Indiana Department of Environmental Management
Office of Air Quality

Technical Support Document (TSD) for a combined Prevention of Significant Deterioration (PSD) Flexible Permit and Part 70 Operating Permit

Source Background and Description

Source Name:	**Eli Lilly and Company – Tippecanoe Laboratories**
Source Location:	**1650 Lilly Road, Lafayette, IN, 47909**
County:	**Tippecanoe**
SIC Code:	**2833 and 2834**
Operation Permit No.:	**T157-6879-00006**
Permit Reviewer:	**Dr. Trip Sinha**

The Office of Air Quality (OAQ) has reviewed a Part 70 permit application and Prevention of Significant Deterioration (PSD) permit application from Eli Lilly and Company – Tippecanoe Laboratories. The PSD permit application is for the construction, modification, and operation of bulk pharmaceutical manufacturing operations and associated support facilities. The Part 70 permit application addresses the bulk pharmaceutical manufacturing operations and associated support facilities, and fermentation and purification operations, research and development facilities, and associated site support facilities.

Because Tippecanoe Laboratories is a large and complex source, this technical support document describes source-wide emissions information and regulatory requirements and references the reader to a series of appendices containing more detailed information on various aspects of the plant site.

Permitted Emission Units and Pollution Control Equipment

The source consists of the following operating areas that are made up of various types of emission units and pollution control devices. These operating areas correspond to the various “D” sections of the Part 70 permit and are described in more detail in Appendix A of this TSD. Appendix A of this TSD also includes a detailed description of the Leak Detection and Repair (LDAR) program that applies to the emission units and control equipment. The LDAR program requirements correspond to the “E” sections of the Part 70 permit.

(a) Utility operations – The utilities operations consist of three coal-fired boilers equipped with an ash handling system and supported by a coal pile and coal conveyor system, and two natural gas boilers with fuel oil backup supplied by one fuel oil tank. The boilers provide steam to process operations in bulk pharmaceutical manufacturing and fermented products.

(b) Utility support operations – The utility support operations consist of a lime system for the potable water system (T9/T23), glycol tanks for heating and cooling of BPM tanks, and chillers, generators and compressors.

(c) Fermentation product 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).

(d) Fermentation product purification operations – The whole broth from fermentation are continuously fed to the purification operations consisting of extraction and elution equipment located in buildings T3 and T40. Products are stored in Building T39. Solvents used in the purification processes are stored in tank module T147 and recovered in the T4 solvent recovery operation.

(e) Fermentation product support operations – The support operations for the Fermented Products (FP) area consists of the FP wastewater treatment plant and FP wastewater sludge storage operations.

(f) Bulk pharmaceutical manufacturing (BPM) process operations – The bulk pharmaceutical manufacturing component of Tippecanoe Labs includes Buildings T27, T28, T29, T31/31A, T99, and T100. Pharmaceutical products are manufactured by chemical synthesis in bulk scale in all of these buildings. Typical production equipment includes process vessels (tanks), centrifuges and dryers. Depending on the process, production facilities may also utilize process condensers and/or process scrubbers. The exhaust streams from the process equipment are vented to the RTO system for control of emissions.

(g) BPM storage tanks – Solvents used as raw material in BPM, used solvents to be recovered in solvent recovery, and waste solvents generated in BPM are stored in several storage tank modules. The modules are identified as T140, T142, T143, T145 and T146. The exhaust streams from the storage tanks are vented to either the T79 fume incinerators or RTOs for control of VOC and VOHAP emissions.

(h) Waste containers – Waste containers from the BPM operations or waste containers from other Lilly facilities consist of any portable container with a capacity greater than or equal to 0.1 cubic meters (26.4 gallons) used to convey, store, treat, or dispose of affected waste streams or residuals. Waste containers are located in the BPM process operation buildings as well as the T149 container storage building.

(i) BPM individual drain system – The individual drain systems are stationary systems, such as sumps, process drains and lift stations, used to convey affected wastewater streams or residuals to a waste management unit in the BPM operating areas. The exhaust streams from the BPM individual drain systems are vented to the RTO system for control of VOC and VOHAP emissions.

(j) BPM solvent recovery - Solvent Recovery occurs in buildings T19, T52, and T61. This department recovers used solvent collected from the BPM production buildings for recycling and reuse. The types of equipment used to recover solvents consist of distillation columns, evaporators, steam strippers, wash columns, and receivers (tanks).

(k) Waste incinerators – Liquid solvent waste generated on site and at other Lilly sites is burned in the T49 Trane incinerator. A rotary kiln incinerator (RKI) is currently under construction and will be capable of burning both liquid and solid wastes generated on site and at other Lilly sites.

(l) BPM Regenerative Thermal Oxidizers (RTO) general description – Emissions from the BPM process operations and some of the BPM storage tanks are routed to a common regenerative thermal oxidizer (RTO) system. The site has two co-located RTOs that typically operate at alternative times. The RTOs are equipped with caustic scrubbing systems to remove acid gases. The RTOs reduce CO, VOC, and organic HAP emissions, while the scrubbers remove acid gases such as SO2, hydrogen chloride (HCl) and hydrogen fluoride (HF).

(m) BPM T79 fume incinerator – Emissions from the BPM solvent recovery operations and some of the BPM storage tanks are routed to the T79 fume incinerator system. The site maintains two identical T79 fume incinerators that typically operate at alternate times. The T79 incinerators are equipped with caustic scrubbing systems to remove acid gases.

(n) BPM wastewater treatment plant – Wastewater generated by BPM production may be voluntarily pretreated by the T79 wastewater treatment system before it is transferred to the BPM wastewater treatment plant. The T79 wastewater treatment system consists of equalization tanks, a neutralization tank, and air stripper columns. The exhaust stream from the equalization tanks and air stripper columns is vented to the T79 fume incinerators for control of VOC and VOHAP emissions.

(o) BPM fugitive emissions – BPM equipment components such as pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves lines, valves, connectors, instrumentation systems, control devices, and closed-vent systems may generate fugitive emissions. These fugitive emissions are minimized through the use of a Leak Detection And Repair (LDAR) program.

Emission Units and Pollution Control Devices Identified Through the Title V Compliance Transition Program

This TSD describes facilities and emission units in this operating area 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]. Those facilities and emission units are listed in the specific sections of this TSD relating to individual operating areas.

New Emission Units and Pollution Control Equipment Receiving Advanced Source Modification Approval

Tippecanoe Laboratories has proposed to modify the Bulk Pharmaceutical Manufacturing operations and supporting areas through a series of product and process changes, equipment changes, equipment replacement, and new equipment. The actual nature of these changes is not specifically defined, but fall into the categories of changes described in Appendix B. The applicable requirements for these changes, including Best Available Control Technology, have been defined in the permit and will apply through the advance approval procedures described in 326 IAC 2-7-6(16).

This permit serves as advance source modification approval, pursuant to 326 IAC 2-2 and 326 IAC 2-7-5(16), of the types of modifications and facilities as described in Section F1.

Insignificant Activities Not Associated with Specific Operating Areas

Most insignificant activities are noted in the specific sections of the TSD relating to an individual operating area. The source also consists of the following insignificant activities, as defined in 326 IAC 2-7-1(21), not otherwise listed in specific sections of this TSD:

(a) Natural gas-fired combustion sources with heat input equal to or less than ten (10) million Btu per hour;

(b) Propane or liquefied petroleum gas, or butane-fired combustion sources with heat input equal to or less than six (6) million (6,000,000) Btu per hour;

(c) Equipment powered by internal combustion engines of capacity equal to or less than 500,000 Btu/hour, except where total capacity of equipment operated by one stationary source exceeds 2,000,000 Btu/hour;

(d) A gasoline fuel transfer and dispensing operation handling less than or equal to 1,300 gallons per day, such as filling of tanks, locomotives, automobiles, having a storage capacity less than or equal to 10,500 gallons.

(e) A petroleum fuel, other than gasoline, dispensing facility, having a storage capacity of less than or equal to 10,500 gallons, and dispensing less than or equal to 230,000 gallons per month;

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

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

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

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

(j) Degreasing operations that do not exceed 145 gallons per 12 months; except if subject to 326 IAC 20-6;

(k) Cleaners and solvents with a combined use less than or equal to 145 gallons per 12 months characterized having a vapor pressure equal to or less than 2 kPa, 15 mm Hg, or 0.3 psi measured at 38C (100F); or having a vapor pressure equal to or less than 0.7 kPa, 5 mmHg, or 0.1 psi measured at 20C (68F).

(l) Closed loop heating and cooling systems;

(m) Structural and bridge fabrication activities including cutting 200,000 linear feet or less of one inch plate or equivalent, or using 80 tons or less of welding consumables;

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

(o) Activities associated with the transportation and treatment of sanitary sewage, provided discharge to the treatment plant is under the control of the owner/operator, that is, an on-site sewage treatment facility;

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

(q) Noncontact cooling tower systems with forced and induced draft cooling tower system not regulated under a NESHAP;

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

(s) Heat exchanger cleaning and repair;

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

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

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

(w) Covered conveyors for coal or coke conveying of less than or equal to 360 tons per day;

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

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

(z) Purging of gas lines and vessels that is related to routine maintenance and repair of buildings, structures, or vehicles at the source where air emissions from those activities would not be associated with any production process;

(aa) Equipment used to collect any material that might be released during a malfunction, process upset, or spill cleanup including catch tanks, temporary liquid separators, tanks and fluid handling equipment;

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

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

(dd) Emergency generators including gasoline generators not exceeding 110 horsepower, diesel generators not exceeding 1600 horsepower; and natural gas turbines or reciprocating engines not exceeding 16,000 horsepower;

(ee) Stationary fire pumps;

(ff) Grinding and machining operations controlled with fabric filters, scrubbers, mist collectors, wet collectors and electrostatic precipitators with a design grain loading of less than or equal to 0.03 grains per actual cubic foot and a gas flow rate less than or equal to 4000 actual cubic feet per minute, including the following: deburring; buffing; polishing; abrasive blasting; pneumatic conveying; and woodworking operations;

(gg) Purge double block and bleed valves;

(hh) Filter or coalescer media changeout;

(ii) Vents from ash transport systems not operated at positive pressure;

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

(kk) Research and development activities defined in 326 IAC 2-7-1(21)(E);

(ll) Farm operations; and

(mm) Activities with emissions equal to or less than thresholds listed in 326 IAC 2-7-1(21)(A)-(C) including:

(1) T100 Unit 1 Drumming Operations;
(2) T99/T100 Solids Particle Sizing Equipment (mills and delumpers);
(3) Portable Cleaning and Collection Tanks;

(4) T4 Sulfuric Acid Tank;
(5) T47 Trash Transfer;
(6) Sump Tanks;
(7) T116 Hydrogen Chloride Storage Tank;
(8) T14 Ranney Well;
(9) T99 Ethylene Glycol Expansion Tank System
(10) Fermentation and Purification Activities; and
(11) T71 Development Engineering Facility.

Existing Approvals

The source has been operating under previous approvals including, but not limited to, operating permits, registrations, construction permits, and source modification approvals. The specific listing of existing approvals and how the conditions in those approvals are incorporated into this permit are described in the various sections of this TSD relating to specific operating areas. Although incorporation of individual terms are discussed in the sections of the TSD specifically relating to an operating, generally the following concepts were followed:

(a) Conditions from operating permits issued pursuant to the now-repealed 326 IAC 2-1-4 are not incorporated into this permit because those conditions are not applicable requirements, as defined by 326 IAC 2-7-1(6).

(b) Conditions from registrations, construction permits, and source modification approvals for areas that will be operating under the flexible permit provisions [Bulk Pharmaceutical Manufacturing, BPM support, and waste incineration] are not incorporated into this permit because those conditions have been replaced by the issuance of the combined Part 70 and PSD permit.

(c) Conditions from registrations, construction permits, and source modification approvals for areas that will not be operating under the flexible permit provisions [Utilities, Fermented Products, and Miscellaneous Operations] were evaluated on a case-by-case basis to determine whether the condition is a relevant and valid applicable requirement. In some cases, conditions from these existing approvals are modified or deleted by this Part 70 permit.

The TSD for each operating area will contain a table or similar discussion that describes the proposed treatment of these conditions

Enforcement Issue

There are no enforcement actions pending.

Recommendation

The staff recommends to the Commissioner that the combined Part 70 permit and PSD permit be approved. This recommendation is based on the following facts and conditions:

Unless otherwise stated, information used in this review was derived from the application and additional information submitted by the applicant.

An administratively complete Part 70 permit application for the purposes of this review was received on October 10, 1996. Various updates to the Part 70 permit application were received between 1997 and 2003. The flexible PSD permit application, which shall be incorporated as part of the Part 70 permit, was received on May 15, 2002. Additional information to this application

was received in 2002 and 2003.

Emission Calculations

The calculation methodologies submitted by the applicant have been verified and found to be accurate and correct. These calculation methodologies can be found in the documentation accompanying the Part 70 permit application for the source.

Potential To Emit

Pursuant to 326 IAC 2-1.1-1(16), Potential to Emit (PTE) is defined as "the maximum capacity of a stationary source to emit any air pollutant under its physical and operational design. Any physical or operational limitation on the capacity of a source to emit an air pollutant, including air pollution control equipment and restrictions on hours of operation or type or amount of material combusted, stored, or processed shall be treated as part of its design if the limitation is enforceable by the U. S. EPA."

This table reflects the PTE of the entire source before controls. Control equipment is not considered federally enforceable until it has been required in a federally enforceable permit.

Pollutant	Potential To Emit (tons/year)
PM	> 100 tpy
PM-10	> 100 tpy
SO_2	>100 tpy
VOC	>100 tpy
CO	>100 tpy
NOx	>100 tpy
Combined HAPs	>25 tpy
Individual HAPs	Several > 10 tpy

Note: For the purpose of determining Title V applicability for particulates, PM-10, not PM, is the regulated pollutant in consideration.

(a) The potential to emit (as defined in 326 IAC 2-1.1-1(16)) of CO, NOx, PM-10, SO2 and VOC are equal to or greater than 100 tons per year. Therefore, the source is subject to the provisions of 326 IAC 2-7.

and

(b) The potential to emit (as defined in 326 IAC 2-1.1-1(16)) of any single HAP is equal to or greater than ten (10) tons per year and the potential to emit (as defined in 326 IAC 2-7-1(29)) of a combination HAPs is greater than or equal to twenty-five (25) tons per year. Therefore, the source is subject to the provisions of 326 IAC 2-7.

and

(c) Fugitive Emissions
Since this type of operation is one of the twenty-eight (28) listed source categories under

326 IAC 2-2, the fugitive emissions are counted toward determination of PSD applicability.

Actual Emissions

The following table shows the actual emissions from the source. This information reflects the 2001 OAQ emission data from the annual emission statement submitted by the source.

Pollutant	Actual Emissions (tons/year)
PM	386.2
PM-10	386.2
SO_2	1589.5
VOC	94.1
CO	182.7
NO_x	377.5
HAP* (specify)	
Chlorine	0.885
Hydrochloric Acid	6.39
Methylene Chloride	5.69

* Report of Billable HAPs Only

Net Emissions Increase Associated with Modification of BPM and BPM support operations

This permit combines the issuance of a Part 70 permit for the entire source and a PSD permit for modifications to the Bulk Pharmaceutical Manufacturing [BPM] area and its supporting operations.

The table below summarizes the net emissions increase calculated pursuant to 326 IAC 2-2.

Pollutant	**Significant net emission increase rate**	**Past actual emissions (1999-2000 avg.)**	**Future potential emissions**	**Net emissions increase**
	(tpy)	**(tpy)**	**(tpy)**	**(tpy)**
Carbon monoxide	100	26.2	150	124
Fluorides	0.3	0.4	6	5.6
Lead	0.6	0.12	0.24	0.12
Nitrogen oxides	40	70.6	300	229
Particulate matter - TSP	25	7.70	<25	7.2
Particulate matter - PM10	15	7.70	<15	7.2
SO2	40	46.3	300	254
VOC	40	92.4	300	207.6
Asbestos	0.007	0.0	<0.007	<0.007
Beryllium	0.0004	0.0	0.00034	<0.0004
Mercury	0.1	0.003	0.02	0.02
Vinyl chloride	1	negligible	negligible	negligible
Sulfuric acid mist	7	0.02	4.0	4.0
Hydrogen sulfide	10	0.32	0.6	0.3
Total reduced sulfur compounds	10	0.32	0.6	0.3
Reduced sulfur compouds	10	negligible	negligible	negligible
MWC organics	3.5×10^{-6}	N/A	N/A	N/A
MWC acid gases	40	N/A	N/A	N/A
MWC metals	15	N/A	N/A	N/A
Landfill gases/non-methane organic compounds	50	N/A	N/A	N/A

Ozone depleting substances	100	4.3	4.3	0

County Attainment Status

The source is located in Tippecanoe County.

Pollutant	Status (attainment, maintenance attainment, or unclassifiable; severe, moderate, or marginal nonattainment)
PM-10	Attainment
SO_2	Attainment
NO_2	Attainment
Ozone	Attainment
CO	Attainment
Lead	Attainment

(a) Volatile organic compounds (VOC) are precursors for the formation of ozone. Therefore, VOC emissions are considered when evaluating the rule applicability relating to the ozone standards. Tippecanoe County has been designated as attainment or unclassifiable for ozone. Therefore, VOC emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2.

(b) Tippecanoe County has been classified as attainment or unclassifiable for CO, lead, NO2, PM10, and SO2. Therefore, these emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2.

(c) Fugitive Emissions
Since this type of operation is one of the twenty-eight (28) listed source categories under 326 IAC 2-2, the fugitive emissions are counted toward determination of PSD applicability.

Part 70 Permit Conditions

This source is subject to the requirements of 326 IAC 2-7, pursuant to which the source has to meet the following:

(a) Emission limitations and standards, including those operational requirements and limitations that assure compliance with all applicable requirements at the time of issuance of Part 70 permits.

(b) Monitoring and related record keeping requirements which assume that all reasonable information is provided to evaluate continuous compliance with the applicable requirements.

Federal Rule Applicability – New Source Performance Standards (NSPS)
[40 CFR Part 60 and 326 IAC 12]

(a) **NSPS applicable to source:**

(1) **Subpart A – General Provisions:** The provisions of 40 CFR 60, Subpart A apply to the facilities described in item (2) below except when otherwise specified in the relevant Subpart.

(2) **Subpart Kb – Solvent Storage Tanks:** This source is subject to 40 CFR Part 60, Subpart Kb, which applies to solvent storage tanks. The specific applicability of this NSPS and the requirements incorporated into this permit are discussed in the relevant portions of this TSD.

(b) **NSPS not applicable to source:** IDEM has determined that the following NSPS are not applicable to this source:

(1) **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) **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) **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) **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) **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) **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) **All other NSPS:** This source is not subject to other NSPS requirements not listed here because the source does not own or operate the affected facilities subject to those NSPS.

Federal Rule Applicability – Section 111(d) Emission Guidelines
[40 CFR Part 60 and 326 IAC 11]

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

Federal Rule Applicability – National Emission Standards for Hazardous Air Pollutants (NESHAPs) [40 CFR Part 61 and 326 IAC 14]

(a) **Part 61 NESHAPs applicable to source:**

(1) **Subpart A – General Provisions:** The provisions of 40 CFR 61 Subpart A - General Provisions, apply to the facilities described in items (2) through (5) below, except when otherwise specified in the relevant Subpart.

(2) **Subpart M – Asbestos:** This source is subject to 40 CFR Part 61, Subpart M and 326 IAC 14-10, which applies to, among other things, demolition and renovation operations and asbestos containing materials. The requirements of this NESHAP are reflected in Condition C.7 of this permit.

(3) **Subpart V - Fugitive Emissions From Equipment Leaks:** This source has elected to comply with the Off-Site Waste and Recovery NESHAPs [40 CFR 63, Subpart DD] in part by following the requirements of 40 CFR Part 61, Subpart V and 326 IAC 14-8. This NESHAP establishes standards for controlling fugitive emissions from equipment leaks. The specific applicability of this NESHAP and the requirements incorporated into this permit are discussed in Section E.1 of this TSD.

(4) **Subpart FF – Benzene Waste Operations:** This source is subject to 40 CFR Part 61, Subpart FF, which applies to benzene waste operations. The specific applicability and the requirements incorporated into this permit are discussed in Sections D.12 (T49 Liquid Incinerator) and D.13 (T149 Rotary Kiln Solids-Liquid Incinerator) of this TSD.

(b) **Part 61 NESHAPs not applicable to source:** IDEM has determined that the following NESHAPs are not applicable to this source:

(1) **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)]

(2) **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.

(3) **Other Part 61 NESHAP:** This source is not subject to other Part 61 NESHAP requirements not listed here because the source does not own or operate the affected facilities subject to those NESHAPs.

Federal Rule Applicability – National Emission Standards for Hazardous Air Pollutants (NESHAPs) [40 CFR Part 63 and 326 IAC 20]

(a) **Part 63 NESHAPs applicable to source:**

(1) **Subpart A – General Provisions:** The provisions of 40 CFR 63, Subpart A apply to the facilities described in items (2) through (5) below, except when otherwise specified in the relevant Subpart.

(2) **Subpart B – Case-by-case MACT determination:** This source may be subject to 40

CFR Part 63, Subpart B, Sections 63.50, through 63.56. This source includes facilities potentially subject to NESHAP standards for which USEPA has not promulgated final standards. If the USEPA fails to promulgate final NESHAPs by the applicable deadlines, this source must submit an application for a case-by-case determination of Maximum Achievable Control Technology (MACT). This source submitted the Part 1 MACT applications, pursuant to 40 CFR 63.52 and 63.53 on May 14, 2002. [40 CFR 63.50]

(3) **Subpart I – Equipment Leaks:** This source is subject to 40 CFR Part 63, Subpart I and 326 IAC 20-12, which applies to pharmaceutical production processes using carbon tetrachloride or methylene chloride. The source may comply with this NESHAP by complying with equipment leak standards in 40 CFR Part 63 Subpart H (Equipment Leaks) or 40 CFR Part 63 Subpart GGG (Pharmaceutical Production MACT). The source has elected to comply with Subpart I by following the requirements of Subpart GGG and streamlined permit conditions reflecting the most stringent of applicable equipment leak standards. The details of these requirements are discussed in Section E.1 (LDAR) of this TSD.

(4) **Subpart DD – Off-site Waste and Recovery Operations:** This source is subject to 40 CFR 63, Subpart DD and 326 IAC 20-23 which applies to facilities treating and recovering wastes originating from other sites. This NESHAP establishes standards for controlling point source and fugitive emissions. The specific applicability of this NESHAP and the requirements incorporated into this permit are discussed in Sections D.7 (Solvent Recovery), D.10 (Waste Tanks), and D.11 (Waste Containers) of this TSD.

(5) **Subparts OO, PP, QQ, RR, SS, TT, UU, VV, WW:** To the extent that these general MACT requirements apply, the source shall demonstrate compliance with these generic standards through compliance with the requirements established in the Pharma MACT, HWC MACT, or OSWRO MACT, as applicable. Specific applicability of 40 CFR Part 63 Subparts OO [Level 1 Tanks], PP [Containers], QQ [Surface Impoundments], RR [Individual Drain Systems], SS [Closed vent systems and control devices], TT [Equipment leaks – Level 1], UU [Equipment leaks – Level 2], VV [Separators], and WW [Storage Tanks – Level 2] (326 IAC 20-35 through 20-43) are discussed in Sections D.8 (Individual Drain Systems), D.9 (Solvent Storage Tanks), D.10 (Waste Tanks), D.11 (Waste Containers), D.14 (RTO Control System and associated Closed Vent System), D.15 (T79 Fume Incinerator and associated Closed Vent System), and E.1 (LDAR) of this TSD.

(6) **Subpart EEE – Hazardous Waste Combustors:** This source is subject to 40 CFR Part 63, Subpart EEE and 326 IAC 20-28, which applies to hazardous waste incinerators, among other things. This NESHAP establishes emission limitations and work practices for controlling point source emissions. The specific applicability of this NESHAP and the requirements incorporated into this permit are discussed in Sections D.12 (T49 Liquid Incinerator) and D.13 (T149 Rotary Kiln Liquids-Solid Incinerator) of this TSD.

(7) **Subpart GGG – Pharmaceuticals Production:** This source is subject to 40 CFR Part 63, Subpart GGG, which applies to pharmaceutical manufacturing facilities. This NESHAP establishes emission limitations and work practice standards for controlling point source and fugitive emissions. The specific applicability of the various aspects of this NESHAP and the requirements incorporated into this permit are discussed in Sections D.6 (BPM Operations), D.7 (BPM Solvent Recovery Operations), D.8 (BPM Wastewater and BPM Individual Drain System Operations), D.9 (BPM Solvent

Storage Tanks), D.10 (Waste Tanks), and D.11 (BPM Waste Containers) of this TSD.

(b) **Part 63 NESHAPs not applicable to source:** IDEM has determined that the following NESHAPs are not applicable to this source:

(1) **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)]

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

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

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

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

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

(7) **Other Part 63 NESHAPs:** This source is not subject to other NESHAP requirements not listed here because the source does not own or operate the affected facilities subject to those NESHAPs.

Federal Rule Applicability – Other Provisions

(a) **Part 64 – Compliance Assurance Monitoring:** The provisions of 40 CFR Part 64 are not applicable to this source because this is the initial issuance of a Part 70 permit to this source, and the source submitted a complete Part 70 permit application prior to April 20, 1998. [40 CFR 64.5]

(b) **Part 68 – Chemical Accident Prevention:** The provisions of 40 CFR Part 68 and 326 IAC 20-2 are applicable to this source because the source may have more than a threshold quantity of a substance regulated by Part 68. The source is required to prepare a Risk Management Plan meeting the requirements of Part 68. The source submitted its most recent plan on September 15, 2000.

(c) **Part 70 – Operating Permits:** This source is a major source, as defined by 40 CFR 70.2 and 326 IAC 2-7-1, and is subject to the Part 70 operating permits program. This permit serves as the Part 70 operation permit for the source.

(d) **Parts 72-78 – Acid Rain Program Provisions:** This source is not an affected source

subject to the Acid Rain Program Provisions found in 40 CFR Parts 72-78 and 326 IAC 21.

(e) **Part 82 – Protection of Stratospheric Ozone:** This source conducts maintenance of appliances containing ozone depleting substances, and therefore is subject to the recycling and emission reduction requirements of 40 CFR Part 82, Subpart F. Condition C.18 of this permit describes the requirements of these provisions.

(f) **Other Clean Air Act Regulations:** This source is not subject to other Clean Air Act requirements not listed in this permit because the source does not own or operate the affected facilities subject to those requirements nor does it conduct the activities subject to those requirements.

State Rules Applicability

(a) **326 IAC 1-5-2 (Emergency Reduction Plans):** The source has submitted its most recent Emergency Reduction Plan (ERP) on December 13, 2000. The ERP has been verified to fulfill the requirements of 326 IAC 1-5-2 (Emergency Reduction Plans). Condition C.11 of this permit describes the requirements of these provisions.

(b) **326 IAC 1-6-3 (Preventive Maintenance Plan):** The source is required to develop and maintain Preventive Maintenance Plans (PMP) for some specific facilities listed in this permit. General PMP requirements are described in Section B of this permit, and specific PMP requirements for individual facilities are described in specific sections of the permit where this requirement is applicable.

(c) **326 IAC 1-7 (Stack Height Provisions):** This source includes facilities subject to the minimum stack height requirements of 326 IAC 1-7. The stack height requirements for the individual facilities subject to these requirements are described in the specific sections of the permit where this requirement is applicable.

(d) **326 IAC 2 (Permit Review Rules):** This source is subject to the permit review rules in 326 IAC 2 as described below.

(1) **326 IAC 2-1.1 – General Provisions:** Except where other rules in 326 IAC 2 require otherwise, the provisions of 326 IAC 2-1.1apply to the entire source.

(2) **326 IAC 2-2 – Prevention of Significant Deterioration [PSD] and 326 IAC 2-2.5 – Pollution Control Projects:** This source is a major stationary source, as defined in 326 IAC 2-2-1, and is therefore subject to PSD requirements when major modifications occur at the source. This permit serves as a PSD permit for the modifications that will occur in Bulk Pharmaceutical Manufacturing [BPM] operations, BPM support operations, and the waste incinerators during the term of this permit.

The following aspects of the PSD permitting program were reviewed and evaluated and determined to satisfy the PSD permitting requirements:

- Best Available Control Technology [326 IAC 2-2-3];
- Air Quality Analysis [326 IAC 2-2-4(a) and 326 IAC 2-2-5],
- Evaluation of PSD increment consumption [326 IAC 2-2-6]; and
- Additional impacts analysis [326 IAC 2-2-7].

The detailed analyses of the BACT review and Air Quality Modeling results can be found in Appendix C and Appendix D of this TSD, respectively.

(3) **326 IAC 2-3 – Emission Offset:** This source is located in an area designated as attainment or unclassifiable for all criteria pollutants. Therefore, the requirements of 326 IAC 2-3 do not apply to this source.

(4) **326 IAC 2-4.1 – Major Sources of Hazardous Air Pollutants [HAPs]:** This source is a major source of hazardous air pollutants. If the source proposes to construct or reconstruct a major source of HAPs, as defined in 40 CFR 63.41, and that major source is not excluded pursuant to 326 IAC 2-4.1(b), then the source must comply with the requirements of 326 IAC 2-4.1-1(c) and (d) for case-by-case Maximum Achievable Control Technology determinations. The source does not anticipate constructing or reconstructing a major source of HAPs that will be subject to these requirements.

(5) **326 IAC 2-5.1 – Construction of New Sources:** This source is an existing source, and therefore cannot be considered to construct a "new source" as defined by 326 IAC 2-1.1-1(10). Therefore, 326 IAC 2-5.1 does not apply to this source.

(6) **326 IAC 2-7 – Part 70 Operating Permit Program:** This source is a major source, as defined by 326 IAC 2-7-1, and is therefore, subject to the requirements of 326 IAC 2-7.

(7) **326 IAC 2-13 – Interim operating permit revision approvals:** This source is eligible to seek interim operating permit revision approvals for minor modifications that may occur at the source.

(8) **Other permit review rules:** This source is an existing source operating under a Part 70 permit, and therefore, is not subject to the requirements of 326 IAC 2-5.5 [Registrations], 326 IAC 2-6.1 [Minor Source Operating Permit Program], 326 IAC 2-8 [Federally Enforceable State Operating Permit Program], 326 IAC 2-9 [Source Specific Operating Agreement Program], 326 IAC 2-10 [Permit by Rule], 326 IAC 2-11 [Permit by Rule for Specific Source Categories], 326 IAC 2-12 [General Permits], and 326 IAC 2-14 [Portable Sources].

(e) **326 IAC 2-6 (Emission Reporting):** This source is subject to 326 IAC 2-6 (Emission Reporting), because it has the potential to emit more than one hundred (100) tons per year) of carbon monoxide, nitrogen dioxides, particulate matter, sulfur dioxide, and volatile organic compounds. Pursuant to this rule, the owner/operator of the source must annually submit an emission statement for the source. The annual statement must be received by July 1 of each year and contain the minimum requirement as specified in 326 IAC 2-6-4. The submittal should cover the period defined in 326 IAC 2-6-2(8)(Operating Year).

(f) **326 IAC 3 (Monitoring requirements):** This source includes facilities subject to the continuous monitoring, source sampling and fuel sampling provisions of 326 IAC 3. The specific monitoring, source sampling, and fuel sampling requirements applicable to the source are described in specific sections of this permit.

(g) **326 IAC 4 (Burning regulations):** This source is subject to two aspects of 326 IAC 4. The open burning limitations and standards in 326 IAC 4-1 are applicable to the entire source. These limitations are described in Condition C.3 of the permit.

326 IAC 4-2 establishes particulate matter limitations and other standards for incinerators. This rule applies to incinerators burning solid or liquid wastes. It does not apply to incinerators used to reduce emissions from process operations. Therefore, this rule is not

applicable to the Regenerative Thermal Oxidizers or T79 Fume Incinerators.

Because the T49 Liquid Waste Incinerator and the T149 Liquid/Solid Waste Incinerator are subject to the requirements of 40 CFR Part 63, Subpart EEE [Hazardous Waste Combustor MACT], these incinerators are not subject to the requirements of 326 IAC 4-2. These incinerators, however, are subject to an older version of 326 IAC 4-2 incorporated into the State Implementation Plan [SIP]. This permit includes specific conditions that describe the SIP-approved requirements applicable to these incinerators. The permit also states that the current SIP-approved requirements will expire if USEPA approves the current version of 326 IAC 4-2 into the SIP.

(h) **326 IAC 5-1 (Opacity Limitations):** This source includes facilities subject to 326 IAC 5, which establishes opacity (visible emissions) standards for operations emitting particulate matter. For some operations, such as boilers, where opacity limitations are more complex, the specific section of the permit addressing those operations will include conditions describing the opacity limitations. For all other operations emitting particulate matter, the opacity requirements are described in a general condition [Condition C.2].

(i) **326 IAC 6 (Particulate Rules)**

(1) **326 IAC 6-1 – Nonattainment Area Limitations:** This source is located in an attainment area for particulate matter. Therefore, 326 IAC 6-1 does not apply to any facilities at this source.

(2) **326 IAC 6-2 – Particulate Emission Limitations for Sources of Indirect Heating:** This source includes boilers that are subject to the requirements of this rule. The specific limitations and other requirements applicable to these facilities are described in Sections D.1 (Utilities Operations) of this TSD.

(3) **326 IAC 6-3 – Process Operations:** This rule establishes particulate matter limits for manufacturing processes that emit particulate matter. This source includes several facilities subject to the requirements of this rule. The permit includes specific conditions, including expression of the particulate matter emission limitations, incorporating this requirement for manufacturing processes and emission units in various locations of the plant site. As a result, this requirement will be described in multiple locations in the permit. In addition, this permit includes a general condition [Condition C.1], that generally describes the emission limitation for all other manufacturing processes subject to 326 IAC 6-3 which are not described in detail in D sections of the permit. Administrative, maintenance, research and development, and other support activities conducted at the source that are not manufacturing are not subject to this rule.

(4) **326 IAC 6-4 – Fugitive Dust Emissions:** This source is subject to the fugitive dust limitations in 326 IAC 6-4. The source may not allow fugitive emissions to cross the property boundaries of the site, including easements and rights-of-way, in a manner that violates this rule. Condition C.4 of this permit describes the requirements of this rule in greater detail.

(5) **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.

(j) **326 IAC 7 (Sulfur dioxide rules):** This source includes boilers that are subject to the requirements of 326 IAC 7. The specific limitations and other requirements applicable to these facilities are described in Section D.1 (Utilities Operations) of this TSD. No other emission units are subject to the requirements of this rule.

(k) **326 IAC 8 (Volatile Organic Compound Rules):** This source is subject to the VOC control rules in 326 IAC 8 as described below.

(1) **326 IAC 8-1 – General Provisions:** Because this source operates facilities subject to rules in 326 IAC 8, the General Provisions in 326 IAC 8-1apply to the source. Where a specific provision of 326 IAC 8-1 is applicable to facilities at this source, those provisions will be contained in a specific section of the permit and described in the appropriate section of the TSD. Sections 326 IAC 8-1-7, 8-1-10, 8-1-11, and 8-1-12 are not applicable to this source.

(2) **326 IAC 8-3 – Organic Solvent Degreasing Operations:** This source does not own or operate open top degreasing facilities containing organic solvent. Therefore, the requirements of 326 IAC 8-3-3/326 IAC 8-3-6 do not apply.

(3) **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.

(4) **326 IAC 8-5-3 – Synthesized Pharmaceutical Manufacturing Operations:** This source includes various operations subject to the requirements of 326 IAC 8-5-3. This rule establishes emission limitations and work practices for production and support equipment engaged in manufacturing pharmaceuticals by chemical synthesis. The permit includes specific conditions incorporating these requirements. The permittee has requested that most of the requirements of this rule be “streamlined” into permit conditions incorporating the requirements of the Pharmaceutical Production MACT [40 CFR Part 63, Subpart GGG] and the BACT emission limitations and standards established as part of the BACT PSD review described in Appendix C this TSD. The specific requirements of this rule, and the streamlining of its requirements into other permit conditions are described in Appendix A of this TSD.

(5) **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.

(6) **Other rules in 326 IAC 8**: This source is not subject to other requirements in 326 IAC 8 not listed here because the source does not own or operate the affected facilities subject to those rules.

(l) **326 IAC 9 (Carbon Monoxide Rules):** Because the T49 Liquid Waste Incinerator and T149 Liquid/Solid Waste Incinerator are subject to the requirements of 40 CFR 63, Subpart EEE [Hazardous Waste Combustor MACT], these incinerators are not subject to the requirements of 326 IAC 9-1. These incinerators, however, are subject to an older version of 326 IAC 9-1 incorporated into the State Implementation Plan [SIP]. This permit includes specific conditions that describe the SIP-approved requirements applicable to these incinerators. The permit also states that the current SIP-approved requirements will expire if USEPA approves the current version of 326 IAC 9-1 into the SIP.

(m) **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.

(n) **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.

(o) **326 IAC 12 (New Source Performance Standards):** The applicability of the New Source Performance Standards, as embodied in Indiana air quality regulations, is described in greater detail in the section of this TSD addressing the federal NSPS program.

(p) **326 IAC 14 (Emission Standards for Hazardous Air Pollutants):** The applicability of these Emission Standards for Hazardous Air Pollutants, as embodied in Indiana air quality regulations, is described in greater detail in the section of this TSD addressing the federal Part 61 NESHAPs program.

(q) **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.

(r) **326 IAC 20 (Hazardous Air Pollutants):** The applicability of Part 63 National Emission Standards for Hazardous Air Pollutants, as embodied in 326 IAC 20, is described in greater detail in the section of this TSD addressing the federal Part 63 NESHAPs program.

(s) **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.

(t) **326 IAC 22 (Emission Standards for Hazardous Air Pollutants):** The applicability of Part 82 Stratospheric Ozone Protection program, as embodied in 326 IAC 22, is described in greater detail in the section of this TSD addressing the Part 82 program.

Assessment of Hazardous Air Pollutant Impacts

The proposed modification may increase hazardous air pollutant emissions. As a result, IDEM conducted an assessment of the impacts of hazardous air pollutant emissions from the source. The results of that assessment are found in Appendix D to this TSD.

Testing Requirements

The detailed testing requirements for individual facilities are described in Appendix A of this TSD.

Compliance Requirements

Permits issued under 326 IAC 2-7are required to ensure that source can demonstrate compliance with applicable state and federal rules on a more or less continuous basis. All state and federal rules contain compliance provisions, however, these provisions do not always fulfill the requirement for a more or less continuous demonstration. When this occurs IDEM, OAQ, in conjunction with the source, must develop specific conditions to satisfy 326 IAC 2-7-5. As a result, compliance requirements are divided into two sections: Compliance Determination Requirements and Compliance Monitoring Requirements.

Compliance Determination Requirements in Section D of the permit are those conditions that are found more or less directly within state and federal rules and the violation of which serves as grounds for enforcement action. If these conditions are not sufficient to demonstrate continuous compliance, they will be supplemented with Compliance Monitoring Requirements, also located in Section D of the permit. Unlike Compliance Determination Requirements, failure to meet Compliance Monitoring conditions would serve as a trigger for corrective actions and not grounds for enforcement action. However, a violation in relation to a compliance monitoring condition will arise through a source's failure to take the appropriate corrective actions within a specific time period.

The compliance determination and compliance monitoring requirements for individual facilities or specific areas of the source are described in detail in Appendix A of this TSD.

The draft permit contains 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 that arise outside of 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 repairs 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."

The applicable state rules, 326 IAC 3-5 (Continuos Monitoring of Emissions) does not contain such specific exemptions. However, 326 IAC 3-5-4(a)(9) requires a preventative 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 when small amounts of data are not collected due to CEMS malfunction. The draft permit contains language at C.10, C.11, D.12.14, D12.15, D12.16, D13.14, D13.15, D13.17, D14.4, D14.6, D14.7, D15.5, and D15.6, which require that the CEMS be operated at all times except during reasonable, and properly documented periods of calibration activities and malfunction. Downtime due to malfunction and subsequent repair is not to exceed 3%. The OAQ will continue to consider this issue, including public comment on this specific permit, prior to making a final decision on this matter.

Conclusion

The operation of this bulk pharmaceutical manufacturing plant and associated support facilities shall be subject to the conditions of the attached proposed **PSD and Part 70 Permit No. T157-6879-00006.**