.15 (a)(3)(B), (C), and (D); and

(B) Ash Feed Rate - Maximum 12-hour average ash feed rate established from the average of the test run averages.

(5) HCl/Cl_2 and Fluorides CMS Requirements – Pursuant to the HWC MACT standards [40 CFR 63.1209(o)] and compliance monitoring requirements for PSD sources [326 IAC 2-1.1-11], the Permittee shall install and operate CMS monitors for the following parameters:

(A) Those parameters identified in Condition D.12.15 (a)(3)(C), (D) and (E).

(B) Waste Feed Rate - Maximum 12-hour rolling average feed rates for chlorine (organic and inorganic) in all waste feedstreams established from the average of the performance test run averages. [40 CFR 63.1209(o)(1)]

(C) Scrubber Liquid pH - Minimum hourly rolling average scrubber liquid pH established from the average of the performance test run averages. [40 CFR 63.1209(o)(3)(iv)]

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

(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 in accordance with Section C - General Record Keeping Requirements of this permit:

(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.

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

(b) Immediate Reporting Requirements

(1) The Permittee shall submit any revision to the SSM Plan that may significantly increase emissions of hazardous air pollutants to the Administrator for approval within 5 days after making a change to the plan to satisfy the reporting requirements under the HWC MACT standards [40 CFR 63.1206(c)(2)(ii)(C)].

(2) The reporting requirements in the NESHAP General Provisions for Startup, Shutdown and Malfunction (SSM) Plans [40 CFR 63.6(e)(3)] shall be used to satisfy the reporting requirements under the HWC MACT standards [40 CFR 63.1206(c)(2)] and PSD BACT requirements [326 IAC 2-1.1-11].

(A) The Permittee shall report all actions taken during 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 where an action taken by the Permittee is not consistent with the procedures specified in the SSM Plan, the Permittee shall submit a letter containing the following information in accordance with 40 CFR 63.10(d)(5):

(i) Name, title and signature of responsible official certifying accuracy;

(ii) Explanation of the circumstances of the event;

(iii) Reason for not following the SSM Plan; and

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

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 ROTARY KILN INCINERATOR, INCLUDING ASSOCIATED AIR POLLUTION CONTROL EQUIPMENT AND CONTINUOUS MONITORING SYSTEMS

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

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

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

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

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 rotary kiln incinerator shall have a permit issued under 40 CFR 270 whenever off-site waste material is treated and destroyed in the T149 rotary kiln 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 63.1203 and 40 CFR 52, Subpart P]

(a) In order to satisfy the HWC MACT standards [40 CFR 63.1203(b)(7)] and the approved Indiana State Implementation Plan (SIP) applicable to incinerators [40 CFR 52, Subpart P], the particulate matter (PM) emissions from the T149 rotary kiln incinerator stack exhaust shall not exceed 34 mg/dscm (0.015 gr/dscf), corrected to 7 percent oxygen.

(b) In order to satisfy the approved SIP applicable to incinerators [40 CFR Part 52, Subpart P], the T149 rotary kiln incinerator shall:

(1) Consist of primary and secondary chambers or the equivalent. The design and operation of this incinerator in accordance with the requirements of this section of the permit is equivalent to the design and operation of a primary and secondary chamber.

(2) Be equipped with a primary burner unless burning wood products,

(3) Comply with 326 IAC 5-1 and 326 IAC 2,

(4) Be maintained properly as specified by the manufacturer and approved by the commissioner. The issuance of this permit shall be considered approval by the commissioner.

(5) Be operated according to the manufacturer's recommendations and only burn waste approved by the commissioner. The issuance of this permit shall be considered approval by the commissioner.

(6) Comply with other state and/or local rules or ordinances regarding installation and operation of incinerators,

(7) Be operated so that emissions of hazardous material including, but not limited to, viable pathogenic bacteria, dangerous chemicals or gases, or noxious odors are prevented,

(8) Not emit particulate matter in excess of three-tenths (0.3) pounds of particulate matter per one thousand (1,000) pounds of dry exhaust gas at standard conditions corrected to fifty percent (50%) excess air, and

(9) Not create a nuisance or a fire hazard.

If any of the above result, the burning shall be terminated immediately.

The terms of Condition D.13.2 (b)(2) will no longer apply upon USEPA approval of the revised requirements of 326 IAC 4-2 (26 Ind. Reg. 1071) into the SIP because the T149 rotary kiln incinerator is subject to 40 CFR 63, Subpart EEE.

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 rotary kiln 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 rotary kiln 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 rotary kiln 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 63.1203]

Except for periods of startup, shutdown and malfunctions, 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 63.1203(b)(2)], the mercury emissions from the T149 rotary kiln incinerator stack exhaust shall not exceed 45 ug/dscm, corrected to 7% oxygen.

(b) Lead and Cadmium – Pursuant to the HWC MACT standards [40 CFR 63.1203(b)(3)], the total semi-volatile metals (lead and cadmium) emissions from the T149 rotary kiln incinerator stack exhaust shall not exceed 120 ug/dscm, corrected to 7 percent oxygen.

(c) Arsenic, Beryllium, and Chromium – Pursuant to the HWC MACT standards [40 CFR 63.1203(b)(4)], the total low volatile metals (arsenic, beryllium, and chromium) emissions from the T149 rotary kiln incinerator stack exhaust shall not exceed 97 ug/dscm, corrected to 7 percent oxygen.

(d) Hydrochloric Acid/Chlorine Gas (HCl/Cl_2) and Fluorides - In order to satisfy the HWC MACT standards [40 CFR 63.1203(b)(6)], the HCl/Cl_2 emissions from the T149 rotary kiln incinerator stack exhaust shall not exceed 21 ppmvdc, expressed as HCl equivalent. In order to satisfy the PSD BACT requirements for fluorides [326 IAC 2-2-3], the T49 liquid waste incinerator control system shall achieve a HCl control efficiency of 98 percent or greater.

(e) Dioxin/Furans – Pursuant to HWC MACT standards [40 CFR 63.1203(b)(1)], the dioxin/furan emissions from the T149 rotary kiln incinerator stack exhaust shall not exceed 0.20 ng TEQ/dscm, corrected to 7 percent oxygen.

(f) Principle Organic Hazardous Constituents (POHCs) – Pursuant to the HWC MACT standards [40 CFR 63.1203(c)(1) and (2)], the Permittee shall comply with the following requirements:

(1) The destruction and removal efficiency (DRE) for each principle organic hazardous constituent (POHC), excluding dioxin-listed hazardous wastes F020, F021, F022, F023, F026, or F027 shall be at least 99.99 percent.

(2) Dioxin-listed hazardous wastes F020, F021, F022, F023, F026, or F027 shall not be burned in the T149 rotary kiln incinerator.

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

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

(b) In order to satisfy the CO emission limitations in the approved State Implementation Plan (SIP) [40 CFR Part 52, Subpart P], the Permittee shall control carbon monoxide emissions in a direct flame afterburner or other controls approved by the Commissioner. Compliance with the emission limits described in D.13.6 (a) constitutes an approved control methodology. The terms of Condition D.13.6 (b) will no longer apply upon USEPA approval of the revised requirements of 326 IAC 9-1-2 into the SIP because the T149 rotary kiln incinerator is subject to 40 CFR 63, Subpart EEE.

D.13.7 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 63.1203(b)(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 rotary kiln 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 SO2 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

(3) 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 rotary kiln 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 rotary kiln 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 rotary kiln 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 rotary kiln incinerator is in operation and the T149 rotary kiln 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), 40 CFR 63.6(e)(3), and 40 CFR 63.8(c), to ensure that the T149 rotary kiln incinerator, including associated air emission control equipment and CEMS and CMS, is operated and maintained in a manner which satisfies the general duty to minimize emissions established by 40 CFR 63.6(e)(1)(i), and that all malfunctions are corrected as soon as practicable after their occurrence in order to minimize excess emissions. The SSM Plan shall contain the following information:

(1) Detailed procedures for operating and maintaining the T149 rotary kiln 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 AIC 3-6]

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

(a) Initial Comprehensive Performance Test Requirements:

(1) The Permittee shall submit a notification of intention to conduct a comprehensive performance test and CMS performance evaluation and a site-specific test plan

and CMS performance evaluation test plan at least one year before the performance test and performance evaluation are scheduled to begin.

(2) The Permittee shall perform initial comprehensive performance tests within 6 months following the initial introduction of hazardous waste in the rotary kiln incinerator 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 initial comprehensive tests shall be conducted under operating conditions representative of the extreme range of normal conditions as specified in 40 CFR 63.6(f)(2)(iii)(B) 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.13.15 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) Subsequent Comprehensive Performance Tests

(1) Pursuant to 40 CFR 63.1207(d)(4)(i), no subsequent comprehensive performance tests (including DRE tests) shall be required until the U.S. EPA promulgates permanent replacement standards pursuant to the Settlement Agreement noticed in the Federal Register on November 16, 2001, unless the Permittee modifies or otherwise alters operations such that compliance with the emission standards of Conditions D.13.2, D.13.5, and D.13.7 cannot be achieved.

(2) Upon promulgation of the permanent replacement standards, the Permittee shall comply with the subsequent comprehensive testing requirements established.

(c) Confirmatory Performance Tests

(1) Pursuant to 40 CFR 63.1207(d)(4)(ii), no confirmatory performance tests shall be required until the U.S. EPA promulgates permanent replacement standards pursuant to the Settlement Agreement noticed in the Federal Register on November 16, 2001.

(2) Upon promulgation of the permanent replacement standards, the Permittee shall comply with the subsequent comprehensive testing requirements established.

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

(a) CO and O_2 CEMS Operation Requirements – The following requirements shall be applied at all times the T149 rotary kiln incinerator is in operation and represent the streamlined requirements of the HWC MACT standards for CO and HC [40 CFR 63.1209(a), (d), (e), (f), and (h)], PSD BACT requirements for CO and VOC [326 IAC 2-1.1-11], and the emission monitoring requirements for MACT and PSD sources [326 IAC 3-5-1(b) and (d)]:

(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 operation is defined as the collection of at least one measurement for each successive 15-second period, regardless of startup, shutdown and malfunction.

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

(1) The Permittee shall install and operate the 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 operation is defined as the collection of at least one measurement for each successive 15-minute period.

□□□ 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™ scrubber 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.

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 CMS in accordance with the quality assurance requirements specified in 40 CFR 63.1209(d) at all times the T149 rotary kiln incinerator is burning waste. To satisfy the HWC MACT standards [40 CFR 63.1209(b), (d), (e), (f), and (h)] and the requirements for PSD sources [326 AIC 2-1.1-11] the following parameters shall be monitored when burning waste:

(1) Dioxin/Furan CMS Requirements – Pursuant to the HWC MACT standards [40 CFR 63.1209(k)], the Permittee shall install and operate CMS monitors for the following parameters:

(A) Combustion Chamber Temperature - Minimum rolling hourly average combustion chamber temperature established from the average temperature measured during the three DRE test runs;

(B) Flue Gas Flow Rate - Maximum hourly rolling average flue gas flow rate established from the average of the maximum hourly rolling average for each performance test run; and

(C) Primary Waste Feed Rate – Maximum hourly rolling average primary waste feed rate as established from the average of the maximum hourly rolling averages for each performance test run.

(D) Secondary Waste Feed Rate - Maximum hourly rolling average secondary waste feed rate as established from the average of the maximum hourly rolling averages for each performance test run.

(2) DRE Standard CMS Requirements – Pursuant to the HWC MACT standards [40 CFR 63.1209(j)], the Permittee shall install and operate CMS monitors for those parameters identified in Condition D.13.16 (a)(1).

(3) Metals CMS Requirements – Pursuant to the HWC MACT standards [40 CFR 63.1209(l) and (n)], the Permittee shall install and operate CMS monitors for the following parameters:

(A) Waste Feed Rate - Maximum 12-hour rolling average feed rates for total Hg, semi-volatile metals (cadmium and lead) and low volatile metals (arsenic, beryllium, and chromium) in all waste feedstreams established from the average of the hourly rolling averages for each performance test run and approved extrapolation techniques;

(B) Scrubber Liquids Solid Content - Maximum 12-hour rolling average solids content of the scrubber liquid using a continuous monitoring system established from the average of the performance test run averages. This parameter does not apply to mercury;

(C) Hydro-Sonic™ Scrubber Pressure Drop - Minimum hourly rolling average pressure drop across the Hydro-Sonic™ scrubber established from the average of the performance test run averages;

(D) Scrubber Liquid Flow Rate - Minimum hourly rolling average scrubber liquid flow rate established from the average of the performance test run averages; and

(E) Flue Gas Flow Rate - Maximum hourly rolling average flue gas flow rate, the maximum production rate, or another surrogate parameter for gas residence time, established from the average of the maximum hourly rolling averages for each test run.

(4) PM CMS Requirements – Pursuant to the HWC MACT standards [40 CFR 63.1209(m)], the Permittee shall install~~ing~~ and operate CMS monitors for the following parameters:

(A) Those parameters identified in Condition D.13.16 (a)(3)(B), (C), and (D); and

(B) Ash Feed Rate - Maximum 12-hour average ash feed rate established from the average of the test run averages.

(5) HCl/Cl_2 and Fluorides CMS Requirements – Pursuant to the HWC MACT standards [40 CFR 63.1209(o)] and compliance monitoring requirements for PSD sources [326 IAC 2-1.1-11], the Permittee shall install and operate CMS monitors for the following parameters:

(A) Those parameters identified in Condition D.13.16 (a)(3)(C), (D) and (E).

(B) Waste Feed Rate - Maximum 12-hour rolling average feed rates for chlorine (organic and inorganic) in all waste feedstreams established from the average of the performance test run averages. [40 CFR 63.1209(o)(1)]

(C) Scrubber Liquid pH - Minimum hourly rolling average scrubber liquid pH established from the average of the performance test run averages. [40 CFR 63.1209(o)(3)(iv)]

(b) Continuous operation is defined as the collection of at least one measurement for each successive 15-second period, regardless of startup, shutdown and malfunction.

(c) Pursuant to the HWC MACT standards [40 CFR 63.1209(a)(5)] and the compliance monitoring methods for PSD sources [326 IAC 2-1.1-11], the Permittee may petition the Administrator to use CEMS for compliance monitoring in lieu of compliance with the operating parameter limits established in (a) of this condition.

(d) If applicable, the Permittee may document compliance using the waiver provisions of 40 CFR 63.1207(m) in lieu of complying with (a) and (c) of this condition.

D.13.16 Fuel Oil Sampling and Analysis for 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 in accordance with Section C - General Record Keeping Requirements of this permit:

(1) Notifications, reports, and other documents, such as the Documentation of Compliance, as required by 40 CFR 63.1200, 63.1211(c), and 63.10(b) and (c).

(2) All data recorded by continuous monitoring systems (CMS), including continuous emission monitoring systems (CEMS), required by Conditions D.13.14, D.13.15, and D.13.17;

(3) Documentation that a change will not adversely affect compliance with the emission standards or operating requirements as required by 40 CFR 63.1206(b)(5)(ii);

(4) Records of the estimated hazardous waste residence time as required by 40 CFR 63.1206(b)(11);

(5) Plans and procedures as required by Condition D.13.12;

(6) Documentation of the results of the investigation, corrective measures taken, and evaluation of excessive exceedances during malfunctions as required by 40 CFR 63.1206(c)(2)(v)(A);

(7) Corrective Measures for any AWFCO that results in an exceedance of an applicable emission standard or operating parameter limit as required by 40 CFR 63.1206(c)(3)(v);

(8) Documentation and results of the AWFCO operability testing as required by Condition D.13.10 (b) and 40 CFR 63.1206(c)(3)(vii);

(9) Corrective measures for any ESV opening as required by 40 CFR 63.1206(c)(4)(iii);

(10) Daily visual inspection records of the T149 rotary kiln incinerator to ensure the combustion zone is sealed as required by Condition D.13.10 (a) and 40 CFR 63.1206(c)(5);

(11) A copy of the Operator Certification and Training Program required by Condition D.13.11 and 40 CFR 63.1206(c)(6); and

(12) Documentation of the changes in modes of operation as required by 40 CFR 63.1209(q).

(13) For days when condition D.13.17 requires that CEMS data must be supplemented, the documentation of the information required by Condition D.13.14 (b)(3).

(b) The record keeping and reporting requirements for the LDAR standards are described in Section E.2 of this permit.

(c) The Permittee shall maintain quarterly records of all fuel oil used in the T149 rotary kiln incinerator on a calendar month average basis, for the following:

(1) Sulfur content;

(2) Heat content;

(3) Fuel consumption; and

(4) Sulfur dioxide emission rate in pounds per MMBtu.

D.13.19 Reporting Requirements

(a) Quarterly Reporting Requirements

(1) The following streamlined quarterly reporting requirements shall satisfy the HWC MACT standards [40 CFR 63.1211], which references the MACT General Provisions [63.7-63.10], PSD BACT requirements [326 IAC 2-1.1-11], and the continuous emissions monitoring requirements [326 IAC 3-5]:

(A) Reports shall be submitted within 30 days following the reporting period using the reporting forms located at the end of this permit, or their equivalent;

(B) Summary reports of excess emissions, parameter exceedances, and monitor downtime including information specified in 63.10(c)(5-(c)(13);

(C) SSM summary reports for the T49 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.

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

(b) Immediate Reporting Requirements

(1) The Permittee shall submit any revision to the SSM Plan that may significantly increase emissions of hazardous air pollutants to the Administrator for approval within 5 days after making a change to the plan to satisfy the reporting requirements under the HWC MACT standards [40 CFR 63.1206(c)(2)(ii)(C)].

(2) The reporting requirements in the NESHAP General Provisions for Startup, Shutdown and Malfunction (SSM) Plans [40 CFR 63.6(e)(3)] shall be used to satisfy the reporting requirements under the HWC MACT standards [40 CFR 63.1206(c)(2)] and PSD BACT requirements [326 IAC 2-1.1-11].

(A) The Permittee shall report all actions taken during T149 incinerator system SSM event that results in an exceedance of a relevant emission standard when those actions are in consistent with the procedures specified in the SSM Plan. The immediate report shall be submitted to the agency via a telephone call or facsimile within 2 working days after commencing actions inconsistent with the plan.

(B) Within 7 working days after the end of an SSM event where an action taken by the Permittee is not consistent with the procedures specified in the SSM Plan, the Permittee shall submit a letter containing the following information in accordance with 40 CFR 63.10(d)(5):

(i) Name, title and signature of responsible official certifying accuracy;

(ii) Explanation of the circumstances of the event;

(iii) Reason for not following the SSM Plan; and

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

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

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

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

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

Emission Unit 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 outlet of the production building roof fans exhausting to the RTO fume transport system and at the outlet side of the tank conservation vents of those tank modules exhausting to the RTO fume transport system and ends at the entrance of the RTO control system.

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

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 includes 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 limits.

(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 63.1260(g), 40 CFR 63.6(e)(3) and 63.8(c), and 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 63.1260(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), provided the Permittee complies with the provisions of the startup, shutdown, and malfunction plan (SSM Plan) required by Condition D.14.3.

(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), 40 CFR 63.6(e)(3), 40 CFR 63.8(c) and 326 IAC 2-2-3]

(a) The NESHAP General Provisions for Startup, Shutdown and Malfunction (SSM) Plans [40 CFR 63.6(e)(3)] 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 2-2.1.11].

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

(1) Detailed 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.

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

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

(a) CO, 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, 40 CFR 63.8, 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 a HCl Gas Continuous Emission Monitor* submitted to EPA OAQPS on August 15, 2003, as allowed by 40 CFR 63.1258(b) and 40 CFR 63.8.

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

(d) CEMS Standard Operating Procedures (SOP) - The Permittee shall prepare and implement an SOP that provides step-by-step procedures and operations in accordance with 326 IAC 3-5-4(a) (9) – Preventive maintenance procedures and corrective maintenance procedures that include those procedures taken to ensure continuous operation and to minimize malfunctions.

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

(a) Initial Comprehensive Performance Test Requirements:

(1) VOC/VOHAP – When applying the control efficiency standard, the following streamlined requirements shall apply only when burning waste fume streams to satisfy the Pharmaceutical MACT standards [40 CFR 63.1257(b), (c), and (d) and 63.1258(b)], Offsite Waste MACT standards [40 CFR 63.693(f)], Volatile Organic Liquid Storage Vessel requirements [40 CFR 60.113b(c)], PSD BACT requirements [326 IAC 2-1.1-11], and emission testing requirements for MACT sources [326 IAC 3-6-3(c)]:

(A) Prior to applying the control efficiency emission standard, the Permittee shall conduct an initial performance test in accordance with the methods set forth in 40 CFR 63.1257.

(B) The Permittee shall submit a notification of the performance test and a site-specific test plan at least 60 days in advance of the intended performance test date.

(C) The operating parameters defined in Condition D.14.1 (a)(4)(B) shall be monitored during the performance test to establish the 24-hour daily average parametric limits, according to the requirements of 40 CFR 63.1258(b)(3).

(D) The Permittee shall submit the performance test reports, and upon request, the CMS performance evaluation, within 45 days following the test. The Permittee is allowed an extension if a reasonable explanation is provided within 40 days following the test.

(2) Hydrogen Halide/Halogen – When applying the control efficiency standard, the following requirements shall apply only when burning waste fume streams to satisfy the Pharmaceutical MACT standards [40 CFR 63.1258(b)] and the PSD BACT requirements for fluorides [326 IAC 2-1.1-11]:

(A) 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.14.6 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, 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.14.7 Excursions [40 CFR 63.1258(b)(6), 40 CFR 63.695(e)(4), 326 IAC 2-1.1-11]

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

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

(2) When the period of control device operation (i.e., receiving waste fume streams) is less than 4 hours in an operating day and more than one of the hours during the period of operation does not constitute a valid hour of data due to insufficient monitoring data.

(b) A valid hour requires at least one data point for each 15-minute period in the operating hour.

D.14.8 Minimum Data Requirements – 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. 4 (a)(3), D.14.9 (a)(1)(L), and D.14.9 (b)(2):

(a) When the period of RTO operation (i.e., receiving waste streams) is 4 hours or greater in an operating day and monitoring data are insufficient to constitute a valid hour of data for at least 75 percent of the operating hours, or

(b) When the period of RTO operation (i.e., receiving waste streams) is less than 4 hours in an operating day and more than one of the hours during the period of operation does not constitute a valid hour of data due to insufficient monitoring data.

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

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

D.14.9 Record Keeping and Reporting Requirements

(a) Record Keeping Requirements

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

(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], which reference the MACT General Provisions [40 CFR 63.7 – 63.10], Volatile Organic Liquid Storage Vessel requirements [40 CFR 60.115b], PSD BACT requirements [326 IAC 2-1.1-11], 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 has 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.

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

(c) Immediate Reporting Requirements

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

(1) The Permittee shall report all actions taken during an RTO system SSM event that results in an exceedance of a relevant emission standard when those actions are inconsistent with the procedures specified in the SSM Plan. The immediate report shall be submitted to the agency via a telephone call or facsimile within 2 working days after commencing actions inconsistent with the plan.

(2) Within 7 working days after the end of an SSM event where an action taken by the Permittee is not consistent with the procedures specified in the SSM Plan, the Permittee shall submit a letter containing the following information in accordance with 40 CFR 63.10(d)(5):

(A) Name, title and signature of responsible official certifying accuracy;

(B) Explanation of the circumstances of the event;

(C) Reason for not following the SSM Plan; and

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

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

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

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

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

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

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

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

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

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

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

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

The T79 control system consists of two fume incinerators, identified as 310 and 311, each equipped with caustic scrubbing systems, and each exhausting to individual stacks.

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

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

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

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

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

(A) The VOC/VOHAP emissions shall be reduced by a control efficiency of 98% or more at the outlet of the T79 control system;

(B) The T79 combustion chamber shall maintain a minimum 24-hour daily average temperature established from a compliant stack test.

(2) Hydrogen halide and halogen Emission Standards – In order to satisfy the Pharmaceutical MACT requirements [40 CFR 63.1253(b), (c), and (d), 63.1254(a) and (c), 63.1256(b), (e) and (h), and 63.1258(b)] and PSD BACT requirements for fluorides [326 IAC 2-2-3], the Permittee shall meet the following streamlined hydrogen halide and halogen (including hydrogen fluoride) emission standards:

(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 from the must be viewable from a readily accessible location to verify that negative pressure is being maintained when waste fume streams are going to the control system.

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

(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 63.1260(g), 40 CFR 63.6(e)(3) and 63.8(c), and 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 63.1260(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), provided the Permittee complies with the provisions of the startup, shutdown, and malfunction plan (SSM Plan) required by Condition D.15.3.

(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), 40 CFR 63.6(e)(3), 40 CFR 63.8(c) and 326 IAC 2-2-3]

(a) The NESHAP General Provisions for Startup, Shutdown and Malfunction (SSM) Plans [40 CFR 63.6(e)(3)] 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 2-2.1.11].

(b) Pursuant to 40 CFR 63.6(e)(3), the Permittee shall develop an SSM Plan to ensure that the T79 fume incinerator control system, including associated CEMS and CMS equipment, is operated and maintained in a manner which satisfies the general duty to minimize emissions established by 40 CFR 63.6(e)(1)(i), and that all malfunctions are corrected as soon as practicable after their occurrence in order to minimize excess emissions. The SSM Plan shall contain the following information:

(1) Detailed procedures for operating and maintaining the 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.

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

D.15.4 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) Initial Comprehensive Performance Test Requirements:

(1) VOC/VOHAP Performance Test Requirements – The following streamlined requirements 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) 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.15.1 (a)(1) 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.

(2) Hydrogen Chloride Performance Test Requirements – The following requirements satisfy the Pharmaceutical MACT standards [40 CFR 63.1258(b)] and the PSD BACT requirements for fluorides [326 IAC 2-1.1-11]:

(A) The Permittee shall conduct a performance test to determine the hydrogen halides and halogens control efficiency standard, which includes fluorides, and 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.15.1 (a)(2) 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:

The Permittee shall repeat the performance tests for VOC/VOHAP and Hydrogen Halide/Halogens at least once every five years from the date of the most recent valid compliance demonstration.

D.15.5 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.15.6 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.15.7 Record Keeping and Reporting Requirements

(a) Record Keeping Requirements

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

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

(A) Reports shall be submitted within 30 days following the reporting period using the reporting forms located at the end of this permit, or their equivalent;

(B) If total duration of excess emissions, parameter exceedances, or excursions is 1% or greater of total operating time or total CMS downtime is greater than 5% for reporting period, include:

(i) 15-minute data and daily averages for all operating days out of range;

(ii) duration of excursions; and

(iii) operating logs and scenarios for all operating days out of range;

(C) Summary reports of excess emissions, parameter exceedances, and monitor downtime including information specified in 63.10(c)(5)-(c)(13);

(D) Report, when applicable, no excess emissions, no exceedances, no excursions, and no CMS has been inoperative, out of control, repaired or adjusted;

(E) CVS bypass lines with flow indicator: report all periods when vent stream is diverted from control device through bypass line;

(F) CVS with bypass lines without flow indicator: report periods which seal mechanism is broken, position has changed or key to unlock bypass line valve was checked out;

(G) Report each new operating scenario that has been operated since last report;

(H) SSM summary reports for the RTO control system, including associated CEMS and CMS equipment.

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

(c) Immediate Reporting Requirements

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

(1) The Permittee shall report all actions taken during 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 where an action taken by the Permittee is not consistent with the procedures specified in the SSM Plan, the Permittee shall submit a letter containing the following information in accordance with 40 CFR 63.10(d)(5):

(A) Name, title and signature of responsible official certifying accuracy;

(B) Explanation of the circumstances for the event;

(C) Reason for not following the SSM Plan; and

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

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

D.15.8 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 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.16 BPM SUPPORT OPERATIONS – RESEARCH AND DEVELOPMENT OPERATIONS

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

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

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

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	Control Device
Building T71:				
T71-TK5700	Waste Tank	Atmosphere	1000 gallons	None
T71-TK9601	Portable Process Tank	Atmosphere	50 gallons	None
T71-TK9602	Portable Process Tank	Atmosphere	50 gallons	None
T71-TK9605	Portable Process Tank	Atmosphere	30 gallons	None
T71-TK9606	Portable Process Tank	Atmosphere	50 gallons	None
T71-TK9609	Portable Process Tank	Atmosphere	30 gallons	None
T71-TK9610	Portable Process Tank	Atmosphere	50 gallons	None
T71-TK9611	Portable Process Tank	Atmosphere	50 gallons	None
T71-TK9612	Portable Process Tank	Atmosphere	50 gallons	None
T71-TK9613	Condensate Collection Tank	Atmosphere	10 gallons	None
T71-TK9614	Condensate Collection Tank	Atmosphere	10 gallons	None
T71-TK9615	Condensate Collection Tank	Atmosphere	10 gallons	None
T71-TK9616	Condensate Collection Tank	Atmosphere	10 gallons	None
T71-TK9617	Condensate Collection Tank	Atmosphere	20 gallons	None
T71-TK9623	Charge Tank	Atmosphere	10 gallons	None
T71-TK9624	Charge Tank	Atmosphere	10 gallons	None
T71-TK9625	Charge Tank	Atmosphere	10 gallons	None
T71-TK9626	Charge Tank	Atmosphere	10 gallons	None
T71-RVD9801	Rotary Vacuum Dryer	Atmosphere	3 cubic feet	None
T71-FLT9901	Single-Plate Filter	Atmosphere	N/A	None
T71-FLT9902	Multi-Plate Filter	Atmosphere	N/A	None

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

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

(a) The emission units listed above are not subject to the requirements of 40 CFR 63, Subpart GGG (Pharmaceutical MACT Standards) because these operations are research and development facilities that are exempt pursuant to 40 CFR 63.1250(d) and 63.1251.

(b) The emission units listed above are not subject to the requirements of 326 IAC 8-5-3 because the potential to emit VOC of any facility is less than 15 pounds per day.

D.16.2 Emission Standards [CP157-4148]

The sulfur dioxide (SO_2) emissions from the emission units in Building T71shall not exceed 16.7 tons per year to avoid the requirements of 326 IAC 2-2 (Prevention of Significant Deterioration). This emission limit correlates to a maximum sulfur containing compound (SCC) usage rate of 521 lbmoles equivalent per twelve consecutive month period using the following equivalency:

1 lbmole SCC equivalent = 1 lb mole SO_2

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

The LDAR standards that apply to components associated with the process operations in Building T71are described in Section E.1 of this permit and the waste tank in T71 are described in Section E.2 of this permit.

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

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

(a) The Permittee shall maintain SCC usage records on a calendar month basis to document compliance with the limitations established in Condition D.16.2.

(b) The Permittee shall submit quarterly summary reports of the monthly SCC usage records.

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

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

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

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

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

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

SECTION D.17 BPM SUPPORT OPERATIONS – GENERAL WASTEWATER CONDITIONS

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

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

(a) BPM Wastewater Operations – The emission units associated with the BPM wastewater operations can generally be described as storage and transfer facilities (wastewater tanks, containers and individual drain systems) and treatment facilities (chemical wastewater treatment plant, incineration, or offsite treatment). The specific emission units are described in Sections D.8, D.10, D.11, D.12, D.13, D.18 and D.19 of this permit.

(b) Fermented Products Wastewater Operations – The emission units associated with the fermented products wastewater operations can generally be described as storage and transfer facilities (biosolids tanks) and treatment facilities (biological wastewater treatment plant. The specific emission units are described in Section D.5 of this permit. The wastewater operations associated with fermented products are not subject to the storage, transfer and treatment requirements of this section of the permit because the wastewater does not meet the definition of an affected wastewater.

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

D.17.1 Definition of Wastewater [40 CFR 63.1251 and 40 CFR 63.1256(a)(1)(i)]

(a) Wastewater in this section of the permit 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 the following:

(1) Stormwater from segregated sewers;

(2) Water from fire-fighting and deluge systems, including testing of such systems;

(3) Spills;

(4) Water from safety showers;

(5) Samples of a size not greater than reasonably necessary for the method of analysis that is used;

(6) Equipment leaks;

(7) Wastewater drips from procedures such as disconnecting hoses after clearing lines;

(8) Noncontact cooling water; and

(9) Primary waste (waste with a net positive heating value).

(b) 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]

(c) Affected wastewater is defined as follows:

(1) 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 [40 CFR 63.1256(a)(1)(i)(A)]

(2) 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. [40 CFR 63.1256(a)(1)(i)(B)]

Maintenance wastewater is not considered an affected wastewater stream.

D.17.2 Maintenance Wastewater [40 CFR 63.1256(a)(4)(iii)]

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). [40 CFR 63.1256(a)(4)(iii)]

D.17.3 Storage and Transfer of Affected Wastewater [40 CFR 63.1256(b), (d), and (e)]

(a) The following emission units are used to store or transfer affected wastewater from the BPM operations:

(1) BPM Containers – The emission units and performance standards are described in Section D.11 of this permit.

(2) BPM Individual Drain Systems – These emission units and performance standards for the individual drain systems are described in Section D.8 of this permit.

(3) Affected Wastewater Tanks – These emission units and performance standards are streamlined with the requirements for BPM waste tanks described in Section D.10 of this permit.

(b) The emission units in the fermented products operations do not store or transfer affected wastewater.

D.17.4 Treatment of Affected Wastewater [40 CFR 63.1256]

Pursuant to the Pharmaceutical MACT requirements under 40 CFR 63.1256, the affected wastewater and residuals shall be treated using the following methods as applicable:

(a) Enhanced biological treatment system – The equipment and performance standards for the treatment of affected wastewater using the enhanced biological treatment system are described in Section D.18 of this permit.

(b) Waste incineration – The equipment and performance standards for the thermal destruction of the affected wastewater by incineration are described in Sections D.12 and D.13 of this permit.

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

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

D.17.5 Testing and Monitoring Requirements

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

Record Keeping and Reporting Requirements

D.17.6 Record keeping and Reporting Requirements

(a) The following record keeping and reporting requirements apply to the maintenance wastewater plan required under 40 CFR 63.1256(a)(4)(iv) and 63.6(e)(3):

(1) Maintain record of original maintenance wastewater plan for the life of the affected source or until the affected source is no longer subject to the provisions of this rule;

(2) Maintain updated versions of the maintenance wastewater plan, as necessary;

(3) Maintain records for each instance the plan was implemented and whether the plan was followed; and

(4) Record and report all instances within 2 working days after commencing actions inconsistent with the SSM plan followed by a written letter within 7 working days after the end of the event.

(b) Each POD as defined in Condition D.17.1 (b) shall be identified and its wastewater HAP concentration documented in the On-Site Implementation Log (OSIL) as required by 40 CFR 63.1259(b)(6) and 40 CFR 63.1251 – Operating Scenario.

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

SECTION D.18 BPM SUPPORT OPERATIONS – CHEMICAL WASTEWATER TREATMENT PLANT CONDITIONS

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

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

(a) The following emission units are subject to applicable requirements described or referred to in this D section. These emission units represent the enhanced biological treatment system.

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	Control Device
BPM Wastewater Treatment Plant (WWTP):				
T78-TK511	Activated Sludge Tank	Atmosphere	8 million gallons	N/A
T78-TK512	Activated Sludge Tank	Atmosphere	8 million gallons	N/A

(b) The following emission units of the wastewater treatment system are not subject to applicable requirements described in this D section.

Emission Unit ID	Emission Unit Description	Stack/Vent	Nominal Capacity	Control Device
BPM Wastewater Treatment Plant (WWTP):				
T78-TK520A*	Clarifier	Atmosphere	1.4 million gallons	N/A
T78-TK520B*	Clarifier	Atmosphere	1.4 million gallons	N/A
T78-TK520C*	Clarifier	Atmosphere	1.4 million gallons	N/A
T78-TK522*	Thickener	Atmosphere	1.4 million gallons	N/A
T78-TK550*	Emergency Diversion Tank	Atmosphere	900,000 gallons	N/A
T78-TK551*	Sludge Collection Tank	Atmosphere	700,000 gallons	N/A
TK525*	Sludge Tank	Atmosphere	193,000 gallons	N/A
TK526*	Sludge Tank	Atmosphere	193,000 gallons	N/A

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

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

D.18.1 Pharmaceutical MACT Standards [40 CFR 63.1256]

(a) Pursuant to the Pharmaceutical MACT standards for wastewater [40 CFR 63.1256(g)(10)], the Permittee may use the enhanced biological treatment system (activated sludge tank T78-TK511 or T78-TK512) to treat affected wastewater streams, defined in Section D.17 of this permit, except:

(1) Mixed (soluble and partially soluble HAP) wastewater streams greater than 5200 ppmw, where the partially soluble HAP component is equal to or greater than 50 ppmw; or

(2) Wastewater streams containing combined partially soluble HAPs greater than 1300 ppmw.

(b) Pursuant to the Pharmaceutical MACT standards for wastewater [40 CFR 63.1251 and 40 CFR 63.1256(g)(10)], the Permittee shall maintain a minimum mixed liquor volatile suspended solids (biomass) concentration of 1 kg/cubic meter (942 mg/l) of the mixed liquor in the enhanced biological treatment system.

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

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

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

(a) Total suspended solids (TSS), chemical oxygen demand (COD); and

(b) Biomass (VSS) concentration.

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

D.18.3 Record Keeping and Reporting Requirements

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

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

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

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

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

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

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

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

(a) Shipment of affected wastewater generated onsite to an offsite treatment facility; or

(b) Receipt of an offsite affected wastewater to be treated onsite.

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

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

(a) Pursuant to the Pharmaceutical MACT standards for wastewater [40 CFR 63.1256(a)(5)(i)(B)], the Permittee shall include a notice with each shipment of affected wastewater or residual removed from affected wastewater to an offsite treatment facility. The notice shall state that the affected wastewater or residual contains organic HAP must be treated in accordance with the treatment requirements of the Pharmaceutical MACT standards. When the transport is continuous or ongoing, the notice shall be submitted to the treatment operator initially and whenever there is a change in the required treatment.

(b) Pursuant to the Pharmaceutical MACT standards for wastewater [40 CFR 63.1256(a)(5)(ii)], the Permittee shall not transfer the affected wastewater or residual unless the transferee has submitted to the EPA a written certification that the transferee will manage and treat any affected wastewater or residual removed from affected wastewater received from a source subject to the requirements of this subpart in accordance with the treatment requirements of the Pharmaceutical MACT standards.

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

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

(b) The Permittee may revoke its certification as allowed under 40 CFR 63.1256(a)(5)(iii).

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

D.19.3 Record keeping and Reporting Requirements

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

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

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

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

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

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

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

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

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

(a) BPM process systems consist of process operations and non-waste storage serving bulk pharmaceutical manufacturing operations. LDAR applies to BPM process system components such as pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves and lines, valves, connectors, instrumentation systems, control devices, and closed-vent systems intended to operate in volatile organic hazardous air pollutant and/or volatile organic compound (VOHAP/VOC) service for 300 hours or more during the calendar year. In VOHAP/VOC service means that a piece or equipment either contains or contacts a fluid (liquid or gas) that is at least 5 percent by weight VOHAP/VOC.

(b) LDAR BPM process system components are located from the point at which raw material serving the BPM operations is unloaded at the plant site to the point of determination (POD) or point where waste exits the pharmaceutical manufacturing process unit (PMPU). The closed-vent systems not used to control emissions from LDAR components are not subject to the conditions of this section, but instead are subject to the conditions in Sections D.14, and D.15, as applicable.

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

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

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

(a) The Permittee shall implement the LDAR program under 40 CFR 63.1255 for all BPM process system component types listed in item (a) of the facility description section from the point at which raw material serving BPM is unloaded at the plant site to the point of determination (POD) or point where waste exits the pharmaceutical manufacturing process unit (PMPU).

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

(1) Existing BPM process system components in VOHAP service shall be initially monitored between October 21, 2002 and October 21, 2003.

(2) Existing BPM process system components in VOC service shall be initially monitored for purposes of this permit between October 21, 2002 and October 21, 2003.

(3) Subsequent monitoring periods shall be calendar periods, beginning October 21, 2003.

(c) Each new or changed BPM process system component in VOC/VOHAP service identified during the course of each monitoring period shall be incorporated into the existing component list as necessary within 90 days, or by the next LDAR Periodic Report, following the end of the monitoring period for the type of component monitored, whichever is later.

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

(1) Pumps in light liquid service shall be operated in accordance with the standard at 63.1255(c). This section provides, generally and in part:

(A) Single seal pumps shall undergo periodic monitoring and visual inspections;

(B) Dual mechanical seal pumps shall meet design, operation, inspection, and alarm requirements;

(C) Pumps designed without a shaft penetrating the pump housing are not required to be inspected or monitored; and

(D) Pumps equipped with a closed-vent system limitable of capturing and transporting any leakage from the seals back to the process or to a control device are not required to be inspected or monitored.

(2) Compressors shall be operated in accordance with the standards at 63.1255(b)(3), which requires compliance with 63.164. This section provides, generally and in part:

(A) Compressors with barrier fluid seal systems shall meet design, operation, inspection, and alarm requirements.

(B) Compressors equipped with a closed-vent system to capture and transport leakage from the compressor drive shaft seal back to a process or a fuel gas system or to a control device are not required to be inspected or monitored.

(C) Compressors designated to operate with an instrument reading of less than 500 ppmv above background shall be monitored initially and annually.

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

(A) Except during pressure releases, pressure relief devices shall be operated with an instrument reading of less than 500 ppmv above background.

(B) After each pressure release, the device shall be returned to a monitored condition of less than 500 ppmv above background within 5 calendar days after the release, except if delay of repair applies.

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

(D) Any pressure relief device satisfies conditions E.1.1 (d)(3)(i) and (ii) without monitoring if it is routed to a process or fuel gas system or equipped with a closed-vent system limitable of capturing and transporting leakage from the pressure relief device to a control device.

(4) Sampling connection systems shall be operated in accordance with the standard at 63.1255(b)(3), which requires compliance with 63.166. This section provides, generally and in part:

(A) Gases displaced during filling of a sample container are not required to be captured or collected.

(B) Each sampling connection system shall be equipped with a closed-purge, closed-loop or closed-vent system, which shall:

(i) Return the purged process fluid directly to the process line;

(ii) Collect and recycle the purged process fluid to a process;

(iii) Be designed and operated to capture and transport the purged process fluid to a control device;

(iv) Collect, store, and transport the purged process fluid to a SOCMI/HON waste management unit (40 CFR Part 63, Subpart G) operated according to the provisions which apply to Group 1 wastewater streams, or to a treatment, storage, or disposal facility subject to regulation under 40 CFR Part 262, 264, 265 or 266 (a RCRA unit), or, if the purged fluids are not hazardous waste, to a facility with an appropriate State permit to manage municipal or industrial solid waste; or

(v) In-situ sampling systems, and sampling systems without purges, have no other obligations under this section.

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

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

(B) The limit, blind flange, plug or second valve shall be in place and closed within one hour of cessation of operations requiring fluid flow through the open-ended valve or line, or maintenance or repair. No records are required to document compliance with this provision.

(C) If a second valve is used, the valve on the process fluid end shall be closed before the other valve is closed.

(D) If a double block and bleed arrangement is used, the bleed valve may remain open during operations requiring venting the line between the block valves, but shall be closed otherwise in accordance with E.1.1 (d)(5)(ii).

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

(F) Open-ended valves or lines containing materials, which would autocatalytically polymerize are not required to comply with E.1.1 (d)(5)(i) through (iii).

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

(6) Valves in gas/vapor and light liquid service shall be operated in accordance with the standard at 63.1255(e). This section provides, generally and in part:

(A) Valves shall undergo periodic monitoring.

(B) Each monitoring period shall be determined by a calculation based on the percentage of leaking valves measured in prior monitoring periods.

(C) Valves may be placed into subgroups for periodic monitoring purposes, and may be reassigned among subgroups.

(D) After a leaking valve is repaired, it shall be monitored again within 3 months after repair. This monitoring may be considered part of the periodic monitoring, or may, if conducted prior to the periodic monitoring, be considered separately from the periodic monitoring data in determining percent leaking valves for the monitoring period.

(7) Closed-vent systems and control devices used to comply with LDAR shall be operated in accordance with the standard at 63.1255(b)(4)(ii). Operation of these systems, in conformance with Sections D.9, D.14, or D.15, shall constitute compliance with this requirements;

(8) Agitators in gas/vapor and light liquid service shall be operated in accordance with the standard at 63.1255(c); This section provides, generally and in part:

(A) Single seal agitators shall undergo periodic monitoring and visual inspections.

(B) Dual mechanical seal agitators shall meet design, operation, inspection, and alarm requirements.

(C) Agitators designed without a shaft penetrating the pump housing are not required to be inspected or monitored.

(D) Agitators equipped with a closed-vent system limitable of capturing and transporting any leakage from the seals back to the process or to a control device are not required to be inspected or monitored.

(9) Pumps, valves, connectors, and agitators in heavy liquid service, instrumentation systems, and pressure relief devices in liquid service shall be operated in

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

(A) If a component presents visual, audible, or olfactory evidence of a leak, the leak shall be deemed repaired without monitoring if the component meets any of the following:

(i) The visual, audible, or olfactory evidence has been eliminated;

(ii) No bubbles are observed at potential leak sites during a leak check using soap solutions; or

(iii) The system will hold a test pressure.

(B) If there is visual, audible, or olfactory evidence of a leak at one of these components, and the leak is not repaired without monitoring, the component shall be monitored within 5 calendar days to confirm whether a leak is in fact present.

(10) Connectors in gas/vapor and light liquid service shall be operated in accordance with the standard at 63.1255(b)(4)(iii). This section provides, generally and in part:

(A) Connectors shall undergo periodic monitoring.

(B) Each monitoring period shall be determined by a calculation based on the percentage of leaking connectors measured in prior monitoring periods.

(C) Nonrepairable connectors may not be counted in monitoring period calculations. C_{AN} shall be set to zero in the percent leaking connector calculation.

(D) Inaccessible, ceramic, or ceramic-lined connectors are not required to be monitored, and are exempt from record keeping and reporting. If they are observed to be leaking, they shall be repaired as soon as practicable, but no later than 15 calendar days after the leak is detected, except if delay of repair applies. There is no obligation to make a first attempt at repair within 5 days.

(E) Connectors that are not required to be monitored are not included in the calculation of the percentage of leaking connectors.

(F) An optional credit may be taken for removed connectors where the weld meets certain testing requirements.

(e) As an alternative to complying with E.1.1(d), except E.1.1(d)(7), BPM process system components may comply with 63.1255(b)(4)(iv), which incorporates by reference 63.178(b) (Alternative Means of Emission Limitation: Batch Processes) as follows:

(1) Components shall be pressure tested each time the equipment is reconfigured for production of a different product or intermediate or at least once per year, whichever is more stringent. The pressure testing shall be conducted in accordance with 63.180(f) or (g); and

(2) Components must comply with the leak repair requirements before startup of a process as described in 63.178(b)(4).

(f) As an alternative to complying with E.1.1 (d), except E.1.1 (d)(7), BPM process system components may comply with 40 CFR 63.179 (Alternative means of emission limitation: Enclosed-vented process units), which requires that process units be enclosed in such a manner that all emissions from equipment leaks are vented through a closed-vent system to a control device. The enclosure is to be maintained under a negative pressure at all times while the process unit is in operation to ensure that all emissions are routed to the control device. The closed vent system and control device must comply with E.1.1 (d)(7).

(g) Any visible leak of a liquid containing VOHAP/VOC shall be considered a leak for purposes of the obligation to repair. If it is not clear whether the liquid contains VOHAP/VOC, then Method 21 may be used to confirm whether a leak exists. For each component type, the relevant leak definition and leak repair requirements in E.1.1 (d) shall apply for this purpose. All leaks shall be marked as provided in 63.1255(a)(10).

(h) The Permittee shall initiate repair of any leak no later than 5 calendar days after identification, and complete the repair within 15 days after identification, except where delay of repair is allowed under 40 CFR 63.1255(b)(4)(i), which incorporates by reference 63.171. This shall not affect repair periods under Conditions E.1.1 (d)(3) or (e). 40 CFR 63.1255(b)(4)(i) provides, generally and in part:

(1) Delay of repair of equipment for which leaks have been detected will be allowed if repair within 15 days is technically infeasible without a process unit shutdown. Repair of this equipment shall occur before the end of the next scheduled process unit shutdown.

(2) Delay of repair for equipment for which leaks have been detected 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. Such repair shall occur by the end of the next scheduled process shutdown.

(3) Delay of repair of equipment for which leaks have been detected will be allowed for equipment that is isolated from the process and that does not remain in VOC/VOHAP service.

(4) Delay of repair for valves, connectors, and agitators will be allowed if emissions immediate repair would result in greater emissions than delay of repair, and if purged material generated during the repair is collected and destroyed or recovered in a control device.

(5) Delay of repair for pumps will be allowed if the repair requires the use of a dual mechanical seal system, or a pump designed without an externally actuated shaft penetrating the pump housing, or ducting of the pump fugitive emissions to a closed vent system and control device, and is completed within 6 months.

(6) Delay of repair beyond a process unit shutdown will be allowed for a valve if valve assembly replacement is necessary during the process unit shutdown, but the supplies, although adequately stocked, have been depleted. Delay of repair beyond the second process unit shutdown is not allowed unless the second shutdown occurs sooner than 6 months after the first shutdown.

(i) Alternative means of emission limitations not already included in 63.1255 may be approved in accordance with 63.1255(b)(3), which incorporates by reference 63.177.

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

(a) The following facilities are not subject to the LDAR standards under this section of the permit:

(1) Research and development facilities, activities and equipment (40 CFR 63.1250(d)) not subject to BACT or construction permit requirements;

(2) Components on transportation equipment and containers such as railroad cars, tanker trucks and drums (40 CFR 63.1256);

(3) Utilities and non-process lines (40 CFR 63.1255(a)(5));

(4) Bench scale processes (40 CFR 63.1255(a)(6));

(5) Equipment in vacuum service (40 CFR 63.1255(a)(8));

(6) Waste components (covered by Section E.2 of this permit).

(7) Fermented Products operations;

(8) Equipment in VOHAP/VOC service but that is in such service less than 300 hours per calendar year (40 CFR 63.1255(a)(9));

(9) Closed loop heat exchange systems (40 CFR 63.1255(a)(5)); and

(10) Welded fittings (40 CFR 63.1251).

(b) Equipment that is designated as unsafe to monitor, unsafe to inspect, difficult to monitor, difficult to inspect, or inaccessible shall comply with 63.1255(f). This section provides, generally, that accessible equipment shall be monitored according to a written plan that provides for monitoring as often as practicable, considering safety concerns, but not more often than otherwise applicable. Inaccessible equipment is not required to be routinely monitored at any time, although any observed leaks must be repaired within 15 days.

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

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

(a) Records shall be kept in accordance with 63.1255(g), including but not limited to:

(1) Identification of components that are subject to the rule with information indicating their method of compliance, with justifications as appropriate, except that inaccessible, ceramic, or ceramic-lined connectors subject to 40 CFR 63.1255(f)(4) need not be identified;

(2) Schedule for monitoring connectors and valves and the percent connectors and valves found leaking;

(3) Design criteria and any changes to these criteria for each dual mechanical seal system;

(4) List of equipment designated as unsafe to monitor/inspect or difficult to monitor/inspect and a copy of the plan for monitoring or inspecting such equipment;

(5) Equipment complying via the provisions of 40 CFR 63.178(c);

(6) List of equipment added since the last monitoring period, and

(7) If monitoring frequencies are adjusted for time in use, records demonstrating the proportion of the time the equipment is in VOC/VOHAP use during the calendar year;

(8) Records of visual inspections;

(9) Records of leaks detected, repair information, and delays of repair;

(10) Records of pressure tests, the test pressure, and the pressure drop observed during the test;

(11) Records of compressor and relief device compliance tests;

(12) Records for closed-vent systems and control devices subject to E.1.1(d)(7);

(13) For components in heavy liquid service, records demonstrating that they are in heavy liquid service;

(14) Identification of components exempt because they are in VOHAP/VOC service for less than 300 hours per year; and

(15) Records of alternative means of compliance determination.

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

(c) Reporting requirements shall be conducted in accordance with 63.1255(h), including:

(1) LDAR Periodic Reports shall cover the monitoring periods from January 1 to June 30, and July 1 to December 31, respectively. Reports shall be submitted 30 days following the 6-month monitoring period. The report shall include any revisions to the information reported earlier if the method of compliance has changed since the last report. The report shall also contain the following information:

(A) For equipment not complying via the alternative standard, the Permittee shall report the following information for pumps, valves, agitators, and connectors subject to periodic LDAR monitoring:

(i) Number of leaks detected and percent leakers;

(ii) Number of leaks not repaired within the required timeframe;

(iii) An explanation of any delay of repairs;

(iv) Notice of a change to monthly monitoring for either pumps or valves, if applicable; and

(v) Notification of a change in connector monitoring alternatives, if applicable.

(B) Results of all monitoring required for applicable compressors, pressure relief devices in gas/vapor service, and closed-vent systems;

(i) Number of leaks not repaired within the required timeframe; and

(ii) An explanation of any delay of repairs.

(C) For equipment complying via the alternative standard at 1255(b)(4)(iv), the Permittee shall report the following information for each product process equipment train:

(i) Number of pressure tests conducted;

(ii) Number of instances where the equipment failed either a retest or 2 consecutive pressure tests;

(iii) Facts that explain any delay of repairs; and

(iv) Results of all monitoring to determine compliance for closed-vent systems used to comply with this section of the permit.

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

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

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

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

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

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

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

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

(a) LDAR applies to BPM waste system components consisting of pumps, compressors, pressure relief devices, sampling connection systems, open-ended valves and lines, valves, connectors, control devices, and closed-vent systems used to comply with this LDAR program, intended to operate in volatile organic hazardous air pollutant and/or volatile organic compound (VOHAP/VOC) service for 300 hours or more during the calendar year. In VOHAP/VOC service means that a piece or equipment either contains or contacts a fluid (liquid or gas) that is at least 10 percent by weight of total VOHAP/VOC.

(b) LDAR BPM waste system components are located from the point of generation (POG) or point of determination (POD), as applicable, to the last component prior to entering the hazardous waste combustor or being loaded onto tankers for transport offsite. The closed-vent systems not used to control emissions from LDAR components are not subject to the conditions of this section, but instead are subject to the conditions in Sections D.10, D.14, and D.15.

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

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

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

(a) The Permittee shall implement the LDAR program under 40 CFR 61 Subpart V for all BPM waste system component types listed in item (a) of the facility description section from the point of determination (POD) or at the exit of the pharmaceutical manufacturing process unit (PMPU) to the last piece of regulated equipment prior to entering the hazardous waste combustor or loaded onto tankers for transport offsite.

(b) Existing BPM waste system components in VOC/VOHAP service are covered under 40 CFR 264 and 265, Subpart BB. Data taken for purposes of Subpart BB shall satisfy the data requirements for entry into the alternate standard at 40 61.243-2. Monitoring periods are calendar periods as defined at 40 CFR 61 Subpart V and 40 CFR 264 and 265, Subpart BB.

(c) Each new or changed BPM waste system component in VOC/VOHAP service identified during the course of each monitoring period shall be incorporated into the existing component list as necessary within 90 days, or by the next LDAR Periodic Report, following the end of the monitoring period for the type of component monitored, whichever is later.

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

(1) Pumps shall be operated in accordance with the standard at 61.242-2. This section provides, generally and in part:

(A) Single seal pumps shall undergo periodic monitoring and visual inspections.

(B) Dual mechanical seal pumps shall meet design, operation, inspection, and alarm requirements.

(C) Pumps designed without a shaft penetrating the pump housing shall be monitored initially and annually, but are not subject to other inspections.

(D) Pumps equipped with a closed-vent system limitable of capturing and transporting any leakage from the seals back to the process or to a control device are not required to be inspected or monitored.

(E) Pumps designated as unsafe-to-monitor shall be monitored according to a written plan by which they are monitored as frequently as possible during safe-to-monitor times, but not more frequently than otherwise applicable.

(2) Compressors shall be operated in accordance with the standard at 61.242-3. This section provides, generally and in part:

(A) Compressors with barrier fluid seal systems shall meet design, operation, inspection, and alarm requirements.

(B) Compressors equipped with a closed-vent system to capture and transport leakage from the compressor drive shaft seal back to a process or a fuel gas system or to a control device are not required to be inspected or monitored.

(C) Compressors designated to operate with an instrument reading of less than 500 ppmv above background shall be monitored initially and annually.

(3) Pressure relief devices in gas/vapor service shall be operated in accordance with the standard at 61.242-4. This section provides, generally and in part:

(A) Except during pressure releases, pressure relief devices shall be operated with an instrument reading of less than 500 ppmv above background.

(B) After each pressure release, the device shall be returned to a monitored condition of less than 500 ppmv above background within 5 calendar days after the release, except if delay of repair applies.

(C) A rupture disk is satisfies conditions E.2.1 (d)(3)(i) and (ii) without monitoring if it is replaced within 5 calendar days after each pressure release, except if delay of repair applies.

(D) Any pressure relief device satisfies conditions E.2.1 (d)(3)(i) and (ii) without monitoring if it is routed to a process or fuel gas system or equipped with a closed-vent system limitable of capturing and transporting leakage from the pressure relief device to a control device.

(4) Sampling Connection Systems shall be operated in accordance with the standard at 61.242-5. This section provides, generally and in part:

(A) Gases displaced during filling of a sample container are not required to be captured or collected.

(B) Each sampling connection system shall be equipped with a closed-purge, closed-loop or closed-vent system, which shall:

(i) Return the purged process fluid directly to the process line;

(ii) Collect and recycle the purged process fluid;

(iii) Be designed and operated to capture and transport the purged process fluid to a control device;

(iv) Collect, store, and transport the purged process fluid to a SOCMI/HON waste management unit (40 CFR Part 63, Subpart G) operated according to the provisions which apply to Group 1 wastewater streams, or to a treatment, storage, or disposal facility subject to regulation under 40 CFR Part 262, 264, 265 or 266 (a RCRA unit), or, if the purged fluids are not hazardous waste, to a facility with an appropriate State permit to manage municipal or industrial solid waste; or

(v) In-situ sampling systems, and sampling systems without purges, have no other obligations under this section.

(5) Open-ended valves or lines shall be operated in accordance with the standard at 61.242-6. This section provides, generally and in part:

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

(B) If a second valve is used, the valve on the process fluid end shall be closed before the other valve is closed.

(C) If a double block and bleed arrangement is used, the bleed valve may remain open during operations requiring venting the line between the block valves, but shall be closed otherwise in accordance with E.2.1 (d)(5)(ii).

(D) Open-ended valves and lines in an emergency shutdown system which are designed to open automatically in the event of a process upset are not required to comply with E.2.1 (d)(5)(i) through (iii).

(E) Open-ended valves or lines containing materials, which would autocatalytically polymerize are not required to comply with E.2.1 (d)(5)(i) through (iii).

(F) Open-ended valves or lines containing materials which could cause a serious safety hazard if capped or equipped with a double block and bleed system are not required to comply with E.2.1 (d)(5)(i) through (iii).

(6) Valves shall be operated in accordance with the standard at 61.242-7. This section provides, generally and in part:

(A) Each valve shall be monitored monthly, except as provided below.

(B) Any valve may be monitored quarterly, in the first month of the quarter, if it has completed two successive months without a leak, as long as it does not leak.

(C) Each leaking valve shall be monitored monthly after it is repaired until it has completed two successive months without a leak.

(D) Valves designed for no detectable emissions, which have no external actuating mechanism in contact with process fluid, are required only to be monitored initially and annually.

(E) Valves designated as unsafe-to-monitor are required to be monitored only according to a written plan, which provides for their monitoring during safe-to-monitor times.

(F) Valves designated as difficult-to-monitor are required to be monitored only according to a written plan that provides for their monitoring at least once per year.

(7) Pressure relief devices in liquid service and connectors shall be operated in accordance with the standard at 61.242-8 This section provides, generally and in part:

(A) If a component presents visual, audible, or olfactory evidence of a leak, the leak shall be deemed repaired without monitoring if the visual, audible, or olfactory evidence has been eliminated.

(B) If there is visual, audible, or olfactory evidence of a leak at one of these components, and the leak is not repaired without monitoring, the component shall be monitored within 5 calendar days to confirm whether a leak is in fact present.

(8) Closed-vent systems and control devices used to comply with Section E.2 of this permit shall be operated in accordance with the standard at 61.242-11, as may be applicable. Operation of these systems in conformance with Sections D.9, D.14 or D.15 shall constitute compliance with these requirements.

(9) As an alternative to complying with E.2.1 (d)(6), above, valves may comply with the alternative standards for valves-allowable percentage of valves leaking under 61.243-1. This section provides, generally and in part:

(A) Upon 90 days' advance notice to the Administrator, the designated process unit shall have no more than 2.0 percent leaking valves.

(B) All valves in the designated process unit shall be monitored initially upon designation, and annually thereafter, and

(C) The annual monitoring of all valves in the designated process unit shall be completed within one week.

(D) Valve leaks detected shall be repaired within 15 days, except if delay of repair applies, in accordance with 40 CFR 61.242-7(d) and (e).

(10) As an alternative to complying with the monitoring requirements in E.2.1 (d)(6), above, with respect to monitoring requirements alone, valves may comply with the alternative standards for valves-skip period leak detection and repair under 61.243-2. This section provides, generally and in part:

(A) All valves in the process unit shall comply initially with the monitoring requirements of E.2.1 (d)(6).

(B) After 2 consecutive quarterly monitoring periods with the percent leaking valves in the process unit at less than or equal to 2.0 percent, upon 90 days' advance notice to the Administrator, the designated process unit may begin to skip one of the quarterly monitoring periods.

(C) After 5 consecutive quarterly monitoring periods with the percent leaking valves in the process unit at less than or equal to 2.0 percent, upon notice to the Administrator, the designated process unit may begin to skip three of the quarterly monitoring periods.

(D) If for any monitoring period the percentage of leaking valves exceeds 2.0 percent, all valves in the process unit shall comply with the monitoring requirements of E.2.1 (d)(6), but may again elect to use this alternative.

(e) Any visible leak of a liquid containing VOHAP/VOC shall be considered a leak for purposes of the obligation to repair. If it is not clear whether the liquid contains VOHAP/VOC, then Method 21 may be used to confirm whether a leak exists. For each component type, the relevant leak definition in E.2.2 (d) shall apply for this purpose. All leaks shall be marked as provided in 40 CFR 61.246(b) with a weatherproof and readily visible identification marked with the equipment identification number. This identification may be removed from the equipment after it has been successfully repaired, except that the identification on a leaking valve may not be removed until the valve has been monitored for 2 successive months without a leak being detected.

(f) The Permittee shall initiate repair of any leak no later than 5 calendar days after identification, and complete the repair within 15 days after identification, except where delay of repair is allowed under 40 CFR 61.242-10. This shall not affect repair periods under Condition E.2.1 (d)(3). 40 CFR 61.242-10 provides, generally and in part:

(A) Delay of repair of equipment for which leaks have been detected will be allowed if repair within 15 days is technically infeasible without a process unit shutdown. Repair of this equipment shall occur before the end of the next process unit shutdown.

(B) Delay of repair of equipment for which leaks have been detected will be allowed for equipment that is isolated from the process and that does not remain in VOC/VOHAP service.

(C) Delay of repair for valves will be allowed if emissions immediate repair would result in greater emissions than delay of repair, and if purged material generated during the repair is collected and destroyed or recovered in a control device.

(D) Delay of repair for pumps will be allowed if the repair requires the use of a dual mechanical seal system, and is completed within 6 months.

(E) Delay of repair beyond a process unit shutdown will be allowed for a valve if valve assembly replacement is necessary during the process unit shutdown, but the supplies, although adequately stocked, have been depleted. Delay of repair beyond the second process unit shutdown is not allowed unless the second shutdown occurs sooner than 6 months after the first shutdown.

(g) Alternative means of emission limitations not already included in 40 CFR 61, Subpart V may be approved in accordance with 40 CFR 61.242-1(d) and 61.244

E.2.2 Exceptions to LDAR Standards for BPM Waste System Components

The following equipment types are not subject to the LDAR standards described in E.2.1:

(a) Research and development facilities, activities and equipment;

(b) Components on transportation equipment and containers such as tanker trucks, railroad cars, and drums (40 CFR 63.1256 and 40 CFR 63, Subpart DD);

(c) BPM process systems including non-waste storage and process operations (covered by Section E.1 of this permit);

(d) Utilities and non-process lines;

(e) Components in vacuum service (40 CFR 61.242-1);

(f) Equipment in VOC/VOHAP service that is in such service less than 300 hours per calendar year (40 CFR 63.680(c)(3)(iii)); and

(g) Closed loop heat exchange systems.

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

E.2.3 Record Keeping and Reporting Requirements

(a) Records shall be kept in accordance with 61.246, including but not limited to:

(1) Identification of components that are subject to the rule with information indicating their method of compliance, with justifications and signatures as appropriate. No identification is required for welded fittings;

(2) For valves complying via the “skip period” alternative, a schedule for monitoring the valves and the percent valves found leaking during each monitoring period;

(3) Changes to each dual mechanical seal system design and operating criteria, including seal system failure criteria;

(4) List of equipment designated as unsafe to monitor/inspect or difficult to monitor/inspect, with the reason for the designation, and a copy of the plan for monitoring or inspecting such equipment;

(5) Records of leaks detected, repair information, and delays of repair;

(6) Records of compliance tests on equipment (compressors, pumps, or valves) designated for no detectable emissions and for pressure relief devices in gas/vapor service;

(7) Records for closed-vent systems and control devices, subject to E.2.1 (d)((8);

(8) Records of information supporting designation that components are not in VOHAP/VOC service or are in vacuum service;

(9) Identification of components exempts because they are in VOC/VOHAP service for less than 300 hours per year;

(10) Records of alternative means of compliance determination; and

(11) Records may be kept in one or more recordkeeping systems, providing each records is identified by process unit.

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

(c) Reporting requirements shall be conducted in accordance with 61.247, including:

(1) LDAR Periodic Reports shall cover the periods from January 1 to June 30, and July 1 to December 31, respectively. Reports shall be submitted 30 days following the 6-month period. The report shall include any revisions to the information reported earlier if the method of compliance has changed since the last report. The report shall also contain the following information, divided and identified by process unit:

(A) For each month during the period covered by the report, the number of leaks detected for valves, pumps, and compressors and the number not repaired within 15 days, with the facts that explain any delay of repairs, and, where appropriate, why a process unit shutdown was technically infeasible;

(B) The results of all performance tests and monitoring to determine compliance with the alternative standards for valves at 40 CFR 61.243-1 and 61.243-2;

(C) Results of all monitoring and performance tests required to determine compliance with no detectable emissions; and

(D) The dates of process unit shutdowns which occurred during the reporting period.

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

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

E.2.4 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 F.1 Change Management and Flexible Permit Conditions

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

The information described in the following paragraphs is descriptive information and does not constitute enforceable conditions:

(a) The areas of the plant site listed below are subject to the change management and flexible permit conditions described in this G 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 Solids-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
(4) D.19 BPM Transfer Activities
(5) Insignificant Activities described in Section A and outside the BPM production and support operations

Emission limits 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
(I) Installation of new production buildings.

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

(3) T49 liquid waste incinerator and T149 solids-liquid waste incinerator:

(A) A change in waste materials disposed in the incinerators;
(B) A change in the use of portable containers, including but not limited to, drums, melons, and tank trailers;
(C) A change in the method of operation that does not affect compliance with 40 CFR 63, Subpart EEE;
(D) Piping changes;
(E) A physical change that does not affect compliance with 40 CFR 63, Subpart EEE;
(F) Reconstruction or replacement of incinerator components and support equipment, including but not limited to, cooling towers and waste container management; and
(G) Installation of new incinerator equipment components, support equipment or emission control equipment.

(b) Advance approval and applicable requirements

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

(c) Notification and records

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

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

F.1.3 Carbon monoxide (CO) emission limit determination

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

(a) The following requirements apply to the RTOs, the T49 liquid waste incinerator, and the T149 solids-liquid waste incinerator:

(1) **CO measurement**: The Permittee shall measure CO concentration in the exhaust of with a CO continuous emission monitoring system (CEMS) that meets the requirements of 40 CFR Part 60, Appendix B and 326 IAC 3.

(2) **Flow rate measurement**: The Permittee shall measure the actual exhaust gas flow rate from the RTOs and T149 solids-liquid waste incinerator, and measure the combustion and atomized air flow rate into the T49 liquid waste incinerator.

(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 solids-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.

(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 solids-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 solids-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 solids-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 solids-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.

(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 = 92 ppmv
(2) T49 NOx concentration = 975 ppmvdc
(3) T149 NOx concentration = 170 ppmvdc

(D) During periods of flow meter maintenance, malfunction, repair, or other periods of invalid exhaust gas flow rate data collection, the Permittee shall substitute the following data in lieu of actual readings from the flow meter:

(i) When combusting only natural gas, the following NOx mass emission rates shall be substituted:

(1) RTO NOx mass emission rate = 0.03 lb/min
(2) T49 NOx mass emission rate = 0.12 lb/min
(3) T149 NOx mass emission rate = 0.08 lb/min

(ii) When incinerating a waste stream, the following exhaust gas flow rates shall be substituted:

(1) RTO exhaust gas flow rate = 93,000 scfm
(2) T49 exhaust gas flow rate = 17,735 dscfm
(3) T149 exhaust gas flow rate = 14,340 dscfm

(5) Minimum data collection requirements:

(A) For the RTOs, the Permittee shall monitor and record NOx concentrations as required in Section D.14.
(B) For the T49 liquid waste incinerator, the Permittee shall monitor and record NOx concentrations as required in Condition D.12.
(C) For the T149 solids-liquid waste incinerator, the Permittee shall monitor and record NOx concentrations as required in Section D.13.

(6) **Emissions during RTO bypass periods**: When determining compliance with the NOx emission limit, the Permittee shall include any known NOx emissions from BPM production buildings or storage tank modules not emitted through the RTO due to diversions in the fume transport system. The Permittee may use **engineering** calculation methods based on ideal gas law equations, stoichiometry, or mass balance to estimate these emissions.

(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 solids-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 solids-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.

(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 solids-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.

(1) **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.

(2) **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%).

(3) **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.

(4) **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 solids-liquid waste incinerator:

(1) **VOC measurement**:

(A) For the RTO operations, the Permittee shall directly measure TOC concentration, as methane**,** in the exhaust gas using a TOC continuous emission monitoring system (CEMS) that meets the requirements of 40 CFR Part 63. The Permittee shall assume VOC, a subset of total organic compounds (TOC), is equal to TOC.

(B) For the T49 liquid waste incinerator and the T149 solids-liquid waste incinerator, the Permittee shall use 10 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 solids-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:**

(E) For the RTOs, the Permittee shall monitor and record VOC concentrations as required in condition D.14.

(F) For the T49 liquid waste incinerator, the Permittee shall monitor and record VOC concentrations as required in condition D.12.

(G) For the T149 solids-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 the “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 limit.

(c) This notification does not require the certification by the "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.14.9 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. The Permittee shall also provide, in its application for renewal of the permit, 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]

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

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

Section D.1 – Utilities Operations
Quarterly Fuel Oil Consumption Report

Source Name: Eli Lilly and Company, Tippecanoe Laboratories
Source Address: 1650 Lilly Road, Lafayette, Indiana 47909
Mailing Address: 1650 Lilly Road, Lafayette, Indiana 47909
Part 70 Permit No.: T157-6879-00006
Facility: Boiler 5
Parameter: SO_2 emissions
Limit: Fuel Oil Usage Limit = 1,120,000 gal/12 consecutive month period

Quarter: __________________ **Year:** _______________

Month	Monthly Fuel Oil Usage (Mgal/month)	12 Month Rolling Avg (Mgal/12 consecutive months)	SO_2 Emissions (tons/12 consecutive months)

Check one of the following:

______ No deviation occurred in this quarter.

______ The following deviation/s occurred in this quarter:

Submitted by: ______________________________________

Title/Position: ______________________________________

Signature: ______________________________________

Date: ______________________________________

Phone: ______________________________________

Attach a signed certification to complete this report.

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY

Section D.1 – Utilities Operations
Quarterly Fuel Oil and Natural Gas Consumption Report

Source Name: Eli Lilly and Company, Tippecanoe Laboratories
Source Address: 1650 Lilly Road, Lafayette, Indiana 47909
Mailing Address: 1650 Lilly Road, Lafayette, Indiana 47909
Part 70 Permit No.: T157-6879-00006
Facility: Boiler 5
Parameter: NO_X emissions
Limit: Natural Gas Usage Limit = 780 MMCF/12 month consecutive month period,
In addition, to account for fuel oil usage, the following equivalency shall be used:
1 MMCF of Natural Gas = 5000 gallons of Fuel Oil

Quarter: ________________ **Year:** ______________

Month	Natural Gas Consumed (MMCF/month)	Fuel Oil Consumed		Month Rolling Avg (MMCF/12 months)	NO_x Emissions (tons/12 months)
		(gal/month)	(MMCF/month)		

Check one of the following:

______ No deviation occurred in this quarter.

______ The following deviation/s occurred in this quarter:

Submitted by: ___________________________________

Title/Position: ___________________________________

Signature: ___________________________________

Date: ___________________________________

Phone: ___________________________________

Attach a signed certification to complete this report.

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY

Section D.1 – Utilities Operations
Quarterly Coal Characteristic and Consumption Report

Source Name: Eli Lilly and Company, Tippecanoe Laboratories
Source Address: 1650 Lilly Road, Lafayette, Indiana 47909
Mailing Address: 1650 Lilly Road, Lafayette, Indiana 47909
Part 70 Permit No.: T157-6879-00006
Facility: Boilers 1, 2 and 3
Parameter: SO_2 emissions
Limit: 6.0 lbs/MMBtu

Quarter: _________________ **Year:** ______________

Month	Sulfur Content (% Wt.)	Heating Value (Btu/lb)	Coal Consumption (tons)	Emission Rate (lbs/MMBtu)

Check one of the following:

______ No deviation occurred in this quarter.

______ The following deviation/s occurred in this quarter:

Submitted by: ___________________________________

Title/Position: ___________________________________

Signature: ___________________________________

Date: ___________________________________

Phone: ___________________________________

Attach a signed certification to complete this report.

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY

Section D.1 – Utilities Operations
Quarterly Fuel Oil Characteristic and Consumption Report

Source Name: Eli Lilly and Company, Tippecanoe Laboratories
Source Address: 1650 Lilly Road, Lafayette, Indiana 47909
Mailing Address: 1650 Lilly Road, Lafayette, Indiana 47909
Part 70 Permit No.: T157-6879-00006
Facility: Boilers 4 and 5
Parameter: SO_2 emissions
Limit: 0.5 lbs/MMBtu

Quarter: _________________ **Year:** ______________

Month	Sulfur Content (% Wt.)	Heating Value (Btu/lb)	Fuel Oil Consumption (gallons)	Emission Rate (lbs/MMBtu)
Boiler 4:				
Boiler 5:				

Check one of the following:

______ No deviation occurred in this quarter.

______ The following deviation/s occurred in this quarter:

Submitted by: ___________________________________

Title/Position: ___________________________________

Signature: ___________________________________

Date: ___________________________________

Phone: ___________________________________

Attach a signed certification to complete this report.

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY

Section D.2 – Utilities Support Operations
Quarterly Generator Hours Report

Source Name: Eli Lilly and Company, Tippecanoe Laboratories
Source Address: 1650 Lilly Road, Lafayette, Indiana 47909
Mailing Address: 1650 Lilly Road, Lafayette, Indiana 47909
Part 70 Permit No.: T157-6879-00006
Facility: Generator T121
Parameter: NOx Emissions
Limit: T121 = 900 hrs of operation per 12 month period, rolled on a monthly basis

Quarter: _________________ Year: ______________

Month	Hours Used This Month	Hours/ 12 Months

Check one of the following:

______ No deviation occurred in this quarter.

______ The following deviation/s occurred in this quarter:

Submitted by: ______________________________________

Title/Position: ______________________________________

Signature: ______________________________________

Date: ______________________________________

Phone: ______________________________________

Attach a signed certification to complete this report.

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY

Section D.12-D.15 – Control Device CMS Operations
Streamlined CMS Periodic Report

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

Quarter: _________________ Year: ______________

PART 1: CMS Exceedance Summary

Regulated Entity	CMS	Brief Description	Limits/UOM	Manufacturer/ Model #	Last Audit/ Annual Calibration Date	Description of changes in CMS/CEMS

PART 2: CMS Downtime Summary

Regulated Entity	Operating Time (days)	CMS	Exceedance Time by Cause (days)					Total Exceedance Time (days)	Exceedances (as % of Operating Time)
			Startup/ Shutdown	Control Equipment Problem	Process Problem	Other known	Other Unknown		

PART 3: CMS Downtime Details, If Applicable

Control Device: ______________________
CMS/CEMS: ______________________
Operating Time: ______________________

Start Date	Start Time	End Date	End Time	Downtime Type	SSM (yes/no)	Nature and Cause of Malfunction	Nature of Repairs or Adjustment/ Corrective Actions/ Preventive Measures

Control Device: ______________________
CMS/CEMS: ______________________
Operating Time: ______________________

Start Date	Start Time	End Date	End Time	Downtime Type	SSM (yes/no)	Nature and Cause of Malfunction	Nature of Repairs or Adjustment/ Corrective Actions/ Preventive Measures

Control Device: ______________________
CMS/CEMS: ______________________
Operating Time: ______________________

Start Date	Start Time	End Date	End Time	Downtime Type	SSM (yes/no)	Nature and Cause of Malfunction	Nature of Repairs or Adjustment/ Corrective Actions/ Preventive Measures

PART 4: CMS Excursion Summary, If Applicable

Regulated Entity	Operating Time (days)	CMS	Number of Excursions	% Excursion

PART 5: CMS Excursion Details, If Applicable

Control Device: ______________________
CMS/CEMS: ______________________
Operating Time: ______________________

Date	Duration (days)

PART 6: Bypass Summary

Regulated Entity	Date	Start Time	Building or Fume Stream	Duration (hrs)	SSM Event?

PART 7: SSM Summary

REGULATED SOURCE	DATE	DURATION (hours)	SSM EVENT TYPE	SSM PLAN FOLLOWED?	NOTES

Submitted by: ______________________________

Title/Position: ______________________________

Signature: ______________________________

Date: ______________________________

Phone: ______________________________

Attach a signed certification to complete this report.

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY

Section D.16 – Research and Development Operations
Quarterly SCC Usage Report

Source Name: Eli Lilly and Company, Tippecanoe Laboratories
Source Address: 1650 Lilly Road, Lafayette, Indiana 47909
Mailing Address: 1650 Lilly Road, Lafayette, Indiana 47909
Part 70 Permit No.: T157-6879-00006
Facility: Building T71
Parameter: Sulfur Dioxide (SO_2)
Limit: 521 lb-moles SCC per 12 month period, rolled on a monthly basis

Quarter: ________________ **Year:** ______________

Month	Actual SCC Use (lb-mol)	Consecutive 12-month use (lb-mol)

Submitted by: ________________________________

Title/Position: ________________________________

Signature: ________________________________

Date: ________________________________

Phone: ________________________________

Attach a signed certification to complete this report.

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY
COMPLIANCE DATA SECTION

Section E – Leak Detection and Repair (LDAR) Program
Streamlined LDAR Periodic Report

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

Period: _________________ **Year:** ______________

PART 1: LDAR Report for Process System Components

Process Unit:
Equipment Type:
Service

Monitoring Period	Number Tested	Number Leakers	Percent Leakers

Process Unit Shutdown Periods

Number of Components	Number Added	Number Removed

Process Unit:
Equipment Type:
Service

Monitoring Period	Number Tested	Number Leakers	Percent Leakers

Process Unit Shutdown Periods

Number of Components	Number Added	Number Removed

PART 2: LDAR Report for Waste Components

Process Unit:
Equipment Type:
Service

Monitoring Period	Number Tested	Number Leakers	Percent Leakers

Process Unit Shutdown Periods

Number of Components	Number Added	Number Removed

Process Unit:
Equipment Type:
Service

Monitoring Period	Number Tested	Number Leakers	Percent Leakers

Process Unit Shutdown Periods

Number of Components	Number Added	Number Removed

Submitted by: ______________________________

Title/Position: ______________________________

Signature: ______________________________

Date: ______________________________

Phone: ______________________________

Attach a signed certification to complete this report.

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY
COMPLIANCE BRANCH

100 North Senate Avenue
P.O. Box 6015
Indianapolis, Indiana 46206-6015
Phone: 317-233-5674
Fax: 317-233-5967

PART 70 OPERATING PERMIT
EMERGENCY OCCURRENCE REPORT

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

This form consists of 2 pages

☐ 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 317-233-5674, ask for Compliance Section); and
- The Permittee must submit notice in writing or by facsimile within two (**2**) working days (Facsimile Number: 317-233-5967), 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

Date/Time Emergency started:
Date/Time Emergency was corrected:
Was the facility being properly operated at the time of the emergency? Y N Describe:
Type of Pollutants Emitted: TSP, PM-10, SO_2, VOC, NO_X, CO, Pb, other:
Estimated amount of pollutant(s) emitted during emergency:
Describe the steps taken to mitigate the problem:
Describe the corrective actions/response steps taken:
Describe the measures taken to minimize emissions:
If applicable, describe the reasons why continued operation of the facilities are necessary to prevent imminent injury to persons, severe damage to equipment, substantial loss of capital investment, or loss of product or raw materials of substantial economic value:

Form Completed by:

Title / Position:

Date:

Phone:

Attach a signed certification to complete 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, Indiana 47909
Part 70 Permit No.: T157-6879-00006
Months: ___________ to ____________ Year: ______________

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

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, Indiana 47909
Part 70 Permit No.:	T157-6879-00006

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.

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY

Section F.1 – Change Management and Flexible Permit Requirements
Quarterly Emission Limit Report

Source Name: Eli Lilly and Company, Tippecanoe Laboratories
Source Address: 1650 Lilly Road, Lafayette, Indiana 47909
Mailing Address: 1650 Lilly Road, Lafayette, Indiana 47909
Part 70 Permit No.: T157-6879-00006
Facility: BPM Operations (RTOs, T79, T49, T149, Chemical WWTP, BPM Building Fugitives)
Parameter: BPM Operations Emission Limit for VOC, CO, NOx, SO_2, and Fluorides; T79 Fume Incinerator System Emission Sublimit for VOC
Limit:

Pollutant	BPM Operations (tons/yr)	T79 Fume Incinerator (tons/yr)
VOC	300	300
CO	150	30
NOx	300	30
SO_2	300	5
Fluorides	6	2

The attached spreadsheet provides the monthly actual emissions for the BPM operations. The information is used to determine compliance with the emission limit limits provided above. This emission summary report was:

Submitted by: ____

Title/Position: ____

Signature: ____

Date: ____

Phone: ____

Attach a signed certification to complete this report.

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

Quarter: ____________ Year: ____________ Pollutant	Actual Emission Estimates, tons								
	Month 1	Previous 11 Months	12-month Total	Month 2	Previous 11 Months	12-month Total	Month 3	Previous 11 Months	12-month total
RTOs									
VOC, Point									
CO									
NOx									
SO_2									
Fluorides									
T79 Fume Incinerator System									
VOC, Point									
CO									
NOx									
SO_2									
Fluorides									
T49 Liquid Waste Incinerator									
VOC, Point									
CO									
NOx									
SO_2									
Fluorides									
T149 Solid-Liquid Waste Incinerator									
VOC, Point									
CO									
NOx									
SO_2									
Fluorides									
Chemical Wastewater Treatment Plant Operations									
VOC, Point									
BPM Building Operations									
VOC, Fugitive									
BPM Total									
VOC (Point+ Fugitive)									
CO									
NOx									
SO_2									
Fluorides									

Indiana Department of Environmental Management
Office of Air Quality

Final Addendum to the
Technical Support Document for a Part 70 Operating Permit

Source Name: **Eli Lilly and Company – Tippecanoe Laboratories**
Source Location: **1650 Lilly Road, Lafayette, IN, 47909**
County: **Tippecanoe**
SIC Code: **2833 and 2834**
Operation Permit No.: **T157-6879-00006**
Permit Reviewer: **Dr. Trip Sinha**

On January 28, and February 17, 2004, Eli Lilly and Company submitted comments on the proposed Title V operation permit. The summary of the comments and corresponding responses is as follows:

Deleted items are crossed out and new additions are bolded for clarity.

Comment 1: Sections B.12 Permit Shield

In TSD Addendum response 2, IDEM indicates that it has changed paragraph B.12 (b)(18) to delete the words "open top", as suggested by Lilly in our comments. That change, however, does not appear in the proposed permit.

Response 1: The typo has been corrected.

Comment 2: **Section C.10 Compliance Monitoring**

The draft permit that went out for public notice and comment on October 3, Condition D.10, which establishes general operating requirements for compliance monitoring systems, included language that read:

(d) The compliance monitoring system shall be operated at all times the emissions unit or process is operating as specified in Section D, except for monitoring system downtime due to malfunctions or reasonable periods of necessary calibration or maintenance activities

This paragraph was deleted from the proposed permit without much explanation. Response 7 in the TSD addendum states that this condition was deleted "because no time for malfunction is specified in the rule, during those times, supplemental monitoring is required".

This is a significant concern for Lilly since many of the emission units in our permit utilize parametric monitoring systems to demonstrate compliance with emission limits in the permit. Deleting this provision is inconsistent with Condition C.11, which provides some excused periods of CEMS downtime. It is also inconsistent with the MACT general provisions, which allow some monitor downtime for Continuous Monitoring Systems [CMS] required by MACT rules.

We believe this language should be re-inserted into the permit.

In addition, we are concerned about and do not understand the statement in the TSD addendum that refers to supplemental monitoring being required when compliance monitoring systems are down.

Lilly's main concern was about the clarification that the permit does not supersede or eliminate the CMS and CEMS monitoring downtime provisions of the applicable MACT and NSPS rules and to address the missing malfunction language in C.11(c).

Response 2: The draft permit contained provisions related to the Permitee's obligation to operate the Continuous Emissions Monitoring Systems (CEMS). The most recent federal rules specifically address certain situations that arise outside of the Permitee's control. The General provisions of the National Emission Standards for Hazardous Air Pollutants addresses this issue at 40 CFR 63.8(c)(4). This provision exempts the collection of emissions information during "system breakdowns, out-of-control periods, repairs, maintenance periods, calibration checks, and zero (low-level) and high-level calibration drift adjustments. " 40 CFR 63 also requires that the CEMS be included in the Startup, Shutdown, and Malfunction Plan for the source to ensure that necessary repair are made as expeditiously as possible. The Compliance Assurance Monitoring rule allows downtime at 40 CFR 64.7(c) for "monitoring malfunctions, associated repairs, and required quality assurance or control activities." There are no federal rules that specifically address these types of situations when the CEMS is required only by a PSD permit.

The applicable state rule, 326 IAC 3-5 (Continuos Monitoring of Emissions) also does not contain such specific exemptions. However, 326 IAC 3-5-4(a)(9) requires a preventive maintenance plan to "ensure continuous operation and to minimize malfunctions." 326 IAC 3-5-7(5) requires reports of continuous monitoring system downtime. Zero and span checks are reported separately; and reports for all other events shall include: the date of the downtime, time of commencement, duration of downtime, reasons for each downtime, and the nature of system repairs and adjustments.

The state rule requires a plan to minimize, not eliminate malfunctions. The IDEM considers the extent and reason for downtime when deciding whether to pursue enforcement action when small amounts of data are not collected due to CEMS malfunction.

The final permit contains language that requires that the CEMS be operated at all times except during reasonable, and properly documented, periods of calibration activities and malfunction. The permit also requires, in addition to the provisions of 326 IAC 3-5 and the applicable provisions of 40 CFR 63, that the Startup, Shutdown, Malfunction Plan required by the NESHAP also include the CEMS required by only by the PSD permit. When ever the CEMS is down, the final permit requires that Eli Lilly monitor relevant parameters, record the results of the monitoring, and include a report providing this information and an analysis of whether the information indicates continuous compliance with the relevant emission limit.

This approach is not applicable to parametric monitoring that is not covered by the specific provisions of 40 CFR 63, because there is no data to substitute for the required data.

The condition C.10 and C.11 are revised as follows:

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)] [326 IAC 3-5]

(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 Branch, Office of Air Quality
100 North Senate Avenue, P. O. Box 6015
Indianapolis, Indiana 46206-6015

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 the “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 supercedes the monitoring provisions in 40 CFR Part 60 or 40 CFR Part 63.

The conditions C.11 has been revised as follows:

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 Branch, Office of Air Quality
100 North Senate Avenue, P. O. Box 6015
Indianapolis, Indiana 46206-6015

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

(~~a~~ 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.

(~~b~~**c**) **This provision applies only to CEMS operated solely for monitoring compliance with BACT limitations.** The ~~continuous emissions monitoring system~~ **CEMS** shall be operated at all times ~~the emissions unit or process is operating~~ as specified in Section D, except ~~for monitor system downtime due to continuous emissions monitoring system~~ **during CEMS** malfunctions ~~or~~**,** reasonable periods of necessary ~~continuous emissions monitoring system~~ **CEMS** calibration**,** or **CEMS** maintenance activities. ~~Continuous emissions monitoring system~~ **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).

(~~c~~**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.

(~~d~~**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.

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

(~~e~~f) **Except where permit conditions streamline similar applicable requirements pursuant to 326 IAC 2-7-24,** nothing in this ~~condition shall excuse the Permittee from complying with the requirements to operate a continuous monitoring system at all times pursuant to 40 CFR Part 63.1209, and 40 CFR 63.8~~ **permit nor in 326 IAC 3-5 supersedes the monitoring provisions in 40 CFR Part 60 or 40 CFR Part 63.**

Comment 3: **Section D.12.2 T49 Incinerator Particulate Matter Standards**

Lilly commented that an incorrect citation to the PM standards for existing hazardous waste incinerators should be corrected from 40 CFR 63.1203(b)(7) to 40 CFR 63.1203(a)(7). In Response 23 of the TSD Addendum, IDEM agrees with this comment. The correction, however, is not reflected in Section D.12.2 of the proposed permit.

Response 3: The typo has been corrected.

Comment 4: **Sections D.12.12, D.13.12, and D.14.3 SSM Plan requirements**

In paragraph (b)(2) of each of the above-referenced sections, language to require corrective actions for CEMS should be included in the SSM plan requirements.

Response 4: The language for the corrective action has been added in Sections D.12.12, D.13.12, and D.14.3 sections and are as follows:

D.12.12 (b)(2) Corrective action program for malfunctioning process, ~~and~~ air pollution control**, CEMS, and CMS** equipment.

D.13.12 (b)(2) Corrective action program for malfunctioning process, ~~and~~ air pollution control**, CEMS, and CMS** equipment.

D.14.3 (b)(2) Corrective action program for malfunctioning air pollution control, **CEMS, and CMS** equipment.

Comment 5: **Sections D.12.14, D.13.14, and D.14.4 CEMS requirements for incinerators and RTOs**

The supplemental monitoring requirements for NOx described in paragraph D.12.14 (b)(3)(B), D.13.14 (b)(3)(B), and D.14.4 (a)(3)(C) are vague and impractical. While Lilly does, for example, monitor combustion chamber temperature, airflow rate, and waste feed rates, we do not "monitor" the nitrogen characteristics of the waste feed in a way we could assess the 24 hour daily average NOx emission rate in pounds per hour. In addition, it is not clear to us why we should be evaluating the 24 hour average NOx emission rate in pounds per hour when the BACT emission limits are expressed in terms of concentration in parts per million. Finally, this requirement is inconsistent with the reporting requirements found in D.12.18 (a)(2)(B)(ii), D.13.19 (a)(2)(B)(ii), and D.14.8 (b)(2)(B)(ii).

Instead of trying to monitoring waste and fume nitrogen characteristics in terms of 24-hour NOx emission rates, Lilly could agree to permit language that was similar to the NOx emission assessment found in the reporting requirements in D.12.18 (a)(2)(B)(ii), D.13.19 (a)(2)(B)(ii), and D.14.8 (b)(2)(B)(ii). In those sections, Lilly would be required to conduct a qualitative assessment of the nitrogen content based on process knowledge, waste testing, waste shipments, etc.

In addition, Lilly requests that the permit specify how long the CEMS downtime must last before collecting supplemental monitoring data is required – especially the supplemental monitoring not already required by other parts of the permit [i.e., the NOx supplemental monitoring]. As written, if a NOx CEMs is down for 5 minutes, then the supplemental monitoring must take place.

Response 5: The PPM emissions were derived from the Best Available Control Technology (BACT) data. As for example BACT was established as the worst-case expected nitrogen feedrate of 1650 pounds per hour for the T-49 liquid incinerator and so on for others.

Instead of monitoring waste and fume nitrogen characteristics in terms of 24-hour NOx emission rates, IDEM, OAQ agrees to have the permit language in the conditions D.12.14 (b)(3)(B), D.13.14 (b)(3)(B), and D.14.4 (a)(3)(C) similar to the NOx emission assessment language found in the reporting requirements in D.12.18 (a)(2)(B)(ii), D.13.19 (a)(2)(B)(ii), and D.14.8 (b)(2)(B)(ii). The revised conditions are as followings:

D.12.14b (3)(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** ~~the nitrogen characteristics of the waste feed and shall assess the 24 hour - daily average NOx emissions in pounds per hour~~.

D.13.14b (3)(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** ~~the nitrogen characteristics of the waste feed and shall assess the 24 hour - daily average NOx emissions in pounds per hour~~.

D.14.4 (a)(3)(C) When the NOx CEMS malfunctions, the Permittee shall monitor and record the combustion chamber temperature and ~~waste fumes rates~~ ~~input to~~ **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 ~~the nitrogen characteristics of the waste fumes, and shall assess the 24 hour - daily average NOx emissions in pounds per hour~~.

Also the condition D.14.4 (a)(3)(B) was revised as follows:

D.14.4 (a)(3)(B) When CO CEMS malfunctions, the Permittee shall monitor and record the RTO combustion chamber temperature, and ~~waste fumes rates input to~~ **airflow rate from the** RTO as required by D.14.6 (a)(1) and (3), respectively.

Comment 6: Sections D.12.16, D.13.17, and D.14.7 CEMS minimum data collection requirements

Lilly strongly opposes the language in D.12.16, D.13.17, and D.14.7 that establishes when we have collected enough CEMS data to demonstrate compliance with BACT emission limits. First, we believe that since the permit requires us to conduct supplemental monitoring during periods of CEMS malfunction, then we are satisfying data collection requirements during those periods. We believe that as long as we are collecting any supplemental monitoring data during CEMS downtime, we are satisfying the minimum data collection requirements.

In addition, the proposed version of Section D.14.7 now omits language from the pharmaceutical MACT rules that establishes "excursion" requirements for the TOC and HCl CEMS. Similarly, excursion reporting requirements required by the pharmaceutical MACT rules have been deleted from Section 14.8(b)(1)(B). It is not clear in the proposed permit how IDEM would address these federal rule requirements.

Response 6 The conditions D.12.16, D.12.17 (a)(12), D.12.18 (a)(2); D.13.17, D.13.18 (a)(13), D.13.19 (a)(2); D.14.7 (Now D.14.8), have been revised. The rule 326 IAC 3-5 requires the operation of CEMS continuously. The supplemental monitoring data during CEMS malfunction duration will establish the compliance or noncompliance with the PSD BACT limits. The revised conditions are as follows:

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

The following defines when CEMS data ~~are insufficient~~ **must be supplemented with data required by conditions D.12.14 (b)(3), D.12.17 (a)(12), and D.12.18 (a)(2)** ~~to demonstrate compliance with the SO_2 BACT limit in Condition D.12.3 or the NOx BACT limit in Condition D.12.4~~:

(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.

D.12.17 (a)(12) For days ~~with~~ **when Condition D.12.16 requires that** CEMS data ~~insufficient~~ **must be supplemented** ~~to demonstrate compliance with the SO_2 and NOx limits established in Condition D.12.3 or D.12.4~~**,** documentation of the information required by Condition D.12.14 (b)(3).

D.12.18 (a)(2)

(A) A list of days ~~with~~ **when condition D.12.16 requires that** CEMS data ~~insufficient~~ **must be supplemented** ~~to demonstrate compliance with the limit established in Condition D.12.3 or D.12.4~~

(B) A detailed report for each day ~~with~~ **when condition D.12.16 requires that** CEMS data ~~insufficient~~ **must be supplemented** ~~to demonstrate compliance with the limit established in Condition D.12.3 or D.12.4~~ that provides:

D.13.17 Minimum Data Requirements – SO_2 and NOx Compliance [326 IAC 2-1.1-11]

The following defines when CEMS data ~~are insufficient~~ **must be supplemented with data required by conditions D.13.14 (b)(3), D.13.18 (a)(13), and D.13.19 (a)(2)** ~~to demonstrate compliance with the SO_2 BACT limit in Condition D.13.3 (a) or the NOx BACT limit in Condition D.13.4~~:

D.13.18 (a)(13) For days ~~with~~ **when Condition D.13.17 requires that** CEMS data ~~insufficient~~ **must be supplemented** ~~to demonstrate compliance with the SO_2 and NOx limits established in Condition D.13.3 or D.13.4~~**,** documentation of the information required by Condition D.13.14 (b)(3).

D.13.19 (a)(2)

(A) A list of days ~~with~~ **when condition D.13.17 requires that** CEMS data ~~insufficient~~ **must be supplemented** ~~to demonstrate compliance with the limit established in Condition D.13.3 or D.13.4~~

(B) A detailed report for each day ~~with~~ **when condition D.13.17 requires that** CEMS data ~~insufficient~~ **must be supplemented** ~~to demonstrate compliance with the limit established in Condition D.13.3 or D.13.4~~ that provides:

~~D.14.7~~ **D.14.8** Minimum Data Requirements – SO_2, CO, and NOx Compliance [326 IAC 2-1.1-11]

The following defines when CEMS data ~~are insufficient~~ **must be supplemented with data required by conditions D.14. 4 (a)(3), D.14.9 (a)(1)(L), and D.14.9 (b)(2)** ~~to demonstrate compliance with the SO_2, CO, and NOx BACT limits established in Condition D.14.1 (a)~~:

D.14.9 (a)(1)(L) For days ~~with~~ **when condition D.14.8 requires that** CEMS data ~~insufficient~~ **must be supplemented** ~~to demonstrate compliance with the SO_2, CO, and NOx limits established in Condition D.14.1~~, documentation of the information required by Condition D.14.4 (a)(3).

D.14.9 (b)(2)

(A) A list of days ~~with~~ **when condition D.14.8 requires that** CEMS data ~~insufficient~~ **must be supplemented** ~~to demonstrate compliance with the limit established in Condition D.14.1~~

(B) A detailed report for each day ~~with~~ **when condition D.14.8 requires that** CEMS data ~~insufficient~~ **must be supplemented** ~~to demonstrate compliance with the limits established in Condition D.14.1~~ that provides: ----------

The draft version of Section D.14.7 that establish "excursion" requirements for the TOC and HCl CEMS has been reinstated, except the (c) condition, because the CEMS for CO, NOx, and SO_2 require continuous operation.

Also, the excursion reporting requirements required by the pharmaceutical MACT rule Section 14.8(b)(1)(B) have been reinstated.

Comment 7 **Sections D.15.7**

Excursion reporting requirements required by the pharmaceutical MACT rule have been deleted from Section 15.7(b)(1)(B). It is not clear in the proposed permit how IDEM would address these federal rule requirements.

Response 7 Excursion reporting requirements required by the pharmaceutical MACT rule have been reinstated in condition 15.7(b)(1)(B).

Comment 8 **Sections E.1.1**

Lilly wants to change the dates in E.1.1 to harmonize non-HAP LDAR testing periods with MACT required LDAR testing periods.

(2) Existing BPM process system components in VOC service shall be initially monitored for purposes of this permit between ~~January 1, 2003 and January 1, 2004~~ **October 21, 2002 and October 21, 2003**.

(3) Subsequent monitoring periods shall be calendar periods, beginning ~~January 1, 2004~~ **October 21, 2003**.

Response 8 The permit has been changed accordingly.

United States Environmental Protection Agency (USEPA) Comments:

Comment 1: USEPA commented that the following conditions serve no purpose and are ambiguous.

Conditions D.2.3, D.2.4, D.3.5, D.3.6, D.4.5, D.4.6, D.4.8, D.5.8, D.11.3, D.11.4, D.16.4, D16.5, D.18.2, D.19.4, E.1.3, E.1.4, E.2.3, E.2.4, and F.1.8.

Response 1: IDEM agrees with this. The above conditions have been deleted. The condition numbers following the deleted condition numbers have been renumbered.

Comment 2: USEPA objected to the blanket exemption language for testing conditions in D.1.6 (b), D.2.3, D.3.5, and D.4.5.

Response 2: IDEM agrees with it and the language has been changed as follows:

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

(a) The Permittee shall perform particulate matter performance tests for Boilers 1, 2 and 3 utilizing Methods 5 or 17 (40 CFR 60, Appendix A) for PM or other methods as approved by the Commissioner. These tests shall be repeated every third calendar year from the calendar year of the most recently completed compliance stack test. ~~The Permittee is not required to test Boiler 4 or Boiler 5 for compliance with the particulate matter limits established in this permit.~~ Tests shall be conducted in accordance with Section C – Performance Testing.

(b) ~~The Permitte is not required to test~~ **No emissions testing is required for compliance with particulate matter** for the boilers **4, and 5**;~~ for compliance with~~ **or** sulfur dioxide or nitrogen oxides emission limits established in Conditions **D.1.1**, D.1.2, and D.1.3 **at this time**, ~~However,~~ **but** IDEM may require performance testing when necessary to determine compliance. Any testing shall be conducted in accordance with Section C – Performance Testing.

Comment 3: USEPA commented that the title of D.1.7 be changed to "Coal Sampling and Analysis for SO_2", and the titles of D.1.8 and D.13.16 be changed to "Fuel Oil Sampling and Analysis for SO_2".

Response 3: The titles of Conditions D.1.7, D.1.8, and D.13.16 have been changed accordingly.

D.1.7 Coal Sampl~~e~~**ing** and Analysis ~~Requirements~~ **for SO_2** [326 IAC 3-7 and 326 IAC 7-2]

D.1.8 ~~No. 2~~ Fuel Oil Sampling and Analysis **for SO_2** [326 IAC 7-2]

D.13.16 ~~No. 2~~ Fuel Oil Sampling and Analysis **for SO_2** [326 IAC 7-2]

Comment 4: USEPA commented that the word "limits" be replaced with "monitor" in the title of D.1.9, D.1.9 (a) be removed in its entirety and (b) be changed to read "The Permittee shall monitor the natural gas and fuel oil usage for boiler no, 5 on a monthly basis.

Response 4: The permit condition D.1.9 has been changed accordingly.

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

~~(a) The Permittee shall monitor the fuel oil usage on a monthly basis to demonstrate compliance with the Boiler No. 5 SO2 emission limitation required by Condition D.1.2 (d).~~

The Permittee shall monitor the natural gas and fuel oil usage ~~on a monthly basis to demonstrate compliance with the~~ for Boiler No. 5 **on a monthly basis** ~~NOx emission limitation required by Condition D.1.3~~.

Comment 5: USEPA commented that the beginning of the first sentence in Condition D.11.2 be modified to read: "The Permittee shall comply with the following standards in accordance with the Pharmaceutical MACT Standards ……".

Response 5: The permit condition D.11.2 has been changed accordingly.

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]

~~Compliance with t~~ **T**he following standards ~~shall constitute compliance~~ **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:

Comment 6: The U.S. EPA commented that numerous permit conditions include language that may preclude the use of any credible evidence in determining whether an emission unit was in or out of compliance with an applicable requirement.

Response 6: The IDEM, OAQ did not intend to limit the information that could be considered in determining compliance or non compliance to the methods required in the permit. The conditions identified by the U.S. EPA have been edited to clarify that. An example includes:

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

(a) The Permittee shall operate the following CMS in accordance with the quality assurance requirements specified in 40 CFR 63.1209(d) at all times the T49 incinerator is burning waste. To satisfy the HWC MACT standards [40 CFR 63.1209(b), (d), (e), (f), and (h)] and the ~~compliance demonstration~~ requirements for PSD sources [326 IAC 2-1.1-11] the following parameters shall be monitored when burning waste:

(1) Dioxin/Furan CMS Requirements – Pursuant to the HWC MACT standards [40 CFR 63.1209(k)], the Permittee shall ~~demonstrate compliance with the dioxin/furan limit of Condition D.12.5(e) by~~ install~~ing~~ and operat**e**~~ing~~ CMS monitors for the following parameters:

(A) Combustion Chamber Temperature - Minimum rolling hourly average combustion chamber temperature established from the average temperature measured during the three DRE test runs;

(B) Combustion Air Flow Rate - Maximum hourly rolling average combustion air flow rate established from the average of the maximum hourly rolling average for each performance test run; and

(C) Primary Waste Feed Rate – Maximum hourly rolling average primary waste feed rate as established from the average of the maximum hourly rolling averages for each performance test run.

(D) Secondary Waste Feed Rate - Maximum hourly rolling average secondary waste feed rate as established from the average of the maximum hourly rolling averages for each performance test run.

(2) DRE Standard CMS Requirements – Pursuant to the HWC MACT standards [40 CFR 63.1209(j)], the Permittee shall ~~demonstrate continuous compliance with the POHC DRE standard established in Condition D.12.5 (f)(1) by~~ install~~ing~~ and operat**e**~~ing~~ CMS monitors for those parameters identified in Condition D.12.15 (a)(1).

(3) Metals CMS Requirements – Pursuant to the HWC MACT standards [40 CFR 63.1209(l) and (n)], the Permittee shall ~~demonstrate continuous compliance with the semi-volatile metal, low-volatile metal, and mercury emission standards established in Conditions D.12.5 (a), (b) and (c) by~~ install~~ing~~ and operat**e**~~ing~~ CMS monitors for the following parameters:

(A) Waste Feed Rate - Maximum 12-hour rolling average feed rates for total Hg, semi-volatile metals (cadmium and lead) and low volatile metals (arsenic, beryllium, and chromium) in all waste feedstreams established from the average of the hourly rolling averages for each performance test run and approved extrapolation techniques;

(B) Scrubber Liquids Solid Content - Maximum 12-hour rolling average solids content of the scrubber liquid using a continuous monitoring system established from the average of the performance test run averages. This parameter does not apply to mercury;

(C) Hydro-Sonic™ Scrubber Pressure Drop - Minimum hourly rolling average pressure drop across the Hydro-Sonic™ scrubber established from the average of the performance test run averages;

(D) Scrubber Liquid Flow Rate - Minimum hourly rolling average scrubber liquid flow rate established from the average of the performance test run averages; and

(E) Flue Gas Flow Rate - Maximum hourly rolling average flue gas flow rate, the maximum production rate, or another surrogate parameter for gas residence time, established from the average of the maximum hourly rolling averages for each test run.

(4) PM CMS Requirements – Pursuant to the HWC MACT standards [40 CFR 63.1209(m)], the Permittee shall ~~demonstrate continuous compliance with the PM standards established in Condition D.12.2 (a) by~~ install~~ing~~ and operat**e**~~ing~~ CMS monitors for the following parameters:

(A) Those parameters identified in Condition D.12.15 (a)(3)(B), (C), and (D); and

(B) Ash Feed Rate - Maximum 12-hour average ash feed rate established from the average of the test run averages.

(5) HCl/Cl_2 and Fluorides CMS Requirements – Pursuant to the HWC MACT standards [40 CFR 63.1209(o)] and ~~compliance~~ monitoring requirements for PSD sources [326 IAC 2-1.1-11], the Permittee shall ~~demonstrate continuous compliance with the HCl/Cl2 and fluorides standards established in Condition D.12.5(d) by~~ install~~ing~~ and operat**e**~~ing~~ CMS monitors for the following parameters:

(A) Those parameters identified in Condition D.12.15 (a)(3)(C), (D) and (E).

(B) Waste Feed Rate - Maximum 12-hour rolling average feed rates for chlorine (organic and inorganic) in all waste feedstreams established from the average of the performance test run averages. [40 CFR 63.1209(o)(1)]

(C) Scrubber Liquid pH - Minimum hourly rolling average scrubber liquid pH established from the average of the performance test run averages. [40 CFR 63.1209(o)(3)(iv)]

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

(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.

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

(a) **Whenever a Testing and Monitoring condition establishes the requirement to implement a Compliance Response Plan (CRP), the Permittee shall prepare a CRP in conformance with this condition.** ~~The Permittee is required to prepare a Compliance Response Plan (CRP) for each compliance monitoring condition of this permit.~~ If a Permittee is required to have an Operation, Maintenance and Monitoring …..

……….

(b) ~~For each compliance monitoring condition of this permit, r~~**R**easonable response steps shall be taken when indicated by the provisions of ~~that compliance~~ **a** monitoring condition as follows:

(1) Reasonable response steps shall be taken as set forth in the Permittee's current……….

………

Appendix A
Technical Support Documentation for
Specific Source Operations

D.1: Utilities Operations

Background and Description

The utilities operations consist of three coal-fired boilers 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 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		
Boiler 1	OP 79-04-90-0373	Expired
Boiler 2	OP 79-04-90-0374	Expired
Boiler 3	OP 79-04-90-0375	Expired
Boiler 4 and 5	OP 79-04-90-0376	Expired
Ash Handling System	OP 79-04-90-0376	Expired
Preconstruction Approvals		
Boiler 5	PC 79-1510	March 22, 1982

* There are no existing approvals for the out coal pile and coal conveyor system or fuel oil storage tank.

The following permit hygiene table for construction permit PC (79) 1510 issued March 22, 1982 describe those permit terms which were either modified or not incorporated into the Title V operating permit. Operation Permits issued by IDEM pursuant to 326 IAC 2-1-4 are not federally enforceable permits, nor are the terms of such permits "applicable requirements" which must be incorporated into the Title V permit.

Term Identification	Original Term Language	Proposed Term Language	Explanation/Comments
Conditions 6, 7, 9 and 10	All construction conditions	Delete all construction conditions	Construction of this project is complete. All construction conditions are obsolete.
Condition 1	That particulate matter emissions shall be limited to 0.31 pounds per MMBtu and less than 25 tons per year.	Those particulate matter emissions shall be limited to 0.31 pounds per MMBtu.	The PM PTE is only 6.1 tpy. Lilly requests that the "less than 25 tons per year" limit be deleted since the PTE never exceeds the PSD significance thresholds.
Condition 2	That sulfur dioxide emissions shall be limited to 6 pounds per MMBtu and less than 40 tons per year.	That sulfur dioxide emissions shall be limited to 0.5 pounds per MMBtu and less than 39 tons per year.	326 IAC 7-1.1-2 limits sulfur dioxide emissions (when burning fuel oil) to 0.5 lbs/MMBtu, not 6 lbs/MMBtu. Lilly's fuel usage calculations are based on a PTE of 39 tpy and therefore requests that 40 tpy be changed to 39 tpy.
Condition 3	That nitrogen oxides emissions shall be limited to less than 40 tons per year.	That nitrogen oxides emissions shall be limited to less than 39 tons per year.	Lilly's fuel usage calculations are based on a PTE of 39 tpy and therefore requests that 40 tpy be changed to 39 tpy.

Term Identification	Original Term Language	Proposed Term Language	Explanation/Comments
Conditions 4 & 5	Condition 4: That the fuel usage rates shall be limited as follows: a) and b)…. Condition 5: That the maximum use of both fuels combined shall be limited as follows: a), b) and c)…..	Condition 4: The total usage of No. 2 fuel oil shall be less than 1565.4 kilogallons per 12 consecutive month period rolled on a monthly basis. This fuel usage limitation is necessary to limit the potential to emit SO2 from Boiler 5 to less than 39 tons per 12 consecutive month period rolled on a monthly basis. In order for SO2 emissions not to exceed 39 tons per year, the sulfur content of the No. 2 fuel oil shall not exceed 0.35% sulfur content. Condition 5: The total usage of natural gas shall be less than 780 million cubic feet per 12 consecutive month period rolled on a monthly basis. For every gallon of No. 2 fuel oil used during each 12 consecutive month period, 200 cubic feet of natural gas shall be deducted from this limit. This fuel usage limitation is necessary to limit the potential to emi of NOx from Boiler 5 to less than 39 tons per 12 consecutive month period rolled on a monthly basis.	This proposed permit language accounts for the change in allowable sulfur emissions from 6 lbs/MMBtu to 0.5 lbs/MMBtu. The NOx calculations utilize the most current AP42 factors upon which the original limitations were based. Lilly requests that the formulas and tables in the original permit be clarified and simplified per the proposed term language.
ondition 8	That this permit to construct does not relieve Eli Lilly and Company, Lafayette, of the responsibility to comply with the control strategy of the State Implementation Plan, as well as other applicable local, state, and federal requirements.	Delete entire term.	This term is redundant with existing legal requirements and will be addressed by Part B of the permit.
ondition 11	That additional control procedures shall be initiated and devices be installed if deemed necessary to bring the total installation described above into compliance with Rules 6-2 and 7-1.	Delete entire term.	This term is redundant with existing legal requirements and will be addressed by Part B of the permit.
ondition 12	That the data and information supplied with the application shall be considered part of this permit. Any change or modification shall be reported in writing to the Board for approval before making such changes.	Delete entire term.	Incorporation by reference terms are environmentally insignificant and not related to compliance with applicable requirements. The second part of the term is redundant with an existing regulatory requirement, and will be addressed in Part B of the permit.

Emission Units and Pollution Control Devices Identified Through the Title V Compliance Transition Program

The following emission units in the utilities operations were identified by the source pursuant to the Title V Compliance Transition Program under IC 13-7-7 and non-rule policy document Air-000-NPD [19 IR 1709]:

Out Coal Pile

The worst-case fugitive particulate emissions from the coal pile were estimated using worst-case assumptions in the emission factor equation in AP-42, Chapter 13.2.4 – Aggregate Handling and Storage Piles and applying the maximum coal rates that could be fed to the boilers:

Max Coal Usage/Boiler, tons/yr	=	1419 Btu/lb steam x 65,000 lb steam/hr 92 MMBtu/hr x 1000000 Btu/MMBtu x 8760 hrs/yr x 1 lb coal/11,4500 Btu x 1 ton coal/2000 lbs coal
	=	35,130 tons coal/yr for each boiler
Total Max Coal Usage, tons/yr	=	35,130 tons coal/yr/boiler x 3 boilers
	=	105,390 tons coal/yr
AP-42 Emission Factor	=	0.0029 lbs fugitive PM/ton coal transferred
Total Fugitive Emissions, tons/yr	=	0.003 lbs fugitive PM/ton coal x 105,390 ton coal/yr x ton PM/2000 lb PM
	=	0.16 tons fugitive PM/year

The fugitive particulate emissions are less than the permitting threshold levels that would require a permit. Therefore, no terms or conditions have been incorporated into the Title V permit.

Federal Rule Applicability

There are no federal rules that apply to the utilities operations. The following non-applicability determinations are included for clarification purposes.

(a) Boilers

40 CFR 60, Subpart Da (New Source Performance Standard (NSPS) for Electric Utility Steam Generating Units) – This standard applies to units constructed after September 18, 1978 with the capability of combusting more than 250 MMBtu per hour heat input of fossil fuel (either alone or in combination with any other fuel). All of the boilers on site have a heat input capacity less than 250 MMBtu per hour and therefore are not subject to this rule.

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 on site 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 on site 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 is not subject to the control requirements of this subpart because the true vapor pressure of fuel oil is less than 3.5 kPa. According to 40 CFR 60.116b(b), the Permittee is required to keep readily accessible records showing the dimension of the storage vessel and an analysis showing the capacity of the storage vessel.

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.

326 IAC 2-2 (Prevention of Significant Deterioration) – To avoid this rule, the emissions from Boiler 5 shall be limited to less than 40 tons SO_2 per year and 40 tons NOx per year. This SO_2 emission limit correlates to a maximum fuel oil usage of 1120 Mgallons per 12 consecutive month period based on a maximum sulfur content of 0.49 percent. This NOx emission limit correlates to a maximum natural gas usage of 780 MMCF per 12 consecutive month period, and to account for fuel oil usage, it was determined that 1 MMCF of natural gas was equivalent to 5000 gallons of fuel oil.

(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; and
P = process weight rate in tons per hour
= 7950 tons ash/yr x 1 yr/8760 hrs
= 0.908 tons ash/hr

$E = 4.10\ (0.908)^{0.67}$
E = 3.84 lbs/hr x 24 hrs/day
E = 92.2 lbs/day x 1 ton/2000 lbs x 365 days/yr
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 (100% ash - 94% eff)] / 100% ash
= 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

326 IAC 6-5 (Fugitive Particulate Matter Emission Limits) –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

326 IAC 8-9 (Volatile Organic Liquid Storage Vessels) – 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. Visible emission notations of the stack exhausts of the coal-fired boilers shall be performed once per shift (Lilly operates 2 shifts), or two times per day, during normal daylight operations when exhausting to the atmosphere.

2. 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.

3. Particulate stack tests for the coal fired boilers (Boilers 1, 2, and 3) shall be performed once every three years 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.

4. Fuel oil and natural gas usage for Boiler 5 must be monitored on a monthly basis to demonstrate compliance with the NOx and SO2 limitations required by 326 IAC 2-2.

5. 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.

6. Preventive maintenance plan required for boilers and multiclones.

(b) Ash Handling System

Pursuant to April 1999 IDEM Guidance, the ash handling system is not subject to compliance monitoring requirements because the allowable PM emissions from the control device are less than 10 pounds per hour.

(c) Out Coal Pile/Coal Conveyor System

The out coal pile and coal conveyor system are not subject to any compliance requirements because the actual PM emissions are less than 25 tons per year (pursuant to April 1999 IDEM Guidance).

(d) Fuel Oil Storage Tank

According to NSPS Subpart Kb, the fuel oil storage tank is not subject to any control or compliance requirements. In addition, the April 1999 IDEM Guidance does not require compliance monitoring for this fuel oil tank because the actual VOC emissions are less than 25 tons per year.

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	Emergency Diesel Generator	None
T135	Emergency Diesel Generator	None
T78	Diesel Compressor	None
T89-1	Diesel Compressor	None
T89-2	Diesel Compressor	None
Building T97/T98:		
T97/T98	Glycol System	None
Building T9/T23:		
T9/T23	Lime Storage Silo	None

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).

Existing Approvals

With respect to the utilities support operations, the source has been operating under the following previous approvals.

Description	Permit #	Date
Operating Permits		
Lime System, T62 Generator	OP 79-04-90-0376	Expired
Preconstruction Approvals		
Glycol System	PC 79-1464	
Generators and Compressors	CP 157-3319	February 21, 1995
T5 Generator	CP 157-2809, A 157-4760	April 5,1993, October 25, 1995

The following permit hygiene table describe those permit terms which were either modified or not incorporated into the Title V operating permit. Operation Permits issued by IDEM pursuant to 326 IAC 2-1-4 are not federally enforceable permits, nor are the terms of such permits “applicable requirements” which must be incorporated into the Title V permit.

Term Identification	Original Term Language	Proposed Term Language	Explanation/Comments
CP-157-2809, Issued April 5, 1993 for a diesel powered emergency generator			
All construction conditions	All construction conditions	Delete all construction conditions	Construction of this project is complete. All construction conditions are obsolete.
Operation Condition No. 1	That the data and information supplied in the application shall be considered part of this permit. Prior to any change in operation which may result in an increase in potential emission exceeding those specified in 326 IAC 2-1-1, this change must be approved by the OAM.	Delete entire term.	Incorporation by reference terms are environmentally insignificant and not related to compliance with applicable requirements. The second part of the term is redundant with an existing regulatory requirement, and will be addressed in Part B of the permit.

Operation Condition No. 2	That the Permittee shall comply with the provisions of the Indiana Environmental Management Law (IC 13-7), Air Pollution Control Law and rules promulgated thereunder.	Delete entire term.	This term is redundant with existing legal requirements and will be addressed by Part B of the permit.
Operation Condition No. 3	That the equipment shall be operated and maintained in accordance with the manufacturer's specifications.	Delete entire term.	This term is environmentally insignificant and not related to compliance with applicable requirements.
A-157-4760, Issued October 25, 1995 Amendment to CP157-2809 Additional condition limiting the diesel generator			
Operation Condition No. 4	That the operation of the T-8 generator shall be limited to a maximum of 1000 hours per year reducing its allowable NOx emissions from 34.2 tons per year to 3.9 tons per year. The log of information necessary to document compliance with this condition shall be maintained. This record shall be kept for at least the past 24 months period and made available upon request to the Office of Air Quality.	Delete entire term.	Based on EPA PTE guidance on generators, the emissions from this source are insignificant and therefore can be deleted.

Emission Units and Pollution Control Devices Identified Through Title V Compliance Transition Program

The following emission units in the utilities operations were identified by the source pursuant to the Title V Compliance Transition Program under IC 13-7-7 and non-rule policy document Air-000-NPD [19 IR 1709]:

T97 and T98 Glycol System

Although the glycol system is not associated with an existing permit, this emission source is not subject to any federal or state control requirements. This facility will be identified in the facility description section of Section D.2 in the Title V Operating Permit.

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

326 IAC 2-2 (PSD Rules) – Construction Permit, CP 157-3319, established operation limitations on generators and compressors to avoid the requirements of PSD. The requirements of this construction permit have been revised under this Title V permit as discussed in the following paragraphs.

Because Generator T135 is only used in emergency situations, the September 6, 1995 memorandum from EPA's John Seitz entitled "Calculating Potential to Emit (PTE) for Emergency Generators" allows the potential to emit from emergency generators be based on 500 hours of operation per year, or less where justifiable. Historical data confirms that this generator is well below the current operation limit of 200 hours per year. Based on the EPA guidance, it is no longer necessary to limit potential to emit as required by the construction permit. Therefore, the limit has not been incorporated into the Title V permit.

Because Compressors T78, T89-1 and T89-2 are mobile units, they are categorized as non-road engines and are not subject to the air permitting regulations. Therefore, the limitations required by the construction permit have not been incorporated into the Title V permit.

Because Generator T121 is used intermittently to supply power during periods of peak electrical consumption, 1995 USEPA guidance does not allow the Permittee to base its potential to emit on 500 hours of operation per year. Therefore, the 900 hour per year operation limitation required by the construction permit has been incorporated into the Title V permit. The permit requires monthly usage records be submitted to IDEM on a quarterly basis.

Construction Permit, CP 157-2809, and Amendment A157-4760, established an operation limitation for the T5 Generator of 1000 hours of operation per year. Because the generator is only used in emergency situations, EPA guidance allows the potential to emit be based on 500 hours of operation per year, or less where justifiable. Historical data confirms that this generator is well below 500 hours per year. Based on the EPA guidance, it is no longer necessary to limit potential to emit as required by the construction permit. Therefore, this limit has not been incorporated in the Title V 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

With the exception of the T121 Generator, the generators and compressors are not subject to any compliance requirements because these emission units are not subject to any state or federal rules.

With respect to the T121 Generator, the Permittee is only required to maintain monthly usage records to demonstrate compliance with the monthly usage limit required to avoid the requirements of 326 IAC 2-2 and 40 CFR 52.21.

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, T2B, 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, T2B, 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.

The equipment associated with building T2B fermentation operations was permanently taken out of service in May 2003. Lilly sent a notification letter to the agency on August 4, 2003 stating that the following equipment has been permanently taken out of service and has not been incorporated into the Title V permit:

Building	Stack/Vent ID	Emission Unit ID	Equipment Description	Status
T2B	S-T2-FERM	T031	Bump Tank	Removed from Service
T2B	S-T2-FERM	T032	Bump Tank	Removed from Service
T2B	S-T2-FERM	T033	Bump Tank	Removed from Service
T2B	S-T2-FERM	T034	Bump Tank	Removed from Service
T2B	S-T2-FERM	T035	Bump Tank	Removed from Service
T2B	S-T2-FERM	T036	Bump Tank	Removed from Service
T2B	S-T2-FERM	T037	Fermentor Tank	Removed from Service
T2B	S-T2-FERM	T038	Fermentor Tank	Removed from Service
T2B	S-T2-FERM	T039	Fermentor Tank	Removed from Service
T2B	S-T2-FERM	T040	Fermentor Tank	Removed from Service
T2B	S-T2-FERM	T041	Fermentor Tank	Removed from Service
T2B	S-T2-FERM	T042	Fermentor Tank	Removed from Service

(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.

(f) Animal Health Finishing and Packaging Area (T1)

The equipment associated with the T1 Animal Health Premix Formulation and Packaging Area was permanently taken out of service in April 2001. Lilly sent a notification letter to the agency on July 13, 2001 stating that the following equipment has been permanently taken out of service and has not been incorporated into the Title V permit:

Building	Stack/Vent ID	Emission Unit ID	Equipment Description	Status
T1	Outside Cartridge Dust Collector	East Diluent Scale	No. 1 Diluent Scales	Removed from Service
T1	Outside Cartridge Dust Collector	Mixer 1	Horizontal Ribbon Mixer at Mixer 1	Removed from Service
T1	Outside Cartridge Dust Collector	Mixer 1 Bagging Station	Bagging Station	Removed from Service
T1	Outside Cartridge Dust Collector	Mixer 3	Vertical Mixer	Removed from Service
T1	Outside Cartridge Dust Collector	Mixer 3 Bagging Station	Bagging Station	Removed from Service
T1	Outside Cartridge Dust Collector	Mixer 4	No. 4 Hygro Mixer	Removed from Service
T1	Outside Cartridge Dust Collector	Mixer 4 Bagging Station	Mixer 4 Bagging Station	Removed from Service
T1	Outside Cartridge Dust Collector	Tote Unloading Conveyor – Mixer 1	Conveyor	Removed from Service
T1	Outside Cartridge Dust Collector	Tote Unloading Conveyor – Portable	Portable Horizontal Conveyor	Removed from Service
T1	Outside Cartridge Dust Collector	West Diluent Scale	No. 3 Diluent Scales	Removed from Service

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).

Existing Approvals

With respect to the fermentation operations, the source has been operating under the following previous approvals.

Description	Permit #	Date
Operating Permits		
Dry Material Bulk Storage, Raw Material Prep Area	79-04-90-0372	Expired
Equipment in T2, T2A, and T2B	157-4270	Expired
Preconstruction Approvals		
T1 Animal Health Finishing Plant – Permanently shutdown	CP 157-6176, A 157-7138	October 11, 1996, December 20, 1996
T1 Animal Health Finishing Plant – Permanently shutdown	Registration 157-2874	April 7, 1993
Fermentation tank, T028, located in T2A	Registration 157-3220	September 3, 1993
Fermentation tank, T008, located in T2	Registration 157-4466	May 8, 1995
Equipment in T2C, T3, and T4	Registration 157-7144	December 4, 1996
Fermentation tank, T008, located in T2	EQ 157-10024	

* There are no approvals for the bulk liquid storage area or product storage area because these facilities are below the permitting threshold levels.

The following permit hygiene table describe those permit terms which were either modified or not incorporated into the Title V operating permit. Operation Permits issued by IDEM pursuant to 326 IAC 2-1-4 are not federally enforceable permits, nor are the terms of such permits “applicable requirements” which must be incorporated into the Title V permit.

Term Identification	Original Term Language	Proposed Term Language	Explanation/Comments
CP-157-6176 and A 157-7138, Construction Permit Issued October 11, 1996 and its amendment Issued December 20, 1996 for the T1 Animal Health Finishing Plant			
All construction conditions	All construction conditions	Delete all construction conditions	Construction of this project is complete. All construction conditions are obsolete.
All operation conditions	All operation conditions	Delete all operation conditions	These operations have been permanently shutdown as documented in a July 13, 2001 notification letter to IDEM.
Registration No. 157-2874, Issued April 7, 1993 for the T1 Animal Health Finishing Plant			
Entire Registration	The Eli Lilly and Company application has been reviewed. Based on the data submitted and the provisions in Sections 1 and 2 of 326 IAC 2-1, it has been determined that the following, to be located at 1650 Lilly Road, Lafayette, Indiana is classified as registered: one (1) high efficiency baghouse to be used as a particulate control system to service the LEV system in building T1 (animal health and premix area).	Delete this paragraph	All operations associated with the T1 Animal Health Premix Formulation/Packaging Area have been permanently shutdown as documented in a July 13, 2001 notification letter to IDEM.
Operating Permit 79-04-90-0372, Issued October 9, 1986 for the T1 Bulk Filter Aid System, T442 Flash Dryer, and T1/T46 Fermentation Makeup Area			
All operation conditions	All operation conditions	Delete all operation conditions	Operating permits are not federally enforceable permits, nor are the terms of such permits "applicable requirements" which must be incorporated into the Title V permit. Although some operating permit conditions are intended to implement terms of previously issued construction permits, the original construction permit conditions are the applicable requirements. Operating permit terms have no effect in the Title V program.
T1 Bulk Filter Aid System	All operation conditions	Delete all operation conditions	The T1 Bulk Filter Aid System has been permanently shutdown as documented in a August 20, 2001 notification letter.
Registration 157-3220, Issued September 3, 1993 for Fermentor Tank 28 in Building T2A			
1st and 2nd Paragraphs	The Eli Lilly application has been reviewed. Based on the data submitted…it has been determined that the following…is classified as registered: one fermentor tank (id#TK28) with a maximum process weight of 2.76 tons per hour, to be installed in building T2A of their Tippecanoe facility. The particulate matter emissions will be controlled by an existing cyclone and the remaining exhaust gases will be discharged through the stack identified as "Tall Stack". Particulate matter emissions from the fermentor shall be limited to 8.09 pounds per hour of operation.	<u>Condition D.3.3 of the Title V permit</u>: Pursuant to 326 IAC 6-3-2 (Particulate Matter Emission Limitations from Process Operations), the bump tanks and fermentor tanks in Building T2A shall not exceed a combined allowable PM emission rate of 28.7 pounds per hour at a maximum process weight rate of 18.3 tons per hour.	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 determined that related equipment should 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.

Term Identification	Original Term Language	Proposed Term Language	Explanation/Comments
2nd paragraph, 3rd sentence	The particulate matter emissions will be assumed to be in compliance with 326 IAC 6-3 provided that the visible emissions do not exceed 10% opacity	Delete entire sentence.	All the fermentors can comply with their allowable emissions limits without the use of controls. Therefore, there is no need for compliance monitoring terms such as this existing permit limitation.
Last paragraph	Any change or modification which may increase the potential emissions to more than 25 tons per year of VOC from the equipment covered in this letter must be approved by the Office of Air Quality before such change may occur.	Delete entire term.	The term is redundant with an existing regulatory requirement, and will be addressed in Part B of the permit.
Registration 157-4466, Issued May 8, 1995 for Fermentor Tank 8 in Building T2			
Last paragraph	Any change or modification which may increase the potential emissions to more than 25 tons per year of VOC from the equipment covered in this letter must be approved by the Office of Air Quality before such change may occur.	Delete entire term.	The term is redundant with an existing regulatory requirement, and will be addressed in Part B of the permit.
Registration 157-7144, Issued December 4, 1996 for Building T2C			
Item a)	Three (3) 240,000 liter fermentor tanks and three (3) 28,000 liter bump tanks in a new fermentation building designated as T2C, with particulate emissions controlled by cyclones, venting to an existing stack designated as the tall stack	Facility Description of Section D.3 of the Title V Permit: Three (3) ~~240,000~~ 245,000 liter fermentor tanks and ~~three (3) 28,000~~ two (2) 37,000 liter bump tanks in a new fermentation building designated as T2C, with particulate emissions controlled by cyclones, venting to an existing stack designated as ~~the tall stack~~ S-T2-FERM.	Only two bump tanks were installed.
Condition 1	Pursuant to 326 IAC 5-1-2 (Visible Emission Limitations) except as provided in 326 IAC 5-1-3 (Temporary Exemptions), the visible emissions shall meet the following: (a) visible emissions shall not exceed an average of 40% opacity in 24 consecutive months; and (b) visible emissions shall not exceed 60% opacity for more than a cumulative total of 15 minutes (60 readings) in a 6-hour period.	Delete entire term.	This term is redundant with an existing regulatory requirement, and will be addressed in Part C of the permit.
Last paragraph	Any change or modification, which may increase the potential VOC emissions to 25 tons per year or more from the equipment covered in this letter, must be approved by the Office of Air Quality before such change, may occur.	Delete entire term.	This term is redundant with an existing regulatory requirement, and will be addressed in Part B of the permit.
Operation Permit 157-4270, Issued June 20, 1996 for Buildings T2, T2A, T2B Fermentation Tanks and Bump Tanks			
All operation conditions	All operation conditions	Delete all operation conditions	Operating permits are not federally enforceable permits, nor are the terms of such permits "applicable requirements" which must be incorporated into the Title V permit. Although some operating permit conditions are intended to implement terms of previously issued construction permits, the original construction permit conditions are the applicable requirements. Operating permit terms have no effect in the Title V program.

Term Identification	Original Term Language	Proposed Term Language	Explanation/Comments
Exemption Qualification 157-10024, Issued August 27, 1998 for Like-Kind Replacement of Tank T004, Building T2			
Condition No. 2	That the owner or operator of the above proposed changes shall comply with any directly applicable federal requirements and rules under 326 IAC 2-7, 326 IAC 2-8, and 326 IAC 2-9.	Delete entire condition.	The term is redundant with an existing regulatory requirement, and will be addressed in Part B of the permit.
Condition No. 3	That the owner or operator of the modification shall comply with any applicable state rules under Indiana Administrative Code 326.	Delete entire condition.	The term is redundant with an existing regulatory requirement, and will be addressed in Part B of the permit.
Last Paragraph	Any change or modification which will alter operations in such a way that it will generate an increase in air pollutant emissions or alter the operations such that it will no longer comply with the applicable restrictions and conditions of this approval letter, must obtain the appropriate approval from the Office of Air Quality (OAM) under 326 IAC 2, before such change may occur.	Delete entire term.	The term is redundant with an existing regulatory requirement, and will be addressed in Part B of the permit.

Emission Units and Pollution Control Devices Identified Through Title V Compliance Transition Program

There were no emission units in the fermentation operations identified by the source pursuant to the Title V Compliance Transition Program under IC 13-7-7 and non-rule policy document Air-000-NPD [19 IR 1709].

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 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 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 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 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.

Compliance Requirements

No compliance monitoring is required for any of the equipment associated with the fermentation operations because the actual PM emissions are less than 25 tons per year (pursuant to April 1999 IDEM Guidance).

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, T40, and T94), 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, T40, T94)

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.

It should be noted that the T3 votator was permanently taken out of service in Spring 2002. A notification letter was submitted to the agency in June 2002. Therefore, this equipment and associated requirements have not been included in the Title V permit.

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.

The equipment associated with Building T94 was permanently taken out of service in April 2002. A notification letter was submitted to the agency in June 2002. A follow-up letter was submitted in August 2002 to clarify that the T94-T101 process tank was not removed from service. This process tank was inadvertently included in the T94 shutdown equipment because this tank supported building T94. Because this tank is not dedicated to building T94, it should not be included with the T94 shutdown equipment. This tank is located outside of building T4 and should be identified as T4-T101. The following equipment associated with Building T94 has not been included in the Title V permit:

Building	Emission Unit ID	Equipment Description	Status
T94	T94-CENT030	Stacked Plate Centrifuge	Removed from Service
T94	T94-CENT031	Stacked Plate Centrifuge	Removed from Service
T94	T94-CENT032	Stacked Plate Centrifuge	Removed from Service
T94	T94-T011	Process Tank	Removed from Service
T94	T94-T012	Process Tank	Removed from Service
T94	T94-T013	Process Tank	Removed from Service
T94	T94-T015	Process Tank	Removed from Service
T94	T94-T002	Process Tank	Removed from Service

Building	Emission Unit ID	Equipment Description	Status
T94	T94-T003	Process Tank	Removed from Service
T94	T94-T004	Process Tank	Removed from Service
T94	T94-T005	Process Tank	Removed from Service
T94	T94-T006	Process Tank	Removed from Service
T94	T94-T007	Process Tank	Removed from Service
T94	T94-T008	Process Tank	Removed from Service

(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) T40 Purification Production Area

With the exception of one tank, T40-TK055, the emission units associated with the T40 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).

(c) 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).

(d) 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).

Existing Approvals

With respect to the purification operations, the source has been operating under the following previous approvals.

Description	Permit #	Date
Operating Permits		
T3 and T94 Purification Operations and T4 Solvent Recovery Operations	OP 79-04-90-0377	Expired
T39 Product Storage Area	79-04-90-0385	Expired
Preconstruction Approvals		
T3 Production Equipment	Registration 157-7144	Dec 4, 1996
T3 Production Equipment	Exemption 157-9280 (Revision to 157-7144)	Feb 25, 1998
T3 Production Equipment	Registration 157-3595	May 2, 1994
T3 RVD	Registration, Amendment to Registration	Nov 8, 1990, Nov 10, 1992
Process Dryers	79-04-90-0385	April 1, 1986
T94 Expansion Project	Registration	March 11, 1985
Increased Production Project	CP 157-5244	June 20, 1996
T147 Storage Tank Module	Registration 4100-0006	August 16, 1990
T147 Storage Tank Module	CP 157-3319	Feb 21, 1995

* There are no approvals for the six tanks (T40-050 thru T40-053, T40-055, and T40-060) associated with Building T40 and two extractors (E190, E290). The two extractors were permanently taken out of service in 1997 and have not included in the Title V permit.

The following permit hygiene table describe those permit terms which were either modified or not incorporated into the Title V operating permit. Operation Permits issued by IDEM pursuant to 326 IAC 2-1-4 are not federally enforceable permits, nor are the terms of such permits “applicable requirements” which must be incorporated into the Title V permit.

Term Identification	Original Term Language	Proposed Term Language	Explanation/Comments
Construction Permit 157-7144, Issued December 4, 1996 for new equipment in Buildings T3 and T4			
Item c)	One (1) flash evaporator in building T4, capable of recovering the solvents used in the purification processes at a rate of 20,668 lbs/hr.	Delete entire term.	The flash evaporator was never installed.
Condition 1	Pursuant to 326 IAC 5-1-2 (Visible Emission Limitations) except as provided in 326 IAC 5-1-3 (Temporary Exemptions), the visible emissions shall meet the following: (a) visible emissions shall not exceed an average of 40% opacity in 24 consecutive months; and (b) visible emissions shall not exceed 60% opacity for more than a cumulative total of 15 minutes (60 readings) in a 6-hour period.	Delete entire term.	This term is redundant with an existing regulatory requirement, and will be addressed in Part C of the permit.
Last paragraph	The Office of Air Quality must approve any change or modification which may increase the potential VOC emissions to 25 tons per year or more from the equipment covered in this letter before such change may occur.	Delete entire term.	This term is redundant with an existing regulatory requirement, and will be addressed in Part C of the permit.
Construction Permit 157-3319, Issued February 21, 1995 for Tank Module T147			
All construction conditions	All construction conditions	Delete all construction conditions	Construction of this project is complete. All construction conditions are obsolete.
Operating Condition #1	That the data and information supplied in the application shall be considered part of this permit. Prior to any change in operation which may result in an increase in potential emission exceeding those specified in 326 IAC 2-1-1, this change must be approved by the Office of Air Quality (OAM).	Delete entire term.	Incorporation by reference terms are environmentally insignificant and not related to compliance with applicable requirements. The second part of the term is redundant with an existing regulatory requirement, and will be addressed in Part B of the permit.
Operating Condition #2	That the Permittee shall comply with the provisions of the Indiana Environmental Management Law (IC 13-7), Air Pollution Control Law and rules promulgated thereunder.	Delete entire term.	This term is redundant with existing legal requirements and will be addressed by Part B of the permit.
Operating Condition #3	That the equipment shall be operated and maintained in accordance with the manufacturer's specifications.	Delete entire term.	This term is environmentally insignificant and not related to compliance with applicable requirements.
Operating Condition #6	That for the storage tanks, 326 IAC 8-5-3(b)(3) shall be met through the use of vent condensers and/or the T79 fume incinerator.	With the exception of the T147 tank module, the storage tanks are subject to the requirements of 326 IAC 8-5-3. Compliance with this rule shall be met through the use of vent condensers and/or the T79 fume incinerator.	The T147 storage tank module only serves the fermented products manufacturing area which does not manufacture pharmaceutical products by chemical synthesis. Therefore, the storage tanks associated with the T147 tank module are not subject to this requirement.

Term Identification	Original Term Language	Proposed Term Language	Explanation/Comments
Operating Condition #11, second sentence	During the first 31 days of operation, VOC emissions shall be limited such that, total VOC emissions divided by days of operation shall not exceed 437.3 pounds per day.	Delete entire term.	These construction conditions establish requirements applicable only during the first year of operation. Since these sources have been operated for longer than a year, these conditions are irrelevant and should be deleted.
Operating Condition #13	That the emissions of volatile organic compound (VOC) from storage tanks shall be limited as follows, based on a 365 day rolling average rolled on a daily basis….	Delete entire term.	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. This flexible permit is vital to the BPM operations because of continual physical changes and changes in the methods of operation to handle the development of new products. 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. The last paragraph of this condition establishes requirements applicable only during the first year of operation. Since these emission units have been operated for longer than a year, these conditions are irrelevant and should be deleted.

Emission Units and Pollution Control Devices Identified Through Title V Compliance Transition Program

The following emission units in the BPM operations were identified by the source pursuant to the Title V Compliance Transition Program under IC 13-7-7 and non-rule policy document Air-000-NPD [19 IR 1709]:

T3 Votator

Although the T3 votator is not associated with an existing permit, this emission source is not subject to any federal or state control requirements. This facility will be identified in the facility description section of Section D.4 in the Title V Operating Permit.

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) Building T40

NSPS 40 CFR 60, Subpart Kb – Volatile Organic Liquid Storage Vessels
Tanks T40-051, T40-052, T40-053, T40-055, and T40-060 are not subject to the requirements of 40 CFR 60, Subpart Kb because these tanks were installed prior to the July 23, 1984 rule applicability date, and have not been modified since that date. Tank T40-50 is not subject to the requirements of 40 CFR 60, Subpart Kb because the tank capacity is less than 40 cubic meters (10,560 gallons).

NESHAP 40 CFR 63, Subpart GGG – Pharmaceutical MACT
The emission units associated with Building 40 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).

(c) 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.

(d) 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 subject to Subpart Kb because they were installed after July 23, 1984 and have individual capacities greater than 40 cubic meters (10,566 gallons). Since these tanks have individual capacities between 10,566 and 19,812 gallons, only a record of the storage tank capacity and dimension must be kept for the life of the source [40 CFR 60.116b(b)].

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 that generate hazardous air pollutant (HAP) emissions in excess of 50 ppmv pursuant to 40 CFR 63.1251 (Process Vent 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) Building T40

326 IAC 8-1-6 – VOC BACT Rule
The T40 tanks are not subject to the requirements of 326 IAC 8-1-6 because the T40-051, T40-052, T40-053, T40-055, T40-060 tanks were installed prior to the January 1, 1980 rule applicability date and because the potential VOC emissions from tank T40-050 fall below the 25 tons per year applicability threshold level.

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 T40 tanks are not subject to the requirements of 326 IAC 8-6-1 because the T40-050, T40-051, T40-052, T40-053, T40-055 tanks were not installed between October 7, 1974 and January 1, 1980 and the potential VOC emissions from the T40-060 tank was less than 100 tons per year.

(c) 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.

(d) 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.

(e) 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 because the actual emissions are less than 25 tons per year.

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 (water with 10% solids) storage tanks. Total reduced sulfur, reduced sulfur compound, and hydrogen sulfide 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.

The bio-solids, also called biological fertilizer supplement (BFS), are stored prior to application to farmland through Lilly's land application program. The storage facility operates such that one tank is filled at a time. Once a tank is filled, another tank begins filling and the full tank is recycled for eight hours to obtain a homogeneous sample for analysis. After sampling is complete, recycle is stopped. As weather permits, the material is then loaded into tank trucks for transportation to local farmland.

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.

Existing Approvals

With respect to the fermented products support operations, the source has been operating under the following previous approvals.

Description	Permit #	Date
Operating Permits		
Thermal Foul Air Incinerator	OP 79-04-90-0386	Expired
Preconstruction Approvals		
FP Wastewater Treatment Plant	Registration	January 16, 1989
Biosolids Storage Tanks	CP157-4363, Amendment 157-8953	August 28, 1996, November 12, 1997

* The T100 equalization tank and T8 thickening tank were demolished in Summer 2001 as documented in an August 2, 2002 notification letter to IDEM. Therefore, this equipment has not been included in the Title V permit.

The following permit hygiene table describe those permit terms which were either modified or not incorporated into the Title V operating permit. Operation Permits issued by IDEM pursuant to 326 IAC 2-1-4 are not federally enforceable permits, nor are the terms of such permits "applicable requirements" which must be incorporated into the Title V permit.

Term Identification	Original Term Language	Proposed Term Language	Explanation/Comments
Construction Permit 157-4363 and Amendment 157-8953, Issued August 28, 1996 and Amended on November 12, 1997, for 4 biosolids tanks and iron sponge reactor control system			
All construction conditions	All construction Conditions	Delete entire term.	This term is redundant with existing legal requirements and will be addressed by Part B of the permit.
Operation Condition #1	That the equipment shall be operated and maintained in accordance with the manufacturer's specifications.	Delete entire term.	This term is environmentally insignificant and not related to compliance with applicable requirements.
Operation Condition #2	That the equipment shall be operated and maintained in accordance with the manufacturer's specifications.	Delete entire term.	This term is environmentally insignificant and not related to compliance with applicable requirements.
Operating Condition #3(a)	Updated in A157-8953: That at least one chamber of the packed bed shall operate at all times that the bio-solids tanks (Tanks A, B, C, and D) are operated maintaining a minimum of 90% hydrogen sulfide (H2S) and 90% total reduced sulfur (TRS) control efficiencies or outlet concentration less than 300 ug/l or an after control emission rate of 0.9 lbs/hr, whichever is less stringent.	To avoid the requirements of 326 IAC 2-2 and 40 CFR 52.21 (Prevention of Significant Deterioration), the total reduced sulfur (TRS) emissions from the bio-solids tanks shall not exceed 2.3 pounds per hour, which is equivalent to 755 micrograms per liter (ug/l). This emission limitation also satisfies the emission limitations for reduced sulfur compounds and hydrogen sulfide.	The emission limitations for total reduced sulfur, reduced sulfur compounds, and hydrogen sulfide have been revised and streamlined in the Title V permit to be consistent with the PSD significant threshold levels. The PSD significant threshold levels for each of these pollutants is 10 tons per year. The emission limitation in the existing construction permit and amendment is 4 tons per year. Because there is no rule that requires emissions to be limited beyond 10 tons per year, the existing permit condition is not enforceable. With respect to streamlining, the hydrogen sulfide and reduced sulfur compounds are a subset of total reduced sulfur. Because each of the pollutant categories have the same significant threshold level of 10 tons per year, compliance with the total reduced sulfur emission limit satisfies compliance with hydrogen sulfide and reduced sulfur compound emission limits.

Term Identification	Original Term Language	Proposed Term Language	Explanation/Comments
Operating Condition #3(b)	That the pressure drop and air flow rate of the iron sponge scrubber shall be monitored;	The Permittee shall monitor and record the pressure drop across the iron sponge reactor once per day to demonstrate that it is operating properly.	Because the pressure drop across the iron sponge reactor and the reactor air flowrate are both used to demonstrate that the bio-solids tanks are exhausting to the iron sponge, only one of these monitoring parameters is necessary.
Operating Condition #3(c)	Updated in A157-8953: That the hydrogen sulfide (H2S) and 90% total reduced sulfur (TRS) outlet concentrations and control efficiencies of the packed bed iron sponge reactor shall be measured once each calendar week, -during which the iron sponge reactor is in use. The weekly test protocol and data analysis method most recently approved by IDEM will be used to generate the required data for the efficiency calculation;	The Permittee shall measure the TRS outlet concentration of the iron sponge reactor once per calendar week to demonstrate compliance with TRS emission limitation. The sampling protocol and analysis method shall be conducted in accordance with the Sampling and Analysis Plan most recently approved by IDEM.	Control efficiency is not a necessary requirement because we have direct emission information from bag samples to demonstrate compliance with the emission limits.
Operating Condition #3(e)	That no more than one of the bio-solids storage tanks (Tanks A, B, C, and D) shall be recycled at a time.	Delete entire term.	The weekly sample results are sufficient to demonstrate that we are meeting our limit. We should be allowed to recycle 2 tanks at the same time as long as we are demonstrating compliance with the limit.
Operating Condition #4(a)	Deleted in A157-8953	Delete entire term.	The terms of this condition are already addressed in Operating Condition 3(b).
Operating Condition #4(b)	Updated in A157-8953: the results of the monitoring of the total reduced sulfur (TRS) control efficiency of the iron sponge packed bed reactor, measured in accordance with Operations Condition 3(c);	Delete entire term.	The terms of this condition are addressed in Operating Condition 3(c). In addition, Lilly intends to demonstrate compliance with the emission limit through weekly testing, not the percent efficiency as determined from a calculation. Therefore, this condition should be deleted.
Operating Condition #4(c)	CP 157-4363 and A157-8953	Delete entire term.	This term is redundant with existing legal requirements and will be addressed by Part C of the permit (Malfunctions).
Operating Condition #4(d)	CP 157-4363 and A157-8953	Delete entire term.	This term is redundant with existing legal requirements and will be addressed by Part C of the permit (Malfunctions).

Term Identification	Original Term Language	Proposed Term Language	Explanation/Comments
Operating Condition #4(e)	CP 157-4363 and A157-8953	Delete entire term.	This term is redundant with existing legal requirements and will be addressed by Part C of the permit (Compliance Response Plan).
Operating Condition #5	That pursuant to 326 IAC 2-1-3 (Construction and Operating Permit Requirements): …	Delete entire term.	These construction conditions establish requirements applicable only during the first 180 days of operation. Since these sources have been operated for longer than 180 days, these conditions are irrelevant and should be deleted.
Operating Condition #6	That pursuant to 326 IAC 1-6-2 (Records; Notice of Malfunctions)….	Delete entire term.	This term is redundant with existing legal requirements and will be addressed by Part B of the permit.
Operating Condition #8	That a log of information necessary to document compliance with condition nos. 3(a), (b), (c), (d); 4; and 6 shall be maintained. These records shall be kept for at least the past 36 month period except that of no. 7 which shall be kept for the life of these tanks and made available upon request to the Office of Air Quality. This record keeping shall begin with the receipt of the Operating Permit Validation Letter.	To document compliance with Condition 3(b) through (d), the Permittee shall maintain daily records of the pressure drop across the iron sponge reactor, maintain records that the vapor balance system was used during transfer of bio-solids from the tanks to the trucks, and maintain weekly records of the TRS outlet concentration from the iron sponge reactor.	This term has been updated to cite the appropriate conditions that require recordkeeping.
Operating Condition #9	That pursuant to 326 IAC 2-6 (Emission Reporting)….	Delete entire term.	This term is redundant with existing legal requirements and will be addressed by Part B of the permit.

Emission Units and Pollution Control Devices Identified Through Title V Compliance Transition Program

The following emission units in the fermented products support operations were identified by the source pursuant to the Title V Compliance Transition Program under IC 13-7-7 and non-rule policy document Air-000-NPD [19 IR 1709]:

T10 Tank 100 (Physically removed in 2001)
T42 Tank 120 (Aeration Tank)
T174 Foul Air Incinerator (Voluntary Fume Incinerator)

Although these emission units are not associated with an existing permit, these emission units are not subject to any federal or state control requirements. In addition, Tank 100 was physically removed from service in 2001. Tank 120 is part of the T10 area. The existing emission units will be identified in the description section of Section D.5 in the Title V Operating Permit.

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 10,566 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 emissions 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. The existing permit term in Operation Permit 79-04-90-0386 relating to the foul air incinerator has not been incorporated into the Title V permit.

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 CP157-4363 and Amendment 157-8953 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 permit 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 lb/hr x 454x10^6 ug/lb) / (800 acfm x 28.3 l/cf x 60 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.

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 are 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).

Existing Approvals

Because the source is seeking a PSD permit as part of the Title V permit, all existing approvals will be superceded by the combined PSD/Title V permit:

<u>Operating Permits</u>
OP 79-04-90-0382 - Building T27
OP 79-04-90-0383 - Buildings T28 and T64
OP 79-04-90-0384 - Building T29 (obsolete, re-permitted on CP 157-2593)
OP 79-04-90-0390 - Buildings T99 and T100

<u>Construction Permits/Registrations</u>
CP 157-11949 – BPM Like Kind Tank Replacements
CP 157-14897 – Added tanks and centrifuge in T28, added tanks in T100, piping changes in T146
CP 157-8655, A 157-9148 – Registration for waste tank 3209
CP 157-9245 – T27 tank additions
CP 157-9722 – T29 Filter Dryer
CP 157-10818 – MSMA in T28 for tank additions TK28-13 and TK28-1A
CP 157-11183 – MSMA in T27 for replacement of TK33-1, addition of TK43-1 and portable tank PT-3
CP 157-11949 – MSMA for Like-Kind Replacements in T27, T28 and T31
CP 157-12124 – MSMA in building T31A for Emergency Tank Replacement Project
CP 157-14265 – MSMA in T27 for TK35-3 and TK47-3 Tank Replacements
CP 157- 15636 – MSMA for tank replacement project in T27 for TK32-05 and in T31 for TK613
CP 157-11031 – SSMA in T100 for addition of TK24
CP 157- 12478 – SSMA in T27 for Tanks TK40-11 and TK53-10
CP 157-7955 - Bulk Pharmaceutical Manufacturing Tank Replacements (Tanks 31-1 and 31-4)
CP157-6220 Environmental Controls Construction Permit (two wastewater sequencing batch reactors)
CP 157-5120, A 157-6307, A157-6963, A157-6698 – BPM Tank Replacements
CP 157-2682 - T27 Filter Dryer and Associated Equipment Registration
CP 157-3041 - T27 Vent Condenser Registration
CP 157-3546 - T27 NT Process, T27 Tank Replacements Construction Permit
CP 157-3109 - T27 40-30 Scrubber Replacement Registration
CP 157-4283 - T27 Tank 32-3 Emergency Replacement Construction Permit
CP 157-4881, A 157-6308, A157-6697 - T27 Tank 36-3 Emergency Replacement Permit
CP 157-4595, A 157-6309, A157-6696 - T27 Tank 33-3, T28 Tank 28-8 Emergency Replacement
Registration Issued on 4/4/91 - T27 Vent Condenser Installations
PC 79 1527 - T27 Units 35/36 Carbon Monoxide Emissions
PC 79 1491 - T27 2-(3-phenoxyphenyl) Proprionitrile Process Emissions
CP 157-1891 - T29 Construction Permit (valid only for T27, Tank 35-2)
CP 157-3005 - T28 NOx Emissions Registration
CP 157-2719 - T28 Scrubber Registration
CP 157-2593, A 157-5139 - Building T29 Upgrade Construction Permit
CP 157-4148, A 157-6315 - T31, T31A Construction Permit
CP 157-2784 - T31A Expansion Construction Permit
CP 157-3296 - T31, 31 A Vent Condensers Registration
CP 157-3856 - T31A Centrifuge 3 Replacement Registration
Registration issued 5/16/89 - T31, Tanks 602, 631, 612, Expansion
CP 157-2861 - Carbon Adsorber Replacement Registration (obsolete, adsorber removed from service)
CP 157-2872 -T99, Dryers 3 and 6 Replacement Construction Permit
CP 157-2558 - T99 Dryers 3, 6 Replacement Registration (obsolete, replaced by CP 157-2872)
Registration issued 12/22/89 - T99 Dryers 7 and 8
CP 157-3319 - T100 Unit 3 Modification Construction Permit
CP 157-1962 - T100 Unit 3 (obsolete, replaced by CP 157-3319)
CP 157-4347 - T99 Upgrade, TI00 Tank 31 Replacement
PC 79 1464 - T99/T100 Expansion for Production of Fenoprefen Rubigan Trimidal and Benoxaprofen

<u>Exemption Qualifications</u>
EQ157-7949, AE 157-8181 HEA 1265 Exemption for Tank Replacements in Building T27 (7 tanks total)

EQ157-8595 HEA 1265 Exemption for the installation of Natural Gas Burners in the Coal fired Boilers
EQ157-8808 HEA 1265 Exemption for Tank Replacement (TK28-19) in T28

Emission Units and Pollution Control Devices Identified Through the Title V Compliance Transition Program

The following emission units in the BPM operations were identified by the source pursuant to the Title V Compliance Transition Program under IC 13-7-7 and non-rule policy document Air-000-NPD [19 IR 1709]:

Building T27
T27-RVD53-1, Rotary Vacuum Dryer
T27-RVD53-2, Rotary Vacuum Dryer
T27-TK31-1, Process Tank
T27-CENT40, Centrifuge
T27-TK31-4, Process Tank
T27-TK35-3, Process Tank
T27-TK40-10, Process Tank
T27-TK40-4, Process Tank
T27-TK31-3, Process Tank
T27-TK40-5, Process Tank
T27-TK44-1, Process Tank
T27-TK44-4, Process Tank
T27-Dryer1, Filter Press, Dryer
T27-TK32-6, Process Tank
T27-TK36-7, Process Tank
T27-TK40-8, Process Tank
T27-TK48-1A, Process Tank

Building T28
T28-FILT3, Drum Filter
T28-TK28-12, Process Tank
T28-TK28-13, Process Tank
T28-TK28-14, Process Tank
T28-CENT1, Heinkel Centrifuge
T28-CENT2, Heinkel Centrifuge
T28-TK28-16, Process Tank
T28-TK28-19, Process Tank
T28-TK28-5, Process Tank
T28-TK28-24, Process Tank
T28-TK28-15, Process Tank
T28-TK28-25, Process Tank

Building 99
T99-TK2, Charge Tank

Building 100
T100-TK28, Process Tank
T100-TK33, Process Tank
T100-CENT61, Centrifuge
T100-TK14A, Accumulator Tank

These emission units will be subject to the conditions required by Section D.6 of the Title V Operating Permit.

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 streamlining is applicable only to the Bulk Pharmaceutical Production (BPM) buildings at Tippecanoe Laboratories. This includes 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 these 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.

Compliance schedule

To satisfy the VOC BACT requirements for BPM process activity types operating in VOC service only, such as open manway operations, charging a liquid from a drum to a tank, centrifuge emptying operations, drum filling and drum cleaning operations, or loading wetcake into driers, the Permittee shall apply the BACT level control standards within 365 days after this permit becomes effective.

Tippecanoe Laboratories intends to be in compliance with all other streamlined applicable requirements at the time the Title V permit is issued.

Affected units: Unit operations in pharmaceutical production buildings	Current applicable requirements 326 IAC 8-5-3 (Synthetic Pharmaceutical RACT)	40 CFR Part 63, Subpart GGG (Pharmaceutical MACT)	326 IAC 2-2-3 (PSD BACT for VOC and Fluorides)	Streamlined applicable requirement
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 lb/day VOC or ≥ 50 ppm VOC	Process vents ≥ 50 ppm HAP and/or ≥ 50 ppm VOC OR Process vents > 15 lb/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	

<table>
<tr><th rowspan="2">Affected units: Unit operations in pharmaceutical production buildings</th><th colspan="3">Current applicable requirements</th><th rowspan="2">Streamlined applicable requirement</th></tr>
<tr><th>326 IAC 8-5-3
(Synthetic Pharmaceutical RACT)</th><th>40 CFR Part 63, Subpart GGG
(Pharmaceutical MACT)</th><th>326 IAC 2-2-3
(PSD BACT for VOC and Fluorides)</th></tr>
<tr><td>Hydrogen Halide (HX) Point Source Emission Limits and Standards</td><td>N/A</td><td>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.</td><td colspan="2">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.</td></tr>
<tr><td>Hydrogen Halide (HX) Point Source Emission Limits and Standards not requiring control device</td><td>None specified</td><td>Uncontrolled process vents within a single process < 900 kg HAP (TOC +HX) AND
Combined Uncontrolled Processes < 1800 kg HAP
[63.1254(a)(3)]</td><td colspan="2">Uncontrolled process vents within a single process < 900 kg HAP (TOC +HX) AND
Combined Uncontrolled Processes < 1800 kg HAP (TOC + HX)</td></tr>
<tr><td>Work Practice Standards</td><td>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)]</td><td>No comparable provision</td><td colspan="2">Enclose centrifuges, rotary vacuum filters and other filters with exposed surfaces

AND

Keep covers in place for inprocess tanks</td></tr>
<tr><td>TOC Fugitive Emission Standards</td><td colspan="4">These emission standards are addressed in the LDAR section of this TSD.</td></tr>
<tr><td colspan="5">Compliance demonstration methods</td></tr>
</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 for VOC and Fluorides)	
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 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, and T61. 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 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).

Existing Approvals

Because the source is seeking a PSD permit as part of the Title V permit, all existing approvals will be superceded by the combined PSD/Title V permit:

<u>Operating Permits</u>
OP 79-04-90-0379
OP 79-04-90-0388
OP 79-04-90-0389

<u>Construction Permits/Registrations</u>
CP157-3715
CP 157-2876
CP 157-2861

Emission Units and Pollution Control Devices Identified Through the Title V Compliance Transition Program

There are no emission units in the BPM solvent recovery operations identified by the source pursuant to the Title V Compliance Transition Program under IC 13-7-7 and non-rule policy document Air-000-NPD [19 IR 1709].

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 streamlining 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.

Compliance schedule

Tippecanoe Laboratories intends to be in compliance with the streamlined applicable requirements at the time the Title V permit is issued. Equipment not currently in operation will comply with the applicable requirements of the Title V permit upon startup of such equipment.

BPM Solvent Recovery Operations: Streamlining Table

Affected units: Solvent 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 for VOCs and fluorides)	
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				

<table>
<tr><th rowspan="2">Affected units:
Solvent recovery operations</th><th colspan="4">Current applicable requirements</th><th rowspan="2">Streamlined applicable requirement</th></tr>
<tr><th>326 IAC 8-5-3
(Synthetic Pharma RACT)</th><th>40 CFR 63, Subpart DD
(Offsite Waste MACT)</th><th>40 CFR 63, Subpart GGG
(Pharma MACT)</th><th>326 IAC 2-2-3
(PSD BACT for VOCs and fluorides)</th></tr>
<tr><td>Hydrogen Halides (HX) Point source emission limits and standards requiring no control device</td><td>N/A</td><td>None Specified</td><td>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)]</td><td colspan="2">Mass Limitations:

Uncontrolled process vents within a single process < 900 kg HAP (TOC + HX)

AND

Combined Uncontrolled Processes < 1800 kg HAP</td></tr>
<tr><td>TOC fugitive emissions</td><td colspan="5">Fugitive TOC emissions are addressed in the LDAR section of this TSD</td></tr>
<tr><td colspan="6">Compliance demonstration methods</td></tr>
<tr><td>TOC and HX CEMS requirements</td><td colspan="5">These compliance standards for control devices are addressed in either the T79 section or RTO section of the TSD</td></tr>
<tr><td>TOC and HX CMS requirements</td><td colspan="5">These compliance standards for control devices are addressed in either the T79 section or RTO section of the TSD</td></tr>
<tr><td>TOC and HX stack testing requirements</td><td colspan="5">These compliance standards for control devices are addressed in either the T79 section or RTO section of the TSD</td></tr>
</table>

<table>
<tr><th rowspan="2">Affected units: Solvent recovery operations</th><th colspan="4">Current applicable requirements</th><th rowspan="2">Streamlined applicable requirement</th></tr>
<tr><th>326 IAC 8-5-3 (Synthetic Pharma RACT)</th><th>40 CFR 63, Subpart DD (Offsite Waste MACT)</th><th>40 CFR 63, Subpart GGG (Pharma MACT)</th><th>326 IAC 2-2-3 (PSD BACT for VOCs and fluorides)</th></tr>
<tr><td colspan="6">Record keeping and reporting</td></tr>
<tr><td>Record keeping</td><td>None</td><td>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</td><td>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</td><td colspan="2">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</td></tr>
<tr><td>Reporting</td><td>None</td><td>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 this TSD</td><td>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 this TSD</td><td colspan="2">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</td></tr>
</table>

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 time 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.

Existing Approvals

There are no existing approvals for these insignificant activity types.

Emission Units and Pollution Control Devices Identified Through the Title V Compliance Transition Program

The BPM IDSs were not identified by the source pursuant to the Title V Compliance Transition Program under IC 13-7-7 and non-rule policy document Air-000-NPD [19 IR 1709].

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.

<u>Applicability</u>
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.

<u>Overview of applicable requirements</u>
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.

Compliance schedule

Tippecanoe Laboratories intends to be in compliance with the streamlined applicable requirements at the time the Title V permit is issued.

BPM Individual Drain Systems: Streamlining Table

Affected units: BPM Individual Drain Systems (IDSs)	Applicable Rules 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)	Streamlined Applicable Requirement
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 purpose of collecting rainfall-runoff at the facility, if it is segregated from all other IDSs [63.1251]	IDSs do not include drains and collection systems that are designed and operated for the sole purpose of collecting rainfall runoff [63.681]	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

<table>
<tr><td rowspan="2">Affected units:

BPM Individual Drain Systems (IDSs)</td><td colspan="3">Applicable Rules</td><td rowspan="2">Streamlined Applicable Requirement</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 colspan="5">Emission limits, control requirements, performance requirements, and work practices</td></tr>
<tr><td>TOC Emission Limits and Standards</td><td>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</td><td>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 ≥ 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]</td><td colspan="2">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 ≥ 500 ppmw or VOC concentration ≥ 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</td></tr>
<tr><td>Work Practice Standards – IDS</td><td>Initial/semiannual inspections of each cover for improper work</td><td>Covers and closure devices on IDSs shall be visually inspected for defects initially and at least once per year</td><td colspan="2">Initial/semiannual inspections of each IDS cover for improper work practices and control device failures (access door open</td></tr>
</table>

Affected units: BPM Individual Drain Systems (IDSs)	Applicable Rules 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)	Streamlined Applicable Requirement
	practices/control device failures [63.1256(e)(2), 63.1258(g)(1), and Table 7] 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)]	[63.964(a)(1)(i)-(iv)] Detected defects must be repaired within 5/15 days, unless delay of repair [63.964(a)(1)(v) and (b)]		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 *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
Record keeping and reporting				

Affected units: BPM Individual Drain Systems (IDSs)	Applicable Rules 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)	Streamlined Applicable Requirement
Records	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 performed and statement that no leaks detected, if applicable; Date of each visual inspection performed and statement that no leaks detected [63.1259(i)]	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]	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	
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, T142, 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.

Existing Approvals

Because the source is seeking a PSD permit as part of the Title V permit to address modifications and construction of solvent storage tanks (among other things), all existing approvals (listed below) will be superceded by the combined PSD/Title V permit:

<u>Construction Permits/Registrations</u>

CP 157-3319 – Tank Modules T143, T145, T146, and T147 Modification Construction Permit
CP 157-1939 – T143, T145 Construction Permit (obsolete, replaced by CP 157-3319)
Registration issued 10/8/88 – T140 Tank Module
Registration issued 2/23/90 – T142 Tank Module
Registration issued 5/16/89 – T143 Tank Module
CP 157-4100 – Registration for T147 Tank Module

Emission Units and Pollution Control Devices Identified Through the Title V Compliance Transition Program

There were no emission units associated with the BPM solvent tank storage areas identified by the source pursuant to the Title V Compliance Transition Program under IC 13-7-7 and non-rule policy document Air-000-NPD [19 IR 1709].

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
This proposal 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; 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).

Compliance schedule

With the exception of the initial inspection requirements, Tippecanoe Laboratories intends to be in compliance with the streamlined applicable requirements at the time the Title V permit is issued. A condition has been included in the Title V permit to allow the Permittee to conduct its initial Method 21 inspections for its existing BPM solvent storage tanks within 150 days after permit issuance.

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 ≥ 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 ≥ 40m3 storing VOL [60.110b(c) and 60.116b(a) and (b)]	Tanks storing liquid with any VOC content with vapor pressure ≥ 10 kPa @ 20C [8-5-3(b)(3)(B)]	Tanks storing liquids with organic HAP content with a vapor pressure ≥ 13.1 kPa [63.1253(a)]	Tanks storing VOC content	
Tank volume	Tanks ≥ 40 m^3 (10,566 gallons) [60.110b(a)]	All volumes [8-5-3(b)(3)(B)]	Tanks ≥ 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	

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)	
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 $\geq$ 40m3 to <75m3	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	

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)	
Work Practice Standards - Closed Vent System Inspections	Closed vent system inspections are addressed in RTO and T79 sections of this TSD				
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				

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)	
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					

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)	
Records	Tank dimensions & capacity for life of facility (to be eliminated for <19,800 gallon tanks per AFPA settlement) [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	Fixed roof inspections and leaks found Delays of repair Records of nonapplicability 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	
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	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 the BPM solvent storage tanks are described in the streamlining proposal 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.

Existing Approvals

Because the source is seeking a PSD permit as part of the Title V permit to address modifications and construction of BPM waste storage tanks (among other things), all existing approvals (listed below) will be superceded by the combined PSD/Title V permit:

<u>Construction Permits/Registrations</u>
CP 157-3319 – Tank Modules T143, T145, T146, and T147 Modification Construction Permit
CP 157-1939 – T143, T145 Construction Permit (obsolete, replaced by CP 157-3319)
Registration issued 10/8/88 – T140 Tank Module
Registration issued 2/23/90 – T142 Tank Module
Registration issued 5/16/89 – T143 Tank Module
CP 157-4100 – Registration for T147 Tank Module

Emission Units and Pollution Control Devices Identified Through Title V Compliance Transition Program

There were no emission units in the BPM operations identified by the source pursuant to the Title V Compliance Transition Program under IC 13-7-7 and non-rule policy document Air-000-NPD [19 IR 1709].

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
This proposal 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 $\geq$ 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.

Compliance schedule

Tippecanoe Laboratories intends to be in compliance with the streamlined applicable requirements at the time the Title V permit is issued.

BPM Waste Tanks: Streamlining Table

Affected units:	Applicable requirements					
BPM Waste Storage Tanks – Fixed Roof Design	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 63, DD)	PSD BACT Standards (40 CFR 52.21, 326 IAC 2-2)	Streamlined Applicable Requirement
Applicability						
Date of construction	Tanks constructed, reconstructed, or 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 ≥ 40m3 to < 75m3 storing VOL 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)]		
Tank volume	Tanks ≥ 40 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)]		Opening allowed for wastewater sampling, removal, or for equipment inspection, maintenance, or repair. [63.1256(b)(3)(i)(B)]		Same exclusions allowed by other rules applied to BACT	Tanks meeting these exclusions will not be listed as tanks subject to streamlined requirements

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 63, DD)	PSD BACT Standards (40 CFR 52.21, 326 IAC 2-2)	
Emission limits, control requirements, performance requirements, and work practices						
TOC and HX Point Source Emission Limits and Standards	The incineration limits are addressed in the RTO and T79 sections of this TSD					
TOC Point Source Emission Limits and Standards requiring no control device	No control requirements for tanks $\geq$ 40 m3 to <75 m3		Fixed roof only required for tanks <75 m3, $\geq$ 75 m^3 to < 151 m^3 @ VP $\leq$ 13.1 kPa, $\geq$ 151m^3 @ $\leq$ 5.2kPa [63.1256(b)(1), Table 6]	Closure device required for tanks $\leq$ 75 m^3 @ $\leq$ 76.6 kPa, $\geq$ 75 m^3 to < 151 m^3 @ $\leq$ 27.6 kPa, $\geq$ 151 m^3 @ $\leq$ 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	Initial/Semiannual tanks inspections for improper work practices	Tanks not under negative pressure:	Initial M21 for components not covered under LDAR on BPM waste 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 63, DD)	PSD BACT Standards (40 CFR 52.21, 326 IAC 2-2)	
		equipment is off-line long enough to repair [8-5-3(b)(6)]	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)(I), (8)(iii), (9), 63.1258(g) and Table 7); 63.1258(h)(6) and (7)] *AND* <u>Tanks not under negative pressure:</u> Initial M21 and semiannual visual 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)]	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)]	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	
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					

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 63, DD)	PSD BACT Standards (40 CFR 52.21, 326 IAC 2-2)	
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					
Closed vent system CMS Monitoring Requirements	These compliance requirements are addressed in the RTO and T79 sections of this TSD					
Record keeping and reporting						

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 63, DD)	PSD BACT Standards (40 CFR 52.21, 326 IAC 2-2)	
Records	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)] 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]	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 Flow indicator operation & bypasses detected Delays of repair [63.1259]	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 operated under negative pressure defect repair Planned routine maintenance periods Control device malfunctions [63.695(b), (c) and 63.696(e), (g), (h)]	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 Tank dimensions & capacity for life of facility per Kb

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 63, DD)	PSD BACT Standards (40 CFR 52.21, 326 IAC 2-2)	
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 will also be located in the T149 container storage building currently under construction as part of the rotary kiln incinerator project.

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.

Existing Approvals

Because the source is seeking a PSD permit in conjunction with the Title V permit, the container requirements in CP 157-13834 will be superceded by the combined PSD/Title V permit.

Emission Units and Pollution Control Devices Identified Through Title V Compliance Transition Program

There were no emission units in the BPM operations identified by the source pursuant to the Title V Compliance Transition Program under IC 13-7-7 and non-rule policy document Air-000-NPD [19 IR 1709].

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.

<u>Applicability</u>
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.

Compliance schedule

Tippecanoe Laboratories intends to be in compliance with the streamlined applicable requirements at the time the Title V permit is issued.

BPM Waste Containers: Streamlining Table

Affected units: BPM Waste Containers	Applicable Requirements			Streamlined Applicable Requirement
	MACT Standards for Pharma Wastewater Containers (40 CFR 63, Subpart GGG)	MACT Standards for OSWRO Containers (40 CFR 63, Subpart DD)	PSD BACT Standards (326 IAC 2-2-3)	
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	BPM waste containers > 0.1 m3 with VOC/ VOHAP content $\geq$ 500 ppmw
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 soluble/partially soluble HAP > 0.25 Mb/yr [63.1256(a)(1)(i) and (ii)]	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	
Waste container volume	Any portable waste management unit (waste container) $\geq$ 0.1 m^3 (26.4 gallons) [63.1251]	Waste containers $\geq$ 0.1 m^3 (26.4 gallons) [63.688(a)(1)]	Waste containers $\geq$ 0.1 m^3 (26.4 gallons)	

Affected units: BPM Waste Containers	Applicable Requirements			Streamlined Applicable Requirement
	MACT Standards for Pharma Wastewater Containers (40 CFR 63, Subpart GGG)	MACT Standards for OSWRO Containers (40 CFR 63, Subpart DD)	PSD BACT Standards (326 IAC 2-2-3)	
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.	

Affected units: BPM Waste Containers	Applicable Requirements MACT Standards for Pharma Wastewater Containers (40 CFR 63, Subpart GGG)	MACT Standards for OSWRO Containers (40 CFR 63, Subpart DD)	PSD BACT Standards (326 IAC 2-2-3)	Streamlined Applicable Requirement
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)*; 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)]	<u>Container Level 2 Controls for > 0.46 m^3, in light-material service [63.688(b)(3)]:</u> DOT compliant container; OR Operate with no detectable organic emissions; OR Vapor tight container demonstration. [63.923(b)]	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 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	Inspections for DOT compliant wastewater containers > 0.1 m^3 to $\leq$	Initial visual inspection, if container not emptied within 24 hours after container	Inspections for DOT compliant Waste Containers > 0.1 m^3 to $\leq$ 0.42 m^3:	

Affected units: BPM Waste Containers	Applicable Requirements: MACT Standards for Pharma Wastewater Containers (40 CFR 63, Subpart GGG)	MACT Standards for OSWRO Containers (40 CFR 63, Subpart DD)	PSD BACT Standards (326 IAC 2-2-3)	Streamlined Applicable Requirement
Waste Container Inspections	$0.42 m^3$, 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)]	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)]	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: MACT Standards for Pharma Wastewater Containers (40 CFR 63, Subpart GGG)	MACT Standards for OSWRO Containers (40 CFR 63, Subpart DD)	PSD BACT Standards (326 IAC 2-2-3)	Streamlined Applicable Requirement
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)] AND Operate with no detectable organic emissions, then must conduct initial Method 21 to demonstrate compliance with this control option. [63.923(b)(2) 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				

Affected units: BPM Waste Containers	Applicable Requirements MACT Standards for Pharma Wastewater Containers (40 CFR 63, Subpart GGG)	MACT Standards for OSWRO Containers (40 CFR 63, Subpart DD)	PSD BACT Standards (326 IAC 2-2-3)	Streamlined Applicable Requirement
Records	The following records shall be maintained for each waste container: Inspections for the container, control device, seal gap 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)]	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; 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 40 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.

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

Because the source is seeking a PSD permit in conjunction with the Title V permit, the construction permit PC (79)819 and operation permit OP 79-04-90-0387 will be superceded by the combined PSD/Title V permit.

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.

40 CFR 60, Subpart Cb: Emission Guidelines and Compliance Times for Large Municipal Waste Combustors That are Constructed On or Before September 20, 1994 – 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 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 does not have the capability to combust solid wastes and therefore will not combust municipal waste as defined in 60.51a and construction will commence after the latest applicable date (September 20, 1994).

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 does not have the capability to combust solid wastes and therefore will not combust municipal waste as defined in 60.51b.

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 does not have the capability to combust solid wastes and therefore will not combust hospital, medical, or infectious waste as defined in 60.51c.

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	170 ppmvdc
	SO2	Caustic scrubber	400 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 and 40 CFR Part 52, Subpart P – Particulate emission requirements for incinerators found in 40 CFR Part 52, Subpart P applies to the incinerator. Pursuant to Subpart P (Burning Regulations for Incinerators), The T49 liquid waste incinerator shall:

(1) consist of primary and secondary chambers or the equivalent,
(2) be equipped with a primary burner unless burning wood products,
(3) comply with 326 IAC 5-1 and 326 IAC 2,
(4) be maintained properly as specified by the manufacturer and approved by the commissioner,
(5) be operated according to the manufacturer's recommendations and only burn waste approved by the commissioner,
(6) comply with other state and/or local rules or ordinances regarding installation and operation of incinerators,
(7) be operated so that emissions of hazardous material including, but not limited to viable pathogenic bacteria, dangerous chemicals or gases, or noxious odors are prevented,
(8) not emit particulate matter in excess of three-tenths (0.3) pounds of particulate matter per one thousand (1,000) pounds of dry exhaust gas at standard conditions corrected to fifty percent (50%) excess air, and
(9) not create a nuisance or a fire hazard.

If any of the above result, the burning shall be terminated immediately.

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) – Pursuant to 40 CFR 52, Subpart P, carbon monoxide emissions shall be controlled by a direct flame afterburner or other approved means. Complying with the CO limits in 40 CFR 63, Subpart EEE constitutes an approved means of complying with Subpart P. When 40 CFR 52, Subpart P is revised to incorporate the revised version of 326 IAC 9, this requirement will no longer apply.

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 initial and subsequent performance tests;

2. Operate CEMS for CO, SO2, and NOx;

3. Continuously monitor the following operating parameters:

   (a) combustion chamber temperature;
   (b) pumpable and nonpumpable waste feed rates;
   (c) pressure drop across scrubber;
   (d) pH of scrubbing liquid;
   (e) scrubbing liquid flowrate or liquid to gas ratio;
   (f) solids content of scrubbing liquid;
   (g) flue gas flowrate, production rate, or surrogate parameter to measure residence time;
   (h) ash federate; and
   (i) fluorides waste feed rate.

D.13: Rotary Kiln Incinerator

Background and Description

The rotary kiln incinerator, which is currently under construction, will provide treatment of Lilly hazardous and non-hazardous waste to support its operational requirements. The rotary kiln incinerator will be 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 rotary kiln incinerator will consist of a rotary kiln incinerator, an emergency backup motor to the rotary kiln drive system, and ancillary equipment. The rotary kiln incinerator will consist 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 will consist 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 will be stored and handled in existing waste holding tanks.

Insignificant Activities

The rotary kiln incinerator is not considered an insignificant activity pursuant to 326 IAC 2-7-1.

Existing Approvals

Because the source is seeking a PSD permit in conjunction with the Title V permit, CP 157-13834 will be superceded by the combined PSD/Title V permit.

Unpermitted Emission Units and Pollution Control Devices

There are no unpermitted emission units associated with the rotary kiln incinerator. This project is currently under construction in accordance with CP 157-13834, issued on August 22, 2002.

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 rotary kiln incinerator will not combust municipal waste and the construction date will be 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 rotary kiln incinerator will not combust hospital, medical, or infectious waste.

<u>40 CFR 60, Subpart E: Standards of Performance for Incinerators</u> – This rule does not apply because the incinerator 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 incinerator will not combust municipal waste as defined in 60.51a and construction will commence after the latest applicable date (September 20, 1994).

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 incinerator will not combust municipal waste as defined in 60.51b.

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 incinerator does not combust hospital, medical, or infectious waste as defined in 60.51c.

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 rotary kiln incinerator will 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 proposed rotary kiln 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 proposed modification 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 proposed rotary kiln incinerator is subject to the requirements of 40 CFR 63, Subpart EEE because the proposed 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 proposed 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 rotary kiln 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 rotary kiln incinerator:

Facility	PSD Pollutants	BACT Control Devices	BACT Limits
Rotary kiln liquid/solid 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 and 40 CFR Part 52, Subpart P – Particulate emission requirements for incinerators found in 40 CFR Part 52, Subpart P applies to the incinerator. Pursuant to Subpart P (Burning Regulations for Incinerators), The rotary kiln incinerator shall:

(1) consist of primary and secondary chambers or the equivalent,
(2) be equipped with a primary burner unless burning wood products,
(3) comply with 326 IAC 5-1 and 326 IAC 2,
(4) be maintained properly as specified by the manufacturer and approved by the commissioner,
(5) be operated according to the manufacturer's recommendations and only burn waste approved by the commissioner,
(6) comply with other state and/or local rules or ordinances regarding installation and operation of incinerators,
(7) be operated so that emissions of hazardous material including, but not limited to viable pathogenic bacteria, dangerous chemicals or gases, or noxious odors are prevented,
(8) not emit particulate matter in excess of three-tenths (0.3) pounds of particulate matter per one thousand (1,000) pounds of dry exhaust gas at standard conditions corrected to fifty percent (50%) excess air, and
(9) not create a nuisance or a fire hazard.

If any of the above result, the burning shall be terminated immediately.

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 rotary kiln incinerator is exempted under 326 IAC 6-3-1(a).

326 IAC 7 (Sulfur Dioxide Emission Limitations) – 326 IAC 7 applies to the rotary kiln 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 rotary kiln 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 rotary kiln 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 and 40 CFR 52, Subpart P (Carbon Monoxide Rules) – Pursuant to 40 CFR 52, Subpart P, carbon monoxide emissions shall be controlled by a direct flame afterburner or other approved means. Complying with the CO limits in 40 CFR 63, Subpart EEE constitutes an approved means of complying with Subpart P. When 40 CFR 52, Subpart P is revised to incorporate the revised version of 326 IAC 9, this requirement will no longer apply.

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 kiln incinerator because it will 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 rotary kiln incinerator because it will 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 rotary kiln incinerator:

1. Conduct initial and subsequent 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. combustion chamber temperature;
    b. pumpable and nonpumpable waste feed rates;
    c. pressure drop across scrubber;
    d. pH of scrubbing liquid;
    e. scrubbing liquid flowrate or liquid to gas ratio;
    f. solids content of scrubbing liquid;
    g. flue gas flowrate, production rate, or surrogate parameter to measure residence time;
    h. ash federate; and
    i. fluorides waste feed rate.

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).

Existing Approvals

Because the source is seeking a PSD permit as part of the Title V permit, all existing approvals will be superseded by the combined PSD/Title V permit:

Construction Permit
CP157-3352, Issued November 27, 1995

Emission Units and Pollution Control Devices Identified Through the Title V Compliance Transition Program

The applicant did not identify either RTO system under the Title V Compliance Transition Program pursuant to IC 13-7-7 and non-rule policy document Air-000-NPD [19 IR 1709].

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.

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
- 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 Monitoring Requirements

Record Keeping and Reporting Requirements

Compliance schedule

Tippecanoe Laboratories intends to be in compliance with the streamlined applicable requirements at the time the Title V permit is issued.

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	
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 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 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">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</td></tr>
<tr><td>BPM Individual Drain Systems (IDSs) to Control Device (D.8)</td><td>N/A</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 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">HX Point Source Emission Limits and Standards</td></tr>
<tr><td>BPM Process Vent
(D.6 – Process, D.7 – Recovery)</td><td>N/A</td><td>N/A</td><td>N/A</td><td>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)]</td><td colspan="2" rowspan="4">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</td></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></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>
</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)	
CO/NOx/SO2 Point Source Emission Limits and Standards						
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	CVSs NOT under negative pressure: 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), 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.	None Specified		Closed-vent systems NOT operated under negative pressure: - 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 Closed-vent systems operated under negative pressure: - 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 Solvent Tanks (D.9)	N/A	N/A		None Specified		
BPM Waste Tanks (D.10)	N/A	N/A		CVSs NOT under negative pressure: 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) 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)]		
BPM IDSs to Control Device (D.8)	N/A	N/A				

<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 colspan="7">Work Practice Standards – Bypass Systems in Closed Vent System</td></tr>
<tr><td>BPM Process Vent
(D.6 – Process, D.7 – 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>
<tr><td colspan="7">Exceptions to Control Device (RTO System) and Closed-Vent System Standards</td></tr>
<tr><td>BPM Process Vent
(D.6 – Process, D.7 – Recovery)</td><td>N/A</td><td>N/A</td><td>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)]</td><td rowspan="4">Control except for SSM events, if SSM plan is followed
[63.1260(g)]</td><td colspan="2" rowspan="4">Control except for SSM events, if SSM plan is followed</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">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)]</td></tr>
<tr><td>BPM IDSs (D.8)</td><td>N/A</td><td>N/A</td></tr>
</table>

<table>
<tr><td rowspan="2">Affected Units Controlled by RTO Control System</td><td colspan="5">Potentially Applicable Regulations</td><td rowspan="2">Streamlined Requirements</td></tr>
<tr><td>326 IAC 3
(Monitoring Requirements)</td><td>40 CFR 60, Subpart Kb
(Volatile Organic Liquid Storage Vessels)</td><td>40 CFR 63, Subpart DD
(Offsite Waste MACT)</td><td>40 CFR 63, Subpart GGG
(Pharma MACT)</td><td>326 IAC 2-2
(PSD BACT for RTO System)</td></tr>
<tr><td colspan="7">Compliance Demonstration Methods</td></tr>
<tr><td colspan="7">TOC Continuous emissions monitoring (CEMS) and Continuous monitoring system (CMS) requirements (if complying with 20 ppmv TOC alternative standard)</td></tr>
<tr><td>BPM Process Vent
(D.6 – Process, D.7 – Recovery)</td><td rowspan="4"><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 [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]</td><td rowspan="4">N/A</td><td>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)]</td><td rowspan="2">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 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)]</td><td colspan="2" rowspan="4">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>:

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 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)]</td></tr>
<tr><td>BPM Solvent Tanks (D.9)</td><td>N/A</td></tr>
<tr><td>BPM Waste Tanks
(D.10)</td><td rowspan="2">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)]</td><td rowspan="2">No CEMS required for these types of operations</td></tr>
<tr><td>BPM IDSs to control device (D.8)</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 colspan="7">HX Continuous CEMS requirements (if complying with 20 ppmv HX alternative standard)</td></tr>
<tr><td>BPM Process Vent
(D.6 – Process Operations, D.7 – Solvent Recovery)</td><td rowspan="4">This rule does not address CEMS for HX or HCl [3-5]</td><td rowspan="4">N/A</td><td rowspan="4">N/A</td><td rowspan="2">The following CEMS requirements apply when demonstrating compliance with the 20 ppmv HCl alternative standard [63.1253(d) and 63.1254(c)]:

<u>Initial Compliance Procedures</u> –
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)]

<u>HCl CEMS Monitoring Requirements</u> –

- 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)]</td><td rowspan="4" colspan="2">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:

<u>Initial Compliance Procedures</u> –
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)]

<u>HCl CEMS Monitoring Requirements</u> –

- 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)]</td></tr>
<tr><td>BPM Solvent Tanks (D.9)</td></tr>
<tr><td>BPM Waste Tanks
(D.10)</td><td rowspan="2">No CEMS required for these types of operations</td></tr>
<tr><td>BPM IDSs (D.8)</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)	
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) BPM IDSs (D.8)	<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 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)]	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, 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 [63.694(l)(1)(i), 63.694(l)(3)]	<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 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)]	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 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	
BPM Solvent Tanks (D.9) BPM Waste Tanks (D.10) BPM IDSs to control device (D.8)			<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.	<u>Measure and record the following parameters during stack test to develop operating parameter limits</u>: - Organic concentration in FTS measured as % LEL - Temperature <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)]		

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
HX Stack Testing requirements (if complying with DRE standard)						
BPM Process Vent (D.6 – Process Operations, D.7 – Solvent Recovery) BPM Solvent Tanks (D.9)	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]	N/A	N/A	<u>The following HCl 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 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		<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 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 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
BPM Waste Tanks (D.10) BPM IDSs to control device (D.8)				None Specified		
RTO 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)]

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)	
Scrubber Parametric 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	N/A	N/A	<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 <u>Caustic liquid flow rate CMS requirements to demonstrate compliance with control device maximum as outlined in the NOC:</u> - Measure caustic flow rate in accordance with CMS requirements under 63.8(c)(1) and (d)	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 the mfr to be accurate within ±10% of design scrubber liquid flowrate - Calibrate annually - O&M and QC for CMSs	

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>:
	
	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 data, emission test results, and emission test reports for a minimum of 5 years.
	
	<u>General Record keeping Requirements [3-5]</u>:
	
	- Retain monitoring data and supporting info for 5 years [3-5-6(a)]
	- Maintain SOP for all CEMS [3-5-4(a)]
		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 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 [63.7(g)(3), 63.10(b)(2)(viii)]
			
			<u>Closed Vent System Records</u>:
			
			- 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]
			
			<u>General Record keeping Requirements [63.693(b)(7), 63.696(b)]</u>:
			
			- Maintain records for 5 yrs [63.10(b)(1)]
				<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), 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)]
				- 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
				
				<u>General Record keeping Requirements</u>
				
				- 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)]
				
				NOTE: SOP for all CEMS shall follow the requirements of 326 IAC 3-5-4(a) because more restrictive than 63.8(d)		

BPM Solvent Tanks (D.9)		- 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)]				
BPM Waste Tanks (D.10)						
BPM IDSs to control device (D.8)		N/A				

<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 colspan="7">Reporting Requirements</td></tr>
<tr><td>BPM Process Vent
(D.6 – Process, D.7 – Recovery)</td>
<td rowspan="4">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 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 emissions and parameters report within 30 days following the quarter [3-5-7(1) and (4)]
- Monitor downtime, except for zero and span checks [3-5-7(5)]

CMS Reporting Requirements:

No parametric CMS requirements under 3-5

Performance Test Reporting Requirements:

- Submit test protocol at least 35 days prior to test [3-6-2(a)]
- Schedule test date/time at least 14 days prior to test date [3-6-2(h)]
- Submit emission test report within 45 days after test complete
- Extension allowed for reasonable explanation if submitted within 40 days after test complete</td>
<td>N/A</td>
<td rowspan="4">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) 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)]
- Exceedances of average concentration limits monitored according to 63.1258(b)(5) are violations of the emission limit, unless SSM [63.1258(b)(8), (b)(8)(iii), (iv)]
- 63.695(e), 63.697(b)(4), 63.10(e)(3)
- CEMS 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.

Performance Test Requirements:

- 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="4">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% 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)]

Performance Test Requirements:

- 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 been operated since last report [63.1260(g)(2)(vii)]

CVS Reporting Requirements:

- CVS bypass lines with flow indicator: report all periods when vent stream is diverted from control device through bypass line [63.1260(g)(2)(iv)]
- 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 [63.1260(g)(2)(iv)]</td>
<td rowspan="4" colspan="2">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:

- The Pharma MACT CMS/CEMS reporting requirements for TOC and hydrogen halides and halogens shall satisfy the reporting requirements for VOC and fluorides (PSD pollutants), respectively, and shall serve as the streamlined reporting requirement.
- The Pharma MACT CEMS reporting requirements shall also satisfy the reporting requirements for NOx/SOx/CO (PSD pollutants) and shall serve as the streamlined reporting requirement.

Performance Test Notification Requirements:

The Pharma MACT performance test requirements for TOC and hydrogen halides and halogens satisfy the PSD VOC and fluorides requirements and shall serve as the streamlined reporting requirement.</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>
<tr><td>BPM IDSs to control device
(D.8)</td><td>N/A</td></tr>
</table>

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).

Existing Approvals

Because the source is seeking a PSD permit as part of the Title V permit, all existing approvals will be superseded by the combined PSD/Title V permit:

<u>Construction Permit</u>
Registration Permit issued on January 16, 1989

Emission Units and Pollution Control Devices Identified Through the Title V Compliance Transition Program

The applicant did not identify either T79 control system under the Title V Compliance Transition Program pursuant to IC 13-7-7 and non-rule policy document Air-000-NPD [19 IR 1709].

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, T142, 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

Compliance schedule
Tippecanoe Laboratories intends to be in compliance with the streamlined applicable requirements at the time the Title V permit is issued.

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	
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 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)	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 $\geq$ 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)]	Control Device Emission Limit Options: 95% DRE OR Min time of $\geq$ 0.75 sec and min temp of $\geq$ 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 [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 $\geq$ 760 F *AND* residence time $\geq$ 0.5 sec [63.962(a)(3)(ii), 63.962(b)(3)(ii)(A), and 63.693(f)(1)(iii)]	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 $\geq$ 0.5 sec *AND* temp $\geq$ 760C [63.1256(b)(3)(ii), 63.1256(e)(1)(ii), and 63.1256(h)(2)(i)(C)]	98% TOC DRE *AND* min temp and max % LEL determined from worst-case compliant stack test	
BPM Individual Drain Systems (IDSs) to Control Device (D.8)		N/A				

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 <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)]	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	
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 <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)]		
BPM Waste Tanks (D.10)	N/A	N/A	N/A	95% DRE achieved via stack testing *AND* establish min recircirculation 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			

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)	
Work Practice Standards – Closed-vent Systems (CVSs)						
BPM Process Vent (D.6 – Process Operations, D.7 – Solvent 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), 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.	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 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 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 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)]		
BPM IDSs to Control Device (D.8)	N/A	N/A				
Work Practice Standards – Bypass Systems in Closed Vent System						
BPM Process Vent (D.6 – Process Operations, D.7 – Solvent 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)] 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)]	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	
BPM Solvent Tanks (D.9)	N/A	N/A	N/A			
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)]			
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 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">Exceptions to Control Device and Closed-Vent System (T79 Fume Incinerator System) Standards</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>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)]</td><td rowspan="4">Control except for SSM events, if SSM plan is followed [63.1260(g)]</td><td rowspan="4" colspan="2">Control except for SSM events, if SSM plan is followed</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">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)]</td></tr>
<tr><td>BPM IDSs (D.8)</td><td>N/A</td><td>N/A</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">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="3"><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)]</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><td>NOTE: These requirements do not apply to solvent tanks. Solvent tanks are not regulated under the Offsite Waste MACT.</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>
<tr><td colspan="7">T79 Fume Incinerator Parametric Continuous Monitoring System (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

<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)]</td><td rowspan="4">N/A</td><td rowspan="4"><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</td><td rowspan="4"><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)</td><td colspan="2" rowspan="4">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)]</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>

<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 rowspan="4" 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):</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 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
Record Keeping and Reporting Requirements						
Record Keeping Requirements						

BPM Process Vent (D.6 – Process Operations, D.7 – Solvent Recovery)	CEMS (includes flow monitor for CERMS data) Record keeping Requirements [3-5-6]:
	- 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
	
	CMS Record keeping Requirements:
	No parametric CMS requirements under 326 IAC 3-5
	
	Performance Testing Record keeping Requirements:
	Keep records of all test protocols, raw testing and support 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	NOTE: The solvent storage tanks are not subject to these conditions
			
			CMS and Control Device Records [63.693(b)(7), 63.696(b)]:
			- 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)
			
			Performance Test Records:
			- Results of control device performance tests & CMS performance evaluations [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)]
				CMS and Control Device (T79) Records:
				- 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).
				
				Performance Test Records:
				- Results of control device performance tests & CMS performance evaluations [63.7(g)(3), 63.10(b)(2)(viii)]
				
				Closed Vent System Records:
				- 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)]
				- 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)]		

BPM Solvent Tanks (D.9)		- 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)]				
BPM Waste Tanks (D.10)						
BPM IDSs to control device (D.8)		N/A				

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)	
Reporting Requirements						
BPM Process Vent (D.6 – Process Operations, D.7 – Solvent Recovery)	Flow Monitor Periodic Reporting Requirements: - 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 emissions and parameters report within 30 days following the quarter [3-5-7(1) and (4)] - Monitor downtime, except for zero and span checks [3-5-7(5)] CMS Record keeping Requirements: No parametric CMS requirements under 3-5 Performance Test Reporting Requirements: - Submit test protocol at least 35 days prior to test [3-6-2(a)] - Schedule test date/time at least 14 days prior to test date [3-6-2(h)] - Submit emission test report within 45 days after test complete - Extension allowed for reasonable explanation if submitted within 40 days after test complete	N/A	NOTE: The solvent storage tanks are not subject to these conditions CMS 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) 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. Performance Test Requirements: - 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)]	CMS and Control Device Reporting Requirements [63.1260(g)]: - 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)] Performance Test Requirements: - 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 been operated since last report [63.1260(g)(2)(vii)] CVS Reporting Requirements: - CVS bypass lines with flow indicator: report all periods when vent stream is diverted from control device through bypass line [63.1260(g)(2)(iv)] - 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 [63.1260(g)(2)(iv)]	CMS and Control Device Reporting Requirements: 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)] Performance Test Notification Requirements: The Pharma MACT performance test requirements for TOC and hydrogen halides and halogens satisfy the PSD VOC and fluorides requirements and shall serve as the streamlined reporting requirement: - 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 been operated since last report [63.1260(g)(2)(vii)] CVS Reporting Requirements: The Pharma MACT CVS requirements shall satisfy the PSD requirements and shall serve as the streamlined reporting requirement: - CVS bypass lines with flow indicator: report all periods when vent stream is diverted from control device through bypass line [63.1260(g)(2)(iv)] - 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 [63.1260(g)(2)(iv)]	
BPM Solvent Tanks (D.9)		None Specified				
BPM Waste Tanks (D.10)						
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 the pilot plant 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 or the emission units in the T71 research and development operations are considered “insignificant activities” as defined in 326 IAC 2-7-1(21)(E).

Existing Approvals

The source has been operating under the following approval:

CP157-4148

The permit for this operation was combined with a modification to an existing BPM production building. With respect to the T71 research and development operations, limitations were established in the permit to avoid the PSD regulations under 326 IAC 2-2. These limitations have been incorporated into the Title V permit.

Emission Units and Pollution Control Devices Identified Through Title V Compliance Transition Program

There are no emission units in the BPM research and development operations that were identified by the source pursuant to the Title V Compliance Transition Program under IC 13-7-7 and non-rule policy document Air-000-NPD [19 IR 1709].

Federal Rule Applicability

<u>40 CFR 60, Subpart Kb – Volatile Organic Liquid Storage Vessels</u>
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).

<u>NSPS 40 CFR 60, Subpart VV – Equipment Leaks of VOC in the Synthetic Organic Chemicals Manufacturing Industry</u> – 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.

326 IAC 2-2 – Prevention of Significant Deterioration – CP 157-4148 established SO2 and VOC emission limits on the T71 research and development operations to avoid the requirements of PSD. The emission limits established in this construction permit will be incorporated into the Title V permit.

The VOC limit is based on the implementation of the Lilly LDAR Program. Although the research and development operations are outside of the scope of the flexible permit, Lilly proposes to implement the LDAR BACT established for the BPM and BPM support operations in lieu of the existing Lilly LDAR program. This allows the plant site to implement one plan for the entire plant site. The compliance method established in the construction permit to demonstrate compliance with the SO2 limit will carry over to the Title V permit.

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:

Definition of Wastewater [40 CFR 63.1251, 63.1256(a)(1)(i)] – 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]

Definition of Affected Wastewater [40 CFR 63.1251, 63.1256(a)(1)(i)(A) and (B)] – 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.

Maintenance Wastewater [40 CFR 63.1256(a)(4)(iii)]

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.

Storage and Transfer of Affected Wastewater [40 CFR 63.1256(b), (d), and (e)] – 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).

Existing Approvals

The source has been operating under an expired Operating Permit that does not contain specific operating requirements.

Emission Units and Pollution Control Devices Identified Through Title V Compliance Transition Program

There are no emission units in the chemical wastewater treatment plant that were identified by the source pursuant to the Title V Compliance Transition Program under IC 13-7-7 and non-rule policy document Air-000-NPD [19 IR 1709].

Federal Rule Applicability

<u>40 CFR 63, Subpart GGG – Pharmaceutical MACT</u>

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

<u>326 IAC 8-1-6 – VOC BACT Rule</u>
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).

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

The Permittee has been issued several permits in the past that contain requirements for fugitive VOHAP/VOC emissions. These permits typically address both point source and fugitive emissions from specific large pieces of equipment or operating areas, not fugitive emission components. Because the source is obtaining a PSD permit to address all point and fugitive emissions from BPM and affiliated operations, the combined PSD/Title V permit will supersede the fugitive emission requirements of the previously issued permits.

Emission Units and Pollution Control Devices Identified Through the Title V Compliance Transition Program

There were no emission units in this section of the permit identified by the source pursuant to the Title V Compliance Transition Program under IC 13-7-7 and non-rule policy document Air-000-NPD [19 IR 1709].

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.

<u>40 CFR 63, Subpart GGG – LDAR Program for Process Systems</u>

40 CFR 63, Subpart GGG (National Emission Standards for Pharmaceutical Production, "Pharma MACT") was originally promulgated in 1998 and most recently amended in 2000. 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 testing to demonstrate compliance with all applicable LDAR requirements. Although not everything can physically be pressure tested, Tippecanoe Labs expects to comply 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 test alternative provides that each process must conduct a pressure 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 pressure test, then a second pressure test must be conducted before start-up of the process. If the process fails the second pressure 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 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 and programs that currently apply, the equipment and programs that will apply under the Title V permit, and the program that allows for the change under the Title V permit.

Equipment Description	**Current Program**	**Program under Title V Permit**	**Authority for Change**
BPM Process Systems:			
General Process Equipment not currently subject to LDAR	None	40 CFR 63, Subpart GGG	326 IAC 2-2 and 40 CFR 52.21 (BACT)
HON	HON, 40 CFR 63, Subpart H and I*	40 CFR 63, Subpart GGG	63.1250(h)(4)
Lilly LDAR via Construction Permits	Lilly LDAR/HON, 40 CFR Subpart H	40 CFR 63, Subpart GGG	326 IAC 2-2 and 40 CFR 52.21 (BACT)
Solvent Recovery Columns – 19-3 and 61-1	OSWRO MACT/ 40 CFR 61, Subpart V	40 CFR 63, Subpart GGG	63.680(a)(2)(v)
BPM Waste Systems:			

Equipment Description	Current Program	Program under Title V Permit	Authority for Change
OSW Storage Tanks and Piping	OSWRO MACT/ 40 CFR 61, Subpart V	40 CFR 61, Subpart V	Remains 40 CFR 61, Subpart V
Lilly LDAR via Construction Permits	Lilly LDAR/HON	40 CFR 61, Subpart V	326 IAC 2-2 and 40 CFR 52.21 (BACT)
All other waste components (currently covered only by RCRA BB)	None (under authority of air program)	40 CFR 61, Subpart V	326 IAC 2-2 and 40 CFR 52.21 (BACT)

- Subpart H applies to VOC under Lilly LDAR, while Subpart I applies only to MeCl2 and carbon tetrachloride in manufacturing processes, not waste.

For ease of reporting under the individual regulations, the following streamlined reporting schedule has been accepted as a means to conduct all reporting under the same period/calendar cycle:

Individual Program	Pre-Title V Permit Monitoring Period Closure Dates	Title V Permit Monitoring Period Closure Dates	2003 Reporting Periods	Future Reporting Periods
LDAR for BPM Process Systems:				
Solvent Recovery Columns 61-1 and 19-3	One Week Schedule (61.243-1: Allowable % Valves Leaking)	One Week Schedule Completed by 12/31/03	1/1/03 to 6/30/03 and 7/1/03 to 12/31/03	1/1 to 6/30 and 7/1 to 12/31
	No Connector Monitoring Required	Initial Monitoring of Connectors by 12/31/03	Permit Issuance Date to 12/31/03	
Pharma MACT	Initial Monitoring of Components by 10/21/03	Initial Monitoring Completed by 10/21/03 12/31, future years	3/20/03 to 6/30/03 and 7/1/03 to 10/31/03	
BACT	NA	Initial Scheduled Monitoring through 12/31/03	Permit Issuance Date to 12/31/03	
LDAR for BPM Waste Systems:				
OSWRO MACT	Skip 3 Periods (61.243-2: Skip Period LDAR)	Skip 3 Period Monitoring Completed by 12/31/03	1/1/03-6/30/03 and 7/1/03-12/31/03	1/1 to 6/30 and 7/1 to 12/31
BACT	NA	Initial Scheduled Monitoring through 12/31/03	Permit Issuance Date – 12/31/03	

* All reports will be submitted 30 days following the reporting period

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 (
- Equipment in vacuum service per 40 CFR 63.1255(a)(8).

Component Types	Standards	Leak Definition	Repair	
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)	E V 3 4 E 4
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	E V 3 4 E 4

Comment: VOHAP per 63.1255(a)(1), VOC per BACT

Comment: VOHAP per 63.1255(a)(1), VOC per BACT

Component Types	**Standards**	**Leak Definition**	**Repair**	
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	E V 3 4 E 4 I s p 4
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	E V 3 4 E 4 C i s o o o li h 4

Comment: VOHAP per 63.1255(a)(1), VOC per BACT

Comment: VOHAP per 63.1255(a)(1), VOC per BACT

Component Types	Standards	Leak Definition	Repair	
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	E V 3 4 E 4 U t u i b
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)	E V 3 4 E 4 I i e n t r 4 U t u i b

Comment: VOHAP per 63.1255(a)(1), VOC per BACT

Comment: VOHAP per 63.1255(a)(1), VOC per BACT

Component Types	Standards	Leak Definition	Repair	
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)	E V 3 4 E 4 I n li c i b
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)	E V 3 4 E 4 U t u i b

Comment: VOHAP per 63.1255(a)(1), VOC per BACT

Comment: VOHAP per 63.1255(a)(1), VOC per BACT

Component Types	Standards	Leak Definition	Repair	
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)	E V 3 4 E 4
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.			F s a t u i b
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	

Comment: VOHAP per 63.1255(a)(1), VOC per BACT

Component Types	Standards	Leak Definition	Repair	
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	
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 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(b)	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 12-month period. 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)	F f c v r d i 4

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 haz
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 reportir
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
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	
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)	
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 ≥ 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	

Component Types	Standards	Leak Definition	Repair	
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	
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	

Component Types	Standards	Leak Definition	Repair	
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)	

Component Types	Standards	Leak Definition	Repair	
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)	
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)	
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)	

Component Types	Standards	Leak Definition	Repair	
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)	
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	
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 ha

Connector means flanged, screwed, or other joined fittings used to connect two pipelines or a pipeline and a piece of equipment. For purposes of reporti
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 in its draft White Paper 3 on implementing the Title V operating permit program.

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 will also simplify ongoing compliance and administrative requirements. The permit will streamline similar regulatory requirements into a single set of requirements. The new permit conditions will 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 100 process and product changes. A flexible permit such will enable 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 is 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. On average, Tippecanoe Laboratories will replace 6 process tanks each year. 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.

Lilly's current plans call for replacement of at least one production building sometime during the life of the flexible permit. The new building (or buildings) would be controlled by the RTOs. Because the new buildings would serve as replacement for existing operations, the utilization of the RTOs would remain stable. The RTOs are currently utilized well below their physical capacity.

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.

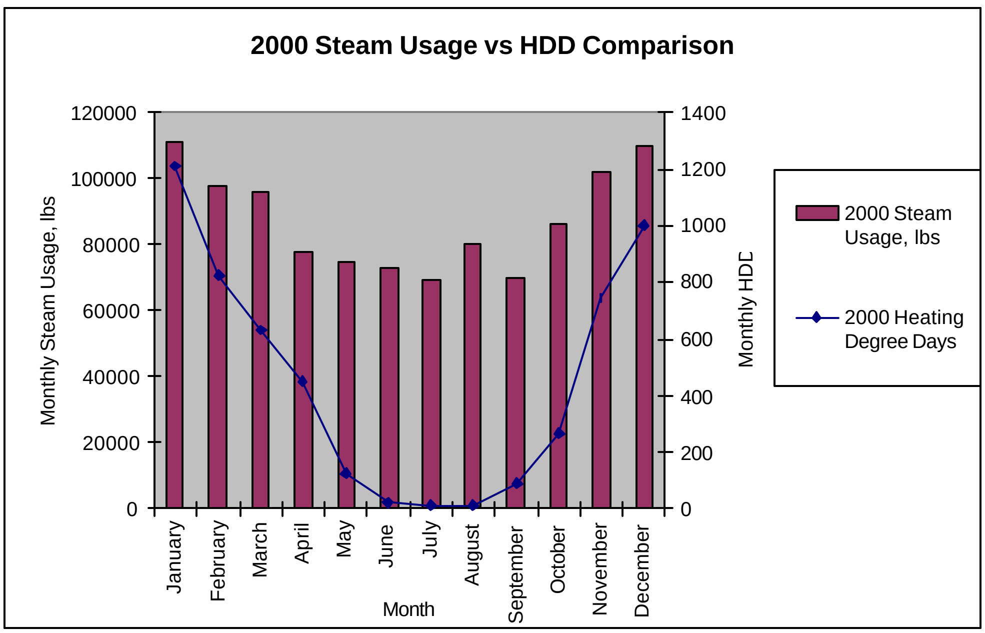
Scope of the flexible permit: As discussed earlier in this TSD, the Permittee will be issued PSD permit for future modifications to the BPM facilities at Tippecanoe Laboratories. In addition to the potential increase in emissions of carbon monoxide (CO), fluorides (F^-), nitrogen oxides (NOx), sulfur dioxide (SO2), and volatile organic compounds (VOC) directly from the modifications, the permit allows the permittee to emit additional quantities of those five 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.

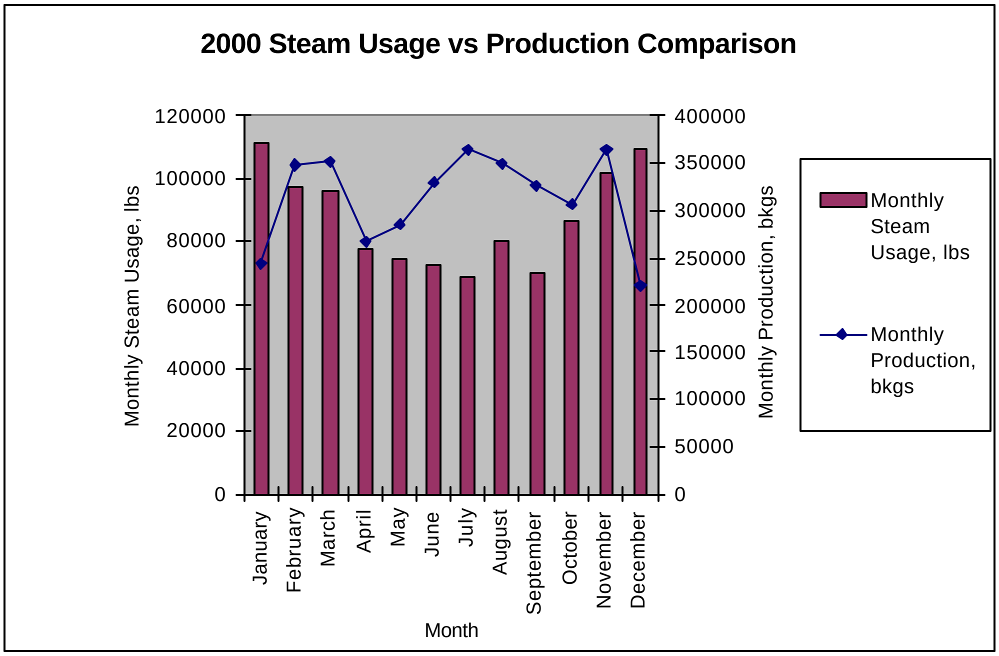
The modifications to BPM include manufacture of new products and intermediates, process changes, equipment replacement, and equipment additions to existing operations in process research/manufacturing buildings T27, T28, T29, T31/T31A, T99 and T100. In addition, the modifications would also include process 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 may be used to address Title V permit modification requirements by describing them as "alternative operating scenarios". If a change that would have otherwise triggered a Title V permit modification is approved in advance as an alternative operating scenario that adequately describes the applicable requirements and compliance assurance obligations of the source, the source may proceed with the change without modifying the Title V permit. This concept has been discussed at great length by USEPA in the draft Title V White Paper 3 on flexible permits and in the preamble to proposed revisions to the federal Title V program rules (August 31, 1995 Federal Register). 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.

USEPA's August 2000 draft guidance, "Design of Flexible Air Permits: Operating Permits Program White Paper Number Three" describes the types of permit conditions that must be present in order to implement advance approval provisions. In addition, 326 IAC 2-7-5(16) describes the requirements necessary in a Title V permit to implement its advance approval provisions. The sections below describe the requirements for advance approval, as described by USEPA White Paper 3, and how the Tippecanoe Laboratories permit would be structured to satisfy those requirements.

According to White Paper 3, each Title V permit implementing advance approval provisions must include the elements listed below [in bold]. For each element, the part of the proposed permit addressing this concept is listed.

(1) **Identification of each existing emissions unit advance approved to change, a description of the anticipated changes to these units, and identification of the advance approved new emissions units**. Each D section of the permit lists the existing emissions units, all of which are advance approved to change. Section F.1.2 describes the types of changes that may occur in those emission units, and the type of new emission units that may be added.

(2) **A list of all applicable requirements applying to the described changes, including any control technology requirements and/or work practice standards (in addition to an emissions cap), monitoring, or testing requirements applying to specific types of emissions units and/or emissions activities.** The applicable requirements for any emission unit are described in the D section of the permit applicable to that operating area or equipment type. Each D section for the areas operating under the flexible permit include a permit condition stating that the applicable requirements described in that D section are applicable to any equipment that is modified or added. This identifies the applicable requirements for future changes.

(3) **Terms, as needed, to link anticipated changes with all applicable requirements and other permit requirements.** The applicable requirements for any emission unit are described in the D section of the permit applicable to that operating area or equipment type. Each D section for the areas operating under the flexible permit include a permit condition stating that the applicable requirements described in that D section are applicable to any equipment that is modified or added. This language serves as the link to the applicable requirements for future changes.

(4) **Either an emissions cap or numerical limit on the amount of expected changes that can occur under the advance approval.** Section F.1.1 establishes the emission caps applicable to the areas operating under the flexible permit. There are emission caps for CO, fluorides, NOx, SO2, and VOC.

(5) **Other terms, as needed to assure compliance with all applicable requirements. These include those to**:

(a) **define the approved capacity of control devices**; [No terms of this nature are needed in this flexible permit. The control devices at Tippecanoe Laboratories have emission control capacities well in excess of the production operations.]
(b) **prevent certain other requirements from being applicable to the advance approved changes**; [This type of term is not required in this permit.]
(c) **define all emissions and/or activities to determine compliance under relevant emissions caps for the relevant time periods**; [The various sections of the permit describe the operations in great detail. Section F pulls them together under the emission cap provisions.]
(d) **require sufficient monitoring, recordkeeping, and reporting for all changes**. [Section F of the permit outlines these requirements in great detail.]

(6) **An advance notice requirement for the addition of advance approved new emissions units and/or new control devices**. Section F.1.12 describes the notification requirements for advance approval of new units.

(7) **A permit requirement to keep an on-site implementation log to contemporaneously record each shift to a new operating scenario and its applicable requirements**. Section F.1.11 describes the recordkeeping requirements for changes.

(8) **A permit requirement to make annual certifications for any changes made during the certification period pursuant to an advance approval contained in the permit**. The permit includes a section requiring annual certification of compliance with all permit conditions, including the advance approval provisions.

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.

Clean Building Approach/BACT Requirements: The second major element of the flexible permit provisions is the use of what USEPA White Paper 3 describes as the “Clean Building Approach”. This aspect of the flexible permit requires the use of Best Available Control Technology (BACT) to fulfill the technology requirement of PSD permitting program. Under the “Clean Building Approach”, BACT applies to both the known modifications occurring upon issuance of the permit and the anticipated modifications that will occur under the advance approval provisions of the permit. The Clean Building provisions in the permit will also ensure compliance with MACT, RACT and other emission control requirements applicable to future changes.

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 five pollutants CO, F^-, NOx, SO2 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) **Building replacement** ■ Replacement of production unit/rig ■ Replacement of production building	VOC point	RTOs	BACT limits/RTO 326 IAC 8-5-3(b)	300	TOC monitor
		VOC fugitive	LDAR	BACT (LDAR)		LDAR data
		CO	RTOs	BACT limits (RTOs)	150	CO monitor
		NOx	Good combustion practice	BACT limits/good combustion	300	NOx monitor
		SO2	RTO scrubbers	BACT limits/RTO scrubbers	300	SO2 monitor
		Fluorides	RTO scrubbers	BACT limits/RTO scrubbers	6	Stack test, Calculation
		HAPs	RTOs/RTO scrubbers	Pharmaceutical MACT SOCMI HON Subpart I	NA	TOC monitor HCl monitor
		Particulate matter	Process controls/filters	326 IAC 6-3	NA	Visible emission evaluations
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	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/LDAM	LDAR/LDAM		LDAR data
		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
		NOx	Good combustion practice	Sub-cap limit = 30 tpy	300	Calculation
		SO2	T79 scrubbers	Sub-cap limit = 5 tpy	300	Calculation Scrubber parametric monitoring
		HAPs	T79/scrubbers	Pharmaceutical MACT SOCMI HON Subpart I Off-site Waste MACT	NA	Stack test/temperature monitoring

Operating area/emission units	Types of changes	Pollutant	Control device(s)	Applicable requirements	Emissions cap (tpy)*	Compliance assurance
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
		NOx	Good combustion practice	BACT limit/good combustion HWC combustor MACT	300	NOx monitor
		SO2	Scrubbers	BACT limit/scrubbers HWC combustor MACT	300	SO2 monitor
		Particulate matter	Scrubbers	HWC combustor MACT 326 IAC 4-2 326 IAC 5	NA	HWC MACT requirements
		HAPs	Good combustion practice/scrubbers	HWC combustor MACT	NA	HWC MACT requirements
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
		NOx	SNCR	BACT limit/SNCR HWC combustor MACT	300	NOx monitor
		SO2	Scrubbers	BACT limit/scrubbers HWC combustor MACT	300	SO2 monitor
		Particulate matter	Scrubbers	HWC combustor MACT 326 IAC 4-2 326 IAC 5	NA	HWC MACT requirements
		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 C
Technical Support Document for
Best Available Control Technology

Background and Description

Eli Lilly and Company (Lilly) is a research-based company that discovers, develops, manufactures and markets pharmaceutical products for people and animals. 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.

A best available control technology (BACT) review must be conducted as part of the PSD process. BACT is an emission limitation based on the best available degree of reduction of each pollutant subject to the PSD requirements. IDEM has performed a federal BACT review for the major modification of future proposed changes to the following areas of the Tippecanoe Laboratories plant site:

(1) BPM Operations – VOC, CO, NOx, SO2, and Fluorides
(2) BPM Support Operations – VOC
(3) Waste Incineration Operations – VOC, CO, NOx, SO2, and Fluorides

IDEM conducts BACT analyses in accordance with the *"Top-Down" Best Available Control Technology Guidance Document* outlined in the 1990 draft US EPA *New Source Review Workshop Manual*, which outlines the steps for conducting a top-down BACT analysis. Those steps are listed below:

(1) Identify all potentially available control options
(2) Eliminate technically infeasible control options
(3) Rank remaining control technologies by control effectiveness
(4) Evaluate the most effective controls and document the results
(5) Select BACT

Also in accordance with the *"Top-Down" Best Available Control Technology Guidance Document*, BACT analyses take 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, and/or operational limitations. The BACT determination is based on the following information:

(1) The EPA RACT/BACT/LAER (RBLC) Clearinghouse
(2) EPA, State, and Local air quality permits, applications and regulations
(3) A compilation of control technologies provided by vendors/suppliers

BACT Determination – BPM Operations

The BPM operations use a variety of process vessels (tanks), centrifuges and dryers to manufacture many different pharmaceutical products and intermediates through a series of chemical synthesis in batch-type operations. Each of these processes utilizes different raw materials and production steps, and thus each product creates different emissions at different rates. Because organic solvents are frequently used throughout the production process, the equipment in a typical production unit typically emit VOCs, a

PSD pollutant. Because of the variety of raw materials used and the variety of chemical reactions used in the chemical synthesis, process tanks are also capable of emitting small quantities of other PSD pollutants, including CO, NOx, SO2, and fluorides. Because pharmaceutical products must be contained, PM is emitted in insignificant quantities and therefore not addressed in this PSD review.

All of the BPM unit operations at Tippecanoe Laboratories 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 and VOC, while the scrubbers remove acid gases such as SO2 and fluorides (as hydrogen fluoride).

It should be noted that future modifications to BPM support operations, such as storage tanks, solvent recovery operations and individual drain systems, may be controlled by either the RTO control system or T79 fume incinerator system to satisfy the BACT requirements. Currently the BPM support operations are primarily controlled by the T79 fume incinerator system.

VOC BACT

Proposed VOC BACT

(1) BPM Process Operations – Lilly proposes to utilize the existing RTO system to control VOC point source emissions greater than 50 ppmv from the BPM equipment by 98% or to 20 ppmv, based on a 24-hour daily period.

(2) Fugitive Emissions – Lilly proposes to utilize an extensive leak detection and repair (LDAR) program to control VOC fugitive emissions from the various pumps, agitators, valves and piping connectors associated with the BPM production equipment. The source will apply the Pharmaceutical MACT LDAR program for all "BPM process systems" and will follow the 40 CFR 61 Subpart V program for all "BPM waste systems" to satisfy the PSD BACT requirements under 326 IAC 2-2.

VOC Technologies Considered Feasible

Volatile organic compounds (VOCs) may be controlled by destruction processes, reclamation processes, or by a combination of reclamation and destruction technologies.

Destruction technologies reduce the VOC concentration by high temperature oxidation into carbon dioxide and water vapor. Reclamation is the capture of VOCs for reuse for disposal.

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.

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.

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.

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.

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.

Regulations Considered

(1) BPM Process Operations – The following table summarizes the current VOC regulations that apply to process operations. In addition to the BPM process operations, regulations that apply to BPM support equipment were also evaluated since the RTO control system may be used to control this equipment as well:

Equipment Type	Regulations			
	326 IAC 8-5-3 (Pharma RACT Rule)	40 CFR 60, Kb (NSPS for solvent storage tanks)	40 CFR 63, DD (Off-site waste MACT)	40 CFR 63, GGG (Pharmaceutical production MACT)
Solvent Tanks	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)]	95% DRE OR Time ≥ 0.75 sec and temp ≥ 816C OR Other parameters determined from a design analysis	N/A	90% DRE *AND* min temp requirement for tanks ≥38 to <75 m3 & VP ≥13.1 kPa *OR* Maintain time ≥ 0.5 sec AND temp ≥760 C for tanks ≥38 to <75 m3 & VP ≥13.1 kPa OR 95% DRE *AND* min temp for tanks ≥75 m3, VP ≥13.1kPa *OR* Maintain time ≥ 0.5 sec *AND* temp ≥ 760 C for solvent tanks ≥ 75 m3, VP ≥ 13.1kPa OR 20 ppmv TOC avg. over 24-hr period *AND* residence time of ≥ 0.5 sec and temp of ≥ 760 C
Waste Tanks			20 ppm TOC, corrected to 3%O2 achieved from a stack test *AND* min temp requirement OR Alternative operating parameter: 20 ppmv TOC 24-hr avg. via CEMS 95% DRE (individual vent percent reduction standard) *AND* min temp requirement OR Maintain temp ≥ 760 F *AND* residence time ≥ 0.5 sec	95% DRE *AND* min temp requirement OR 20 ppmv via stack test *AND* min temp requirement OR Maintain time ≥ 0.5 sec *AND* temp ≥ 760C
Individual Drain Systems		N/A		
BPM Process Operations and Solvent Recovery Operations		N/A		93% DRE for process vents in a process ≤ 25 tpy *AND* min temp requirement OR 98% DRE for individual vents > 25 tpy AND min temp requirement OR 20 ppmv TOC, as calibrated on methane, avg. over 24-hr period, corrected to 3% O2 OR 20 ppmv TOC over 24-hr avg. *AND* time of ≥ 0.75 sec and temp ≥ 816 C

(2) <u>Fugitive Emissions</u> – The fugitive VOHAP/VOC emissions from the BPM operations are subject to the three federal Clean Air Act LDAR requirements listed below:

40 CFR 63.1255, Pharmaceutical Production (Pharma) MACT
40 CFR 63.691, Off-site Waste and Recovery Operations (OSWRO) MACT
40 CFR Subpart I, the Negotiated Regulation for Equipment Leaks

The Pharma 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."

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.

RBLC Comparison

(1) BPM Process Operations - The process code (69.011) was identified that contained summaries applicable to pharmaceutical operations. The following permit limitations on VOC emissions were found in USEPA RBLC data, and an analysis was done to see if Eli Lilly's control technologies employed were equal to or better than the limits in these permits.

Company (RBLC Entry Number)	Process Description	Control Type	Control Efficiency
Pfizer, Inc. (MI-0276)	Reactor and process vents, Storage Tanks, Wastewater Treatment, Solvent Recovery	Three Thermal Oxidizers, followed by (HCl) Caustic Scrubbers, Fabric Filter, PMP, Malfunction Abatement Plan, LDAR	99.99% for VOC and Combustibles- Guaranteed efficiency Scrubber's efficiency – 99.4% of HCl
ICN Pharmaceuticals (CA-0348)	Drying Ovens (4)	Carbon Adsorption	65 lbs/day (Control eff not specified) BACT
Kelco-Division of Merck (CA-0570)	Biogum Processing Line	Water Scrubbers	95% (BACT)
American Cyanamid Co. (CT-0037)	Pharmaceutical Generation	Activated Carbon Adsorption	90% (BACT)
Pfizer (CT-0103)	Pharmaceutical Manufacturing Equipment	Regenerative Oil Absorption System	93% (BACT)
Pfizer (CT-0108)	Coater	Catalytic Oxidizer	95% (BACT)
Pfizer (CT-0109)	Dryer	Catalytic Oxidizer	95% (BACT)
Pfizer (CT-0110)	Dryer	Catalytic Oxidizer	95% (BACT)
Pfizer (CT-0129)	Pharmaceutical Manufacturing Process	Scrubber and / or Carbon Adsorber	85% (BACT)
Pfizer (CT-0133)	Coater	Catalytic Oxidizer	95% (BACT)
Pfizer (CT-0134)	Dryer	Catalytic Oxidizer	95% (BACT)
Pfizer (CT-0135)	Dryer	Catalytic Oxidizer	95% (BACT)
Eli Lilly & Company (IN-0035)	Insulin Manufacturing	Low Temperature Vent Condensers	97% (BACT)
Upjohn (MI-0201)	Filter, Pressure for Product Drying	2 Nitrogen Recycle Drying Systems	98% (LAER)
Dow Chemical (MI-0223)	Reactor, Distillation, Crystallizer, Centrifuge, Vacuum Dryer, Filter	Condenser followed by Wet Scrubber	90% Isopropyl Alcohol, 95% Ethyl Alcohol
Upjohn (MI-0235)	Expansion of HF Chemistry	Refrigerated Condenser	94.7% (BACT)

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.

(2) Fugitive Emissions - There are no control requirements for fugitive VOC emissions listed in the USEPA RBLC database.

Justification for Selection

(1) BPM Process Operations - The IDEM has approved the proposed VOC BACT of 20 ppmv TOC OR 98% control efficiency based on a 24-hour daily period. This BACT determination is based on the following facts and findings:

(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 – The IDEM 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.

CO BACT

Proposed CO BACT

Lilly proposes that CO BACT for this unit is proper combustion to limit CO emissions at the RTO outlet exhaust stream to no more than 73 ppmv, based on a 24-hour daily average.

CO Technologies Considered Feasible

Good Combustion Techniques – CO emissions are generally controlled by proper combustion techniques. Good combustion techniques focus on proper air to fuel ratios, good mixing of air and fuel and control of combustion chamber temperatures to minimize CO emissions.

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 temperatures lower than this range CO conversion to CO_2 reduces rapidly.

Regulations Considered

There are no regulatory limits for CO emissions for pharmaceutical operations.

RBLC Comparison

There are no CO limits contained in RBLC for pharmaceutical operations. The current construction permit (CP157-3352) limits the CO emissions from the RTO to 160 pounds per hour (24-hour rolling average) to avoid PSD review. This mass emission limit is equivalent to a concentration limit of 401 ppmv.

Justification for Selection

The IDEM has approved the proposed CO BACT of 73 ppmv CO, based on a 24-hour daily average based on the following facts and findings:

(1) The installation of an oxidation catalyst is considered economically infeasible. Based on the *EPA Cost Manual* used to estimate capital and operating costs for the addition of a catalytic incineration system on the RTO systems, the incremental cost to control CO emissions to 10 ppmv is approximately $12,500 per ton. The control costs are expected to be even higher because the retrofitting costs were not taken into consideration. The system would need to be retrofitted to raise the exhaust stream temperature (300-350F) to an appropriate temperature range (600-900F) for successful catalytic incineration. In addition, the ductwork would also need to be replaced to withstand the increased temperatures needed for this add-on control device.

(2) There are no regulatory limits or RBLC entries limiting CO emissions from this type of operation.

(3) The CO BACT limit is more restrictive than the current CO limit in the existing construction permit for the RTO control system.

NOx BACT

Proposed NOx BACT

Lilly proposes that NOx BACT for the RTO is the use of low NOx burners to limit NOx emissions to no more than 91 ppmv, based on a 24-hour daily average.

NOx Technologies Considered Feasible

(1) Combustion Controls – NO_x emissions can be reduced significantly by minimizing the rate at which NO_x is formed in the combustion process. This can be accomplished by manipulating the combustion process to occur under fuel rich conditions or by reducing the peak flame temperature. NOx emissions from the RTO are controlled through the use of low-NOx burners.

(2) Selective Catalytic Reduction (SCR) – The SCR process involves the mixing of anhydrous or aqueous ammonia vapor with flue gas and passing the mixture through a catalytic reactor to reduce NO_x to N_2. Under optimal conditions, SCR can have a removal efficiency up to 90% when used on steady state processes. The efficiency of removal will be reduced for processes that are not stable or require frequent changes in the mode of operation.

(3) Selective Non-Catalytic Reduction (SNCR) – With selective non-catalytic reduction (SNCR), NO_x is selectively removed by the injection of ammonia or urea into the flue gas at an appropriate temperature window of 1600ºF to 2000ºF and without employing a catalyst[i]. Similar to SCR (with the exception of the catalyst bed), the injected chemicals selectively reduce the NO_x to molecular nitrogen and water. This approach avoids the problem related to catalyst fouling but the temperature window and reagent mixing residence time is critical for conducting the necessary chemical reaction. At the proper temperature, urea decomposes to produce ammonia which is responsible for NO_x reduction. At a higher temperature, the rate of a competing reaction for the direct oxidation of ammonia that actually forms NO_x becomes significant[ii]. At a lower temperature, the rates of NO_x reduction reactions become too slow resulting in urea slip (i.e., emissions of unreacted urea). EPA literature also states that a control efficiency of 60% is achievable for SNCR technology[iii].

Regulations Considered

There are no regulatory limits for NOx emissions for pharmaceutical operations.

RBLC Comparison

There are no NOx limits contained in RBLC for pharmaceutical operations. The current construction permit (CP157-3352) limits the NOx emissions from the RTO to 226 pounds per hour (24-hour rolling average) to avoid PSD review. This mass emission limit is equivalent to a concentration limit of 787 ppmv.

Justification for Selection

The IDEM has approved the proposed NOx BACT of 91 ppmv NOx, based on a 24-hour daily average. This BACT determination is based on the following facts and findings:

(1) The installation of either a selective catalytic reduction unit or selective non-catalytic reduction unit is considered economically infeasible. Capital and operating cost estimates, based on the EPA Cost Manual, conclude that the cost to further control NOx from the BPM exhaust would be $24,800 per ton for SNCR and $75,400 per ton for SCR. These estimates far exceed the levels that would be considered to be economically feasible for NOx control.

(2) There are no regulatory limits or RBLC entries limiting NOx emissions from this type of operation.

(3) The NOx BACT limit is more restrictive than the current NOx limit in the existing construction permit for the RTO control system.

SO_2 BACT

Proposed SO_2 BACT

Lilly proposes that SO_2 BACT for the RTO is a caustic scrubbing system that limits SO_2 emissions to no more than 100 ppmv, based on a 24-hour daily average.

SO_2 Technologies Considered Feasible

Sulfur dioxide is formed from the oxidation of sulfur compounds in fuels or in waste streams. Control measures include minimization of sulfur in the fuel or product quality) or through the use of add-on control measures.

Add-on control measures are generally based upon exposure of sulfur dioxide molecules to reagents that react with sulfur dioxide to form a sulfate molecule that can then be captured as a particulate.

Sulfur dioxide control systems vary in reagent utilized to react with sulfur dioxide, the manner in which the reagent is exposed to sulfur dioxide, and the manner in which sulfate molecules are captured.

Flue Gas Desulfurization System (Wet or Dry Scrubber) – A flue gas desulfurization system (FGD) is comprised of a spray dryer that uses lime as a reagent followed by particulate control or wet scrubber that uses limestone as a reagent. FGD is an established technology. FGD typically operates at an inlet temperature of approximately 400^0F to 500^0F. The concentration of SO_2 in the exhaust gas is the driving force for the reaction between SO_2 and the reagent. Therefore, removal efficiencies are significantly reduced with lower inlet concentrations of SO_2. FGD systems are listed in the RBLC as BACT for sources high in SO_2 emissions. Even though the SO_2 concentrations in the exhaust gases are very low, and the airflow volume is large, the scrubbing systems are technically feasible. Wet scrubbing FGD system is considerably cheaper than dry scrubbing.

The basic equipment cost for installation of a wet scrubber is an average of $5 per cubic feet per minute of flow rate. The cost estimate is based on a vendor information from 1994 obtained by the applicant. The cost has been scaled up to account for inflation. The total capital cost of a wet scrubber is estimated at $14 million. The annualized cost for the wet scrubbing operation is $ 5.34 million per year. Assuming a control efficiency of 99% (which is unlikely for the dilute airflow from the exhaust), the cost effectiveness of this control option will be $57,700 per ton of total SO_2 removed.

The wet scrubber FGD systems also have energy and environmental impacts associated with their operation. A significant amount of energy is required to operate a FGD system due to the pressure drop over the scrubbers. There are also environmental impacts due to the disposal of the spent reagent and the high water use required for a wet scrubbing system.

For the economic, energy, and environmental reasons presented above, FGD was excluded from further consideration in the BACT analysis.

Regulations Considered

There are no regulatory limits for SO2 emissions for pharmaceutical operations.

RBLC Comparison

There is one SO2 limit contained in RBLC for pharmaceutical operations, which is for a pharmaceutical operation at Pfizer, Inc. in Groton, Connecticut. Uncontrolled SO2 emissions from this process must be controlled through the use of a wet scrubber. The permit does not contain an enforceable removal efficiency or a requirement for stack testing to determine control efficiency.

Justification for Selection

The IDEM agrees that SO2 BACT is the use of a caustic scrubber system and a SO2 limit of 100 ppmv, based on a 24-hour daily average. This BACT determination is based on the following facts and findings:

(1) The caustic scrubber system is the best control technology available for controlling SO2 emissions.

(2) There are no regulatory limits or RBLC entries limiting SO2 emissions from this type of operation.

Fluorides BACT

Proposed Fluorides BACT

Lilly proposes that fluoride BACT from this unit is a caustic scrubbing system to achieve a fluorides removal efficiency of 98% or a 20 ppmv HCl outlet concentration based on a 24-hour daily average.

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.

Regulations Considered

There are no regulatory limits for fluoride emissions for pharmaceutical operations. However, while the Pharmaceutical MACT (40 CFR 63 Subpart GGG) does not regulate fluoride emissions, it does regulate hydrogen chloride. Through the combustion process fluoride ions are converted to hydrogen fluoride. Hydrogen fluoride and hydrogen chloride are both acid gases and react in a similar manner. The hydrogen chloride emission limit in the Pharmaceutical MACT is 98% control efficiency or 20 ppmv.

RBLC Comparison

There are no fluoride limits contained in RBLC for pharmaceutical operations.

Justification for Selection

The IDEM has approved the proposed fluorides BACT of 20 ppmv HCl OR 98% control efficiency 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.

BACT Determination – BPM Support Operations

The BPM Support operations include solvent and waste storage tanks, waste containers, solvent recovery, and individual drain systems. The BPM support equipment only emit organic solvents, such as VOCs, a PSD pollutant. The VOC point source emissions from the storage tanks, solvent recovery operations and individual drain system may be controlled by either the T79 fume incinerator system or the RTO control system. Currently the T79 fume incinerator system controls VOC point source emissions from the solvent recovery operations and the majority of storage tanks, while the individual drain systems are controlled by the RTO control system.

The T79 fume incinerator control system is equipped with two afterburner/scrubber control units, however only one is typically operated at a time. The current required VOC control efficiency of the fume incinerators is 95%. Historical actual point source VOC emissions after the fume incinerator T79 are 3.9 tons per year (1999-2000 average). Expected future actual point source VOC emissions from BPM support are 5 tons per year.

VOC BACT

Proposed VOC BACT

(1) BPM Waste Tanks, Solvent Recovery Equipment, and Individual Drain Systems – Lilly proposes to utilize the existing T79 fume incinerator system as one option to control VOC point source emissions from BPM individual drain systems greater than 500 ppmw, BPM storage tanks, and BPM solvent recovery equipment by 98%. These equipment types may alternatively be controlled by the RTO control system described above in the BPM Operations BACT section.

(2) Fugitive Emissions – Lilly proposes to implement an extensive leak detection and repair (LDAR) program to control VOC fugitive emissions from the various pumps, agitators valves and piping connectors associated with the BPM support equipment.

(3) BPM Waste Containers – Lilly proposes to utilize good work practices required by applicable MACT standards to minimize VOC emissions from waste containers.

VOC Technologies Considered Feasible

There are three categories of controls for volatile organic compounds (VOCs): destruction processes, reclamation processes, and combinations of reclamation and destruction technologies. Destruction technologies reduce the VOC concentration by high temperature oxidation into carbon dioxide and water vapor. Reclamation is the capture of VOCs for reuse for disposal.

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.

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.

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.

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.

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.

Regulations Considered

(1) BPM Waste Tanks, Solvent Recovery Equipment, and Individual Drain Systems – The following table summarizes the current VOC regulations that apply:

Equipment Type	Regulations			
	326 IAC 8-5-3 (Pharma RACT Rule)	40 CFR 60, Kb (NSPS for solvent storage tanks)	40 CFR 63, DD (Off-site waste MACT)	40 CFR 63, GGG (Pharmaceutical production MACT)
Solvent Tanks	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)]	95% DRE OR Time ≥ 0.75 sec and temp ≥ 816C OR Other parameters determined from a design analysis	N/A	90% DRE *AND* min temp requirement for tanks ≥38 to <75 m3 & VP ≥13.1 kPa *OR* Maintain time ≥ 0.5 sec AND temp ≥760 C for tanks ≥38 to <75 m3 & VP ≥13.1 kPa OR 95% DRE *AND* min temp for tanks ≥75 m3, VP ≥13.1kPa *OR* Maintain time ≥ 0.5 sec *AND* temp ≥ 760 C for solvent tanks ≥75 m3, VP ≥13.1kPa OR 20 ppmv TOC avg. over 24-hr period *AND* residence time of ≥ 0.5 sec and temp of ≥ 760 C
Waste Tanks			20 ppm TOC, corrected to 3%O2 achieved from a stack test *AND* establish min temp from stack test OR Alternative operating parameter: 20 ppmv TOC avg. over 24-hr period via CEMS 95% DRE (individual vent percent reduction standard) *AND* establish min temp from stack test OR Maintain temp ≥ 760 F *AND* residence time ≥ 0.5 sec	95% DRE *AND* min temp requirement OR 20 ppmv via stack test *AND* min temp requirement OR Maintain residence time ≥ 0.5 sec *AND* temp ≥ 760C
Individual Drain Systems		N/A		
Solvent Recovery Operations		N/A		93% DRE for process vents in a process ≤ 25 tpy *AND* min temp requirement OR 98% DRE for individual vents > 25 tpy AND min temp requirement OR 20 ppmv TOC, as calibrated on methane, avg. over 24-hr period, corrected to 3% O2 OR 20 ppmv TOC over 24-hr avg. *AND* time of ≥ 0.75 sec and temp ≥ 816 C

(2) Fugitive Emissions – The fugitive VOHAP/VOC emissions from the BPM support operations are subject to the three federal Clean Air Act LDAR requirements listed below:

40 CFR 63.1255, Pharmaceutical Production (Pharma) MACT
40 CFR 63.691, Off-site Waste and Recovery Operations (OSWRO) MACT
40 CFR Subpart I, the Negotiated Regulation for Equipment Leaks

The Pharma 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."

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.

(3) BPM Waste Containers – The following table summarizes the current VOC regulations that apply to waste containers:

Equipment Type	Regulations	
	40 CFR 63, GGG (Pharma MACT)	40 CFR 63, DD (Off-site waste MACT)
Limits/Standards: Small BPM Waste Containers	Containers >0.1 m^3 to $\leq$ 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)]	Containers > 0.1 m^3 to < 0.46 m^3 : DOT compliant container; OR Cover/closure device secured on container; OR Organic vapor-suppressing barrier on open-top container. [63.922(b)]
Limits/Standards: Large BPM Waste Containers	Containers > 0.42 m^3 : Maintain cover/openings without leaks [63.1256(d)(1)(i) and 63.1258(h)] AND Use submerged fill pipe for filling operations *(Lilly's compliance strategy)*; OR Locate container within an enclosure with closed-vent system that routes emissions to control device; 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)]	Containers > 0.46 m^3 : DOT compliant container; OR Operate with no detectable organic emissions; OR Vapor tight container demonstration. [63.923(b)]
Work Practice Standards: Small Waste Container	Inspections for DOT compliant wastewater containers > 0.1 m^3 to $\leq$ 0.42 m^3, not operated under negative pressure:	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.

Inspections	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)]	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)]
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)] AND Operate with no detectable organic emissions, then must conduct initial Method 21 to demonstrate compliance with this control option. [63.923(b)(2) and 63.925(a)]

RBLC Comparison

(1) BPM Waste Tanks, Solvent Recovery Equipment and Individual Drain Systems – The process code (69.011) was identified that contained summaries applicable to pharmaceutical operations. Limitations for VOC emissions that are contained in these permits are summarized below:

The following permits were found in USEPA RBLC data, and an analysis was done to see if Eli Lilly's control technologies employed were equal to or better than the limits in these permits.

Company (RBLC Entry Number)	Process Description	Control Type	Control Efficiency
Pfizer, Inc. (MI-0276)	Reactor and process vents, Storage Tanks, Wastewater Treatment, Solvent Recovery	Three Thermal Oxidizers, followed by (HCl) Caustic Scrubbers, Fabric Filter, PMP, Malfunction Abatement Plan, LDAR	99.99% for VOC and Combustibles-Guaranteed efficiency Scrubber's efficiency – 99.4% of HCl
ICN Pharmaceuticals (CA-0348)	Drying Ovens (4)	Carbon Adsorption	65 lbs/day (Control eff not specified) BACT
Kelco-Division of Merck (CA-0570)	Biogum Processing Line	Water Scrubbers	95% (BACT)
American Cyanamid Co. (CT-0037)	Pharmaceutical Generation	Activated Carbon Adsorption	90% (BACT)
Pfizer (CT-0103)	Pharmaceutical Manufacturing Equipment	Regenerative Oil Absorption System	93% (BACT)
Pfizer (CT-0108)	Coater	Catalytic Oxidizer	95% (BACT)
Pfizer (CT-0109)	Dryer	Catalytic Oxidizer	95% (BACT)
Pfizer (CT-0110)	Dryer	Catalytic Oxidizer	95% (BACT)
Pfizer (CT-0129)	Pharmaceutical Manufacturing Process	Scrubber and / or Carbon Adsorber	85% (BACT)
Pfizer (CT-0133)	Coater	Catalytic Oxidizer	95% (BACT)
Pfizer (CT-0134)	Dryer	Catalytic Oxidizer	95% (BACT)
Pfizer (CT-0135)	Dryer	Catalytic Oxidizer	95% (BACT)
Eli Lilly & Company (IN-0035)	Insulin Manufacturing	Low Temperature Vent Condensers	97% (BACT)
Upjohn (MI-0201)	Filter, Pressure for Product Drying	2 Nitrogen Recycle Drying Systems	98% (LAER)
Dow Chemical (MI-0223)	Reactor, Distillation, Crystallizer, Centrifuge, Vacuum Dryer, Filter	Condenser followed by Wet Scrubber	90% Isopropyl Alcohol 95% Ethyl Alcohol
Upjohn (MI-0235)	Expansion of HF Chemistry	Refrigerated Condenser	94.7% (BACT)

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.

(2) Fugitive Emissions – There are no control requirements listed in the USEPA RBLC database.

(3) BPM Waste Containers – There are no control requirements for waste containers listed in USEPA RBLC database.

Justification for Selection

(1) BPM Waste Tanks, Solvent Recovery Equipment, and Individual Drain Systems – The IDEM has approved the proposed VOC BACT of 98% control efficiency based on the following facts and findings:

(a) The proposed BACT is consistent with the most stringent applicable regulatory requirement (Pharma MACT). This rule requires organic HAP emissions to be controlled by 91% to 98% or to 20 ppm. 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.

(2) Fugitive Emissions – The IDEM 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:

(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.

(3) Waste Containers – The IDEM has approved the proposed work practice and inspection requirements of the Pharma MACT standards to satisfy the VOC BACT requirements for waste containers. This conclusion is based on the following facts and findings:

(a) The proposed BACT is consistent with the most stringent applicable regulatory requirement (Pharma MACT). This rule requires work practice standards and periodic inspections. There are no emission limits for similar sources that would create any more stringent emission limits for pharmaceutical operations.

(b) There were no control requirements for containers listed in the RBLC database.

BACT Determination – Waste Incineration Operations

There are two waste incineration operations consist of an existing T49 Trane incinerator to burn liquid waste and a rotary kiln incinerator, currently under construction, to treat both liquid and solid wastes. The incinerators are designed to destroy VOCs contained in the waste streams. PSD pollutants generated in the combustion process include SO2, NOx, and fluorides (as HF).

The T49 liquid waste incinerator control system is equipped with a Hydro-Sonic scrubber system to control PM, SO2 and acid gases such as HF. Assuring good combustion practice in the incinerator minimizes CO, NOx and VOC emissions.

The rotary kiln incinerator is equipped with a selective non-catalytic reduction (SNCR) system for NOx abatement, a condenser/absorber column (packed tower) in series with a Hydro-Sonic scrubber system to control PM, SO and acid gases. CO and VOC emissions are minimized by assuring good combustion practices in the incinerator.

VOC BACT

Proposed VOC BACT

Lilly proposes that VOC BACT for both the T49 liquid waste incinerator and the rotary kiln incinerator be established as 10 ppm TOC (or 100 ppm CO surrogate), which is equivalent to the MACT THC limits contained in 40 CFR Part 63, Subpart EEE.

VOC Technologies Considered Feasible

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 VOC concentrations.

Regulations Considered

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) of 99.99% for each principle organic hazardous constituent in organic materials.

RBLC Comparison

There are no listings in the RBLC that contained stack limitations or concentration limits for VOC emissions from incineration operations. The RBLC did contain listings that contain DRE requirements at 99.99%.

Justification for Selection

The IDEM agrees that the VOC BACT for both the T49 liquid waste incinerator and the rotary kiln 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.

CO BACT

Proposed CO BACT

Lilly proposes that CO BACT for both the T49 incinerator and rotary kiln incinerator is proper combustion to limit CO emissions to no more than 100 ppmvdc, based on a 1-hour rolling average.

CO Technologies Considered Feasible

Carbon Monoxide (CO) is formed through the incomplete combustion (Oxidation) of organic material to carbon dioxide (CO_2). Factors that may lead to the formation of carbon monoxide include inadequate airflow 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 CO_2.

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).

CO 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 ^oF to 900 ^oF. At temperatures lower than this range CO conversion to CO_2 reduces rapidly. Cost of an oxidation catalyst can be high with the largest cost associated with the catalyst itself. Catalyst life varies, but typically a 3 to 6 year life can be expected.

Regulations Considered

There are several regulatory limits for CO emissions from incineration units as follows:

HWC MACT Standards – 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 ppmv.

Hospital/Medical/Infectious Waste MACT Standards – The Hospital/Medical/Infectious Waste Combustors found in 40 CFR Part 60, Subpart Ec, limits CO emissions to 40 ppm. However, the Hospital/Medical/Infectious Waste incineration limit is not appropriate for hazardous waste incineration units for the following reasons:

(1) Incinerators of the type regulated under Subpart Ec are typically much smaller than units such as the T49 incinerator and the rotary kiln incinerator; and

(2) The waste stream for these units of the type regulated under Subpart Ec is generally more uniform than that encountered in the T49 incinerator and the rotary kiln incinerator.

RBLC Comparison

There are a few CO limits in RBLC for hazardous waste incinerators and other waste incinerators. The most stringent CO emission limit is 100 ppm.

Justification for Selection

IDEM agrees that the CO BACT for both the T49 incinerator and rotary kiln incinerator is proper combustion techniques to limit CO emissions to no more than 100 ppmvdc, based on 1-hour rolling period. This BACT determination is based on the following facts and findings:

(1) This BACT limit is equivalent to the CO limit contained in the HWC MACT standards at 40 CFR Part 63, Subpart EEE and consistent with the most stringent limit found in the RBLC database.

(2) Although the CO limit contained in the Hospital/Medical/Infectious Waste Combustors found in 40 CFR Part 60, Subpart Ec, is more stringent, this 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 the T49 incinerator and the rotary kiln incinerator; and

(b) The waste stream for these units of the type regulated under Subpart Ec is generally more uniform than that encountered in the T49 incinerator and the rotary kiln incinerator.

(3) The most stringent BACT limitation found in other permits for hazardous waste incinerators is 100 ppm:

NOx BACT

Proposed NOx BACT

T49 Incinerator – Lilly proposes that NOx BACT for the T49 incinerator is proper combustion to limit NOx emissions to no more than 975 ppmvdc, based on a 24-hour daily average.

Rotary Kiln Incinerator – Lilly proposes that NOx BACT for the rotary kiln incinerator is proper combustion to limit NOx emissions to no more than 170 ppmvdc, based on a 24-hour daily average.

NOx Technologies Considered Feasible

Nitrogen oxides (NOx) emissions include nitric oxide (NO) and nitrogen dioxide (NO_2). Approximately 95 percent of the NOx formed during combustion processes is NO, with most of the remaining emitted as NO_2. Because NO emissions tend to oxidize as NO_2 in the atmosphere, NO_2 emissions are generally expressed in units of NO_2 equivalent emissions. NOx is formed from the chemical reaction between nitrogen and oxygen at high temperatures.

For the T49 incinerator and rotary kiln incinerator, NOx formation may occur both from thermal NOx and fuel NOx. Feasible add-on control technologies and combustion control approaches are discussed below.

Selective Catalytic Reduction – The selective Catalytic Reduction (SCR) process involves the mixing of anhydrous or aqueous ammonia vapor with flue gas and passing the mixture through a catalytic reactor to reduce NOx to N_2. Under optimal conditions, SCR can have removal efficiency up to 90% when used on steady state processes. The efficiency of removal will be reduced for processes that are not stable or require frequent changes in the mode of operation.

Selective Non-Catalytic Reduction – With selective non-catalytic reduction (SNCR), NOx is selectively removed by the injection of ammonia or urea into the flue gas at an appropriate temperature window of 1600^{o}F to 2000^{o}F and without employing a catalyst. Similar to SCR (with the exception to catalyst bed), the injected chemicals selectively reduce the NOx to molecular nitrogen and water. This approach avoids the problem related to catalyst fouling but the temperature window and reagent mixing residence time is critical for conducting the necessary chemical reaction. At the proper temperature, urea decomposes to produce ammonia that is responsible for NOx reduction. At a higher temperature, the rate of a competing reaction for the direct oxidation of ammonia that actually forms NOx becomes significant. At a lower temperature, the rates of NOx reduction reactions become too slow resulting in urea slip (i.e., the emissions of unreacted urea). A control efficiency of 60% is achievable for SNCR technology.

Combustion Controls – NOx emissions can be reduced significantly by minimizing the rate at which NOx is formed in the combustion process. This can be accomplished by manipulating the combustion process to occur under fuel rich conditions or by reducing the peak flame temperature.

Potential control options for achieving fuel rich combustion include Low Excess Air (LEA) operation, Off-Stoichiometric (OS) Firing, which refers to Burners Out Of Service (BOOS) or Over Fire Air (OFA), and Low NOx burners (LNBs). Reducing the flame temperature inhibits thermal NOx production and can be implemented by Flue Gas Recirculation (FGR).

Regulations Considered

There are no regulatory limits for NOx emissions that are applicable to hazardous waste incinerators, including the MACT standard for hazardous waste incineration units. There are regulatory limits for other incinerators, which vary from 150 to 500 ppm, depending upon the specific type of unit regulated.

RBLC Comparison

Company (RBLC Number)	Process Description	Control Type	Control Efficiency/ Emission Limit
Anniston Army Depot (AL-0135)	Liquid Incinerator	Quench Tower Venturi Scrubber	98.5% control; 1.513 g/dscm (BACT)
Anniston Army Depot (AL-0137)	Metal Parts Furnace	Quench Tower Venturi Scrubber	98.5% control; 621 g/dscm (BACT)
Safety Kleen (Rollins) (NJ-00034)	Commercial Haz Waste Incinerator	Modifying existing burner - reshaping air slots, enlarging firebox, enhancing air flow pattern	30% (RACT)
Aptus Inc. (UT-0044)	Kiln	No controls feasible	0.0% (BACT)

Justification for Selection

T49 Liquid Incinerator –IDEM agrees that the NOx BACT for the T49 incinerator is proper combustion techniques to limit NOx emissions to no more than 975 ppmvdc, based on 24-hour rolling period. This BACT determination is based on the following facts and findings:

(1) The NOx BACT is based on the estimated amount of nitrogen containing compounds in the process waste streams and was developed using historical waste analysis data and the worst-case projected waste profile based on the 5-year production forecast for new products at Eli Lilly and Company. Based on the waste stream analyses and the design flowrates of the T49 incinerator, the worst-case expected nitrogen feedrate is 1650 pounds per hour, which was used to calculate the NOx BACT for the T49 incinerator.

(2) The installation of either a selective catalytic reduction unit or selective non-catalytic reduction unit is considered economically infeasible. Capital and operating cost estimates, based on the EPA Cost Manual, conclude that the cost to further control NOx from the T49 incinerator exhaust would be $11,500 per ton for SNCR and $12,270 per ton for SCR. These estimates far exceed the levels that would be considered to be economically feasible for NOx control.

(3) There are no regulatory limits for NOx emissions that are applicable to hazardous waste incinerators, including the MACT standard for hazardous waste incineration units.

(4) The regulatory limits for other types of incinerators (150-500 ppmv) are not comparable to this hazardous waste incinerator because these other incinerators are not of the same size and do not incinerate the same types of waste streams.

(5) The NOx limits contained in the RBLC database are not comparable to the T49 hazardous waste incinerator because the NOx emissions are dependent on the waste stream characteristics. The higher the nitrogen-containing compounds in the waste stream, the higher the resulting NOx emissions. This analogy can be seen in the Anniston Army Depot facility. The NOx limits from the Anniston Army Depot permits identified in the RBLC range from 392 ppmv to 1,565 ppmv, even though the same types of controls are used on both units. This is most likely a result of different nitrogen levels in the varied waste stream.

Rotary Kiln Incinerator –IDEM agrees that the NOx BACT for the rotary kiln incinerator is selective non-catalytic reduction (SNCR) add-on control system to limit NOx emissions to no more than 170 ppmvdc, based on 24-hour daily period. This BACT determination is based on the following facts and findings:

(1) There are no regulatory limits for NOx emissions that are applicable to hazardous waste incinerators, including the MACT standard for hazardous waste incineration units.

(2) The regulatory limits for other types of incinerators (150-500 ppmv) are not comparable to this hazardous waste incinerator because these other incinerators are not of the same size and do not incinerate the same types of waste streams.

(3) This BACT limit is more restrictive than the most stringent permit limit contained in RBLC (Anniston Army Depot, 392 ppmv limit).

SO_2 BACT

Proposed SO2 BACT

T49 Incinerator – Lilly proposes that SO_2 BACT for the T49 incinerator is proper combustion to limit SO_2 emissions to no more than 500 ppmvdc, based on a 24-hour daily average.

Rotary Kiln Incinerator – Lilly proposes that SO_2 BACT for the rotary kiln incinerator is proper combustion to limit SO_2 emissions to no more than 400 ppmvdc, based on a 24-hour daily average.

SO2 Technology Evaluation

Sulfur dioxide is formed from the oxidation of sulfur compounds in fuels or in waste streams. Control measures include minimization of sulfur in the fuel or product quality) or through the use of add-on control measures.

Add-on control measures are generally based upon exposure of sulfur dioxide molecules to reagents that react with sulfur dioxide to form a sulfate molecule that can then be captured as a particulate. Sulfur dioxide control systems vary in reagent utilized to react with sulfur dioxide, the manner in which the reagent is exposed to sulfur dioxide, and the manner in which sulfate molecules are captured.

Flue Gas Desulfurization System (Wet or Dry Scrubber) – A flue gas desulfurization system (FGD) is comprised of a spray dryer that uses lime as a reagent followed by particulate control or wet scrubber that uses limestone as a reagent. FGD is an established technology. FGD typically operates at an inlet temperature of approximately 400^0F to 500^0F. The concentration of SO_2 in the exhaust gas is the driving force for the reaction between SO_2 and the reagent. Therefore, removal efficiencies are significantly reduced with lower inlet concentrations of SO_2. FGD systems are listed in the RBLC as BACT for sources high in SO_2 emissions. Even though the SO_2 concentrations in the exhaust gases are very low, and the airflow volume is large, the scrubbing systems are technically feasible. Wet scrubbing FGD system is considerably cheaper than dry scrubbing. Therefore wet scrubbing is analyzed further in this analysis.

The basic equipment cost for installation of a wet scrubber is an average of $5 per cubic feet per minute of flow rate. The cost estimate is based on a vendor information from 1994 obtained by the applicant. The cost has been scaled up to account for inflation. The total capital cost of a wet scrubber is estimated at $14 million. The annualized cost for the wet scrubbing operation is $ 5.34 million per year. Assuming a control efficiency of 99% (which is unlikely for the dilute airflow from the exhaust), the cost effectiveness of this control option will be $57,700 per ton of total SO_2 removed.

The wet scrubber FGD systems also have energy and environmental impacts associated with their operation. A significant amount of energy is required to operate a FGD system due to the pressure drop over the scrubbers. There are also environmental impacts due to the disposal of the spent reagent and the high water use required for a wet scrubbing system.

For the economic, energy, and environmental reasons presented above, FGD was excluded from further consideration in the BACT analysis.

Regulations Considered

There are no regulatory limits for SO_2 emissions that are applicable to hazardous waste incinerators, including the MACT standard for hazardous waste incineration units. There are regulatory limits for other incinerators, which vary from 20 to 55 ppmv, depending upon the specific type of unit regulated.

RBLC Comparison

SO_2 emissions were identified for hazardous waste incineration units (process code 22.002). No listing for “Other Incineration” in process code 29.999 was found. RBLC listings for SO_2 limitations for hazardous waste incinerator are summarized below:

Company (RBLC Entry Number)	Process Description	Control Type	Control Efficiency or Emission Limit
Anniston Army Depot (AL-0135)	Liquid Incinerator	Quench Tower, Venturi Scrubber, demister, clean fuel	97.5% control; 8.77 g/dscm (BACT)
Anniston Army Depot (AL-0137)	Metal Parts Furnace	Quench Tower, Venturi Scrubber, demister, clean fuel	97.5% control; 150 g/dscm (BACT)
Aptus Inc. (UT-0044)	Kiln	Dry Scrubber	149 ppm @ 7% O2 (BACT)

Justification for Selection

T49 Incinerator – IDEM agrees that the SO_2 BACT for the T49 incinerator is caustic scrubbing to limit SO_2 emissions to no more than 500 ppmvdc, based on a 24-hour block period, which is equivalent to a SO_2 removal efficiency of 97.5%. This BACT determination is based on the following facts and findings:

(1) The SO_2 BACT is based on the estimated amount of sulfur-containing compounds in the process waste streams and was developed using historical waste analysis data and the worst-case projected waste profile based on the 5-year production forecast for new products at Eli Lilly and Company.

(2) The caustic scrubber system is the best control technology available for controlling SO_2 emissions.

(3) There are no regulatory limits for SO_2 emissions that are applicable to hazardous waste incinerators, including the MACT standard for hazardous waste incineration units.

(4) The regulatory limits for other types of incinerators (20-55 ppmv) are not comparable to this hazardous waste incinerator because these other incinerators are not of the same size and do not incinerate the same types of waste streams.

(5) This BACT limit is comparable to the most stringent control efficiency permit limit contained in RBLC database.

(6) The SO_2 concentration limit contained in the RBLC database is not comparable to the T49 hazardous waste incinerator because the SO_2 emissions are dependent on waste stream characteristics. The higher the sulfur-containing compounds in the waste stream, the higher the resulting SO2 emissions.

Rotary Kiln Incinerator - IDEM agrees the SO_2 BACT for the rotary kiln incinerator is caustic scrubbing to limit SO_2 emissions to no more than 400 ppmvdc, based on a 24-hour block period, which is equivalent to a SO_2 removal efficiency of 97.5%. This BACT determination is based on the following facts and findings:

(1) The SO_2 BACT is based on the estimated amount of sulfur-containing compounds in the process waste streams and was developed using historical waste analysis data and the worst-case projected waste profile based on the 5-year production forecast for new products at Eli Lilly and Company.

(2) The caustic scrubber system is the best control technology available for controlling SO_2 emissions.

(3) There are no regulatory limits for SO_2 emissions that are applicable to hazardous waste incinerators, including the MACT standard for hazardous waste incineration units.

(4) The regulatory limits for other types of incinerators (20-55 ppmv) are not comparable to this hazardous waste incinerator because these other incinerators are not of the same size and do not incinerate the same types of waste streams.

(5) This BACT limit is comparable to the most stringent control efficiency permit limit contained in RBLC database.

(6) The SO_2 concentration limit contained in the RBLC database is not comparable to the T49 hazardous waste incinerator because the SO_2 emissions are dependent on waste stream characteristics. The higher the sulfur-containing compounds in the waste stream, the higher the resulting SO_2 emissions.

Fluorides BACT

Proposed Fluorides BACT

Lilly proposes that the fluorides BACT for both the T49 incinerator and rotary kiln incinerator is the use of a caustic scrubbing system to control fluoride emissions by at least 98%.

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.

Regulations Considered

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 for hazardous waste incinerators (40 CFR Part 63, Subpart EEE) is 21 ppm.

RBLC Comparison

RBLC entries for "Other Incineration" (process code 29.999) and for hazardous waste incineration (process code 22.002) were searched to identify emission limitations for fluoride compounds. No limitations for fluoride emissions under these process codes are contained within RBLC. Municipal waste incineration listings under process code 21.001 were reviewed. The process code lists numerous RBLC entries, many of which include fluoride, fluorine, or hydrogen fluoride emission limitations. The summary of RBLC listing is given below:

Company (RBLC Entry Number)	Process Description	Control Type	Control Efficiency
NRG Recovery Group (FL-0038)	Refuse incinerator, 2 each, 250 tons/day	Acid Gas Control	1.5 gr/dscf (BACT)
Pasco County (FL-0039)	Refuse incinerator, 2 each, 1200 tons/day	Dry Scrubber/Baghouse	90.0% control; 0.008 lb/MMBtu (BACT)
Lee County Energy Recovery Facility (FL-0067)	Boiler, Municipal Waste Incineration (3) 660 tons/day	Spray Dryer (Lime dry scrubber)/fabric filter	5 ppm fluorides @ 7% O2 (BACT)
Central Wayne Energy Recovery Limited Partnership (MI-0252)	Municipal Waste Combustors (3 units)	Dry Scrubber	5 ppmdv (BACT)
Mercer & Atlantic Co. Resource Recovery Facility (NJ-0020)	Municipal Waste Combustor 833.8tons/day	Dry Scrubber	90.0% (BACT)
San Juan Resource Recovery Facility (PR-0001)	Mass Burn Combustor, 3 1040 tons/day	Dry Scrubber	90.0% (BACT)
Ogden Martin Systems of Fairfax, Inc. (VA-0055)	Incinerator, 4 each 750 tons/day	Dry Scrubber	90.0% (BACT)

There are no permit limits in RBLC for fluoride emissions from hazardous waste incinerators. There are several listings in RBLC for fluoride/fluorine/hydrogen fluoride emission limit for municipal waste combustors.

Justification for Selection

IDEM agrees the fluorides BACT for both the T49 incinerator and rotary kiln incinerator is the use of a caustic scrubbing system to achieve a fluorides removal efficiency of 98%. This BACT determination is based on the following facts and findings:

(1) This level of control is as stringent as or more stringent than any limit contained in applicable rules or permits for comparable emission units.

i EPA-453 / R-93-034.
ii EPA-453 / R-93-034.
iii EPA-453 / R-93-034.

Attachment to Appendix C

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 a non steady-state mode. During these events the emission control equipment for the emission unit 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:

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 Regenerative Thermal Oxidizers (RTOs) and incinerators, these units will burn only natural gas, which results in low CO emissions except for the brief periods of ignition of the gas. When process fumes or wastes 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 intends to operate T149 in a normal manner until the waste is cleared from the kiln. Emissions are expected to be normal during this period.

Fluorides 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 wastes 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 intends to operate T149 in a normal manner until the waste is cleared from the kiln. Emissions are expected to be normal during this period.

NOx Emissions:

The NAAQS for NOx is an annual average. The permit includes an annual emission limit of 300 tons per year NOx for the units subject to PSD requirements. The PSD permit review included a worst case assessment that if all 300 tons of NOx were emitted from the T49 incinerator, the NOx NAAQS and NOx PSD increment requirements would not be violated. NOx 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 NOx BACT limits for the RTOs and waste incinerators are based on burning fume streams or waste streams with high nitrogen content that leads to higher NOx emissions. During startup and shutdown of the RTOs and incinerators, these units will burn only natural gas, which will have lower emissions. When process fumes or wastes are first introduced into the combustion chambers of these units [also considered to be a startup activity], NOx 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 intends to operate T149 in a normal manner until the waste is cleared from the kiln. Emissions are expected to be normal during this period.

SO_2 Emissions:

There are three NAAQS for SO_2: an annual average, a 24-hour average, and a 3-hour average. The permit includes an annual emission limit of 300 tons per year SO_2 for the units subject to PSD requirements. The PSD permit review included a worst case assessment that if all 300 tons of SO_2 were emitted from the T49 incinerator, the SO_2 NAAQS and SO_2 PSD increment requirements would not be violated. SO_2 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 SO_2 BACT limits for the RTOs and waste incinerators are based on burning fume streams or waste streams with high sulfur content that leads to higher SO_2 emissions. During startup and shutdown of the RTOs and incinerators, these units will burn only natural gas, which will have lower emissions. When process fumes or wastes are first introduced into the combustion chambers of these units [also considered a startup activity], SO_2 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 intends to operate T149 in a normal manner until the waste is cleared from the kiln. Emissions are expected to be normal during this period. Therefore, the SO_2 emissions that occur during startup and shutdown will not cause violations of the 3-hour or 24-hour NAAQS for SO_2.

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 burn 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 is required to continue to operate T149 in a normal manner until the waste is cleared from the kiln. Emissions are expected to be normal during this period.

The permit includes annual emission limits that were modeled to ensure the protection of National Ambient Air Quality Standards and PSD increment. Emissions during startups and shutdowns will be monitored and measured and will be included in the determination to show compliance with these emissions limits.

The permit requires the Permittee to minimize the emissions during startup and shutdown periods. The Permittee is required to develop a startup, shutdown, and malfunction plan to minimize the emissions during these periods.

Appendix D
Technical Support Documentation for
Air Quality Analysis

Introduction

Eli Lilly and Company (Lilly) in Lafayette, Indiana (Tippecanoe Plant) has applied for a flexible operating permit under Indiana permitting regulations and guidance provided by USEPA. Lilly manufactures various pharmaceutical products. As a result of emission limits desired under the flexible permit, Lilly is required to perform an air quality analysis under the Federal and State PSD regulations. All air quality modeling and analysis treats the increase in emissions as a major PSD modification.

Environmental Resources Management (ERM) prepared the permit application for Lilly. The Office of Air Quality (OAQ) received the modeling portion of the permit application on January 16, 2003. Increment modeling additions to the application were received on March 7, 2003. HAPs modeling was received on May 23, 2003, which was performed by Lilly. This document provides a review of the air quality modeling provided by the applicant and an air quality analysis performed by OAQ.

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 of the source's emissions and background air quality levels.

D. Demonstrate that the source will not cause or contribute to a violation of the National Ambient Air Quality Standard (NAAQS) or PSD increment if the applicant exceeds significant impact levels.

E. Perform an analysis of any air toxic compoundhazardous air pollutant with a health risk factor on the general population.

F. Perform a qualitative analysis of the source's impact on general growth, soils, and vegetation. The nearest Class I area is Kentucky's Mammoth Cave National Park, which is more than 100 kilometers from the site in Tippecanoe County, Indiana.

G. Summarize the Air Quality Analysis

Analysis Summary

The air quality impact analysis determined that refined modeling would be required since pollutant concentrations did exceed significant impact levels. NAAQS and increment analysis showed the facility below the standards. The Reactive Plume Model–IV (RPM-IV) results showed no significant impact to ozone formation. Hazardous Air Pollutant (HAP) analysis showed no concentrations above 0.5% of the Permissible Exposure Limit (PEL), but some HAPs concentrations were above the National Air Toxic Assessment/ Cumulative Exposure Project (NATA/CEP) benchmark. Based on these modeling results, the proposed modifications to Tippecanoe Laboratories will not have a significant impact to air quality.

Section A

Pollutants Analyzed for Air Quality Impact

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. Sulfur Dioxide (SO_2), Nitrogen Dioxide (NO_2), Volatile Organic Compounds (VOC)(an Ozone (O_3) precursor), Carbon Monoxide (CO) and Fluoride (F-) are the pollutants that will be emitted in significant amounts from Tippecanoe Laboratories. Therefore, an air quality analysis is required for these pollutants.

TABLE 1
Significant Emission Rates for PSD

POLLUTANT	SOURCE EMISSION RATE	SIGNIFICANT EMISSION RATE	PRELIMINARY AQ ANALYSIS REQUIRED
	(tons/year)	(tons/year)	
Fluoride	6	3	Yes
NO_2	300	40.0	Yes
VOCs (O_3)	300	40.0	Yes
CO	150	100.0	Yes
SO_2	300	40	Yes

Section B

Stack Height Compliance with Good Engineering Practice (GEP)

Stacks should comply with GEP requirements established in 326 IAC 1-7-1. If stacks are lower than GEP, excessive ambient concentrations due to aerodynamic downwash may occur. Stacks taller than 65 meters (213 feet) are limited to GEP, the stack height for 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)

Since the stack heights of the facility were below GEP stack height the effect of aerodynamic downwash will be accounted for in the air quality analysis for the pharmaceutical facility.

Meteorological Data

The meteorological data used in the Industrial Source Complex Short Term (ISCST3) model consisted of 1990 through 1994 surface data from the Indianapolis International Airport Weather Service station merged with the mixing heights from Peoria, Illinois Airport National Weather Service station. The meteorological data was purchased through the National Oceanic and Atmospheric Administration (NOAA) and National Climatic Data Center (NCDC) and preprocessed into ISCST3 ready format using U.S.EPA's PCRAMMET.

Model Description

For this project ERM used two models. They were ISCST3 and ISC3 Prime for the criteria pollutants. The OAQ used the ISCST3 model, version 02035 and ISC3 PRIME, version 01228 to determine maximum off-property concentrations or impacts for each pollutant. The details of why a model or option was used for each situation are outlined below.

Worst Case Stack Impact Analysis - Because the flexible permit would allow Lilly to release emissions from one of several stacks, a worst case stack analysis was performed. The worst case impact was performed using ISCST3, version 02035. The non-regulatory default option (HE>ZI) was chosen over the regulatory default. This was done because Lilly had some receptor elevations below stack base elevations. The Model Change Bulletin Number 9 allows the use of this option to address the potential problem of the model over-predicting concentrations.

NAAQS Analysis - The NAAQS analysis was performed using ISC3 PRIME, version 01228. Lilly requested the use of this model and obtained formal approval from U.S. EPA in August 2002. The regulatory default was chosen. Tippecanoe Laboratories has 3 boilers with downwash problems due to stack/structure geometry.

Increment Analysis - The increment analysis was modeled using ISCST3, version 02035. The non-regulatory default option (HE>ZI) was chosen over the regulatory default. This was done because Lilly has some receptor elevations below stack base elevations. The Model Change Bulletin Number 9 allows the use of this option to address the potential problem of the model over-predicting concentrations.

Fluoride Analysis - The fluoride modeling used ISCST3, version 02035. The non-regulatory default options were chosen over the regulatory default. The non-regulatory options chosen are the toxics option, which allows for dry deposition. The HE>ZI option which checks if the source base is greater than receptor elevation. Again, the model Change Bulletin number 9 allows the use of (HE>ZI). The toxic option selection allows the use of a dry deposition settling velocity. Dry deposition of particles can basically be thought of as similar to dust collecting on a table. Also, the option allowing for missing met data was also selected.

HAP Analysis - For the HAPs modeling, ISCST3 version 02035 was used. The regulatory default options were chosen.

The Auer Land Use Classification Scheme was used to determine the land use in the area. The area is considered primarily rural; therefore, a rural classification was used for all modeling.

Receptor Grid

OAQ modeling utilized the same receptor grids generated by ERM. The grids for each modeling exercise are outlined below.

Worst Case Stack Impact and HAP Analysis - A Cartesian receptor grid was utilized and was based on the following spacing: 100-meter spacing along the fence line; 100 meter spacing from fence line to (and including) 500 meter distance from stacks; 200 meter spacing 600 to 1000 meter distance from stacks; 500 meter spacing 1500 to 3000 meter distance from stacks; and 1000 meter spacing 4000 to 10000 meter distance from stacks.

NAAQS Analysis, Increment Analysis, and Fluoride Analysis - A Cartesian receptor grid was established across the significant impact area which extended to 12 kilometers from the plant site (100 meter spacing along fence line; 100 meter spacing from the fence line to (and including) 500 meter distance from stacks; 200-meter spacing 600 to 1000 meter distance from stacks; 500 meter spacing 1500 to 3000 meter distance from stacks; 1000 meter spacing 4000 to 12000 meter distance from stacks.

Section C

Worst Case Stack Analysis

Before the significant impact analysis was performed, an analysis was performed to determine the worst case stack. This was done to determine which stack would represent the most constraining situation since the flexible permit will allow emissions to occur from any of the four stacks up to permitted levels. The stack with the highest impact was then used in the significant impact analysis, increment, and NAAQS modeling. Four stacks were considered. They are the RTO, T79, T49, and the Kiln. In order to determine which of the four stacks represented the worst case scenario, an emission rate of 1 gram per second (34.79 tons per year) was assumed for each of the four stacks. By comparing the predicted maximum ground level concentrations from each stack, it could be determined which stack represented the worst case stack. The table below shows the results of the analysis.

TABLE 2
Worst Case Stack Analysis

Averaging Period	RTO (ug/m3)	T79 (ug/m3)	T49 (ug/m3)	Kiln (ug/m3)
1-hour	67.8	111.7	77.4	18.5
3-hour	22.6	67.54	33.62	15.4
8-hour	13.2	42.8	22.2	15.4

24-hour	5.7	24.8	9.1	5.2
Annual	.42	1.82	.56	.39

The T79 stack demonstrates to have the highest ground-level concentration for each averaging period. Lilly reviewed this stack and determined it will be mainly a source of potential VOCs only. As a consequence of this analysis, Lilly is accepting a limit on CO, SO2, NOx, and fluoride emissions from the T79 that is separate from the flexible permit cap limit. With separate limits for the T79, the T49 stack becomes the unit with the highest predicted ground level concentrations for each pollutant of concern in this analysis.

Significant Impact Level/Significant Impact Area (SIA)

Since the T49 stack has been identified to be the stack with the maximum ground level ambient air quality concentration, the analysis can now examine the significant impact level. If the source's concentrations exceed these levels, further air quality analysis is required. Since ground level concentrations from ISCST modeling are directly proportional to stack emission rates, the worst case stack modeling can be used for the significant impact level analysis.

TABLE 3
Significant Impact Analysis

POLLUTANT	TIME AVERAGING PERIOD	PREDICTED IMPACT FROM 1 g/s (ug/m3)	PERMIT EMISSION RATE (ton/year)	PREDICTED IMPACT AT PERMIT EMISSION RATE (ug/m3)	SIGNIFICANT IMPACT LEVEL (ug/m3)	REFINED MODELING REQUIRED
NO_2	Annual	.56	300	5	1	YES
CO	1 Hour	77.4	150	333	2000	NO
CO	8 Hour	22.2	150	96	500	NO
SO_2	3 Hour	33.6	300	290	25	YES
SO_2	24 Hour	9.1	300	79	5	YES
SO_2	Annual	.56	300	5	1	YES

From the table above, NOx and SO2 will require a refined modeling analysis. Predicted CO concentrations will not exceed significant impact concentrations so no further modeling is required.

Pre-construction Monitoring Analysis

A comparison of the preliminary modeling results was compared to the PSD preconstruction monitoring thresholds. The results are shown in the table below.

TABLE 4
Preconstruction Monitoring Analysis

POLLUTANT	TIME AVERAGING PERIOD	PREDICTED IMPACT FROM 1 g/s (ug/m3)	PERMIT EMISSION RATE (ton/year)	PREDICTED IMPACT AT PERMIT EMISSION RATE (ug/m3)	DEMINIMIS LEVEL (ug/m3)	ABOVE DE MINIMIS LEVEL
NO_2	Annual	.56	300	5	14	NO
CO	8 Hour	22.2	150	96	575	NO
SO_2	24 Hour	9.1	300	79	13	YES
Fluorides	24 Hour	9.1	6.0	1.57	.25	YES

NOx and CO did not the trigger the preconstruction monitoring. Lilly can satisfy the one-year preconstruction monitoring requirement for SO2 since there is an existing air quality monitoring data representative of the area. The fluoride monitoring issue is addressed latter in this technical support document.

Background Concentrations

Although these monitors are approximately 97 kilometers from the Lilly, it is thought they are representative of the overall region. EPA's "Ambient Monitoring Guidelines for Prevention of Significant Deterioration" (EPA-450/4-87-007) Section 2.4.1 is cited for approval of the regional monitoring sites for this area. The monitoring results from these monitoring sites are considered conservative. For all 3 hour and 24 hour background concentrations, the averaged second highest monitoring values were used. Annual background concentrations were taken from the maximum annual values. It was agreed between Lilly and IDEM that a conservative approach be taken in place of the preconstruction monitoring requirement.

TABLE 5
Existing Monitoring Data Used For Background Concentrations (1998- 2000)

Pollutant	Monitoring Site	Distance From Site	Averaging Period	Concentration ug/m3
NO2	Naval Avionics, Marion County	97 km	Annual	35.7
SO2	All Four Indianapolis Sites	97 km	3 Hour	154.5
SO2	All Four Indianapolis	97 km	24 Hour	49.7

	Sites			
SO2	All Four Indianapolis Sites	97 km	Annual	13.1

<u>Section D</u>

Ozone formation tends to occur in hot, sunny weather when NOx and VOC emissions photochemically react to form ozone. Many factors such as light winds, hot temperatures and sunlight are necessary for higher ozone production

OAQ Ozone Analysis

OAQ incorporates a three-tiered approach in evaluating ozone impacts from a single source. The first step is to determine how VOC emissions from the new source compares to area-wide VOC emissions from Tippecanoe County. Results from this analysis show Lilly's 300 tons per year of VOC would comprise 2% of the area-wide VOC emissions from point, area, onroad and nonroad mobile source and biogenic (naturally-occurring emissions from trees, grass and plants) emissions. For NOx, the 300 tons per year would comprise 1.7% of the area-wide NOx emissions.

A second step is to review historical monitored data to determine ozone trends for an area. The nearest ozone monitor within the facility is a Marion County monitor. The highest design value (1999-2001) for the Marion County monitor for the 1-hour ozone standard is 103 parts per billion (ppb). Tippecanoe County has no ozone monitors.

A third step in evaluating the ozone impacts from a single source is to estimate the source individual impact through a screening procedure. The Reactive Plume Model-IV (RPM-IV) has been used in past air quality reviews to determine 1-hour ozone impacts from single VOC/NOx source emissions. RPM-IV is listed as an alternative model in Appendix B to the 40 Code of Federal Register Part 51, Appendix W A Guideline on Air Quality Models. The model is unable to simulate all meteorological and chemistry conditions present during an ozone episode (period of days when ozone concentrations are high). Results from RPM-IV are an estimation of potential ozone impacts. Modeling for 1-hour ozone concentrations was conducted for a typical high ozone day to compare to the ozone National Ambient Air Quality Standard (NAAQS) limit. The maximum cell concentration of ozone for each time and distance specified was used to compare to the ambient ozone. OAQ modeling results are shown in Table 6 below. The impact (difference between the plume-injected and ambient modes) from Lilly was 1.0 ppb. All ambient plus plume-injected modes were below the NAAQS limit for ozone at every time period and every distance. No modeled 1-hour NAAQS violations of ozone occurred.

The most current available Indiana meteorological data used is 1994. The meteorological conditions chosen are conducive to ozone formation. Since RPM-IV is used as screening model, the meteorological conditions are not specific to a locality but are more regional in nature. These meteorological conditions can occur at any given location in the state.

It is assumed that all VOCs and NOx emissions come from the one stack, since RPM-IV is used as a screening tool. The OAQ had to adjust the initial concentrations to obtain a 120 ppb ambient ozone concentration. The RPM-IV modeling results are shown in Table 6.

TABLE 6
NAAQS Analysis for Ozone

SIMULATION TIME	DISTANCE	AMBIENT MODE SIMULATION	PLUME INJECTED SIMULATION	DIFFERENCE PLUME - AMBIENT
(minutes)	(meters)	(ppb)	(ppb)	(ppb)
0	100	28	28	0.0
60	7120	49.5	49.0	0.5
120	13100	68.1	67.1	1.0
180	19700	84.4	84.4	0.0
240	26700	98.1	98.0	0.1
300	32600	109	108	1.0
360	40200	114	115	-1
420	51600	116	118	-2
480	63600	117	119	-2
540	81100	117	119	-2
600	101000	116	120	-4
660	115000	116	120	-4
720	126000	116	120	-4

All ambient plus plume injected modes are below the NAAQS limit for every time period and every distance. The proposed impact is less than 3ppb and will not violate the NAAQS standard of 120 ppb for O_3. Since no modeled NAAQS violations occurred, further modeling for O_3 impacts from this source is not required.

NAAQS Compliance Analysis and Results

IDEM supplied emission inventories of NOx and SO2 sources within a 50-kilometer radius of Lilly to ERM.

NAAQS modeling for the second highest 3 hour, 24 hour and highest annual concentrations for SO2 and

NOx was conducted and compared to the respective NAAQs limit. OAQ modeling results are shown in Table 7. All maximum modeled concentrations of the NOx and SO2 was conducted and compared to the respective NAAQS limit. All maximum-modeled concentrations during the five years were below the NAAQS limits and further modeling was not required.

TABLE 7
NAAQS Analysis

Pollutant	**Year**	**Time-Averaging Period**	**Maximum Concentration ug/m3**	**Background Concentration ug/m3**	**Total ug/m3**	**NAAQS Limit ug/m3**
NOx	1992	Annual	9.5 (1992)	35.7	45.2	100
SO2	1990	Annual	22.9 (1992)	13.1	36	80
SO2	1992	3 hour	787.2 (1992)	154.5	941.7	1300
SO2	1193	24 hour	297.9 (1993)	49.7	347.6	365

Analysis and Results of Source Impact on the PSD Increment

Maximum allowable increases (PSD increments) are established by 326 IAC 2-2 for NOx and SO2. This rule also limits a source to no more than 80 percent of the available PSD increment to allow for future growth. Since the impacts for NOx and SO2 from Lilly modeled above significant impact levels, a PSD increment analysis for the existing major sources in Tippecanoe County and its surrounding counties was required. Results of the NOx increment modeling are summarized in Table 8 below.

TABLE 8
NOx Increment Analysis

Pollutant	**Year**	**Time-Averaging Period**	**Maximum Concentration ug/m3**	**PSD Increment ug/m3**	**Percent Impact on the PSD Increment**
NOx	1994	Annual	17	20	68%

Results of the SO2 increment modeling are summarized in Table 9 below.

TABLE 9
SO2 Increment Analysis

Pollutant	**Year**	**Time-Averaging Period**	**Maximum Concentration**	**PSD Increment Ug/m3**	**Percent Impact on the PSD Increment**

			ug/m3		
SO2	1990	3 hour	208.6	512	41%
SO2	1994	24 hour	77.4	91	85.1%
SO2	1993	Annual	10.9	20	55%

The results for the 3-hour and annual averaging period demonstrate the modeled results do not exceed 80% of the available increment. No further modeling is necessary for those time averaging periods. However, one or more values for the 24-hour time averaging period for SO2 is above the 80% available increment. A more detailed analysis was performed to verify that the predicted impact from Lilly does not exceed 80% of the available increment.

An example of the process is provided below:

1. In 1990, one receptor was identified with a high second high concentration that was above 72.8 ug/m3 (80% of available increment). This receptor had a predicted high second high concentration of 73.6 ug/m3.
2. The predicted impact at this receptor was evaluated in order to determine the contribution from the T49 stack and the concentration from all other sources. This showed that the contribution from all other sources was 50 ug/m3.
3. Based on the impact from other sources, the increment available was computed by subtracting the other source impact from the total allowable impact of 91ug/m3 and multiplying the result by 0.8. For this receptor, the available increment was computed to be 32.8 ug/m3 [(91-50)*80].
4. The available increment was then compared to the concentration contributed by T49 stack to assure that the available increment was not consumed. In this case, the T49 concentration was 23.6 ug/m3, which is within the available increment of 32.8.

This process was repeated for every receptor over 72.8 ug/m3. The results of this analysis are shown in Table 10 below. All T49 stack modeled impacts were shown to be below the available increment for each receptor of concern.

TABLE 10
SO2 Increment Analysis

Year	Total Conc. ug/m3	Rank	Increment Consumed by other sources	Available increment	T49 Stack concentration ug/m3
1990	73.6	H2H	50.0	32.7	23.6
1991	75.5	H2H	54.9	28.8	20.6
1991	73.1	H2H	48.4	34.0	24.6
1991	72.9	H3H	71.9	15.2	1.0
1992	74.8	H2H	46.2	35.8	28.6
1993	74.1	H2H	34.1	45.5	40.0
1993	73.8	H2H	46.5	35.5	27.3
1994	77.5	H2H	65.1	20.6	12.3
1994	74.9	H2H	37.2	43.0	37.6
1994	73.1	H2H	47.5	34.8	25.6
1994	72.9	H3H	61.7	23.3	11.1

Fluoride Analysis

As an alternative to preconstruction monitoring for ambient fluoride concentrations, Lilly performed an area wide assessment of predicted fluoride concentrations in the vicinity of the plant. The purpose of this analysis is to evaluate whether fluoride concentrations around the Lilly facility may cause adverse impacts.

Although the preliminary modeling results showed that fluoride concentrations would exceed the preconstruction monitoring trigger of .25 ug/m3, EPA guidelines show that monitoring for non-criteria pollutants such as fluorides should not be required. The Ambient Monitoring Guidelines for Prevention of Significant Deterioration [EPA 450/4-87-007, May 1987] states that as a general rule, modeling impacts are preferred and ambient monitoring for non-criteria pollutants, such as fluorides, should not be required. More recent guidance from EPA, including the 1990 New Source Review Workshop Manual, reiterates this guidance. There are no ambient air quality standards for fluorides in Indiana.

In order to account for Hydrofluoric Acid reactivity, ISCST3 options were selected to implement dry deposition within the model. Dry deposition of particles can basically be thought of as similar to dust collecting on a table. The deposition velocity used in ISCST3 was set at a value of 3.1 cm/s, as documented in the publication "Meteorology and Atomic Energy (1984), Chapter 12, Deposition and Resuspension, by George A. Sehmel, Table 12-5.

Lilly reviewed other state rules in order to identify criteria with which to analyze area wide modeling results. Lilly focused its analysis on 24-hour standards found in the other states' rules. New York State had the most conservative standard surveyed. There standard was 2.85 ug/m3 for a 24 hour time averaging period. OAQ performed modeling based on the above assumptions. The results are listed in the Table 11 below.

TABLE 11
Fluoride Analysis

Averaging Period	Predicted Concentration ug/m3	NY Acceptable Concentration
24 hour	1.77	2.85

Based on these results, fluoride concentrations in the vicinity of the Tippecanoe Plant are not anticipated to exceed acceptable concentrations.

Part E

Hazardous Air Pollutants Analysis and Results

The OAQ presently requests data concerning the emission of 189 HAPs listed in the 1990 Clean Air Act Amendments (CAAA) which 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 Y. Any HAP emissions are subject to modeling analysis.

As a precautionary measure, OAQ modeled the toxics using ISCST3 and compared the maximum-modeled 8-hour concentration with the .5% Permissible Exposure Limit (PEL) value and the National Air Toxic Assessment/ Cumulative Exposure Project (NATA/CEP) annual benchmarks. The maximum-modeled concentrations are shown in Table 12 in the back of this technical support document.

OAQ adjusted Lilly's modeling to account for some downwash at the T49 and the Kiln. OAQ used ERM's downwash files for consistency.

None of the HAPs exceed 0.5% of the PEL. Five HAPs exceeded the NATA/CEP benchmarks.

Part F

Economic Growth and Impact of Construction 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 soils, vegetation, and visibility caused by any increase in emissions of any regulated pollutant from the source. The Lilly PSD permit application provided an additional impact analysis performed by ERM.

Economic Growth

Primarily existing residents in the Lafayette area will fill these positions. No appreciable increase in emissions is expected as a result of any growth, which might be associated with the proposed project.

Soils Analysis

Secondary NAAQS limits were established to protect general welfare, which includes soils, vegetation, animals and crops. Soil types in Tippecanoe County are of the Loamy Glacial Till, Moderate Thick Loess Over Loamy Glacial Till, and Thin Loess Over Loamy Glacial Till. The general landscape consists of flat to gently rolling terrain (1816-1966 Natural Features of Indiana - Indiana Academy of Science). According to the modeled concentrations of VOC and HAPs analysis, the soils will not be adversely affected by the facility.

Vegetation Analysis

Due to the agricultural nature of the land, crops in the Tippecanoe County area consist mainly of corn, wheat and soybeans (1997 Agricultural Census for Tippecanoe County). The maximum modeled concentrations for Lilly are well below the threshold limits necessary to have adverse impacts on surrounding vegetation such as autumn bent, nimblewill, barnyard grass, bishopscap and horsetail milkweed (Flora of Indiana - Charles Deam). Livestock in Tippecanoe County consist mainly of hogs, beef and milk cows (1992 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

Federally endangered or threatened species as listed in the U.S. Fish and Wildlife Service, Division of Endangered Species for Indiana includes 12 species of mussels, 4 species of birds, 2 species of bat and butterflies and 1 species of snake. The agricultural nature of the land overall has disturbed the habitats of the butterflies and snake and the proposed facility is not expected to impact the area further. The mussels and birds listed are commonly found along major rivers and lakes while the bats are found near caves. A detailed listing of Federal and State endangered species for Indiana can be found on the internet at www.in.gov/dnr/naturepr/species/. The impacts from Lilly's facility are not expected to adversely impact these species.

Federally endangered or threatened plants as listed in the U.S. Fish and Wildlife Service, Division of Endangered Species for Indiana list two threatened and one endangered species of plants. The endangered plant is found along the sand dunes in northern Indiana while the two threatened species do not thrive on cultivated or grazing land. The proposed facility is not expected to impact the area further.

The state of Indiana list of endangered, special concern and extirpated nongame species, as listed in the Department of Natural Resources, Division of Fish and Wildlife, contains species of birds, amphibians, fish, mammals, mollusks and reptiles which may be found in the area. However, the impacts are not expected to have any additional adverse effects on the habitats of the species than what has already occurred from the agricultural activity in the area.

Additional Analysis Conclusions

The nearest Class I area to the electric cogeneration facility is Mammoth Cave National Park located approximately 355 km to the south in Kentucky well outside the 100 km Class I range.

Finally, the results of the additional impact analysis conclude the operation of the Eli Lilly will have no significant impact on economic growth, soils, vegetation or visibility in the immediate vicinity or on any Class I area.

Part G

Summary of Air Quality Analysis

Eli Lilly and Company (Lilly) in Lafayette, Indiana (Tippecanoe Plant) has applied for a flexible operating permit under the guidance provided by USEPA. As a result of emission limits desired under the flexible permit, Lilly is required to perform an air quality analysis under the Federal and State PSD regulations. Environmental Resources Management of Carmel, Indiana prepared the PSD application. Tippecanoe County is designated as attainment for all criteria pollutants. SO_2, NO_2, VOC, and CO emission rates associated with the facility exceeded the respective significant emission rates. RPM-IV modeling results showed no significant impact to ozone formation. Modeling results showed SO_2 and NO_2 impacts were predicted to be greater than the significant impact levels. Refined modeling was required. Preconstruction monitoring for SO2 can be satisfied with existing air quality monitoring. The NO2 and SO2 NAAQS and increment analysis showed the facility below the standards. The RPM IV results show no significant impact to ozone formation. The preliminary modeling results showed the fluoride concentration to exceed the preconstruction monitoring trigger but the values are less than most states acceptable levels. An air toxic analysis was preformed as a precautionary measure and no modeled concentrations were above the 0.5% of PEL but some HAPs were above the NATA/CEP benchmark. The nearest Class I area is Mammoth Cave National Park in Kentucky 355 kilometers away from the source. Additional impact analysis showed no significant impact on economic growth, soils, vegetation or visibility in the areas surrounding the facility.

	Emissions			Comparison to IDEM benchmarks			Comparison to OSHA PELs					Results	
Chemical	**Potential BPM/BPM support point source emissions (lbs/yr) (RTO,T79, Other Point)**	**Potential BPM/BPM support fugitive emissions (lbs/yr)**	**Potential incinerator point source emissions (lbs/yr) (T49, Klin)**	**Lilly Maximum offsite concentration - annual average (ug/m3)**	**Maximum concentration adjusted based on OAQ Modeling**	**NATA/CEP carcinogen benchmark (ug/m3)**	**Lilly Maximum offsite concentration - 8-hour average (ug/m3)**	**Maximum concentration adjusted based on OAQ Modeling**	**OSHA (or ACGIH) 8 hour TWA PEL (ug/m3)**	**Maximum 8 hour concentration as a % of the 8 hour PEL For Lilly Modeling**	**Maximum 8 hour concentration as a % of the 8 hour PEL For OAQ Modeling**	**Predicted ambient concentration less than the PEL benchmark**	**Predicted ambient concentration less than the carcinogenic benchmark**
HAPs emitted primarily by BPM/BPM support													
Acetonitrile	149	6,095	49.5	0.83000	0.84227		43.65000	44.11691	70,000	0.06%	0.06%	Yes	
Acetophenone	1	1		0.00000	0.00000		0.01000	0.01000	49,041	0.00%	0.00%		
Benzene*	1	0	4.4	0.00000	0.00000	0.13000	0.00000	0.00000	3,200	0.00%	0.00%	Yes	Yes
Benzyl chloride*	17	67		0.01000	0.01000	0.02000	0.51000	0.51000	5,000	0.01%	0.01%		Yes
Chlorine	2,960	16		0.02000	0.02000		1.18000	1.18000	3,000	0.04%	0.04%	Yes	
Chlorobenzene	0	0	0.3	0.00000	0.00000		0.00000	0.00000	350,000	0.00%	0.00%	Yes	
Chloroform*	182	1,748	20.4	0.24000	0.24472	0.04300	12.61000	12.78937	240,000	0.01%	0.01%	Yes	No
Dimethylformamide	619	619		0.11000	0.11000		5.76000	5.76000	30,000	0.02%	0.02%	Yes	
Ethylbenzene	216	957	0.042	0.14000	0.14001		7.28000	7.28035	435,000	0.00%	0.00%	Yes	
Ethylene dichloride*	576	432	1.2	0.08000	0.08018	0.03800	4.32000	4.32699	200,000	0.00%	0.00%	Yes	No
Ethylene glycol	0	5,265		0.71000	0.71000		37.49000	37.49000	125,000	0.03%	0.03%	Yes	
Ethylene glycol dimethyl ether	653	554		0.10000	0.10000		5.37000	5.37000	18,392	0.03%	0.03%	Yes	
Formaldehyde*	9	613	0.021	0.08000	0.08001	0.07700	4.37000	4.37020	930	0.47%	0.47%	Yes	No
Hexane	741	3,853	29	0.54000	0.54637		28.29000	28.53135	1,800,000	0.00%	0.00%	Yes	
Hydrochloric Acid	295	86		0.02000	0.02000		0.79000	0.79000	7,000	0.01%	0.01%	Yes	
Hydrogen Fluoride	1,513	0		0.02000	0.02000		0.96000	0.96000	2,000	0.05%	0.05%	Yes	
Methanol	783	12,111		1.65000	1.65000		86.82000	86.82000	260,000	0.03%	0.03%	Yes	
Methyl chloride*	218	613		0.08000	0.08000	0.56000	4.43000	4.43000	210,000	0.00%	0.00%	Yes	Yes
Methyl Ethyl Ketone	212	847		0.12000	0.12000		6.10000	6.10000	590,000	0.00%	0.00%	Yes	
Methyl tert butyl ether	1,874	493	49.5	0.11000	0.11424		5.87000	6.03353	144,000	0.00%	0.00%	Yes	
Methylene Chloride*	6,543	7,474	37.2	1.12000	1.12557	2.10000	59.05000	59.26257	86,633	0.07%	0.07%	Yes	Yes
Phenol	41	21		0.00000	0.00000		0.24000	0.24000	19,000	0.00%	0.00%	Yes	
Triethylamine	1,159	2,460		0.38000	0.38000		20.05000	20.05000	100,000	0.02%	0.02%	Yes	
Toluene	1,734	3,264	5.6	0.50000	0.50105		26.49000	26.53032	750,000	0.00%	0.00%	Yes	
Xylene	36	301		0.04000	0.04000		2.18000	2.18000	435,000	0.00%	0.00%	Yes	
HAP Compounds emitted primarily by incinerators													
Metals	Highlighted emissions included in calculations above												
Mercury (Hg+2)			20.94	0.00013	0.00037		0.00670	0.01581	100	0.01%	0.02%	Yes	
Mercury (Hg0)			0.09	0.00000	0.00000		0.00003	0.00007	100	0.00%	0.00%	Yes	
Antimony			5.25	0.00002	0.00005		0.00099	0.00234	500	0.00%	0.00%	Yes	
Arsenic			79.05	0.00048	0.00065	0.00023	0.02500	0.03402	10	0.25%	0.34%	Yes	No
Beryllium			4.45	0.00003	0.00008	0.00042	0.00140	0.00330	2	0.07%	0.17%	Yes	Yes
Cadmium			17.2	0.00013	0.00037	0.00056	0.00680	0.01605	5	0.14%	0.32%	Yes	Yes
Chromium (Hexavalent)			5.65	0.00003	0.00009		0.00150	0.00354		0.00%		Yes	
Chromium (Total)			56.47	0.00030	0.00086	0.00008	0.01500	0.03540	500	0.00%	0.01%	Yes	No
Lead	0.12	0	168.31	0.00110	0.00317	0.08300	0.06000	0.14154	50	0.12%	0.28%	Yes	Yes
Nickel			7.97	0.00003	0.00008	0.00380	0.00140	0.00330	1,000	0.00%	0.00%	Yes	Yes
Selenium			0.81	0.00000	0.00001		0.00019	0.00045	200	0.00%	0.00%	Yes	
Dioxins and Furans													
TCDD (2,3,7,8-)	1.28E-04	0	3.10E-04	0.00000	0.00000	0.00000	0.00000	0.00000		0.00%	0.00%		Yes
PeCDD (1,2,3,7,8-)			1.10E-04	0.00000	0.00000		0.00000	0.00000		0.00%	0.00%		
HxCDD (1,2,3,4,7,8-)			1.69E-04	0.00000	0.00000		0.00000	0.00000		0.00%	0.00%		
HxCDD (1,2,3,6,7,8-)			1.61E-04	0.00000	0.00000		0.00000	0.00000		0.00%	0.00%		
HxCDD (1,2,3,7,8,9-)			1.61E-04	0.00000	0.00000		0.00000	0.00000		0.00%	0.00%		
HpCDD (1,2,3,4,6,7,8-)			4.03E-04	0.00000	0.00000		0.00000	0.00000		0.00%	0.00%		
OCDD (1,2,3,4,6,7,8,9-)			5.83E-04	0.00000	0.00000		0.00000	0.00000		0.00%	0.00%		
TCDF (2,3,7,8-)			9.77E-05	0.00000	0.00000		0.00000	0.00000		0.00%	0.00%		
PeCDF (1,2,3,7,8-)			7.17E-05	0.00000	0.00000		0.00000	0.00000		0.00%	0.00%		
PeCDF (2,3,4,7,8-)			1.02E-04	0.00000	0.00000		0.00000	0.00000		0.00%	0.00%		
HxCDF (1,2,3,4,7,8-)			3.99E-04	0.00000	0.00000		0.00000	0.00000		0.00%	0.00%		
HxCDF (1,2,3,6,7,8-)			2.21E-04	0.00000	0.00000		0.00000	0.00000		0.00%	0.00%		
HxCDF (1,2,3,7,8,9-)			1.02E-04	0.00000	0.00000		0.00000	0.00000		0.00%	0.00%		
HxCDF (2,3,4,6,7,8-)			1.65E-04	0.00000	0.00000		0.00000	0.00000		0.00%	0.00%		
HpCDF (1,2,3,4,7,8,9-)			1.95E-04	0.00000	0.00000		0.00000	0.00000		0.00%	0.00%		
HpCDF (1,2,3,4,6,7,8-)			4.29E-04	0.00000	0.00000		0.00000	0.00000		0.00%	0.00%		
OCDF (1,2,3,4,6,7,8,9-)			3.81E-04	0.00000	0.00000		0.00000	0.00000		0.00%	0.00%		
Polycyclic Organic Matter													
Benzo(a)pyrene			0.1	0.00000	0.00000	0.00091	0.00003	0.00008		0.00%	0.00%		Yes
Benzo(a)anthracene			0.11	0.00000	0.00000	0.00910	0.00003	0.00008		0.00%	0.00%		Yes
Benzo(b)fluoranthene			0.09	0.00000	0.00000	0.00910	0.00003	0.00006		0.00%	0.00%		Yes
Benzo(k)fluoranthene			0.1	0.00000	0.00000	0.00910	0.00003	0.00007		0.00%	0.00%		Yes
Chrysene			0.06	0.00000	0.00000	0.09100	0.00002	0.00004		0.00%	0.00%		Yes
Dibenzo(a,h)anthracene			0.1	0.00000	0.00000	0.00083	0.00003	0.00007		0.00%	0.00%		Yes
Indeno(1,2,3-cd)pyrene			0.08	0.00000	0.00000	0.00910	0.00002	0.00005		0.00%	0.00%		Yes

Other HAPs												
Acetaldehyde		0.04	0.00000	0.00000	0.45000	0.00001	0.00003	360,000	0.00%	0.00%	Yes	Yes
Acetonitrile	Emissions included above	49.46	0.00030	0.00086		0.01600	0.03776	70,000	0.00%	0.00%	Yes	
Acrolein		0	0.00000			0.00000		250	0.00%	0.00%	Yes	
Acrylonitrile		5.91	0.00004	0.00010	0.01500	0.00190	0.00448	4,320	0.00%	0.00%	Yes	Yes
Aroclor 1254		0.55	0.00000	0.00001	0.00910	0.00017	0.00040		0.00%	0.00%		Yes
Benzene	Emissions included above	4.38	0.00003	0.00007		0.00140	0.00330	3,200	0.00%	0.00%	Yes	Yes
Benzidine		0	0.00000		0.00002	0.00000			0.00%	0.00%	Yes	Yes
Bromoform		168.93	0.00110	0.00317	0.91000	0.05800	0.13688	5,000	0.00%	0.00%		Yes
Butadiene (1,3-)		29.04	0.00018	0.00052	0.10000	0.00920	0.02171	2,200,000	0.00%	0.00%	Yes	Yes
Butanone (2-) (MEK)		0.29	0.00000	0.00000		0.00007	0.00017	590,000	0.00%	0.00%	Yes	
Carbon disulfide		0.1	0.00000	0.00000		0.00003	0.00008	60,000	0.00%	0.00%	Yes	
Carbon tetrachloride		0.52	0.00000	0.00001	0.06700	0.00018	0.00042	65,000	0.00%	0.00%	Yes	Yes
Chlordane		0.02	0.00000	0.00000	0.01000	0.00001	0.00002	500	0.00%	0.00%	Yes	Yes
Chloroacetophenone (2-)		38.76	0.00023	0.00066		0.01200	0.02832	300	0.00%	0.01%	Yes	
Chlorobenzene	Emissions included above	0.27	0.00000	0.00000	0.01300	0.00008	0.00018	350,000	0.00%	0.00%	Yes	Yes
Chlorobenzilate		77.52	0.00047	0.00135	0.01300	0.02500	0.05900		0.00%	0.00%		Yes
Chloroform	Emissions included above	20.35	0.00011	0.00032	0.04300	0.00600	0.01416	240,000	0.00%	0.00%	Yes	Yes
Cumene		19.38	0.00012	0.00035		0.00620	0.01463	245,000	0.00%	0.00%	Yes	
Dichlorobenzene (1,4-)		0.34	0.00000	0.00001	0.09100	0.00010	0.00024	450,000	0.00%	0.00%	Yes	Yes
Dichlorobenzidine (3,3'-)		0.3	0.00000	0.00001	0.00290	0.00009	0.00022		0.00%	0.00%		Yes
Dichloroethane (1,2-)	Emissions included above	1.2	0.00000	0.00001	0.03800	0.00020	0.00047	200,000	0.00%	0.00%	Yes	Yes
Dichloropropene (1,3-)		0.05	0.00000	0.00000	0.25000	0.00001	0.00003	4,531	0.00%	0.00%	Yes	Yes
Dichloropropene (cis-1,3-)		0.05	0.00000	0.00000	0.25000	0.00001	0.00003	4,531	0.00%	0.00%	Yes	Yes
Dichloropropene (trans-1,3-)		0.05	0.00000	0.00000	0.25000	0.00001	0.00003	4,531	0.00%	0.00%	Yes	Yes
Dinitrotoluene (2,4-)		0.73	0.00000	0.00001	0.01100	0.00022	0.00052	1,500	0.00%	0.00%	Yes	Yes
Ethylbenzene	Emissions included above	0.04	0.00000	0.00000		0.00001	0.00003	435,000	0.00%	0.00%	Yes	
Ethylene dibromide		39.73	0.00024	0.00069	0.00450	0.01300	0.03068	190,000	0.00%	0.00%	Yes	Yes
Ethylene oxide		0	0.00000		0.01100	0.00000		1,800	0.00%	0.00%	Yes	Yes
Formaldehyde	Emissions included above	0.02	0.00000	0.00000	0.07700	0.00001	0.00002	930	0.00%	0.00%	Yes	Yes
Hexachlorobenzene		0.63	0.00000	0.00001	0.02200	0.00019	0.00045	2	0.00%	0.02%	Yes	Yes
Hexachlorobutadiene		0.66	0.00000	0.00001	0.04500	0.00020	0.00047	240	0.00%	0.00%	Yes	Yes
Hexachlorocyclohexane (alpha-)		0.04	0.00000	0.00000	0.00056	0.00001	0.00003		0.00%	0.00%	Yes	Yes
Hexachlorocyclohexane (beta-)		0.04	0.00000	0.00000	0.00190	0.00001	0.00003		0.00%	0.00%	Yes	Yes
Hexachlorocyclopentadiene		0.61	0.00000	0.00001		0.00018	0.00042	111	0.00%	0.00%	Yes	
Hexane (n-)	Emissions included above	29.04	0.00018	0.00052		0.00920	0.02171	180,000	0.00%	0.00%	Yes	
Methyl isobutyl ketone		0.09	0.00000	0.00000		0.00002	0.00004	410,000	0.00%	0.00%	Yes	
Methy tert-butyl ether (MTBE)	Emissions included above	49.46	0.00030	0.00086		0.01600	0.03776	143,951	0.00%	0.00%	Yes	
Methylene chloride	Emissions included above	37.16	0.00020	0.00058		0.01000	0.02360	86,633	0.00%	0.00%	Yes	
Naphthalene		2.81	0.00002	0.00005		0.00094	0.00222	50,000	0.00%	0.00%	Yes	
Nitrobenzene		0.35	0.00000	0.00001		0.00011	0.00026	5,000	0.00%	0.00%	Yes	
Pentachloronitrobenzene		15.53	0.00009	0.00027	0.01400	0.00490	0.01156	500	0.00%	0.00%		Yes
Pentachlorophenol		1	0.00001	0.00002	0.20000	0.00030	0.00071	500	0.00%	0.00%	Yes	Yes
Styrene		0.21	0.00000	0.00000		0.00004	0.00009	420,000	0.00%	0.00%	Yes	
Toluene	Emissions included above	5.65	0.00004	0.00010		0.00190	0.00448	750,000	0.00%	0.00%	Yes	
Trichlorobenzene (1,2,4-)		0.37	0.00000	0.00001		0.00011	0.00026	37,000	0.00%	0.00%	Yes	
Trichloroethane (1,1,2-)		17.53	0.00005	0.00015	0.06300	0.00270	0.00637	45,000	0.00%	0.00%	Yes	Yes
Trichloroethene		0.25	0.00000	0.00000	0.50000	0.00009	0.00021	535,000	0.00%	0.00%	Yes	Yes
Trichlorophenol (2,4,6-)		0.61	0.00000	0.00001	0.03200	0.00019	0.00045		0.00%	0.00%		Yes
Vinyl acetate		0.05	0.00000	0.00000		0.00001	0.00003	30,000	0.00%	0.00%	Yes	
Vinyl chloride		0.5	0.00000	0.00000	0.11000	0.00008	0.00020	2,600	0.00%	0.00%	Yes	Yes