City of Indianapolis DPW Department of Public Works
Bart Peterson, Mayor

TO: Interested Parties / Applicant

RE: Eli Lilly and Company - Lilly Technology Center / 097-6846-00072

FROM: Felicia A. Robinson
Administrator

Notice of Decision: Approval – Effective Immediately

Please be advised that on behalf of the Commissioner of the Department of Environmental Management, I have issued a decision regarding the enclosed matter. Pursuant to IC 13-15-5-3, this permit is effective immediately, unless a petition for stay of effectiveness is filed and granted, and may be revoked or modified in accordance with the provisions of IC 13-15-7-1.

If you wish to challenge this decision, IC 4-21.5-3-7 and IC 13-15-6-1(b) or IC 13-15-6-1(a) require that you file a petition for administrative review. This petition may include a request for stay of effectiveness and must be submitted to the Office of Environmental Adjudication, 100 North Senate Avenue, Government Center North, Room 1049, Indianapolis, IN 46204.

For an **initial Title V Operating Permit**, a petition for administrative review must be submitted to the Office of Environmental Adjudication within **thirty (30)** days from the receipt of this notice provided under IC 13-15-5-3, pursuant to IC 13-15-6-1(b).
For a **Title V Operating Permit renewal**, a petition for administrative review must be submitted to the Office of Environmental Adjudication within **fifteen (15)** days from the receipt of this notice provided under IC 13-15-5-3, pursuant to IC 13-15-6-1(a).

The filing of a petition for administrative review is complete on the earliest of the following dates that apply to the filing:
(1) the date the document is delivered to the Office of Environmental Adjudication (OEA);
(2) the date of the postmark on the envelope containing the document, if the document is mailed to OEA by U.S. mail; or
(3) The date on which the document is deposited with a private carrier, as shown by receipt issued by the carrier, if the document is sent to the OEA by private carrier.

The petition must include facts demonstrating that you are either the applicant, a person aggrieved or adversely affected by the decision or otherwise entitled to review by law. Please identify the permit, decision, or other order for which you seek review by permit number, name of the applicant, location, date of this notice and all of the following:
(1) the name and address of the person making the request;
(2) the interest of the person making the request;
(3) identification of any persons represented by the person making the request;
(4) the reasons, with particularity, for the request;
(5) the issues, with particularity, proposed for considerations at any hearing; and

Department of Public Works
Office of Environmental Services
2700 Belmont Avenue
Indianapolis, IN 46221
317-327-2234
Fax 327-2274
TDD 327-5186
indygov.org/dpw

(6) identification of the terms and conditions which, in the judgment of the person making the request, would be appropriate in the case in question to satisfy the requirements of the law governing documents of the type issued by the Commissioner.

Pursuant to 326 IAC 2-7-18(d), any person may petition the U.S. EPA to object to the issuance of an initial Title V operating permit, permit renewal, or modification within sixty (60) days of the end of the forty-five (45) day EPA review period. Such an objection must be based only on issues that were raised with reasonable specificity during the public comment period, unless the petitioner demonstrates that it was impractible to raise such issues, or if the grounds for such objection arose after the comment period.

To petition the U.S. EPA to object to the issuance of a Title V operating permit, contact:

U.S. Environmental Protection Agency
401 M Street
Washington, D.C. 20406

If you have technical questions regarding the enclosed documents, please contact the Indianapolis Office of Environmental Services, Air Permits at (317) 327-2234.

Enclosures

PART 70 OPERATING PERMIT

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY
and
INDIANAPOLIS OFFICE OF ENVIRONMENTAL SERVICES

Eli Lilly and Company
Lilly Technology Center
1555 South Harding Street
Indianapolis, Indiana 46221

(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 and the Code of Indianapolis and Marion County, Chapter 511. 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 2-7-10.5, applicable to those conditions.

Operation Permit No.: T097-6846-00072	
Issued by: Original Signed by Nisha Sizemore Nisha Sizemore, Chief Permits Branch Office of Air Quality Original Signed by Felicia A. Robinson Felicia A. Robinson, Administrator Office of Environmental Services	Issuance Date: October 31, 2006 Expiration Date: Occtober 31, 2011

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SECTION A SOURCE SUMMARY

This permit is based on information requested by the Indiana Department of Environmental Management (IDEM), Office of Air Quality (OAQ) and the City of Indianapolis Office of Environmental Services (OES). The information describing the source contained in conditions A.1 through A.5 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 and research and development facility.

Responsible Officials:	Vice President of Global Parenteral Operations, Engineering, Environmental, Health and Safety; Vice President, Product Research & Development; Vice President, Global Active Pharmaceutical Intermediate (API) Manufacturing; or President, Manufacturing Operations
Source Address:	1555 South Harding Street, Indianapolis, IN 46221
Mailing Address:	Eli Lilly and Company, Lilly Corporate Center, Indianapolis, IN 46285
General Source Phone Number:	(317) 276-2000 (source number) OR (317) 276-6415 (Manager of Environmental Services)
SIC Code:	2833, 2834
County Location:	Marion
Source Location Status:	Nonattainment for Ozone 8-hour standard and PM 2.5 Attainment for all other criteria pollutants
Source Status:	Part 70 Permit Program Minor Source under PSD and Nonattainment NSR Major Source under Emission Offsets 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) A chemical development pilot plant facility and laboratories (identified as Building 110) used to develop new chemical processes and to produce new pharmaceutical compounds for subsequent use in toxicology studies and clinical trial research, with Modules A, B, C, D, E, 30 gallon A, 30 gallon B, Solids Containment and D-wing, and with process condensers.

(b) Manufacture of bulk pharmaceutical products (Building 358) by:

(1) protein isolation with a carbon adsorber for VOC and HAP control with laboratory support;
(2) chemical synthesis,

units subject to BACT [326 IAC 8-1-6].

(c) Manufacture of bulk pharmaceutical products (Building 358) by:

(1) protein isolation with laboratory support;
(2) chemical synthesis, or non-synthesized chemical processes;

units not subject to BACT [326 IAC 8-1-6].

(d) Manufacture of vancomycin (VANCO) by isolation (base) and purification (HPLC) with a condenser for VOC and HAP control located in Building 348.

(e) The BHI area consists of five buildings (building 132, 133, 134, 142 and 138) where manufacturing of bulk pharmaceutical products through chemical synthesis takes place using condensers and a scrubber as VOC control.

(f) Building 130 Complex (buildings 130, 135 and 136) consisting of laboratories and manufacturing of bulk pharmaceutical products through chemical synthesis.

(g) Dry pharmaceutical manufacturing, identified as PC100 and located in Building 100, with processes including milling, mixing, granulation, sieving, microwave drying, compression, and filling and with a carbon block condenser on the dryer for VOC control and a HEPA filter for particulate control which is integral to the room.

(h) Dry pharmaceutical manufacturing, identified as PC1 and located in Building 328, with processes including milling, mixing, granulation, sieving, drying, compression, and filling, with a HEPA filter for particulate control which is integral to the dryer, and a scrubber for VOC control.

(i) An outside storage tank area (Tank Farm North) with the storage tanks holding raw material and waste solvents.

(j) Two (2) peak diesel generators, one (1) Model number DFHD, identified as Generator A, and one Model number DFJD, identified as Generator B, both located at the Building 141 (B141), constructed, respectively, in 1999 and 2004, with a maximum capacity of 1,350 HP each, using no control, and exhausting to stack B141 Generator A.

(k) One (1) peak diesel generator, Model number DQKC, identified as Generator C, located at the Building 141 (B141), constructed in 2006, with a maximum capacity of 2,700 HP, using no control, and exhausting to stack B141 Generator C.

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

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

(a) Degreasing operations that do not exceed 145 gallons per 12 months, except if subject to 326 IAC 20-6. [326 IAC 8-3]

(b) Activities with emissions equal to or less than insignificant thresholds: Cold cleaner degreasers that use more than 145 gallons per year, but have emissions less than 15 pounds per day of VOC. [326 IAC 8-3-2]

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

This stationary source also includes the following insignificant activities as defined in 326 IAC 2-7-1(21):

(a) 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.

(b) The following VOC and HAP storage containers:
  (1) Storage tanks with capacity less than or equal to 1,000 gallons and annual through puts less than 12,000 gallons.
  (2) Vessels storing lubricating oils, hydraulic oils, machining oils, and machining fluids.

(c) Application of oils, greases, lubricants or other nonvolatile materials applied as temporary protective coatings.

(d) Cleaners and solvents characterized as follows:
(1) having a vapor pressure equal to or less than 2 kPa; 15mm Hg; or 0.3 psi measured at 38 degrees C (100^{o}F) or;
(2) having a vapor pressure equal to or less than 0.7 kPa; 5mm Hg; or 0.1 psi measured at 20 degrees C (68oF);
the use of which for all cleaners and solvents combined does not exceed 145 gallons per 12 months.

(e) Closed loop heating and cooling systems.

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

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

(h) Noncontact cooling tower systems with the following: forced and induced draft cooling tower system not regulated under a NESHAP.

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

(j) Heat exchanger cleaning and repair.

(k) Process vessel degassing and cleaning to prepare for internal repairs.

(l) Paved and unpaved roads and parking lots with public access. [326 IAC 6-4]

(m) Asbestos abatement projects regulated by 326 IAC 14-10.

(n) 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.

(o) 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.

(p) Blowdown for any of the following: sight glass; boiler; compressors; pumps; and cooling tower.

(q) On-site fire and emergency response training approved by the department.

(r) Emergency generators as follows: Diesel generators not exceeding 1600 horsepower.

(s) Stationary fire pumps.

(t) Purge double block and bleed valves.

(u) Filter or coalescer media changeout.

(v) Laboratories as defined in 326 IAC 2-7-1(21)(D).

(w) Research and development activities as defined in 326 IAC 2-7-1(21)(E).

(x) Any unit emitting greater than 1 pound per day but less than 5 pounds per day or 1 ton per year of a single HAP:
  (1) Loading and unloading of raw materials and wastes into tank trucks and/or rail cars. There are at least two of these installations. Emissions include methanol and acetonitrile.
  (2) Equipment cleaning. Emissions include methanol.

(y) Any unit emitting greater than 1 pound per day but less than 12.5 pounds per day or 2.5 tons per year of any combination of HAPs.
  (1) Optimization and testing of developmental fermentation processes in fermenters less than or equal to 6,000 liter capacity. This description applies to a minimum of ten fermenters. The emissions include methanol.
  (2) Manufacturing in fermenters less than 40,000 liters. This applies to at least four fermenters. Emissions include methanol.
  (3) Filtration of fermentation broths in lots less than 2,000 liters. This description applies to a minimum of three installations. The emissions include methanol.
  (4) Processing in development area portable tanks, less than 500 liters. This description applies to a minimum of two tanks. The emissions include methanol.
  (5) Hydrogenation equipment less than 50 gallons located in developmental area. This description applies to a minimum of two installations. The emissions include methanol and methylene chloride.

(z) Activities with emissions equal to or less than insignificant thresholds:
  (1) Optimization, testing, and manufacturing with fermentors. Emissions less than 5 pounds per hour and 25 pounds per day particulate matter and 3 pounds per hour and 15 pounds per day of VOC.
  (2) Testing of cartridge filters used as part of fermentation and sterile area operations. Emissions are less than 3 pounds per hour and 15 pounds per day of VOC.
  (3) Equipment cleaning. Emissions are less than 3 pounds per hour and 15 pounds per day of VOC.
  (4) Pilot plant equipment used in optimization of the purification of potential manufacturing fermentation processes. Emissions are less than 3 pounds per hour and 15 pounds per day of VOC.
  (5) Printing operations for product identification. Emissions are less than 3 pounds per hour and 15 pounds per day of VOC.
  (6) Fluid bed dryers in dry products manufacturing. Emissions are less than 5 pounds per hour and 25 pounds per day particulate matter.
  (7) Process equipment or storage tanks which contain a VOC with a vapor pressure less than 0.1 mm Hg.

A.5 Part 70 Permit Applicability [326 IAC 2-7-2]

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

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

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

SECTION B GENERAL CONDITIONS

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

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

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

(a) This permit, T097-6846-00072, is issued for a fixed term of five (5) years from the issuance date of this permit, as determined in accordance with IC 4-21.5-3-5(f) and IC 13-15-5-3. Subsequent revisions, modifications, or amendments of this permit do not affect the expiration date of this permit or of permits issued pursuant to Title IV of the Clean Air Act and 326 IAC 21 (Acid Deposition Control).

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

B.3 Term of Conditions [326 IAC 2-1.1-9.5]

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

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

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

B.4 Enforceability [326 IAC 2-7-7]

(a) 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 and OES, the United States Environmental Protection Agency (U.S. EPA) and by citizens in accordance with the Clean Air Act.

(b) The Indianapolis Air Pollution Control Board (IAPCB) has adopted by reference state rules listed in Attachment A of this permit. The version adopted by reference includes all amendments, additions and repeals filed with the Secretary of State through May 10, 2003 and published in the Indiana Register June 1, 2003, unless otherwise indicated in the adoption by reference or in Appendix A of this permit. For the purposes of this permit, all state rules adopted by reference by the IAPCB are enforceable by OES using local enforcement procedures. Unless otherwise stated, all terms and conditions in this permit that are local requirements, including any provisions designed to limit the source's potential to emit, are enforceable by OES.

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, and OES within a reasonable time, any information that IDEM, OAQ, and/or OES 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 Aresponsible official@ as defined by 326 IAC 2-7-1(34). Upon request, the Permittee shall also furnish to IDEM, OAQ, and OES 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 no later than April 15 of each year to:

Indiana Department of Environmental Management
Compliance Branch, Office of Air Quality
100 North Senate Avenue
Indianapolis, Indiana 46204-2251

and

Office of Environmental Services (OES)
Air Quality Management Section
2700 South Belmont Avenue
Indianapolis, IN 46221

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, and OES 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, and OES may require to determine the compliance status of the source.

The submittal by the Permittee does require the certification by the Aresponsible 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 time frame, 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
Indianapolis, Indiana 46204-2251

and

Office of Environmental Services (OES)
Air Quality Management Section
2700 South Belmont Avenue
Indianapolis, IN 46221

The PMP extension notification does not require the certification by the Aresponsible 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, and OES upon request and within a reasonable time, and shall be subject to review and approval by IDEM, OAQ, and OES. IDEM, OAQ, and OES 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 Aresponsible official@ as defined by 326 IAC 2-7-1(34).

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

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

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

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

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

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

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

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

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

OES=s phone and facsimile numbers:
Telephone Number: 317/327-2234
Facsimile Number: 317/327-2274

(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
Indianapolis, Indiana 46204-2251

and

Office of Environmental Services (OES)
Air Quality Management Section
2700 South Belmont Avenue
Indianapolis, IN 46221

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 Aresponsible 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, and/or OES 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, and OES 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) 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 and OES have made the following determinations regarding this source:

(1) This source is not subject to 40 CFR 63, Subpart I and 326 IAC 20-12, which applies to pharmaceutical production processes using carbon tetrachloride or methylene chloride. The source does not have any pharmaceutical production processes using carbon tetrachloride or methylene chloride.

(2) This source is not subject to 40 CFR 63, Subpart T (National Emission Standards for Halogenated Solvent Cleaning) because the source does not use a solvent containing methylene chloride, perchloroethylene, trichloroethylene, 1, 1, 1-trichloroethylene, carbon tetrachloride, or chloroform or any combination of these halogenated HAP solvents, in a total concentration greater than five percent (5%) by weight as a cleaning and/or drying agent in an individual batch vapor, in-line vapor, in line cold and batch cold solvent cleaning machine.

(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, and OES 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, and OES 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, and OES has issued the modification. [326 IAC 2-7-12(b)(8)]

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

(a) All terms and conditions of permits established prior to T097-6846-00072 and issued pursuant

to permitting programs approved into the state implementation plan have been either

(1) incorporated as originally stated,

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

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

(b) Provided that all terms and conditions are accurately reflected in this combined permit, all previous registrations and permits are superseded by this combined new source review and part 70 operating permit, except for permits issued pursuant to Title IV of the Clean Air Act and 326 IAC 21 (Acid Deposition Control).

B.14 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.15 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
Indianapolis, Indiana 46204-2251

and

Office of Environmental Services (OES)
Air Quality Management Section
2700 South Belmont Avenue
Indianapolis, IN 46221

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 Aresponsible 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.16 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 Aresponsible 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, or OES 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, or OES 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, or OES at least thirty (30) days in advance of the date this permit is to be reopened, except that IDEM, OAQ, or OES may provide a shorter time period in the case of an emergency. [326 IAC 2-7-9(c)]

B.17 Permit Renewal [326 IAC 2-7-4] [326 IAC 2-7-3]

(a) The application for renewal shall be submitted using the application form or forms prescribed by IDEM, OAQ, and OES 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 Aresponsible 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
Indianapolis, Indiana 46204-2251

and

Office of Environmental Services (OES)
Air Quality Management Section
2700 South Belmont Avenue
Indianapolis, IN 46221

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

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

(2) If the date postmarked on the envelope or certified mail receipt, or affixed by the shipper on the private shipping receipt, is on or before the date it is due. If the document is submitted by any other means, it shall be considered timely if received by IDEM, OAQ, and OES on or before the date it is due.

(c) If the Permittee submits a timely and complete application for renewal of this permit, the source=s failure to have a permit is not a violation of 326 IAC 2-7 until IDEM, OAQ, and OES, 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, and OES, any additional information identified as being needed to process the application.

B.18 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
Indianapolis, Indiana 46204-2251

and

Office of Environmental Services (OES)
Air Quality Management Section
2700 South Belmont Avenue
Indianapolis, IN 46221

Any such application shall be certified by the Aresponsible 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.19 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.20 Operational Flexibility [326 IAC 2-7-20] [326 IAC 2-7-10.5]

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

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

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

(3) The changes do not result in emissions which exceed the 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
Indianapolis, Indiana 46204-2251

and

Office of Environmental Services (OES)
Air Quality Management Section
2700 South Belmont Avenue
Indianapolis, IN 46221

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, on a rolling five (5) year basis, which document 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, and OES 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.

(e) Advance Approval of Modifications [326 IAC 2-7-5(16)
The permittee may modify any existing emission unit, replace any existing emission unit, or add a new process vessel, filter, centrifuge, dryer, or any other pharmaceutical processing equipment to the operations described in a given section without a source modification

required by 326 IAC 2-7-10.5 or a permit revision required by 326 IAC 2-7-12 provided the following requirements are satisfied:

(1) All the applicable requirements for the modified, replaced or newly constructed emission unit are described or referenced in the appropriate D section of the permit or in Sections B and C of this permit.
(2) The modification, replacement or construction of the emission unit does not require new or additional applicable requirements to be added to the D section of the permit.
(3) The modification, replacement or construction of the emission unit does not require revision of applicable requirements in the permit.
(4) The modification, replacement or construction of the emission unit does not meet the definition of a major modification as defined in 326 IAC 2-2-1 or under nonattainment new source review.

B.21 Source Modification Requirement [326 IAC 2-7-10.5] [326 IAC 2-3-2] [326 IAC 2-2-2]

(a) A modification, construction, or reconstruction is governed by the requirements of 326 IAC 2 and 326 IAC 2-7-10.5.

(b) Any modification at an existing major source is governed by the requirements of 326 IAC 2-2-2 and/or 326 IAC 2-3-2.

B.22 Inspection and Entry [326 IAC 2-7-6] [IC 13-14-2-2] [IC 13-30-3-1]

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, and OES 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.23 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
Indianapolis, Indiana 46204-2251

and

Office of Environmental Services (OES)
Air Quality Management Section
2700 South Belmont Avenue
Indianapolis, IN 46221

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.24 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, and OES 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, or OES, 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, Policy, Planning, and Coordination Section), to determine the appropriate permit fee.

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

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

SECTION C SOURCE OPERATION CONDITIONS

Entire Source

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

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

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

C.2 Opacity [326 IAC 5-1]

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

(a) Opacity shall not exceed an average of thirty percent (30%) 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 Incineration [326 IAC 4-2] [326 IAC 9-1-2]

The Permittee shall not operate an incinerator or incinerate any waste or refuse except as provided in 326 IAC 4-2 and 326 IAC 9-1-2.

C.5 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.6 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.

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

C.7 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
Indianapolis, Indiana 46204-2251

and

Office of Environmental Services (OES)
Air Quality Management Section
2700 South Belmont Avenue
Indianapolis, IN 46221

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 and OES not later than forty-five (45) days after the completion of the testing. An extension may be granted by IDEM, OAQ, and OES, 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.8 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.9 Compliance Monitoring [326 IAC 2-7-5(3)] [326 IAC 2-7-6(1)]

(a) Unless otherwise specified in this permit, all monitoring and record keeping requirements not already legally required shall be implemented within sixty (60) days of permit issuance. If required by Section D or E, 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 sixty (60) days, the Permittee may extend the compliance schedule related to the equipment for an additional sixty (60) days provided the Permittee notifies:

Indiana Department of Environmental Management
Compliance Branch, Office of Air Quality
100 North Senate Avenue
Indianapolis, Indiana 46204-2251

and

Office of Environmental Services (OES)
Air Quality Management Section
2700 South Belmont Avenue
Indianapolis, IN 46221

in writing, prior to the end of the initial sixty (60) 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 Aresponsible official@ as defined by 326 IAC 2-7-1(34).

(b) 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.

(c) The Permittee shall keep records of required 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.

(d) The Permittee shall submit a report of monitoring system downtime where specified in Section D or Section E. 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.

(e) Nothing in this permit nor in 326 IAC 3-5 supercedes the applicable monitoring provisions in 40 CFR Part 60 or 40 CFR Part 63.

C.10 Monitoring Methods [326 IAC 3] [40 CFR 60] [40 CFR 63]

Any monitoring or testing required by Section D or Section E of this permit shall be performed according to the provisions of 326 IAC 3, 40 CFR 60, Appendix A, 40 CFR 60 Appendix B, 40 CFR 63, or other approved methods as specified in this permit. Nothing in this permit nor in 326 IAC 3-5 supercedes the applicable 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.11 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 in October of 1996. An updated plan was submitted in December of 1999.

(b) Upon direct notification by IDEM, OAQ, and/or OES 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.12 Risk Management Plan [326 IAC 2-7-5(12)] [40 CFR 68.215]

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

(a) The Permittee is required to prepare a Compliance Response Plan (CRP) for each compliance monitoring condition of this permit. If the Permittee is required to have an Operation, Maintenance and Monitoring (OMM) Plan under 40 CFR 63, such plans shall be deemed to satisfy the requirements for a CRP for those compliance monitoring conditions. A CRP shall be submitted to IDEM, OAQ and OES 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 Operation, Maintenance and Monitoring (OMM) Plan and the Permittee documents such response in accordance with subsection (e) below, the Permittee shall amend its Compliance Response Plan to include such response steps taken.

The OMM Plan shall be submitted within the time frames specified by the applicable 40 CFR 63 requirement.

(b) For each compliance monitoring condition of this permit, reasonable response steps shall be taken when indicated by the provisions of that compliance 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

(2) If none of the reasonable response steps listed in the Compliance Response Plan or Operation, Maintenance and Monitoring (OMM) 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 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 status of the applicable compliance monitoring parameter with respect to normal, and the results of the actions taken up to the time of notification.

(4) Failure to take reasonable response steps shall be considered 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 compliance 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 compliance 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.14 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 and OES reserve 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.15 Emission Statement [326 IAC 2-7-5(3)(C)(iii)] [326 IAC 2-7-5(7)] [326 IAC 2-7-19(c)][326 IAC 2-6]

(a) Pursuant to 326 IAC 2-6-3(b)(2), starting in 2005 and every three (3) years thereafter, the Permittee shall submit by July 1 an emission statement covering the previous calendar year. The emission statement shall contain, at a minimum, the information specified in 326 IAC 2-6-4(c) and shall meet the following requirements:

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

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

The statement must be submitted to:

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

and

Office of Environmental Services (OES)
Air Quality Management Section
2700 South Belmont Avenue
Indianapolis, IN 46221

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

(b) The emission statement required by this permit shall be considered timely if the date postmarked on the envelope or certified mail receipt, or affixed by the shipper on the private shipping receipt, is on or before the date it is due. If the document is submitted by any other means, it shall be considered timely if received by IDEM, OAQ, and OES on or before the date it is due.

C.16 General Record Keeping Requirements [326 IAC 2-7-5(3)] [326 IAC 2-7-6] [326 IAC 2-3]

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

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

(c) If there is a reasonable possibility that a "project" (as defined in 326 IAC 2-3-1(ll)) at a major source other than projects at a Clean Unit, which is not part of a "major modification" (as defined in 326 IAC 2-3-1(z)) may result in a significant emissions increase and the Permittee elects to utilize the "projected actual emissions" (as defined in 326 IAC 2-3-1(mm)), the Permittee shall comply with the following:

(1) Before beginning actual construction of the "project" (as defined in 326 IAC 2-3-1(ll)) at an existing emission unit, document and maintain the following records:
  (A) A description of the project;
  (B) Identification of any emissions unit whose emissions of a regulated new source review pollutant could be affected by the project;
  (C) A description of the applicability test used to determine that the project is not a major modification for any regulated NSR pollutant, including:
    (i) Baseline actual emissions;
    (ii) Projected actual emissions;
    (iii) Amount of emissions excluded under section 326 IAC 2-3-1(mm)(2)(A)(iii); and
    (iv) An explanation for why the amount was excluded, and any netting calculations, if applicable.

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

(3) Calculate and maintain a record of the annual emissions, in tons per year on a

calendar basis, for a period of five (5) years following resumption of regular operations after the change, or for a period of ten (10) years following resumption of regular operations after the change if the project increases the design capacity of or the potential to emit of that regulated NSR pollutant at the emissions unit.

C.17 General Reporting Requirements [326 IAC 2-7-5(3)(C)] [326 IAC 2-1.1-11] [326 IAC 2-3]

(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 Aresponsible 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 and Section E of this permit shall be submitted to:

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

and

Office of Environmental Services (OES)
Air Quality Management Section
2700 South Belmont Avenue
Indianapolis, IN 46221

unless specifically stated otherwise for a specific report.

(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, and OES on or before the date it is due.

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

(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.

(f) If the Permittee is required to comply with the record keeping provisions of (c) in Section C - General Record Keeping Requirements for any Aproject@ (as defined in 326 IAC 2-3-1(ll)) at an existing emission unit, and the project meets the following criteria, then the Permittee shall submit a report to IDEM, OAQ and OES:

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

(2) The emissions differ from preconstruction projection as documented and maintained

under Section C - General Record Keeping Requirements (c)(1)(C)(ii).

(g) The report required by C.18(f) shall be submitted within sixty (60) days after the end of the year and contain the following:

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

(2) The annual emissions calculated in accordance with (c)(2) and (3) in Section C - General Record Keeping Requirements.

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

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

Reports required in this part shall be submitted to:

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

and

Office of Environmental Services (OES)
Air Quality Management Section
2700 South Belmont Avenue
Indianapolis, IN 46221

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

Stratospheric Ozone Protection

C.18 Compliance with 40 CFR 82 and 326 IAC 22-1

Pursuant to 40 CFR 82 (Protection of Stratospheric Ozone), Subpart F, except as provided for motor vehicle air conditioners in Subpart B, the Permittee shall comply with the applicable standards for recycling and emissions reduction contained in 40 CFR 82.

SECTION D.1 FACILITY OPERATION CONDITIONS

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

(a) A chemical development pilot plant facility and laboratories (identified as Building 110) used to develop new chemical processes and to produce new pharmaceutical compounds for subsequent use in toxicology studies and clinical trial research, with Modules A, B, C, D, E, 30 gallon A, 30 gallon B, Solids Containment and D-wing, and with process condensers.

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

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

D.1.1 Synthesized Pharmaceutical Manufacturing Operations [326 IAC 8-1-5] [326 IAC 8-5-3]

Pursuant to 326 IAC 8-1-5, CP097-3341 (the RACT plan issued on July 27, 1994), A097-5322, A097-12128, 326 IAC 8-5-3, and 40 CFR 52.770(c)(157) the following shall be met:

(a) The volatile organic compound (VOC) emissions from the pilot plant in Building 110 shall be limited to less than 10 tons per twelve (12) consecutive month period rolled on a monthly basis.

(b) The primary reactor condensers shall operate during reactor venting, material transfer, distillation, and storage of filtrates in reactors, which are transferred from the filters. The primary reactor condensers working fluid inlet temperature shall be -10 degrees C or colder for mixtures that will not freeze at -10 degrees C (includes most non-aqueous streams).

(c) The emission units which have the potential to emit VOC greater than 15 pounds per day shall comply with the requirements of 326 IAC 8-5-3(b)(3) through (6).

(1) Pursuant to 326 IAC 8-5-3(b)(3), the Permittee shall provide a vapor balance system or equivalent control that is at least 90% effective in reducing emissions from truck or railcar deliveries to storage tanks, which have the potential to emit VOC greater than 15 pounds per day and which have capacities greater than seven thousand five hundred (7,500) liters (two thousand (2,000) gallons) that store VOC with vapor pressures greater than twenty-eight (28) kiloPascals (four and one-tenth (4.1) pounds per square inch) at 20 degrees C.

(2) Pursuant to 326 IAC 8-5-3(b)(3), the Permittee shall install a pressure / vacuum conservation vents set at plus or minus two-tenths (±0.2) kiloPascals on all storage tanks which have the potential to emit VOC greater than 15 pounds per day and that store VOC with vapor pressures greater than ten (10) kiloPascals (one and five-tenths (1.5) pounds per square inch) at 20 degrees C, unless a more effective control system is used.

(3) Pursuant to 326 IAC 8-5-3(b)(4), the Permittee shall enclose all centrifuges, rotary vacuum filters, and other filters which have the potential to emit VOC greater than 15 pounds per day and which have an exposed liquid surface, where the liquid contains VOC and exerts a total VOC vapor pressure of three and five-tenths (3.5) kiloPascals (five-tenths (0.5) pounds per square inch) or more at 20 degrees C.

(4) Pursuant to 326 IAC 8-5-3(b)(5), the Permittee shall install covers on all in process tanks which have the potential to emit VOC greater than 15 pounds per day and which contain a volatile organic compound at any time. These covers must remain

closed, unless production, sampling, maintenance, or inspection procedures require operator access.

(5) Pursuant to 326 IAC 8-5-3(b)(6), the Permittee shall, for the emission units which have the potential to emit VOC greater than 15 pounds per day, repair all leaks from which a liquid, containing VOC, can be observed running or dripping. The repair shall be completed the first time the equipment is off line for a period of time long enough to complete the repair.

D.1.2 Advance Approval of Modifications [326 IAC 2-7-5(16)]

The Permittee may modify any existing emission unit, replace any existing emission unit, or add a new process vessel, filter, centrifuge, dryer or any other pharmaceutical processing equipment to the operations described in this section without a source modification approval required by 326 IAC 2-7-10.5 or a permit revision required by 326 IAC 2-7-12 provided the following requirements are satisfied:

(a) All the applicable requirements for the modified, replaced or newly constructed emission unit are described or referenced in this section of the permit or in Sections B or C of this permit.

(b) The modification, replacement or construction of the emission unit does not require new or additional applicable requirements to be added to this section of the permit.

(c) The modification, replacement or construction of the emission unit does not require revision of applicable requirements in this section of the permit.

(d) The modification, replacement or construction of the emission unit does not meet the definition of a major modification as defined in 326 IAC 2-2 or 326 IAC 2-3.

Compliance Determination

D.1.3 Volatile Organic Compounds (VOC)

To determine compliance with D.1.1(a), emissions shall be calculated by mass balance, by appropriate unit operation emissions estimation procedures (e.g., Appendix B of "Control of Volatile Organic emissions from Manufacture of Synthesized Pharmaceutical Products," EPA-450/2-78-029), or by other generally accepted methods (e.g., AP-42 emission factors), as approved by the Commissioner.

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

D.1.4 Instrument Specifications [326 IAC 2-1.1-11] [326 IAC 2-7-5(3)] [326 IAC 2-7-6(1)]

(a) The instrument employed for the measurement of temperature shall have a scale such that the expected normal reading shall be no less than twenty percent (20%) of full scale and be accurate within plus or minus two percent (∀2%) of full scale reading.

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

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

D.1.5 Record Keeping Requirements

To document compliance with Condition D.1.1, the Permittee shall maintain a log of information necessary to document compliance. These records shall be made available upon request to the Office of Air Quality and/or the Office of Environmental Services.

D.1.6 Reporting Requirements

(a) Pursuant to 326 IAC 8-1-5, CP097-3341, A097-5322, A097-12128, 326 IAC 8-5-3, and 40 CFR 52.770(c)(157), the Permittee shall submit a quarterly certification that the condensers were operating and controlling emissions at all times as required by Condition D.1.1. If any exceptions occurred, the certification shall include any notes of exceptions, what caused the exception and how it was corrected

(b) The Permittee shall submit an annual summary of volatile organic compounds (VOC) emissions to document compliance with Condition D.1.1 of this permit, using the reporting form located at the end of this permit, or its equivalent. This annual report submitted by the Permittee does require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

(c) The reports required in (a) and (b) of this condition shall be submitted within sixty (60) days after the end of the reporting period and shall be submitted to the following address:

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

and

Indianapolis Office of Environmental Services
Air Compliance
2700 South Belmont Avenue
Indianapolis, IN 46221

SECTION D.2 FACILITY OPERATION CONDITIONS

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

(b) Manufacture of bulk pharmaceutical products (Building 358) by:

(1) protein isolation with a carbon adsorber for VOC and HAP control with laboratory support;
(2) chemical synthesis,

units subject to BACT [326 IAC 8-1-6].

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

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

D.2.1 General Provisions Relating to HAPs [326 IAC 20-1-1][40 CFR 63, Subpart A]

The provisions of 40 CFR Part 63, Subpart A - General Provisions, which are incorporated as 326 IAC 20-1-1, apply to the facility described in this section except when otherwise specified in Table 1 of 40 CFR 63, Subpart GGG.

D.2.2 Applicability [40 CFR 63, Subpart GGG] [326 IAC 20]

The provisions of 40 CFR 63, Subpart GGG, National Emission Standards for Pharmaceutical Manufacturing, apply to the facility described in this section.

(a) The applicable Process Vent limits, pursuant to 40 CFR 63.1254, are described in Section E.1.

(b) The applicable Equipment Leak standards of 40 CFR 63.1255 are described in Section E.2 - Pharmaceutical Manufacturing NESHAP Equipment Leaks Provisions.

(c) The applicable Wastewater standards of 40 CFR 63.1256 are described in Section E.3 - Pharmaceutical Manufacturing NESHAP Wastewater Provisions.

(d) The Permittee may open a safety device, as defined in 40 CFR 63.1251, at any time conditions require it to avoid unsafe conditions.

D.2.3 Volatile Organic Compounds (VOC) [326 IAC 8-1-6]

Pursuant to 326 IAC 8-1-6 and CP-960073-01 issued on September 25, 1996, the Permittee shall employ Best Available Control Technology (BACT):

(a) BACT for all point sources of VOC in aggregate in Building 358 shall be a reduction of emissions by 95%, or to a level of 0.20 pounds per hour, whichever is less stringent, by applying air pollution control equipment.

(b) BACT for fugitive emissions shall be a Leak Detection and Repair program as described in Condition D.2.4.

(c) This requirement applies to the following equipment:

B358 equipment subject to BACT (CP 960073-01)					
Bldg.	**Stack/Vent ID**	**Emission Unit ID**	**Equipment Description**	**Maximum Capacity**	**UOM**
358	COL-2121	COL-2121	100 cm column	500 L	Liters
358	TK-4101	TK-4101	TANK	10000 L	Liters
358	TK-4111	TK-4111	TANK	10000 L	Liters
358	TK-4121	TK-4121	TANK	5000 L	Liters
358	TK-4131	TK-4131	TANK	5000 L	Liters
358	TK-4141	TK-4141	TANK	2500 L	Liters
358	TK-4151	TK-4151	TANK	2500 L	Liters
358	LYPH-1611	LYPH-1611	Freeze Dryer	N/A	N/A
358	TK-4201	TK-4201	TANK	10000 L	Liters
358	TK-4211	TK-4211	TANK	10000 L	Liters
358	TK-4221	TK-4221	TANK	5000 L	Liters
358	TK-4231	TK-4231	TANK	5000 L	Liters
358	TK-4241	TK-4241	TANK	2500 L	Liters
358	TK-4251	TK-4251	TANK	2500 L	Liters
358	TK-1961	TK-1961	Haz. Waste tank	4000 G	Gallons
358	TK-1962	TK-1962	Haz. Waste tank	200 G	Gallons
358	TK-1963	TK-1963	Haz. Waste tank	200 G	Gallons
358	TK-1964	TK-1964	Haz. Waste tank	200 G	Gallons
358	TK-1965	TK-1965	Haz. Waste tank	200 G	Gallons

D.2.4 LDAR [326 IAC 8-1-6] [40 CFR 63, Subpart GGG] [40 CFR 61 Subpart V] [CP-960073-01]

(a) The Permittee shall implement Conditions E.2.1 and E.2.2 for process components in VOC service. In VOC 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 organic compound (VOC). Process components are those components from the arrival of raw materials at the source to the Pharmaceutical MACT point of determination (POD).

(b) BACT for fugitive emissions from waste components in VOC service shall be the Leak Detection and Repair requirements of 40 CFR 61, Subpart V. In VOC 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 organic compound (VOC). Waste components are those components after the Pharmaceutical Production MACT point of determination (POD).

(1) Pumps shall be operated in accordance with the standard at 40 CFR 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 40 CFR 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 40 CFR 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 satisfies D.2.4(b)(3)(A) and (B) without monitoring if it is replaced within 5 calendar days after each pressure release, except if delay of repair applies.

(D) Any pressure relief device satisfies conditions D.2.4(b)(3)(A) and (B) without monitoring if it is routed to a process or fuel gas system or equipped with a closed-vent system limitable of capturing and transporting leakage from the pressure relief device to a control device.

(4) Sampling Connection Systems shall be operated in accordance with the standard at 40 CFR 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 a regulation under 40 CFR 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 40 CFR 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 D.2.4(b)(5)(B).

(D) Open-ended valves and lines in an emergency shutdown system which are designed to open automatically in the event of a process upset are not required to comply with D.2.4(b)(5)(A) through (C).

(E) 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 D.2.4(b)(5)(A) through (C).

(6) Valves shall be operated in accordance with the standard at 40 CFR 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 40 CFR 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) As an alternative to complying with D.2.4(b)(6), valves may comply with the alternative standards for valves- allowable percentage of valves leaking under 40 CFR 61.243-1.
(9) As an alternative to complying with the monitoring requirements in D.2.4(b)(6), with respect to monitoring requirements alone, valves may comply with the alternative standards for valves – skip period leak detection and repair under 40 CFR 61.243-2.

(10) 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.

D.2.5 Synthesized Pharmaceutical Manufacturing Operations [326 IAC 8-5-3]

The bulk manufacture of pharmaceutical products by chemical synthesis takes place in a portion of Building 358 (rGlucagon area). However, there are no facilities in this area with the potential to emit greater than 15 pounds per day of VOC, therefore, the requirements of 326 IAC 8-5-3 were not included in this permit.

D.2.6 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 protein isolation manufacturing and the carbon adsorber.

Compliance Determination

D.2.7 Volatile Organic Compounds

To determine compliance with Condition D.2.3(a), the Permittee shall monitor emissions as outlined in Condition E.1.2 of this permit.

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

D.2.8 Record Keeping Requirements

(a) Records required to be kept by 40 CFR 63, Subpart GGG are described in Sections E.1, E.2, and E.3 of this permit.

(b) To document compliance with Condition D.2.6, the Permittee shall maintain records of inspections prescribed by the Preventive Maintenance Plan.

D.2.9 Reporting Requirements

Reports required by 40 CFR 63, Subpart GGG are described in Sections E.1, E.2, and E.3 of this permit.

SECTION D.3 FACILITY OPERATION CONDITIONS

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

(c) Manufacture of bulk pharmaceutical products (Building 358) by:

(1) protein isolation with laboratory support;
(2) chemical synthesis, or non-synthesized chemical processes;

units not subject to BACT [326 IAC 8-1-6].

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

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

D.3.1 General Provisions Relating to HAPs [326 IAC 20-1-1][40 CFR 63, Subpart A]

The provisions of 40 CFR Part 63, Subpart A - General Provisions, which are incorporated as 326 IAC 20-1-1, apply to the facility described in this section except when otherwise specified in Table 1 of 40 CFR 63, Subpart GGG.

D.3.2 Applicability [40 CFR 63, Subpart GGG] [326 IAC 20]

The provisions of 40 CFR 63, Subpart GGG, National Emission Standards for Pharmaceutical Manufacturing, apply to the facility described in this section.

(a) The applicable Process Vent limits, pursuant to 40 CFR 63.1254, are described in Section E.1.

(b) The applicable Equipment Leak standards of 40 CFR 63.1255 are described in Section E.2 - Pharmaceutical Manufacturing NESHAP Equipment Leaks Provisions.

(c) The applicable Wastewater standards of 40 CFR 63.1256 are described in Section E.3 - Pharmaceutical Manufacturing NESHAP Wastewater Provisions.

(d) The Permittee may open a safety device, as defined in 40 CFR 63.1251, at any time conditions require it to avoid unsafe conditions.

D.3.3 Advance Approval of Modifications [326 IAC 2-7-5(16)]

The Permittee may modify any existing emission unit, replace any existing emission unit, or add a new process vessel, filter, centrifuge, dryer or any other pharmaceutical processing equipment to the operations described in this section without a source modification approval required by 326 IAC 2-7-10.5 or a permit revision required by 326 IAC 2-7-12 provided the following requirements are satisfied:

(a) All the applicable requirements for the modified, replaced or newly constructed emission unit are described or referenced in this section of the permit or in Sections B and C of this permit.

(b) The modification, replacement or construction of the emission unit does not require new or additional applicable requirements to be added to this section of the permit.

(c) The modification, replacement or construction of the emission unit does not require revision of applicable requirements in this section of the permit.

(d) The modification, replacement or construction of the emission unit does not meet the definition of a major modification as defined in 326 IAC 2-2-1 or 326 IAC 2-3-1.

D.3.4 Synthesized Pharmaceutical Manufacturing Operations [326 IAC 8-5-3]

The bulk manufacture of pharmaceutical products by chemical synthesis takes place in a portion of Building 358 (rGlucagon area). However, there are no facilities in this area with the potential to emit greater than 15 pounds per day of VOC, therefore, the requirements of 326 IAC 8-5-3 do not apply.

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

D.3.5 Record Keeping Requirements

(a) Records required to be kept by 40 CFR 63, Subpart GGG are described in Sections E.1, E.2 and E.3 of this permit.

D.3.6 Reporting Requirements

Reports required by 40 CFR 63, Subpart GGG are described in Sections E.1, E.2 and E.3 of this permit.

SECTION D.4 FACILITY OPERATION CONDITIONS

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

(d) Manufacture of vancomycin (VANCO) by isolation (base) and purification (HPLC) with a condenser for VOC and HAP control located in Building 348.

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

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

D.4.1 General Provisions Relating to HAPs [326 IAC 20-1-1][40 CFR 63, Subpart A]

The provisions of 40 CFR Part 63, Subpart A - General Provisions, which are incorporated as 326 IAC 20-1-1, apply to the facility described in this section except when otherwise specified in Table 1 of 40 CFR 63, Subpart GGG.

D.4.2 Applicability [40 CFR 63, Subpart GGG] [326 IAC 20]

The provisions of 40 CFR 63, Subpart GGG, National Emission Standards for Pharmaceutical Manufacturing, apply to the facilities in the VANCO area.

(a) The applicable Process Vent limits, pursuant to 40 CFR 63.1254, are described in Section E.1.

(b) The applicable Equipment Leak Standards for all compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, connectors, instrumentation systems, control devices, and closed vent systems required by 40 CFR 63.1255 that are intended to operate in organic hazardous air pollutant service 300 hours or more during the calendar year, pursuant to 40 CFR 63.1255, are described in Section E.2.

(c) The applicable Wastewater standards of 40 CFR 63.1256 are described in Section E.3 - Pharmaceutical Manufacturing NESHAP Wastewater Provisions.

(d) The Permittee may open a safety device, as defined in 40 CFR 63.1251, at any time conditions require it to avoid unsafe conditions.

D.4.3 New Source General Emission Reduction Requirements [326 IAC 8-1-6] [326 IAC 2-7-24] [40 CFR 63, Subpart GGG] [326 IAC 2-3]

(a) Pursuant to the BACT determination under 326 IAC 8-1-6, the Permittee shall route all vapors from Evaporator 116 (EV116) to a condenser that achieves a 95% reduction in VOC. Compliance with BACT makes 326 IAC 2-3 (Emission Offset) not applicable.

(b) Pursuant to 326 IAC 2-7-24, the requirement in (a) above is streamlined with 40 CFR 63, Subpart GGG after April 2, 2007 or when EV116 is reconstructed or replaced, whichever is earlier. After April 2, 2007 (or upon reconstruction or replacement if earlier than April 2, 2007), the Permittee shall comply with 40 CFR 63.1254(a)(3)(ii)(A)(3) and (4) which requires the Permittee to upgrade or replace the condenser on EV116 such that the control device achieves a 98% reduction in HAP.

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 required for the condenser used for VOC and HAP control.

Compliance Determination

D.4.5 New Source General Emission Reduction Requirements [326 IAC 8-1-6] [326 IAC 2-2] [326 IAC 2-7-24] [40 CFR 63, Subpart GGG] [326 IAC 2-3]

Pursuant to 326 IAC 2-7-24, the compliance determination requirements for BACT (Condition D.4.3) have been streamlined with the monitoring and compliance determination requirements of 40 CFR 63, Subpart GGG. The applicable requirements for EV116 are described in Section E.1.2 of this permit.

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

D.4.6 Record Keeping Requirements

(a) Pursuant to 326 IAC 2-7-24, the recordkeeping requirements to document compliance with Condition D.4.3 have been streamlined with the requirements of 40 CFR 63, Subpart GGG. The record keeping requirements to document compliance with D.4.3, are described in Section E.1.3 of this permit.

(b) To document compliance with Condition D.4.4, the Permittee shall maintain records of inspections prescribed by the Preventive Maintenance Plan.

(c) Records required to be kept by 40 CFR 63, Subpart GGG are described in Sections E.1, E.2 and E.3 of this permit.

D.4.7 Reporting Requirements

(a) Pursuant to 326 IAC 2-7-24, the reporting requirements to document compliance with Condition D.4.3 have been streamlined with 40 CFR 63, Subpart GGG. Therefore, the Permittee shall document compliance with Conditions D.4.3 and D.4.6 by submitting the Periodic Report required by 40 CFR 63.1260(g).

(b) Reports required by 40 CFR 63, Subpart GGG are described in Sections E.1, E.2, and E.3 of this permit.

SECTION D.5 FACILITY OPERATION CONDITIONS

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

(e) The BHI area consists of five buildings (Buildings 132, 133, 134, 138, and 142) where manufacturing of bulk pharmaceutical products through chemical synthesis takes place using condensers and a scrubber as VOC control.

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

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

D.5.1 General Provisions Relating to HAPs [326 IAC 20-1-1][40 CFR 63, Subpart A]

The provisions of 40 CFR Part 63, Subpart A - General Provisions, which are incorporated as 326 IAC 20-1-1, apply to the facility described in this section except when otherwise specified in Table 1 of 40 CFR 63, Subpart GGG.

D.5.2 Applicability [40 CFR 63, Subpart GGG] [326 IAC 20]

The provisions of 40 CFR 63, Subpart GGG, National Emission Standards for Pharmaceutical Manufacturing, apply to the facilities in the BHI area.

(a) The applicable Process Vent limits, pursuant to 40 CFR 63.1254, are described in Section E.1.

(b) The applicable Equipment Leak Standards of 40 CFR 63.1255 for all compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, connectors, instrumentation systems and for control devices and closed vent systems required to comply with 40 CFR 63.1255 that are intended to operate in organic hazardous air pollutant service 300 hours or more during the calendar year are described in Section E.2 - Pharmaceutical Manufacturing NESHAP Equipment Leaks Provisions.

(c) The applicable Wastewater standards of 40 CFR 63.1256 are described in Section E.3 - Pharmaceutical Manufacturing NESHAP Wastewater Provisions.

(d) The Permittee may open a safety device, as defined in 40 CFR 63.1251, at any time conditions require it to avoid unsafe conditions.

D.5.3 Prevention of Significant Deterioration Minor Limit [326 IAC 2-2][40 CFR 52.21]

Pursuant to Permit Number 910072-01 issued on October 2, 1991 and Amendment A072-0001 issued on June 3, 1997, VOC emissions from Building 132 are limited to less than 40 tons per 12 consecutive month period with compliance determined at the end of each month such that 326 IAC 2-2 is not applicable.

D.5.4 Leak Detection and Repair [326 IAC 2-2] [40 CFR 52.21] [40 CFR 63 Subpart GGG]

Pursuant to CP-910072-01 and Amendment A072-0001, the permittee shall implement leak detection and repair (LDAR). The LDAR requirements for pumps, valves, and flanges in the BHI area in VOC service are described in Conditions E.2.1 and E.2.2. In VOC service means that a piece of equipment either contains or contacts a fluid (liquid or gas) that is at least ten (10) percent by weight a volatile organic compound (VOC).

D.5.5 Particulate [326 IAC 6-3-2]

Pursuant to 326 IAC 6-3-2 (Particulate Emission Limitations for Manufacturing Processes), the allowable particulate emission rate from the urea prills unloading operation shall meet the particulate emission rate established by the equation below. The urea prills unloading operation shall not

exceed 47.2 pounds per hour when operating at a process weight rate of 66 tons per hour. A particulate scrubber is an integral part of the urea prill unloading process and will operate at all times this process is in operation.

The pounds per hour limitation was calculated with the following equation:

Interpolation and extrapolation of the data for the process weight rate in excess of 60,000 pounds per hour shall be accomplished by use of the equation:

$E = 55.0 P^{0.11} - 40$ where E = rate of emission in pounds per hour; and P = process weight rate in tons per hour

D.5.6 Synthesized Pharmaceutical Manufacturing Operations [326 IAC 8-5-3]

(a) Volatile organic compound emissions from all reactors, distillation operations, crystallizers, centrifuges, and vacuum dryers, which have the potential to emit VOC greater than 15 pounds per day, shall be controlled by surface condensers or equivalent controls.

(1) If surface condensers are used, the condenser outlet gas temperature must not exceed minus twenty five degrees Celsius (-25EC) when condensing VOC of vapor pressure greater than forty (40) kilo Pascals (5.8 pounds per square inch);

(2) If surface condensers are used, the condenser outlet gas temperature must not exceed minus fifteen degrees Celsius (-15EC) when condensing VOC of vapor pressure greater than twenty (20) kilo Pascals (2.9 pounds per square inch);

(3) If surface condensers are used, the condenser outlet gas temperature must not exceed zero degrees Celsius (0EC) when condensing VOC of vapor pressure greater than ten (10) kilo Pascals (1.5 pounds per square inch);

(4) If surface condensers are used, the condenser outlet gas temperature must not exceed ten degrees Celsius (10EC) when condensing VOC of vapor pressure greater than seven (7) kilo Pascals (1 pound per square inch);

(5) If surface condensers are used, the condenser outlet gas temperature must not exceed twenty five degrees Celsius (25EC) when condensing VOC of vapor pressure greater than three and a half (3.5) kilo Pascals (0.5 pound per square inch);

(6) The vapor pressures listed in (1) through (5) above shall be measured at twenty degrees Celsius (20EC).

(7) If equivalent controls are used, the Volatile Organic Compound emissions must be reduced by at least as much as they would be by using a surface condenser which meets the requirements of (1) through (5) above.

(b) Pursuant to 326 IAC 8-5-3(b)(2), VOC emissions from all air dryers and production equipment exhaust systems shall be reduced:

(1) by at least ninety percent (90%) if emissions are one hundred fifty (150) kilograms per day (three hundred thirty (330) pounds per day) or more of VOC; or

(2) to fifteen (15) kilograms per day (thirty three (33) pounds per day) or less if emissions are less than one hundred fifty (150) kilograms per day (three hundred thirty (330) pounds per day) of VOC.

(c) Pursuant to 326 IAC 8-5-3(b)(3)(A), the Permittee shall provide a vapor balance system or equivalent control that is at least 90% effective in reducing emissions from truck or railcar deliveries to storage tanks, which have the potential to emit VOC greater than 15 pounds per

day and which have capacities greater than seven thousand five hundred (7,500) liters (two thousand (2,000) gallons) that store VOC with vapor pressures greater than twenty-eight (28) kiloPascals (four and one-tenth (4.1) pounds per square inch) at 20 degrees C.

(d) Pursuant to 326 IAC 8-5-3(b)(3)(B), the Permittee shall install a pressure / vacuum conservation vents set at plus or minus two-tenths (∀0.2) kiloPascals on all storage tanks which have the potential to emit VOC greater than 15 pounds per day and that store VOC with vapor pressures greater than ten (10) kiloPascals (one and five-tenths (1.5) pounds per square inch) at 20 degrees C, unless a more effective control system is used.

(e) Pursuant to 326 IAC 8-5-3(b)(4), the Permittee shall enclose all centrifuges, rotary vacuum filters, and other filters which have the potential to emit VOC greater than 15 pounds per day and which have an exposed liquid surface, where the liquid contains VOC and exerts a total VOC vapor pressure of three and five-tenths (3.5) kiloPascals (five-tenths (0.5) pounds per square inch) or more at 20 degrees C.

(f) Pursuant to 326 IAC 8-5-3(b)(5), the Permittee shall install covers on all inprocess tanks which have the potential to emit VOC greater than 15 pounds per day and which contain a volatile organic compound at any time. These covers must remain closed, unless production, sampling, maintenance, or inspection procedures require operator access.

(g) Pursuant to 326 IAC 8-5-3(b)(6), the Permittee shall, for the emission units which have the potential to emit VOC greater than 15 pounds per day, repair all leaks from which a liquid, containing VOC, can be observed running or dripping. The repair shall be completed the first time the equipment is off line for a period of time long enough to complete the repair.

D.5.7 Advance Approval of Modifications [326 IAC 2-7-5(16)]

The Permittee may modify any existing emission unit, replace any existing emission unit, or add a new process vessel, filter, centrifuge, dryer or any other pharmaceutical processing equipment to the operations described in this section without a source modification approval required by 326 IAC 2-7-10.5 or a permit revision required by 326 IAC 2-7-12 provided the following requirements are satisfied:

(a) All the applicable requirements for the modified, replaced or newly constructed emission unit are described or referenced in this section of the permit or in Sections B and C of this permit.

(b) The modification, replacement or construction of the emission unit does not require new or additional applicable requirements to be added to this section of the permit.

(c) The modification, replacement or construction of the emission unit does not require revision of applicable requirements in this section of the permit.

(d) The modification, replacement or construction of the emission unit does not meet the definition of a major modification as defined in 326 IAC 2-2 or 326 IAC 2-3.

D.5.8 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 emission units and control devices subject to Condition D.5.6 Synthesized Pharmaceutical Manufacturing Operations [326 IAC 8-5-3].

Compliance Determination

D.5.9 Volatile Organic Compounds (VOC)

Source emissions shall be calculated by mass balance, by appropriate unit operation emissions estimation procedures (e.g., Appendix B of “Control of Volatile Organic emissions from Manufacture of Synthesized Pharmaceutical Products,” EPA-450/2-78-029), or by other generally accepted

methods (e.g., AP-42 emission factors), as approved by the Commissioner to determine compliance with D.5.3.

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

D.5.10 Synthesized Pharmaceutical Manufacturing Operations [326 IAC 8-5-3]

(a) For emitting units, subject to Condition D.5.6, controlled by a surface condenser, the Permittee shall record the condenser outlet gas temperature at least once per batch when the emitting unit is in operation.

(b) For emitting units, subject to Condition D.5.6, controlled by a scrubber, the Permittee shall record the recirculation flow rate at least once per batch when the emitting unit is in operation.

D.5.11 Instrument Specifications [326 IAC 2-1.1-11] [326 IAC 2-7-5(3)] [326 IAC 2-7-6(1)]

(a) The instrument employed for the measurement of temperature as required by Conditions D.5.6 and D.5.10 shall have a scale such that the expected normal reading shall be no less than five percent (5%) of full scale and be accurate within plus or minus 2.5°C.

(b) The instrument employed for the measurement of flowrate as required by Condition D.5.10 shall be accurate within plus or minus ten percent (10%) of design flow rate.

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

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

D.5.12 Record Keeping Requirements

(a) To document compliance with Condition D.5.4, the Permittee shall keep records as described in Condition E.2.3 for fugitive emission components in VOC service.

(b) To document compliance with Condition D.5.3, the Permittee shall keep a record of the weight of VOCs emitted each month. Records necessary to demonstrate compliance shall be available within 30 days of the end of each month.

(c) To document compliance with Conditions D.5.6 and D.5.10, the Permittee is required to:

(1) Keep an on-site log of emitting units subject to Condition D.5.6, the condensing VOC vapor pressure, the respective control device, and the applicable limitation.

(2) Keep records of once per batch temperature as per Condition D.5.10 for surface condensers subject to Condition D.5.6.

(3) Keep records of once per batch liquid flow rates as per Condition D.5.10 for scrubbers subject to Condition D.5.6.

(d) To document compliance with Condition D.5.8, the Permittee shall maintain records of any inspections prescribed by the Preventive Maintenance Plan.

(e) Records required to be kept by 40 CFR 63, Subpart GGG are described in Section E of this permit.

D.5.13 Reporting Requirements

(a) A quarterly summary of the information to document compliance with Condition D.5.3 shall be submitted according to Section C - General Reporting Requirements.

(b) To document compliance with Condition D.5.4, the Permittee shall submit reports as described in Condition E.2.4 for fugitive emission components in VOC service.

(c) Reports required by 40 CFR 63, Subpart GGG are described in Section E of this permit.

SECTION D.6 FACILITY CONDITIONS

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

(f) Building 130 Complex (buildings 130, 135 and 136) consisting of laboratories and manufacturing of bulk pharmaceutical products (Building 130) through chemical synthesis.

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

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

D.6.1 General Provisions Relating to HAPs [326 IAC 20-1-1][40 CFR 63, Subpart A]

The provisions of 40 CFR Part 63, Subpart A - General Provisions, which are incorporated as 326 IAC 20-1-1, apply to the processes described in this section except when otherwise specified in Table 1 of 40 CFR 63, Subpart GGG when manufacturing pharmaceutical product and processing, using or producing HAP.

D.6.2 Applicability [40 CFR 63, Subpart GGG] [326 IAC 20]

The provisions of 40 CFR 63, Subpart GGG, National Emission Standards for Pharmaceutical Manufacturing, apply to the processes described in this section when manufacturing pharmaceutical product and processing, using or producing HAP.

(a) The applicable Process Vent limits, pursuant to 40 CFR 63.1254, for Building 130 are described in Section E.1.

(b) The applicable Equipment Leak standards of 40 CFR 63.1255 for all compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, connectors, instrumentation systems, control devices, and closed vent systems required by 40 CFR 63.1255 that are intended to operate in organic hazardous air pollutant service 300 hours or more during the calendar year are described in Section E.2 - Pharmaceutical Manufacturing NESHAP Equipment Leaks Provisions.

(c) The applicable Wastewater standards of 40 CFR 63.1256 are described in Section E.3 - Pharmaceutical Manufacturing NESHAP Wastewater Provisions.

(d) The Permittee may open a safety device, as defined in 40 CFR 63.1251, at any time conditions require it to avoid unsafe conditions.

D.6.3 Particulate [326 IAC 6-3-2]

Pursuant to 326 IAC 6-3-2 (Particulate Emission Limitations for Manufacturing Processes), the allowable particulate emission rate from the urea prills unloading operation located in Building 130 shall meet the particulate emission rate established by the equation below. The urea prills unloading operation shall not exceed 27.0 pounds per hour when operating at a process weight rate of 16.7 tons per hour. A scrubber is integral to the urea prill unloading process and will operate at all times this facility is in operation. The pounds per hour limitation was calculated with the following equation:

Interpolation of the data for the process weight rate up to 60,000 pounds per hour shall be accomplished by use of the equation:

$E = 4.10\ P^{0.67}$ where E = rate of emission in pounds per hour; and
P = process weight rate in tons per hour

D.6.4 Synthesized Pharmaceutical Manufacturing Operations [326 IAC 8-5-3]

The bulk manufacture of pharmaceutical products takes place in the Building 130 Complex. However, there are no facilities in this area with the potential to emit greater than 15 pounds per day of VOC, therefore, the requirements of 326 IAC 8-5-3 are not included.

D.6.5 Advance Approval of Modifications [326 IAC 2-7-5(16)]

The Permittee may modify any existing emission unit, replace any existing emission unit, or add a new process vessel, filter, centrifuge, dryer or any other pharmaceutical processing equipment to the operations described in this section without a source modification approval required by 326 IAC 2-7-10.5 or a permit revision required by 326 IAC 2-7-12 provided the following requirements are satisfied:

(a) All the applicable requirements for the modified, replaced or newly constructed emission unit are described or referenced in this section of the permit or in Sections B and C of this permit.

(b) The modification, replacement or construction of the emission unit does not require new or additional applicable requirements to be added to this section of the permit.

(c) The modification, replacement or construction of the emission unit does not require revision of applicable requirements in this section of the permit.

(d) The modification, replacement or construction of the emission unit does not meet the definition of a major modification as defined in 326 IAC 2-2-1 or 326 IAC 2-3-1.

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

D.6.6 Record Keeping Requirements

Records required to be kept by 40 CFR 63, Subpart GGG are described in Sections E.1, E.2, and E.3 of this permit.

D.6.7 Reporting Requirements

Reports required by 40 CFR 63, Subpart GGG are described in Sections E.1, E.2 and E.3 of this permit.

SECTION D.7 FACILITY OPERATION CONDITIONS

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

(g) Dry pharmaceutical manufacturing, identified as PC100 and located in Building 100, with processes including milling, mixing, granulation, sieving, microwave drying, compression, and filling and with a carbon block condenser on the dryer for VOC control and a HEPA filter for particulate control which is integral to the room.

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

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

D.7.1 General Provisions Relating to HAPs [326 IAC 20-1-1][40 CFR 63, Subpart A]

The provisions of 40 CFR Part 63, Subpart A - General Provisions, which are incorporated as 326 IAC 20-1-1, apply to the facility described in this section except when otherwise specified in Table 1 of 40 CFR 63, Subpart GGG when manufacturing pharmaceutical product and processing, using or producing HAP.

D.7.2 Applicability [40 CFR 63, Subpart GGG] [326 IAC 20]

The provisions of 40 CFR 63, Subpart GGG, National Emission Standards for Pharmaceutical Manufacturing, apply to the facility described in this section when manufacturing pharmaceutical product and processing, using or producing HAP.

(a) The applicable Process Vent limits, pursuant to 40 CFR 63.1254, are described in Section E.1.

(b) The applicable Equipment Leak standards of 40 CFR 63.1255 are described in Section E.2 - Pharmaceutical Manufacturing NESHAP Equipment Leaks Provisions for all compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, connectors, instrumentation systems, control devices, and closed vent systems required by 40 CFR 63.1255 that are intended to operate in organic hazardous air pollutant service 300 hours or more during the calendar year.

(c) The applicable Wastewater standards of 40 CFR 63.1256 are described in Section E.3 - Pharmaceutical Manufacturing NESHAP Wastewater Provisions.

(d) The Permittee may open a safety device, as defined in 40 CFR 63.1251, at any time conditions require it to avoid unsafe conditions.

D.7.3 VOC Emission Limit [326 IAC 8-1-6]

Pursuant to CP 950073-01, issued on January 5, 1995, VOC input to equipment in PC100 is limited to less than 25 tons per 12 consecutive month period with compliance determined at the end of each month such that 326 IAC 8-1-6 is not applicable.

D.7.4 Particulate [326 IAC 6-3-2]

Pursuant to 326 IAC 6-3-2 (Particulate Emission Limitations for Manufacturing Processes), the allowable particulate emission rate from the dryer shall not exceed 0.551 pounds per hour when operating at a process weight rate less than 100 pounds per hour.

D.7.5 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 carbon block condenser controlling VOC emissions.

Compliance Determination Requirements

D.7.6 Volatile Organic Compounds (VOC)

To demonstrate compliance with Condition D.7.3, VOC input shall be calculated by mass balance or by appropriate unit operation emissions estimation procedures (e.g., Appendix B of "Control of Volatile Organic emissions from Manufacture of Synthesized Pharmaceutical Products," EPA-450/2-78-029).

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

D.7.7 Record Keeping Requirements

(a) The Permittee shall maintain the following records to document compliance with D.7.3 and D.7.5:

(1) Input of VOC per month.
(2) Twelve month rolling VOC input.

Records necessary to demonstrate compliance shall be available within 30 days of the end of each twelve month period.

(b) Records required to be kept by 40 CFR 63, Subpart GGG are described in Sections E.1, E.2, and E.3 of this permit.

(c) To document compliance with Condition D.7.5, the Permittee shall maintain records of inspections prescribed by the Preventive Maintenance Plan.

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

D.7.8 Reporting Requirements

(a) A quarterly summary of the information to document compliance with Condition D.7.3 shall be submitted according to Section C - General Reporting Requirements, of this permit.

(b) Reports required by 40 CFR 63, Subpart GGG are described in Sections E.1, E.2, and E.3 of this permit.

SECTION D.8 FACILITY OPERATION CONDITIONS

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

(h) Dry pharmaceutical manufacturing, identified as PC1 and located in Building 328, with processes including milling, mixing, granulation, sieving, drying, compression, and filling, with a HEPA filter for particulate control which is integral to the dryer, and a scrubber for VOC control.

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

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

D.8.1 General Provisions Relating to HAPs [326 IAC 20-1-1][40 CFR 63, Subpart A]

The provisions of 40 CFR Part 63, Subpart A - General Provisions, which are incorporated as 326 IAC 20-1-1, apply to the facility described in this section except when otherwise specified in Table 1 of 40 CFR 63, Subpart GGG when manufacturing pharmaceutical product and processing, using or producing HAP.

D.8.2 Applicability [40 CFR 63, Subpart GGG] [326 IAC 20]

The provisions of 40 CFR 63, Subpart GGG, National Emission Standards for Pharmaceutical Manufacturing, apply to the facility described in this section when manufacturing pharmaceutical product and processing, using or producing HAP.

(a) The applicable Process Vent limits, pursuant to 40 CFR 63.1254, are described in Section E.1.

(b) The applicable Equipment Leak standards of 40 CFR 63.1255 for all compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, connectors, instrumentation systems, control devices, and closed vent systems required by 40 CFR 63.1255 that are intended to operate in organic hazardous air pollutant service 300 hours or more during the calendar year are described in Section E.2 - Pharmaceutical Manufacturing NESHAP Equipment Leaks Provisions.

(c) The applicable Wastewater standards of 40 CFR 63.1256 are described in Section E.3 - Pharmaceutical Manufacturing NESHAP Wastewater Provisions.

(d) The Permittee may open a safety device, as defined in 40 CFR 63.1251, at any time conditions require it to avoid unsafe conditions.

D.8.3 VOC Emission Limit [326 IAC 8-1-6]

Pursuant to CP 950073-02, issued on January 5, 1995, input of VOC into equipment located in PC1 is limited to less than 25 tons per 12 consecutive month period with compliance determined at the end of each month such that 326 IAC 8-1-6 is not applicable.

D.8.4 Particulate [326 IAC 6-3-2]

Pursuant to 326 IAC 6-3-2 (Particulate Emission Limitations for Manufacturing Processes), the allowable particulate emission rate from the dryer shall not exceed 0.551 pounds per hour when operating at a process weight rate of less than 100 pounds per hour.

Compliance Determination Requirements

D.8.5 Volatile Organic Compounds (VOC)

To demonstrate compliance with Condition D.8.3, VOC input shall be calculated by mass balance or by appropriate unit operation emissions estimation procedures (e.g., Appendix B of “Control of

Volatile Organic emissions from Manufacture of Synthesized Pharmaceutical Products," EPA-450/2-78-029).

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

D.8.6 Record Keeping Requirements

(a) The Permittee shall maintain the following records to document compliance with D.8.3 and D.8.6:

(1) Input of VOC per month.
(2) Twelve month rolling VOC input.

Records necessary to document compliance shall be available within 30 days of the end of each twelve month period.

(b) Records required to be kept by 40 CFR 63, Subpart GGG are described in Sections E.1, E.2, and E.3 of this permit.

D.8.7 Reporting Requirements

(a) A quarterly summary of the information to document compliance with Condition D.8.3 shall be submitted according to Section C - General Reporting Requirements, of this permit.

(b) Reports required by 40 CFR 63, Subpart GGG are described in Sections E.1, E.2, and E.3 of this permit.

SECTION D.9 FACILITY OPERATION CONDITIONS

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

(a) Degreasing operations that do not exceed 145 gallons per 12 months, except if subject to 326 IAC 20-6. [326 IAC 8-3].

(b) Activities with emissions equal to or less than insignificant thresholds: Cold cleaner degreasers that use more than 145 gallons per year, but have emissions less than 15 pounds per day of VOC [326 IAC 8-3-2].

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

Emission Limitations and Standards [326 IAC 2-7-5(1)] (Cold Cleaning Degreaser Operations)

D.9.1 Volatile Organic Compounds (VOC) [326 IAC 8-3-2]

Pursuant to 326 IAC 8-3-2 (Cold Cleaner Operations), for cold cleaning operations constructed after January 1, 1980, the Permittee shall:

(a) Equip the cleaner with a cover;

(b) Equip the cleaner with a facility for draining cleaned parts;

(c) Close the degreaser cover whenever parts are not being handled in the cleaner;

(d) Drain cleaned parts for at least fifteen (15) seconds or until dripping ceases;

(e) Provide a permanent, conspicuous label summarizing the operation requirements;

(f) Store waste solvent only in covered containers and not dispose of waste solvent or transfer it to another party, in such a manner that greater than twenty percent (20%) of the waste solvent (by weight) can evaporate into the atmosphere.

D.9.2 Volatile Organic Compounds (VOC) (Cold Cleaner Degreaser Operation and Control)[326 IAC 8-3-5]

(a) Pursuant to 326 IAC 8-3-5(a) (Cold Cleaner Degreaser Operation and Control), the owner or operator of cold cleaner degreasers without remote solvent reservoirs existing as of January 1, 1980, located in Clark, Elkhart, Floyd, Lake, Marion, Porter or St. Joseph counties, or constructed after July 1, 1990, located in any county, shall ensure that the following requirements are met:

(1) Equip the degreaser with a cover. The cover must be designed so that it can be easily operated with one (1) hand if:

(A) The solvent volatility is greater than two (2) kiloPascals (fifteen (15) millimeters of mercury or three-tenths (0.3) pounds per square inch) measured at thirty-eight degrees Celsius (38^{o} C) (one hundred degrees Fahrenheit (100^{o} F));
(B) The solvent is agitated; or
(C) The solvent is heated.

(2) Equip the degreaser with a facility for draining cleaned articles. If the solvent volatility is greater than four and three-tenths (4.3) kiloPascals (thirty-two (32) millimeters of mercury or six-tenths (0.6) pounds per square inch) measured at thirty-eight degrees Celsius (38°C) (one hundred degrees Fahrenheit (100^{o} F)), then the drainage facility must be internal such that articles are enclosed under the cover while draining. The

drainage facility may be external for applications where an internal type cannot fit into the cleaning system.

(3) Provide a permanent, conspicuous label which lists the operating requirements outlined in subsection (b).

(4) The solvent spray, if used, must be a solid, fluid stream and shall be applied at a pressure which does not cause excessive splashing.

(5) Equip the degreaser with one (1) of the following control devices if the solvent volatility is greater than four and three-tenths (4.3) kiloPascals (thirty-two (32) millimeters of mercury or six-tenths (0.6) pounds per square inch) measured at thirty-eight degrees Celsius (38°C) (one hundred degrees Fahrenheit (100°F)), or if the solvent is heated to a temperature greater than forty-eight and nine-tenths degrees Celsius (48.9°C) (one hundred twenty degrees Fahrenheit (120°F)):

(A) A freeboard that attains a freeboard ratio of seventy-five hundredths (0.75) or greater.
(B) A water cover when solvent is used is insoluble in, and heavier than water.
(C) Other systems of demonstrated equivalent control such as a refrigerated chiller of carbon adsorption. Such systems shall be submitted to the U.S. EPA as a SIP revision.

(b) Pursuant to 326 IAC 8-3-5(b) (Cold Cleaner Degreaser Operation and Control), the owner or operator of a cold cleaning facility construction shall ensure that the following operating requirements are met:

(1) Close the cover whenever articles are not being handled in the degreaser.

(2) Drain cleaned articles for at least fifteen (15) seconds or until dripping ceases.

(3) Store waste solvent only in covered containers and prohibit the disposal or transfer of waste solvent in any manner in which greater than twenty percent (20%) of the waste solvent by weight could evaporate.

D.9.3 Advance Approval of Modifications [326 IAC 2-7-5(16)]

The Permittee may modify any existing degreasing operation, replace any existing degreasing operation, or add a new degreasing operation without a source modification approval required by 326 IAC 2-7-10.5 or a permit revision required by 326 IAC 2-7-12 or 326 IAC 2-7-11 provided the following requirements are satisfied:

(a) All the applicable requirements for the modified, replaced or newly constructed emission unit are described or referenced in this section of the permit or in Sections B and C of this permit.

(b) The modification, replacement or construction of the emission unit does not require new or additional applicable requirements to be added to this section of the permit.

(c) The modification, replacement or construction of the emission unit does not require revision of applicable requirements in this section of the permit.

(d) The modification does not modify the degreasing operations to greater than 145 gallons per 12 months, except if subject to 326 IAC 20-6.

(e) Any new degreasing operation does not exceed 145 gallons per 12 months, except if subject to 326 IAC 20-6.

SECTION D.10 FACILITY OPERATION CONDITIONS

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

(a) Two (2) peak diesel generators, one (1) Model number DFHD, identified as Generator A, and one Model number DFJD, identified as Generator B, both located at the Building 141 (B141), constructed, respectively, in 1999 and 2004, with a maximum capacity of 1,350 HP each, using no control, and exhausting to stack B141 Generator A.

(b) One (1) peak diesel generator, Model number DQKC, identified as Generator C, located at the Building 141 (B141), constructed in 2006, with a maximum capacity of 2,700 HP, using no control, and exhausting to stack B141 Generator C.

D.10.1 General Provisions Relating to National Emission Standards for Hazardous Air Pollutants under 40 CFR Part 63 [326 IAC 20-1] [40 CFR Part 63, Subpart A]

(a) Pursuant to 40 CFR *63*.6665, the Permittee shall comply with the provisions of 40 CFR Part 63, Subpart A – General Provisions, which are incorporated by reference as 326 IAC 20-1-1 for the diesel Generators A, B, and C as specified in 40 CFR 63.6665 in accordance with schedule in 40 CFR 63 Subpart ZZZZ*.*

(b) Pursuant to 40 CFR 63.10, the Permittee shall submit all required notifications and reports to:

Indiana Department of Environmental Management
Compliance Branch, Office of Air Quality
100 North Senate Avenue
Indianapolis, Indiana 46204-2251

and

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

and

Indianapolis Office of Environmental Services
Air Compliance
2700 South Belmont Avenue
Indianapolis, IN 46221

D.10.2 Emission Offset Minor Limit [326 IAC 2-3]

(a) Time of operation of each of the Generators A, B, and C shall be limited to less than 99 hours per 12 consecutive month period, with compliance determined at the end of each month.

(b) NOx emission from each of the Generators A and B shall be limited to less than 32.40 pounds per hour; NOx emission from the Generator C shall be limited to less than 64.80 pounds per hour.

Compliance with these limits shall render requirements of 326 IAC 2-3 not applicable.

D.10.3 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 this facility and any control device.

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

D.10.4 Record Keeping Requirements

To document compliance with Condition D.10.3, the Permittee shall maintain records of actual hours of operation for each of the Generators A, B, and C. Records shall be taken monthly and shall be complete and sufficient to establish compliance with the time of operation limit established in Condition D.10.3. Records necessary to demonstrate compliance shall be available within 30 days of the end of each compliance period.

D.10.5 Reporting Requirements

A quarterly summary of the information to document compliance with Condition D.10.3 shall be submitted according to Section C - General Reporting Requirements, of this permit.

SECTION E.1 FACILITY OPERATION CONDITIONS

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

Process Vents - Pharmaceutical NESHAP [40 CFR 63.1254]: vents from processes or areas in the D sections of this permit which reference this E Section as applicable through which a HAP containing gas stream is or has the potential to be released to the atmosphere.

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

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

E.1.1 Pharmaceutical NESHAP [40 CFR 63, Subpart GGG] [326 IAC 20]

Pursuant to 40 CFR 63.1254(a), the Permittee shall, for each process, comply with one of the compliance options summarized below.

(a) **900 / 1800 kg Compliance Option:**
[40 CFR 63.1254(a)(2) and(3)]

(1) Actual HAP emissions from the sum of all process vents within a process (as defined in 40 CFR 63.1251) must not exceed 900 kilograms (kg) in any 365 day period.
(2) Actual HAP emissions from the sum of all process vents at the source within processes complying with the 900 kilogram limit in 40 CFR 63.1254(a)(2)(i) are limited to a maximum of 1,800 kilogram in any 365 day period.
(3) Emissions from vents that are subject to the requirements of 40 CFR 63.1254(a)(3) and emissions from vents that are controlled in accordance with the alternative limit in 40 CFR 63.1254(c) shall be excluded from the sums calculated in (1) and (2) above.
(4) The Permittee may switch from compliance with 40 CFR 63.1254(a)(2) to compliance with 40 CFR 63.1254(a)(1) only after at least one year of operation in compliance with 40 CFR 63.1254(a)(2).

(b) **93%/ 98% Reduction Compliance Option**
[40 CFR 63.1254(a)(1) and (3)]

(1) Uncontrolled HAP emissions from the sum of all process vents within a process that are not subject to 40 CFR 63.1254(a)(3) shall be reduced by 93 percent or greater by weight or any one or more vents within a process may be controlled in accordance with any of the following procedures:

(A) To outlet concentrations less than or equal to 20 ppmv as TOC and less than or equal to 20 ppmv as hydrogen halides and halogens; OR
(B) By a control device specified in 40 CFR 63.1257(a)(4).

(2) If the uncontrolled HAP emissions from any process vent exceed 25 tons per year and the flow-weighted average flow rate (FR_a) calculated using Equation 1 in 40 CFR 63.1254(a)(3) is less than or equal to the flow rate index (FRI) calculated using Equation 2 of 40 CFR 63.1254(a)(3), then the Permittee must either:

(A) Reduce uncontrolled HAP emissions from that process vent by 98 percent or in accordance with any of the procedures in 40 CFR 63.1254(a)(1)(ii)(A) through (D); OR
(B) As an alternative to the 98% reduction in E.1.1(b)(2)(A) above, the Permittee may comply with the provisions in 40 CFR 63.1254(a)(3)(ii)(A), (B), or (C).

E.1.2 Pharmaceutical NESHAP Monitoring and Compliance Demonstration Requirements [40 CFR 63, Subpart GGG] [326 IAC 20]

Pursuant to 40 CFR 63.1258(b), the Permittee must monitor control devices and demonstrate compliance as follows.

900 / 1800 kg Compliance Option and 93% / 98% Reduction Option:

(1) For control devices that control vent streams totaling less than 1 ton per year HAP emissions, before control, the Permittee shall verify daily that the control device is operating properly. If the control device is used to control batch process vents alone or in combination with other streams, the verification may be on a per batch basis. This verification shall include, but not be limited to, a daily or per batch demonstration that the unit is working as designed. Measurements taken for this verification are not considered continuous monitoring systems.

(2) For condensers that control vent streams totaling greater than 1 ton per year HAP emissions, before control:

(A) The Permittee shall establish the maximum condenser outlet temperature as a site-specific operating parameter.

(B) The Permittee shall measure and record the outlet gas temperature at least every 15 minutes during the period in which the condenser is functioning in achieving HAP removal.

(C) The temperature monitoring device must be accurate to within ∀ 2 percent of the temperature measured in degrees Celsius or ∀ 2.5 degrees Celsius whichever is greater.

(D) The temperature monitoring device must be calibrated annually.

(E) Averaging periods for the site-specific operating parameters shall be established according to 40 CFR 63.1258(b)(2)(i) through (iii).

(F) The site specific operating parameters shall be set pursuant to 40 CFR 63.1258(b)(3).

(G) The outlet gas temperature continuous monitoring system must meet all applicable requirements of 40 CFR 60.8.

(3) For scrubbers that control vent streams totaling greater than 1 ton per year HAP emissions, before control:

(A) The Permittee shall establish a minimum scrubber liquid flow rate or pressure drop as a site-specific operating parameter. If the scrubber uses a caustic solution to remove acid emissions, the Permittee shall establish a minimum pH of the effluent scrubber liquid as a site-specific operating parameter.

(B) The Permittee shall measure and record either the scrubber liquid flow rate or pressure drop every 15 minutes during the period in which the scrubber is functioning in achieving HAP removal. If the scrubber uses a caustic solution to remove acid emissions, the Permittee shall monitor the pH of the effluent scrubber liquid at least once per day.

(C) The monitoring device(s) used to determine the pressure drop shall be certified by the manufacturer to be accurate to within a gage pressure of ∀10 percent of the maximum pressure drop measured.

(D) The monitoring device(s) used for measurement of scrubber liquid flow rate shall be certified by the manufacturer to be accurate within ∀10 percent of the design scrubber liquid flow rate.

(E) The monitoring device(s) shall be calibrated annually.

(F) The site specific operating parameters shall be set pursuant to 40 CFR 63.1258(b)(3).

(G) The continuous monitoring system must meet all applicable requirements of 40 CFR 63.8.

(4) For regenerative carbon adsorbers that control vent streams totaling greater than 1 ton per year HAP emissions, before control:

(A) Establish the following regeneration cycle characteristics under worst-case conditions, as defined in 40 CFR 63.1257(b)(8)(i):
(i) Minimum regeneration frequency (i.e. operating time since last regeneration);
(ii) Minimum temperature to which the bed is heated during regeneration;
(iii) Maximum temperature to which the bed is cooled, measured within 15 minutes of completing the cooling phase; and
(iv) Minimum regeneration stream flow.

(B) Monitor and record the following regeneration cycle characteristics for each regeneration cycle:
(i) Regeneration frequency (operating time since end of last regeneration);
(ii) Temperature to which the bed is heated during regeneration;
(iii) Temperature to which the bed is cooled, measured within 15 minutes of the completion of the cooling phase; and
(iv) Regeneration stream flow.

(C) Use a temperature-monitoring device that is accurate to within ∀2 percent of the temperature measured in degrees Celsius or ∀2.5EC, whichever is greater.

(D) Use a regeneration stream flow monitoring device capable of recording the total regeneration stream flow to within 10 percent of the established value (i.e., accurate to within 10 percent of the reading.)

(E) Calibrate the temperature and flow monitoring devices annually.

(F) Conduct an annual check for bed poisoning in accordance with manufacturer's specifications.

(5) Pursuant to 40 CFR 63.1258(c), the Permittee shall demonstrate continuous compliance with the 900 and 1,800 kilogram per year emission limits by calculating daily 365 day rolling summations of emissions.

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

E.1.3 Record Keeping Requirements [40 CFR 63, Subpart GGG] [326 IAC 20]

(a) Pursuant to 40 CFR 63.1259(c), the Permittee shall keep records of each operating scenario, which demonstrates compliance with 40 CFR 63, Subpart GGG.

(b) For control devices that control vent streams totaling less than 1 ton per year HAP emissions, before control, the Permittee shall keep records of the daily verifications that each control device is operating properly as required in Condition E.1.2.

(c) For each process using the 900 / 1800 kg Compliance Option, the Permittee shall keep daily records of the rolling annual total emissions required in E.1.2.

(d) For each condenser or scrubber controlling vent streams totaling greater than 1 ton per year HAP emissions, before control, the Permittee shall keep records of outlet gas temperature and scrubber liquid flow rate or pressure drop as applicable and as required in Condition E.1.2.

(e) For each process using continuous monitoring systems, the Permittee shall maintain continuous monitoring system records specified in 40 CFR 63.10(c)(1) through (14). Pursuant to 40 CFR 63.1259(b)(3), the Permittee shall maintain records documenting the completion of calibration checks and maintenance of continuous monitoring systems.

(f) The Permittee shall keep the current and superseded versions of the startup, shutdown and malfunction plan onsite, as specified in 40 CFR 63.6(e)(3)(v). The Permittee shall keep the startup, shutdown and malfunction records specified in 40 CFR 63.1259(a)(3)(i) through (iii).

(g) Pursuant to 40 CFR 63.1259(b)(5), the Permittee shall keep records of the following, as appropriate:

(1) The number of batches per year for each batch process;
(2) The operating hours per year for continuous processes;
(3) Standard batch uncontrolled and controlled emissions for each process;
(4) Actual uncontrolled and controlled emissions for each nonstandard batch;
(5) A record whether each batch operated was considered a standard batch;

(h) The Permittee shall keep a schedule or log of each operating scenario updated daily or, at a minimum, each time a different operating scenario is put into operation.

(i) The Permittee shall keep a description of worst-case operating conditions as required in 40 CFR 63.1257(b)(8);

(j) The Permittee shall keep records of all maintenance performed on the air pollution control equipment.

E.1.4 Reporting Requirements [40 CFR 63, Subpart GGG] [326 IAC 20]

(a) The Permittee shall submit semiannual Periodic Reports.

(1) Pursuant to 40 CFR 63.1260(g)(1)(i), the Administrator may determine on a case by case basis that more frequent reporting is necessary to accurately assess the compliance status of the affected source.

(2) When a new operating scenario has been operated since the last Periodic report, quarterly reports shall be submitted.

(3) When the Permittee experiences an exceedance of a temperature limit monitored according to 40 CFR 63.1258(b)(1)(iii) or an exceedance of the outlet concentration

monitored according to the provisions of 40 CFR 63.1258(b)(1)(x) or (b)(5), the Permittee shall submit the Periodic Reports quarterly. Once the Permittee reports quarterly pursuant to this condition, the Permittee shall follow a quarterly reporting format until a request to reduce reporting frequency is approved.

(4) The Periodic Report shall include the information required in 40 CFR 63.1260(g)(2), as applicable.

(b) The Permittee must submit a report 60 days before the scheduled implementation date of either any change in the activity covered by the Precompliance report or a change in the status of a control device from small to large.

(c) Except as specified in (b) above, whenever a process change is made or there is 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:

(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;
(4) Information required by the Notification of Compliance Status Report for changes involving the addition of processes or equipment.

(d) The Permittee shall submit startup, shutdown, and malfunction reports as outlined in 40 CFR 63.1260(i).

(e) The Permittee shall notify IDEM and OES of the planned date of a performance test at least 60 days before the test in accordance with 40 CFR 63.7(b) and 40 CFR 63.1260(l).

SECTION E.2 FACILITY OPERATION CONDITIONS

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

Equipment Leaks - Pharmaceutical NESHAP [40 CFR 63.1255]: Pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, instrumentation systems, control devices, and closed-vent systems from processes or areas in the D sections of this permit which reference this E Section as applicable that are intended to operate in organic hazardous air pollutant service 300 hours or more during the calendar year. This Section is not applicable to lines and equipment not containing process fluids, utilities and other nonprocess lines, bench scale processes, equipment that is in vacuum service and equipment that is in organic HAP service less than 300 hours per calendar year, unless required for other equipment as specified in a D Section of this permit.

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

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

E.2.1 General Equipment Leak Requirements [40 CFR 63.1255(a)] [326 IAC 20]

(a) Equipment to which this section applies shall be identified such that it can be distinguished readily from equipment that is not subject to this section.

(b) When each leak is detected by visual, audible, or olfactory means, or by monitoring as described in 40 CFR 63.180(b) or (c), a weatherproof and readily visible identification, marked with the equipment identification number, shall be attached to the leaking equipment. The identification on a valve in light liquid or gas/vapor service may be removed after it has been monitored as specified in 40 CFR 63.1255(e)(7)(iii) and no leak has been detected during follow-up monitoring. The identification on equipment except on a valve in light liquid or gas/vapor service may be removed after it has been repaired.

(c) In all cases where the provisions of 40 CFR 63, Subpart GGG require the Permittee to repair leaks by a specified time after the leak is detected, it is a violation to fail to take action to repair the leaks within the specified time. If action is taken to repair the leaks within the specified time, failure of that action to successfully repair the leak is not a violation. However, if the repairs are unsuccessful, a leak is detected and the Permittee shall take further action as required by Subpart GGG.

E.2.2 LDAR Standards [40 CFR 63.1255] [326 IAC 20]

(a) The Permittee shall implement the LDAR program, for components in organic hazardous air pollutant service, as defined in 40 CFR, Subpart GGG, for 300 hours or more during the calendar year or for other equipment as specified in a D section of this permit, from the point at which raw material is unloaded at the plant site to the point of determination (POD) or point where waste exits the pharmaceutical manufacturing process unit (PMPU).

(b) Each new or changed process system component shall be incorporated into the existing component list as necessary within 90 calendar days, or by the next LDAR Periodic Report, following the end of the monitoring period for the type of component monitored, whichever is later.

(c) The following process components shall comply with design standards, shall be operated in accordance with work practice standards or shall undergo periodic monitoring in accordance with the provisions cited below. Periodic monitoring shall be performed in accordance with 40 CFR 60, Appendix A, Method 21 and 40 CFR 63.1255(b)(4)(v) and 40 CFR 63.1255(a)(11)(iv).

(1) Pumps in light liquid service shall be operated in accordance with the standard at 40 CFR 63.1255(c);
(2) Compressors shall be operated in accordance with the standards at 40 CFR 63.1255(b)(3);
(3) Pressure relief devices in gas/vapor service shall be operated in accordance with the standard at 40 CFR 63.1255(b)(3);
(4) Sampling connection systems shall be operated in accordance with the standard at 40 CFR 63.1255(b)(3);
(5) Open ended valves or lines shall be operated in accordance with the standard at 40 CFR 63.1255(d);
(6) Valves in gas/vapor and light liquid service shall be operated in accordance with the standard at 40 CFR 63.1255(e);
(7) Closed-vent systems and control devices used to comply with LDAR shall be operated in accordance with the standard at 40 CFR 63.1255(b)(4)(ii);
(8) Agitators in gas/vapor and light liquid service shall be operated in accordance with the standard at 40 CFR 63.1255(c);
(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 40 CFR 63.1255(b)(3); and
(10) Connectors in gas/vapor and light liquid service shall be operated in accordance with the standard at 40 CFR 63.1255(b)(4)(iii).

(d) As an alternative to complying with (c) above, except (c)(7), system components may comply with 40 CFR 63.1255(b)(4)(iv), which incorporates by reference 40 CFR 63.178 (Alternative Means of Emission Limitation: Batch Processes) which includes:

(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 40 CFR 63.180(f) or (g); and
(2) Components must comply with the leak repair requirements before startup of a process as described in 40 CFR 63.178(b)(4).

(e) Pursuant to 40 CFR 63.1255(b)(3), which references 40 CFR 63.179 (Alternative means of emission limitation: Enclosed-vented process units), process units enclosed in such a manner that all emissions from equipment leaks are vented through a closed-vent system to a control device meeting the requirements of 40 CFR 63.172 and 40 CFR 1255(b)(4)(ii) are exempted from the requirements of 40 CFR 63.163 through 171, and 40 CFR 63.173 through 174 as referenced by 40 CFR 63.1255. The enclosure shall 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.2.2(c)(7).

(f) Alternative means of emission limitations not already included in 40 CFR 63.1255 may be approved in accordance with 40 CFR 63.1255(b).

(g) The following equipment is exempt from the monitoring requirements as specified in 40 CFR 63.1255(f)(1)(i) through (iv) provided the Permittee meets the requirements specified in 40 CFR 63.1255(f)(2), (3) or (4) as applicable. All equipment must be assigned to a group of processes.

(1) Equipment that is designated as unsafe to monitor or unsafe to inspect pursuant to 40 CFR 63.1255(f)(2);
(2) Equipment that is difficult to monitor or difficult to inspect pursuant to 40 CFR 63.1255(f)(3); and
(3) Connectors that are inaccessible, ceramic, or ceramic-lined pursuant to 40 CFR 63.1255(f)(4).

(h) The following facilities are not subject to the LDAR standards in 40 CFR 63.1255:

(1) Research and development facilities, activities, and equipment [40 CFR 63.1250(d)];
(2) Components on transportation equipment and containers (e.g., railroad cars, tanker trucks and drums);
(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;
(7) Equipment that is in HAP service but that is in such service less than 300 hours per calendar year [40 CFR 63.1255(a)(10)]; and
(8) Closed loop heat exchange systems [40 CFR 63.1255(a)(5)].

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

E.2.3 Record Keeping Requirements [40 CFR 63, Subpart GGG] [326 IAC 20]

(a) Record keeping requirements to demonstrate compliance with E.2.1 and E.2.2 shall be kept in accordance with 40 CFR 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, which are subject to periodic monitoring, 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 and a copy of the plan for monitoring or inspecting the equipment;
(5) For equipment complying via the provisions of 40 CFR 63.178(c): a list of equipment added since the last monitoring period and if monitoring frequencies are adjusted for time in use, records demonstrating the proportion of time the equipment is in use and subject to the requirements of 40 CFR 63, Subpart GGG during the calendar year;
(6) Records of visual inspections;
(7) Records of leaks detected and repair information, and delays of repair;
(8) If the Permittee elects to pressure test a process equipment train or supply lines between storage and processing areas to demonstrate compliance, the permittee shall keep records as outlined in 40 CFR 63.1255(g)(5);
(9) Records of compressor and relief device compliance tests;
(10) Records for closed-vent systems and control devices subject to 40 CFR 63.1255(b)(4)(ii), if applicable;
(11) For components in heavy liquid service, records demonstrating that they are in heavy liquid service;
(12) Identification of equipment in organic HAP service less than 300 hours per year; and
(13) Records of alternative means of compliance demonstration.
(14) Connectors that are inaccessible or that are ceramic or ceramic-lined as defined in 40 CFR 63.1255(f)(4) are exempt from these record keeping requirements.

E.2.4 Reporting Requirements [40 CFR 63, Subpart GGG] [326 IAC 20]

(a) Periodic reports shall be submitted in accordance with 40 CFR 63.1255(h) including:

(1) For equipment not complying via the alternative standard, the Permittee shall report the following information pursuant to 40 CFR 63.1255(h)(3)(ii):

(A) The number of leaks detected, the percent leakers and the total number of units monitored, separately for valves, compressors, and connectors;

(B) For pumps and agitators, the number of leaks detected and the total number monitored. For pumps, the percent leakers.
(C) The number of leaks not repaired within the required timeframe for valves, pumps and agitators, compressors, and connectors and the identifying number of any valves or connectors that were determined nonrepairable;
(D) An explanation of any delay of repairs;
(E) Results of all monitoring to show compliance with 40 CFR 63.164(i), 63.165(a) and 63.172(f) conducted within the semiannual reporting period;
(F) Notice of a change to monthly monitoring for either pumps or valves, if applicable; and
(G) Notification of a change in connector monitoring alternatives, if applicable.

(2) For equipment complying via the alternative standard at 40 CFR 63.1255(b)(4)(iv), the Permittee shall report the following information pursuant to 40 CFR 63.1255(h)(3)(iii) for each process:

(A) The number of pressure tests conducted;
(B) The number of instances where the equipment failed either a retest or 2 consecutive pressure tests;
(C) Facts that explain any delay of repairs; and
(D) Results of all monitoring to determine compliance for closed-vent systems used to comply with LDAR.

(3) Any revisions to items reported in the Notification of Compliance Status Report, if the method of compliance has changed since the last report.

SECTION E.3 FACILITY OPERATION CONDITIONS

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

Wastewater - Pharmaceutical NESHAP [40 CFR 63.1256]: Water that is discarded from processes or areas in the D sections of this permit which reference this E Section as applicable through a single point of determination.

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

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

E.3.1 Pharmaceutical Manufacturing NESHAP [40 CFR 63.1256] [326 IAC 20]

The Permittee shall determine the characteristics of each wastewater stream at each Point of Determination to determine if a wastewater stream is an affected wastewater stream by one of the means below:

(a) The Permittee shall comply with the provisions of 40 CFR 63.1257(e)(1) to determine the annual average concentrations and annual load of partially soluble and soluble HAP compounds; OR

(b) The Permittee shall designate the wastewater stream as meeting the criteria to be an affected wastewater stream. If the Permittee chooses to designate a wastewater stream, the Permittee shall comply with 40 CFR 63.1256(a)(1)(ii)(A) and (B) and is not required to determine the annual average concentration or load for each designated wastewater stream for the purposes of this Condition.

E.3.2 Pharmaceutical Manufacturing NESHAP [40 CFR 63.1256] [326 IAC 20]

(a) For each wastewater tank that receives, manages, or treats affected wastewater or a residual removed from affected wastewater, the Permittee shall operate and maintain a fixed roof.

(1) The Permittee may install any wastewater tanks that meet the three criteria below without modifying this section of the permit:

(A) wastewater tanks with a capacity less than seventy five (75) cubic meters,

(B) wastewater tanks with a capacity greater than seventy five (75) cubic meters and less than one hundred fifty one (151) cubic meters and a maximum true vapor pressure less than thirteen and one tenth (13.1) kPa; or

(C) wastewater tanks with a capacity greater than one hundred fifty one (151) cubic meters and a maximum true vapor pressure less than five and two tenths (5.2) kPa.

(2) The Permittee may not install any wastewater tanks that meet the two criteria below without modifying this section of the permit.

(A) wastewater tanks with a capacity greater than seventy five (75) cubic meters and less than one hundred fifty one (151) cubic meters and a maximum true vapor pressure greater than thirteen and one tenth (13.1) kPa; or

(B) wastewater tanks with a capacity greater than one hundred fifty one (151) cubic meters and a maximum true vapor pressure greater than five and two tenths (5.2) kPa.

(3) If the contents of a wastewater tank are heated, treated by means of an exothermic reaction, or sparged, the Permittee must demonstrate that the total soluble and partially soluble HAP emissions from the wastewater tank are no more than five (5) percent higher than the emissions would be if the contents of the wastewater tank were not heated, treated by an exothermic reaction or sparged. This demonstration shall be included in the operating scenario.

(4) For each wastewater tank that receives, manages, or treats wastewater, a residual removed from wastewater, a recycled wastewater, or a recycled residual removed from wastewater, the Permittee shall comply with the inspection requirements in 40 CFR 63.1258(g), as applicable.

(b) For each container that receives, manages, or treats affected wastewater or a residual removed from affected wastewater, the Permittee shall comply with the following requirements:

(1) The Permittee shall operate and maintain a cover on each container used to handle, transfer, or store affected wastewater or a residual removed from affected wastewater in accordance with 40 CFR 63.1256(d)(1)(i) through (iii).

(2) Pumping affected wastewater or a residual removed from affected wastewater into a container with a capacity greater than or equal to 0.42 cubic meters shall be conducted in accordance with 40 CFR 63.1256(d)(2)(i) and (ii).

(3) Except as provided in 40 CFR 63.1256(i), when an improper work practice or a control equipment failure is identified, first efforts at repair shall be made no later than five (5) calendar days after identification and repair shall be completed within fifteen (15) calendar days after identification. Delay of repair of equipment for which a control equipment failure or a gap, crack, tear, or hole has been identified, is allowed only in accordance with the provisions of 40 CFR 63.1256(i). Repair of this equipment shall occur by the end of the next shutdown.

(4) The Permittee shall comply with the inspection requirements of 40 CFR 63.1258(g), as applicable.

(c) For each individual drain system that receives or manages affected wastewater or a residual removed from affected wastewater, the Permittee shall comply with the requirements of 40 CFR 63.1256(e)(4)(i) through (iii). Except as provided in 40 CFR 63.1256(i), when a gap, hole or crack is identified in a joint or cover, first efforts at repair shall be made no later than five (5) calendar days after identification, and repair shall be completed within fifteen (15) calendar days after identification. Delay of repair of equipment for which a control equipment failure or a gap, crack, tear, or hole has been identified, is allowed only in accordance with the provisions of 40 CFR 63.1256(i). Repair of this equipment shall occur by the end of the next shutdown. The Permittee shall comply with the inspection requirements of 40 CFR 63.1258(g), as applicable.

(d) The Permittee shall comply with the wastewater treatment requirements by transferring affected wastewater streams or a residual removed from such a wastewater to an offsite treatment operation in accordance with 40 CFR 63.1256(a)(5).

(e) The Permittee shall comply with the requirements of 40 CFR 63.1256(a)(4)(i) through (iv) for maintenance wastewater containing partially soluble or soluble HAP listed in 40 CFR 63, Subpart GGG Tables 2 and 3. Maintenance wastewater is exempt from all other provisions of 40 CFR 63, Subpart GGG.

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

E.3.3 Record Keeping Requirements [40 CFR 63.1256] [40 CFR 63.1259] [326 IAC 20]

(a) The Permittee shall keep records documenting decisions to use a delay of repair due to unavailability of parts, as specified in 40 CFR 63.1256(i). The record 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.

(b) For transfers of affected wastewater streams or residuals removed from an affected wastewater stream in accordance with 40 CFR 63.1256(a)(5), the Permittee shall keep a record of the notice sent to the treatment operator stating that the wastewater stream or residual contains organic HAP which are required to be managed and treated in accordance with the provisions 40 CFR 63, Subpart GGG.

(c) The Permittee shall keep records, as applicable, that each waste management unit inspection required by 40 CFR 63.1256(b) through (f) was performed.

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY
AND
INDIANAPOLIS OFFICE OF ENVIRONMENTAL SERVICES

PART 70 OPERATING PERMIT
CERTIFICATION

Source Name: Eli Lilly and Company - Lilly Technology Center
Source Address: 1555 South Harding Street, Indianapolis, IN 46221
Mailing Address: Eli Lilly and Company, Lilly Corporate Center, Indianapolis, IN 46285
Part 70 Permit No.: T097-6846-00072

This certification shall be included when submitting monitoring, testing reports/results or other documents as required by this permit.

Please check what document is being certified:

- ☐ Annual Compliance Certification Letter
- ☐ Test Result (specify)
- ☐ Report (specify)
- ☐ Notification (specify)
- ☐ Affidavit (specify)
- ☐ Other (specify)

I certify that, based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate, and complete.

Signature:

Printed Name:

Title/Position:

Phone:

Date:

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY
COMPLIANCE BRANCH
100 North Senate Avenue
Indianapolis, Indiana 46204-2251
Phone: 317-233-0178
Fax: 317-233-6865
and
INDIANAPOLIS OFFICE OF ENVIRONMENTAL SERVICES
AIR QUALITY MANAGEMENT SECTION
2700 South Belmont Ave.
Indianapolis Indiana 46221
Phone: 317-327-2234
Fax: 317-327-2274

PART 70 OPERATING PERMIT
EMERGENCY OCCURRENCE REPORT

Source Name: Eli Lilly and Company - Lilly Technology Center
Source Address: 1555 South Harding Street, Indianapolis, IN 46221
Mailing Address: Eli Lilly and Company, Lilly Corporate Center, Indianapolis, IN 46285
Part 70 Permit No.: T097-6846-00072

This form consists of 2 pages **Page 1 of 2**

This is an emergency as defined in 326 IAC 2-7-1(12)

X The Permittee must notify the Office of Air Quality (OAQ), within four (**4**) business hours (1-800-451-6027 or 317-233-0178, ask for Compliance Section); and

X The Permittee must submit notice in writing or by facsimile within two (**2**) working days (Facsimile Number: 317-233-6865), and follow the other requirements of 326 IAC 2-7-16.

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

Facility/Equipment/Operation:
Control Equipment:
Permit Condition or Operation Limitation in Permit:
Description of the Emergency:
Describe the cause of the Emergency:

If any of the following are not applicable, mark N/A **Page 2 of 2**

Date/Time Emergency started:
Date/Time Emergency was corrected:
Was the facility being properly operated at the time of the emergency? Y N Describe:
Type of Pollutants Emitted: TSP, PM-10, SO_2, VOC, NO_X, CO, Pb, other:
Estimated amount of pollutant(s) emitted during emergency:
Describe the steps taken to mitigate the problem:
Describe the corrective actions/response steps taken:
Describe the measures taken to minimize emissions:
If applicable, describe the reasons why continued operation of the facilities are necessary to prevent imminent injury to persons, severe damage to equipment, substantial loss of capital investment, or loss of product or raw materials of substantial economic value:

Form Completed by:

Title / Position:

Date:

Phone:

A certification is not required for this report.

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY
COMPLIANCE DATA SECTION
and
INDIANAPOLIS OFFICE OF ENVIRONMENTAL SERVICES
AIR QUALITY MANAGEMENT SECTION

Part 70 Annual Report

Source Name: Eli Lilly and Company - Lilly Technology Center
Source Address: 1555 South Harding Street, Indianapolis, IN 46221
Mailing Address: Eli Lilly and Company, Lilly Corporate Center, Indianapolis, IN 46285
Part 70 Permit No.: T097-6846-00072
Facility: **Building 110**
Parameter: VOC emissions
Limit: 10 tons of VOC per twelve (12) month consecutive month period rolled on a monthly basis.

YEAR:

MONTH	Tons of VOC emitted this Month	Tons of VOC emitted in last twelve months

□ No deviation occurred in this period.
□ Deviation/s occurred in this period. Deviation has been reported on:

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
and
INDIANAPOLIS OFFICE OF ENVIRONMENTAL SERVICES
AIR QUALITY MANAGEMENT SECTION

Part 70 Quarterly Report

Source Name: Eli Lilly and Company - Lilly Technology Center
Source Address: 1555 South Harding Street, Indianapolis, IN 46221
Mailing Address: Eli Lilly and Company, Lilly Corporate Center, Indianapolis, IN 46285
Part 70 Permit No.: T097-6846-00072
Facility: **BHI Complex – Building 132**
Parameter: VOC
Limit: less than 40 tons per twelve (12) consecutive month period with compliance determined at the end of each month

QUARTER: _____ YEAR: _____

Month	Column 1	Column 2	Column 1 + 2
	This Month	Previous 11 Months	12 Month Total
Month 1			
Month 2			
Month 3			

☐ No deviation occurred in this quarter.

☐ Deviation/s occurred in this quarter.
Deviation has been reported on:

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
and
INDIANAPOLIS OFFICE OF ENVIRONMENTAL SERVICES
AIR QUALITY MANAGEMENT SECTION

Part 70 Quarterly Report

Source Name: Eli Lilly and Company - Lilly Technology Center
Source Address: 1555 South Harding Street, Indianapolis, IN 46221
Mailing Address: Eli Lilly and Company, Lilly Corporate Center, Indianapolis, IN 46285
Part 70 Permit No.: T097-6846-00072
Facility: **PC100**
Parameter: VOC input
Limit: emissions of VOC are limited to less than 25 tons per 12 consecutive month period with compliance determined at the end of each month

QUARTER: _____ YEAR: _____

Month	Column 1	Column 2	Column 1 + Column 2
	This Month	Previous 11 Months	12 Month Total
Month 1			
Month 2			
Month 3			

☐ No deviation occurred in this quarter.

☐ Deviation/s occurred in this quarter.
Deviation has been reported on:

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
and
INDIANAPOLIS OFFICE OF ENVIRONMENTAL SERVICES
AIR QUALITY MANAGEMENT SECTION

Part 70 Quarterly Report

Source Name: Eli Lilly and Company - Lilly Technology Center
Source Address: 1555 South Harding Street, Indianapolis, IN 46221
Mailing Address: Eli Lilly and Company, Lilly Corporate Center, Indianapolis, IN 46285
Part 70 Permit No.: T097-6846-00072
Facility: **PC1**
Parameter: VOC input
Limit: emissions of VOC are limited to less than 25 tons per 12 consecutive month period with compliance determined at the end of each month

QUARTER: _____ YEAR: _____

Month	Column 1	Column 2	Column 1 + Column 2
	This Month	Previous 11 Months	12 Month Total
Month 1			
Month 2			
Month 3			

☐ No deviation occurred in this quarter.

☐ Deviation/s occurred in this quarter.
Deviation has been reported on:

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
and
INDIANAPOLIS OFFICE OF ENVIRONMENTAL SERVICES
AIR COMPLIANCE

Part 70 Quarterly Report

Source Name: Eli Lilly and Company, Lilly Technology Center
Source Address: 1555 South Harding Street, Indianapolis, IN
Mailing Address: Eli Lilly and Company, Lilly Corporate Center, Indianapolis, IN 46285
Minor Source Modification No.: 097-22049-00072
Facility: **Generators A, B, and C**
Parameter: Time (hours) of operation
Limit: 99 hours of operation per 12 consecutive month period, with compliance determined in the end of each month (each of Generators A, B, and C)

QUARTER: _____ YEAR: _____

Month/Generator	Column 1 Hours of Operation	Column 2 Hours of Operation	Column 1 + Column 2
	This Month	Previous 11 Months	12 Month Total
Month 1. Generator A			
Month 1. Generator B			
Month 1. Generator C			
Month 2. Generator A			
Month 2. Generator B			
Month 2. Generator C			
Month 3. Generator A			
Month 3. Generator B			
Month 3. Generator C			

☐ No deviation occurred in this quarter.

☐ Deviation/s occurred in this quarter.
Deviation has been reported on:

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
and
INDIANAPOLIS OFFICE OF ENVIRONMENTAL SERVICES
AIR COMPLIANCE

Part 70 Quarterly Report

Source Name: Eli Lilly and Company - Lilly Technology Center
Source Address: 1555 South Harding Street, Indianapolis, IN 46221
Mailing Address: Eli Lilly and Company, Lilly Corporate Center, Indianapolis, IN 46285
Part 70 Permit No.: T097-6846-00072
Facility: **VANCO**
Parameter: VOC Limit: less than 40 tons per twelve (12) consecutive month period with compliance determined at the end of each month

QUARTER: _____ YEAR: _____

Month	Column 1	Column 2	Column 1 + Column 2
	This Month	Previous 11 Months	12 Month Total
Month 1			
Month 2			
Month 3			

☐ No deviation occurred in this quarter.

☐ Deviation/s occurred in this quarter.
Deviation has been reported on:

Submitted by:
Title / Position:
Signature:
Date:
Phone:

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY
COMPLIANCE DATA SECTION
and
INDIANAPOLIS OFFICE OF ENVIRONMENTAL SERVICES
AIR QUALITY MANAGEMENT SECTION

PART 70 OPERATING PERMIT
QUARTERLY DEVIATION AND COMPLIANCE MONITORING REPORT

Source Name: Eli Lilly and Company - Lilly Technology Center
Source Address: 1555 South Harding Street, Indianapolis, IN 46221
Mailing Address: Eli Lilly and Company, Lilly Corporate Center, Indianapolis, IN 46285
Part 70 Permit No.: T097-6846-00072

Months: _____ **to** _____ **Year:** _____

This report shall be submitted quarterly based on a calendar year. Any deviation from the requirements, the date(s) of each deviation, the probable cause of the deviation, and the response steps taken must be reported. Deviations that are required to be reported by an applicable requirement shall be reported according to the schedule stated in the applicable requirement and do not need to be included in this report. Additional pages may be attached if necessary. If no deviations occurred, please specify in the box marked "No deviations occurred this reporting period".

☐ NO DEVIATIONS OCCURRED THIS REPORTING PERIOD.

☐ THE FOLLOWING DEVIATIONS OCCURRED THIS REPORTING PERIOD

Permit Requirement (specify permit condition #)
Date of Deviation: **Duration of Deviation:**
Number of Deviations:
Probable Cause of Deviation:
Response Steps Taken:

Permit Requirement (specify permit condition #)
Date of Deviation: **Duration of Deviation:**
Number of Deviations:
Probable Cause of Deviation:
Response Steps Taken:

Page 2 of 2

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.

Attachment A

The following state rules have been adopted by reference by the Indianapolis Air Pollution Control Board and are enforceable by Indianapolis Office of Environmental Services (OES) using local enforcement procedures.

(1) 326 IAC 1
(1) 326 IAC 2-3-1 through 2-3-5;
(2) 326 IAC 2-4-1 through 2-4-6;
(3) 326 IAC 2-6-1 through 2-6-4;
(4) 326 IAC 2-7-1 through 2-7-18, 2-7-20 through 2-7-25;
(5) 326 IAC 2-8-1 through 2-8-15, 2-8-17 through 2-8-10;
(6) 326 IAC 2-9-1 through 2-9-14;
(7) 326 IAC 2-10-1 through 2-10-5 (The IAPCB adoption adds the language “state or local” immediately after the word “federal” in 326 IAC 2-10-1);
(8) 326 IAC 2-11-1, 2-11-3 and 2-11-4 (The IAPCB adoption adds the language “federal, state or local” immediately after the word “by” in 326 IAC 2-11-1);
(9) 326 IAC 3-1.1-1 through 3-1.1-5;
(10) 326 IAC 3-2.1-1 through 3-2.1-5;
(11) 326 IAC 3-3-1 through 3-3-5;
(12) 326 IAC 4-2-1 through 4-2-2;
(13) 326 IAC 5-1-1 (a), (b) and c) (5), 5-1-2 (1), (2)(A), (2)c) (4), 5-1-3 through 5-1-5, 5-1-7;
(14) 326 IAC 6;
(15) 326 IAC 7-1.1-1 and 7-1.1-2;
(16) 326 IAC 7-2-1;
(17) 326 IAC 7-3-1 and 7-3-2;
(18) 326 IAC 7-4-2(28) through (31) (Instead of adopting by reference 7-4-2(1) through (27), the IAPCB regulation substitutes the same requirements listed in a format in which the companies are alphabetized and emission points known to no longer exist have been deleted);
(19) 326 IAC 8-1-0.5 except (b), 8-1-1 through 8-1-2, 8-1-3 except c), (g) and (i), 8-1-5 through 8-1-12;
(20) 326 IAC 8-2-1 through 8-2-12 (The IAPCB adoption by reference of 8-2-5 adds additional language specific to Zimmer Paper Products, Incorporated as subpart c);
(21) 326 IAC 8-3-1 through 8-3-7;
(22) 326 IAC 8-4-1 through 8-4-5, 8-4-6 (a)(6), (a)(8) and (a)(14) and 8-4-6(b)(1), (b)(3) and 8-4-6c) (In place of 8-4-6(b)(2), which was not adopted, the IAPCB adopted language requiring a pressure relief valve set to release at no less than four and eight-tenths (4.8) Kilo Pascals (seven-tenths (0.7) pounds per square inch)), 8-4-7 except (e), 8-4-8 and 8-4-9;
(23) 326 IAC 8-5-1 through 8-5-4, 8-5-5 except (a)(3) and (d)(3);
(24) 326 IAC 8-6-1 and 8-6-2;
(25) 326 IAC 9-1-1 and 9-1-2;
(26) 326 IAC 10; (adopted January 8, 2004)
(27) 326 IAC 11-1-1 through 11-1-2;
(28) 326 IAC 11-2-1 through 11-2-3;
(29) 326 IAC 11-3-1 through 11-3-6;
(30) 326 IAC 14-1-1 through 14-1-4;
(31) 326 IAC 14-2-1 except 40 CFR 61.145;
(32) 326 IAC 14-3-1;
(33) 326 IAC 14-4-1;
(34) 326 IAC 14-5-1;
(35) 326 IAC 14-6-1;
(36) 326 IAC 14-7-1;
(37) 326 IAC 14-8-1 through 14-8-5;
(38) 326 IAC 15-1-1, 15-1-2(a)(1), (a)(2) and (a)(8), 15-1-3 and 15-1-4;
(39) 326 IAC 20;
(40) 326 IAC 21;
(41) 326 IAC 21-1-1 (The adoption states that “or the administrator of OES” is added in (b));
(42) 326 IAC 22-1-1 (The adoption states that “or the administrator of OES” is added in (b)).

Indiana Department of Environmental Management
Office of Air Quality

Addendum to the Technical Support Document for a Part 70 Operating Permit

Source Background and Description

Source Name:	Eli Lilly and Company - Lilly Technology Center
Source Location:	1555 South Harding Street, Indianapolis, Indiana 46221
County:	Marion
SIC Codes:	2833, 2834
Operation Permit No.:	T097-6846-00072
Permit Reviewer:	Amanda Hennessy/Boris Gorlin

On May 19, 2006, the Office of Air Quality (OAQ) and City of Indianapolis, Office of Environmental Services (OES) had a notice published in The Indianapolis Star stating that Eli Lilly and Company - Lilly Technology Center had applied for a Title V Part 70 Operating Permit relating to the operation of a pharmaceutical research, development and manufacturing facility.

The notice also stated that OAQ and OES proposed to issue a permit for this operation and provided information on how the public could review the proposed permit and other documentation. Finally, the notice informed interested parties that there was a period of thirty (30) days to provide comments on whether or not this permit should be issued as proposed.

On June 16, 2006, Eli Lilly and Company - Lilly Technology Center submitted comments on the proposed Part 70 permit. No other comments were received by the OAQ and OES. The following is a summary of the comments and responses to all comments. The Technical Support Document (TSD) will remain as it originally appeared when published. Changes to the permit or technical support material that occur after the permit has published for public notice are documented in this Addendum to the Technical Support Document. This accomplishes the desired result of ensuring that these types of concerns are documented and part of the record regarding this permit decision. Text shown in the responses with a line through it has been deleted from the permit and bold text has been added to the permit. The Table of Contents has been updated as necessary.

Comment 1:

Lilly requests an update to the General Information section relating to the change in the job title of a Responsible Official.

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 and research and development facility.

Responsible Officials: Vice President of Global Parenteral Operations, Engineering, Environmental, Health and Safety; Vice President, Product Research & Development; Vice President, Global Active Pharmaceutical Intermediate (API) Manufacturing; or President, Manufacturing Operations

Source Address: 1555 South Harding Street, Indianapolis, IN 46221

Response to Comment 1:

The following changes were made to Condition A.1:

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 and research and development facility.

Responsible Official**s**: Vice President~~,~~ **of Global** Parenteral **Operations,** ~~Manufacturing; Vice President of Global~~ Engineering, Environmental**,** Health and Safety; Vice President, Product Research & Development; Vice President, Global Active Pharmaceutical Intermediate (API) Manufacturing; or President, Manufacturing **Operations**

.....

Comment 2:

Lilly requests that corrections be made to both subsections describing B358 [A.2(b) and A.2(c)]. The only part of B358 that has a control device is the portion of the operations that is subject to BACT. Also, please note that B130 does not have any condensers or other control devices. For this reason, Lilly requests that the phrase "with condensers to control VOC emissions" be deleted from subsection A.2(f).

Response to Comment 2:

The following changes were made to Condition A.2:

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:

.....

(b) Manufacture of bulk pharmaceutical products (Building 358) by:

(1) protein isolation with a carbon adsorber for VOC and HAP control with laboratory support**;**

(2) ~~through~~ chemical synthesis ~~(purification and manufacturing)~~,

units subject to BACT [326 IAC 8-1-6].

(c) Manufacture of bulk pharmaceutical products (Building 358) by:

(1) protein isolation ~~with a carbon adsorber for VOC and HAP control~~ with laboratory support**;**

(2) ~~through~~ chemical synthesis ~~(purification and manufacturing)~~, or non-synthesized chemical processes~~,~~**;**

units not subject to BACT [326 IAC 8-1-6].

.....

(f) Building 130 Complex (buildings 130, 135 and 136) consisting of laboratories and manufacturing of bulk pharmaceutical products through chemical synthesis ~~with condensers to control VOC emissions~~.

Comment 3:

B.3 – Term of Conditions
Lilly proposes deleting the words "pursuant to Title I of the Clean Air Act" because this phrase is not in 326 IAC 2-1.1-9.5, and it has the effect of imposing more stringent requirements than currently provided by rule. Lilly has requested this language be deleted from a proposed permit modification for our Tippecanoe Laboratories facility, and IDEM agreed with that request.

Response to Comment 3:

The following change was made to Condition B.3(a):

B.3 Term of Conditions [326 IAC 2-1.1-9.5]

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

(a) the condition is modified in a subsequent permit action ~~pursuant to Title I of the Clean Air Act~~; or

Comment 4:

B.9 – Annual Compliance Certification
Lilly proposes changing the due date of the annual compliance certification to July 1 instead of April 15. The date of April 15 was originally chosen to coincide with the due date of the annual emission statement. However, the due date for the annual emission statement has been changed to July 1. Lilly's facilities in both Tippecanoe and Clinton have the July 1 date in their Title V permits.

Response to Comment 4:

The Annual Compliance Certification (ACC) is due April 15th for sources located in Clark, Elkhart, Floyd, Lake, Marion, Porter, St. Joseph, and Vanderburgh Counties; and ACC are due July 1 for all other sources. Eli Lilly and Company - Lilly Technology Center is located in Marion County. Therefore, the ACC is due by April 15 of each year. No changes were made to the Condition B.9.

Comment 5:
B.12 - Permit Shield
Lilly proposes to include additional terms to the permit shield section of the permit (certain NSPS's and NESHAP's nonapplicability). These statements have been reviewed by the agencies and similar statements have been included in permits for both the Tippecanoe and Clinton facilities. Thus, Lilly recommends adding the following term (h) to Section B.12:

(h) In addition to the nonapplicability determinations set forth in Sections D of this permit, the IDEM, OAQ and OES have made the following determinations regarding this source:

(1) This source is not subject to the requirements of 40 CFR 60, Subparts VV, III, NNN, and RRR (Synthetic organic chemical manufacturing) 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, 40 CFR 60.617, 40 CFR 60.667 or 40 CFR 60.707.

(2) This source is identified as the type of facility subject to the National Emission Standards for Hazardous Air Pollutants (NESHAPs), 40 CFR 61, Subpart FF, which applies to benzene waste operations. However, the total annual benzene quantity from facility waste is less than 10 megagrams per year (11 tons per year) and

therefore, the source is exempt from the specific requirements of 40 CFR 61, Subpart FF. [40 CFR 61.342(a)]

(3) This source is not subject to the requirements of 40 CFR 61, Subpart V because this source is not subject to any other standard in Part 61 which refers to Subpart V. Pursuant to 40 CFR 61.240, Subpart V applies to equipment at sources after the date of promulgation of a specific subpart in part 61. In addition, pursuant to 40 CFR 63.1255(a)(2), equipment subject to 40 CFR 63, Subpart GGG that is also subject to either 40 CFR 60 and/or 40 CFR 61 will be required to comply only with the provisions of 40 CFR 63, Subpart GGG.

(4) This source is not subject to 40 CFR 63, Subpart I and 326 IAC 20-12, which applies to pharmaceutical production processes using carbon tetrachloride or methylene chloride. The source does not have any pharmaceutical production processes using carbon tetrachloride or methylene chloride.

(5) This source is not subject to 40 CFR 63, Subpart F (National Emission Standards for Organic Hazardous Air Pollutants from the Synthetic Organic Chemical Manufacturing Industry) because they do not manufacture as a primary product one or more of the chemicals listed in 40 CFR 63.100(b)(1)(i) or (b)(1)(ii) or use as a reactant or manufacture as a product, or co-product, one or more of the organic hazardous air pollutants listed in 40 CFR 63, Subpart F Table 2.

(6) This source is not subject to 40 CFR 63, Subpart T (National Emission Standards for Halogenated Solvent Cleaning) because the source does not use a solvent containing methylene chloride, perchloroethylene, trichloroethylene, 1, 1, 1-trichloroethylene, carbon tetrachloride, or chloroform or any combination of these halogenated HAP solvents, in a total concentration greater than five percent (5%) by weight as a cleaning and/or drying agent in an individual batch vapor, in-line vapor, in line cold and batch cold solvent cleaning machine.

(7) This source is not subject to 40 CFR 63, Subpart FFFF (National Emission Standards for Miscellaneous Organic Chemical Production and Processes) because all facilities that would otherwise be subject to Subpart FFFF are subject to 40 CFR 63, Subpart GGG (Pharmaceutical Production MACT).

Response to Comment 5:

The applicability of state and federal rules presented in the Technical Support Document is based on the information provided in the Part 70 application and contained in IDEM's files. This information was not comprehensive enough to provide a nonapplicability determination in the TSD or to provide a permit shield in the Part 70 Permit itself except for (4) and (6) above. If the Permittee elects to provide supplemental information to demonstrate nonapplicability, IDEM and OES will review the supplemental information, make a determination, and include the appropriate determination in Condition B.12. The following changes were made to the Permit:

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

.....

(b) In addition to the nonapplicability determinations set forth in Sections D of this permit, the IDEM, OAQ and OES have made the following determinations regarding this source:

(1) This source is not subject to 40 CFR 63, Subpart I and 326 IAC 20-12, which applies to pharmaceutical production processes using carbon tetrachloride or methylene chloride. The source does not have any pharmaceutical production processes using carbon tetrachloride or methylene chloride.

(2) This source is not subject to 40 CFR 63, Subpart T (National Emission Standards for Halogenated Solvent Cleaning) because the source does not use a solvent containing methylene chloride, perchloroethylene, trichloroethylene, 1, 1, 1-trichloroethylene, carbon tetrachloride, or chloroform or any combination of these halogenated HAP solvents, in a total concentration greater than five percent (5%) by weight as a cleaning and/or drying agent in an individual batch vapor, in-line vapor, in line cold and batch cold solvent cleaning machine.

Subsequent Condition B.12 paragraphs were renumbered.

Comment 6:

Lilly requests the addition of the language below to section B.18. This term clarifies that nonroad engines are not subject to Title V permitting requirements. This provision is included in the Clinton Laboratories, Lilly Corporate Center, and Tippecanoe Laboratories Title V permits.

B.18 Permit Amendment or Modification

.....

(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.

Response to Comment 6:

40 CFR 89, Appendix A specifically indicates that states are not precluded from regulating the use and operation of nonroad engines, such as regulations on hours of usage, daily mass emission limits, or sulfur limits on fuel; nor are permits regulating such operations precluded, once the engine is no longer new. No changes were made to Permit Condition B.18.

Comment 7:

C.4 – Incineration
Lilly requests that the sentence "326 IAC 9-1-2 is not federally enforceable" be removed from section C.4. 326 IAC 9 was approved into the Indiana SIP on November 30, 2004, with an effective date of January 31, 2005. It is no longer accurate to state this provision is not federally enforceable.

Response to Comment 7:

The following change was made to Condition C.4:

C.4 Incineration [326 IAC 4-2] [326 IAC 9-1-2]

The Permittee shall not operate an incinerator or incinerate any waste or refuse except as provided in 326 IAC 4-2 and 326 IAC 9-1-2. ~~326 IAC 9-1-2 is not federally enforceable.~~

Comment 8:

C.6 Operation of Equipment [326 IAC 2-7-6(6)]
Lilly requests that the following term be deleted. This term is not based on any specific regulatory requirements, and has the effect of creating redundant requirements in the Title V permit. When a source is required to operate emission control devices to comply with emission limitations, the specific sections of the permit should clearly state this requirement. It is Lilly's understanding that IDEM has recently deleted this provision from other Title V permits. The rest of Section C of the permit should be renumbered accordingly.

Response to Comment 8:

The Condition C.6 was deleted. The subsequent Section C conditions were renumbered.

~~C.6 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 are in operation.~~

Comment 9:
C.9. Compliance Monitoring
Lilly requests that the wording be changed in the LTC Title V permit Condition C.10(d) to help clarify that no additional downtime monitoring requirements are being added.

Response to Comment 9:

The following change was made to Condition C.9 (formerly C.10):

C.~~10~~**9** Compliance Monitoring [326 IAC 2-7-5(3)] [326 IAC 2-7-6(1)]

.....

(d) The Permittee shall submit a report of monitoring system downtime ~~as~~ **where** specified in Section D or Section E. 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.

.....

Comment 10:

Lilly requests that the following term be deleted from the LTC Title V permit. The term is redundant with term C.9 (formerly C.10), plus this term is not related in any way to the compliance response plan.

C.13 (formerly C.14). Compliance Response Plan - Preparation, Implementation, Records, and Reports [326 IAC 2-7-5] [326 IAC 2-7-6]

.....

~~(f) Except as otherwise provided by a rule or provided specifically in Section D, all monitoring as required in Section D shall be performed when the emission unit is operating, except for time necessary to perform quality assurance and maintenance activities.~~

Response to Comment 10:

The following change was made to Condition C.13 (formerly C.14):

C.~~14~~**13** Compliance Response Plan - Preparation, Implementation, Records, and Reports [326 IAC 2-7-5] [326 IAC 2-7-6]

.....

~~(f) Except as otherwise provided by a rule or provided specifically in Section D, all monitoring as required in Section D shall be performed when the emission unit is operating, except for time necessary to perform quality assurance and maintenance activities.~~

Comment 11:

C.17 (formerly C.18) – General Reporting Requirements
For Section C.17, Lilly requests that the reporting periods be changed from **calendar quarters** to **semi-annual reporting**. Also, Lilly requests that minor editing changes be included in the LTC Title V permit in order to provide better clarification, replacing "in Section C – General Record Keeping Requirements" with "C.16".

Response to Comment 11:

(a) The regulation 326 IAC 2-7-5(3)(C)(i) cited in the Condition C.17 (formerly C.18) gives IDEM, OAQ and OES the authority to require reports "at least" every six months. IDEM, OAQ and OES feel that a period of time longer than every quarter will usually not provide sufficient reporting of continuous compliance monitoring.

(b) Changing the Section C Condition name to Condition number may cause problems in the future if/when permit modifications will be needed. Renumbering particular permit conditions inside the Section C may cause need for corrections throughout the permit.

No changes were made to the Permit Condition C.17 (formerly C.18).

Comment 12:

Lilly requests that the redundant language in D.1.3 be deleted.

Response to Comment 12:

The following change was made to Condition D.1.3:

D.1.3 Volatile Organic Compounds (VOC)

To determine compliance with D.1.1(a), emissions shall be calculated by mass balance, by appropriate unit operation emissions estimation procedures (e.g., Appendix B of "Control of Volatile Organic emissions from Manufacture of Synthesized Pharmaceutical Products," EPA-450/2-78-029), or by other generally accepted methods (e.g., AP-42 emission factors), as approved by the Commissioner ~~to determine compliance with D.1.1~~.

Comment 13:

D.1.6(c) - Reporting Requirements
Lilly believes that IDEM's address should be added to section D.1.6(c).

Response to Comment 13:
The following change was made to the Condition D.1.6(c):

(c) The reports required in (a) and (b) of this condition shall be submitted within sixty (60) days after the end of the reporting period and shall be submitted to the following address:

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

and

Indianapolis Office of Environmental Services
Air Compliance
2700 South Belmont Avenue
Indianapolis, IN 46221

Comment 14:

D.2. Facility Description
Lilly requests that the facility description in Section D.2 be changed to more accurately reflect the operation of B358.

Response to Comment 14:

The following change was made to the Section D.2 Facility Description:

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

(b) Manufacture of bulk pharmaceutical products (Building 358) by:

(1) protein isolation with a carbon adsorber for VOC and HAP control with laboratory support**;**
(2) ~~through~~ chemical synthesis ~~(purification and manufacturing)~~.

units subject to BACT [326 IAC 8-1-6].

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

Comment 15:

D.2.4 - LDAR
Lilly requests that a typographical error be corrected in D.2.4(b)(4).

Response to Comment 15:

The following change was made to the Condition D.2.4(b)(4):

(4) Sampling Connection Systems shall b**e** operated in accordance with the standard at 40 CFR 61.242-5. This section provides, generally and in part:
.....

Comment 16:

D.2.5 - Synthesized Pharmaceutical Manufacturing Operations
Lilly requests that the statement in Section D.2.5 regarding the applicability of 326 IAC 8-5-3 for B358 be changed to reflect the fact that if a process had potential VOC emissions >15 lb/day, the carbon bed adsorber would be used to comply with 8-5-3 requirements. B358's carbon bed adsorber control device is currently used to comply with 326 IAC 8-1-6 BACT requirements. Therefore, Lilly requests that the following changes be included in the LTC Title V permit as shown below.

The r-glucagon process (discussed in Section D.3 of the permit) is not subject to BACT requirements. Future products manufactured in this area may potentially be subject to 326 IAC 8-5-3. However, potential emissions would not exceed 15 lb/day as equipment in this area is not connected to the carbon bed adsorber control device.

D.2.5 Applicability of 326 IAC 8-5-3

If any process has the potential to emit >15 lb/day and chemical synthesis occurs, then it complies with 326 IAC 8-5-3 by Condition D.2.3. ~~The bulk manufacture of pharmaceutical products by chemical synthesis takes place in a portion of Building 358 (r-glucagon area). However, there are no facilities in this area with the potential to emit greater than 15 pounds per day of VOC; therefore, the requirements of 326 IAC 8-5-3 were not included in this permit.~~

Response to Comment 16:

If any equipment or process at the Building 358 becomes subject to 326 IAC 8-5-3, this change may be subject to prior permitting approval. No changes have been made to Condition D.2.5.

Comment 17:

D.2.6. Preventive Maintenance Plan
Lilly believes that a requirement for a PMP should be incorporated into the LTC Title V permit, as the carbon bed adsorber is the control device for Section D.2.

Response to Comment 17:

A Condition to require a Preventive Maintenance Plan for the carbon adsorber in Building 358 has been added. The section D.2 permit conditions were renumbered.

D.2.6 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 protein isolation manufacturing and the carbon adsorber.

Compliance Determination

D.2.~~6~~**7** Volatile Organic Compounds

To determine compliance with Condition D.2.3(a), the Permittee shall monitor emissions as outlined in Condition E.1.2 of this permit.

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

D.2.~~7~~**8** Record Keeping Requirements

(a) Records required to be kept by 40 CFR 63, Subpart GGG are described in Sections E.1, E.2, and E.3 of this permit.

(b) **To document compliance with Condition D.2.6, the Permittee shall maintain records of inspections prescribed by the Preventive Maintenance Plan.**

D.2.~~8~~**9** Reporting Requirements

Reports required by 40 CFR 63, Subpart GGG are described in Sections E.1, E.2, and E.3 of this permit.

Comment 18:

D.3. Facility Description: Lilly requests that these changes be included in the LTC Title V permit.

(c) Manufacture of bulk pharmaceutical products (Building 358) by:

(1) protein isolation ~~with a carbon adsorber for VOC and HAP control~~ with laboratory support
(2) ~~through~~ chemical synthesis ~~(purification and manufacturing)~~ or non-synthesized chemical processes

Response to Comment 18:

The following changes were made to the Section D.3 Facility Description:

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

(c) Manufacture of bulk pharmaceutical products (Building 358) by:

(1) protein isolation ~~with a carbon adsorber for VOC and HAP control~~ with laboratory support;
(2) ~~through~~ chemical synthesis ~~(purification and manufacturing)~~ **or non-synthesized chemical processes**~~.~~**;**

units not subject to BACT [326 IAC 8-1-6].

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

Comment 19:

D.5.5 – Particulate
Lilly requests that the following changes be incorporated into the LTC Title V air permit. First, Lilly requests that the term "the scrubber" be changed to "a scrubber" since there are two scrubbers in BHI; one is for VOC control and one is for particulate control. Second, Lilly recommends revising the first sentence of the condition to state more clearly that the allowable emission limit applicable to the prills unloading is based on the equation appearing in the condition. Finally, Lilly requests that the phrase "and will operate at all times this process is in operation" in Section D.5.5 be deleted from the LTC Title V permit since the scrubber is integral to the process this term is duplicative and not necessary.

D.5.5 Particulate [326 IAC 6-3-2]

Pursuant to 326 IAC 6-3-2 (Particulate Emission Limitations for Manufacturing Processes), the allowable particulate emission rate from the urea prills unloading operation shall be in accordance with the particulate emission rate established by the equation below. The urea prills unloading operation shall not exceed 47.2 pounds per hour when operating at a process weight rate of 66 tons per hour. ~~The~~ A scrubber is an integral part of the urea prill unloading process ~~and will operate at all times this process is in operation~~.

Response to Comment 19:

Based on the emission factor utilized to calculate potential emissions from the urea prills unloading operation, the urea prills unloading operation will be in compliance with the limit established by the equation in 326 IAC 6-3-2. The phrase "and will operate at all times this process is in operation" clarifies that the integral scrubber will be operating at all times the urea prills unloading operation is taking place. The following changes were made to the Condition D.5.5:

D.5.5 Particulate [326 IAC 6-3-2]

Pursuant to 326 IAC 6-3-2 (Particulate Emission Limitations for Manufacturing Processes), the allowable particulate emission rate from the urea prills unloading operation shall meet the particulate emission rate **established by** ~~from~~ the equation below. The urea prills unloading operation shall not exceed 47.2 pounds per hour when operating at a process weight rate of 66 tons per hour. ~~The~~ **A particulate** scrubber is an integral part of the urea prill unloading process and will operate at all times this process is in operation.

.....

Comment 20:

D.5.8 – Preventative Maintenance Plan
Lilly requests that the following term in Section D.5.8 be changed in the LTC Title V permit to clarify that the PMP requirement is applicable to required control devices only – and not the emission units themselves. Please note that there is no maintenance that can be done on the emission units in this operation that affect the quantity or type of emissions produced.

D.5.8 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 ~~emission units and~~ control devices used to comply with ~~subject to~~ Condition D.5.6 Synthesized Pharmaceutical Manufacturing Operations [326 IAC 8-5-3].

Response to Comment 20:

The Preventive Maintenance Plan (PMP) requirement must be included in every applicable Title V permit pursuant to 326 IAC 2-7-5(13). This rule refers to the Preventive Maintenance Plan requirement as described in 326 IAC 1-6-3. This rule sets out the requirements for:

(a) Identification of the individuals responsible for inspecting, maintaining and repairing the emission control equipment (326 IAC 1-6-3(a)(1)),

(b) The description of the items or conditions in the facility that will be inspected and the inspection schedule for said items or conditions (326 IAC 1-6-3(a)(2)), and

(c) The identification and quantification of the replacement parts for the facility which the Permittee will maintain in inventory for quick replacement (326 IAC 1-6-3(a)(2)).

It is clear from the structure of the wording in 326 IAC 1-6-3 that the PMP requirement affects the entirety of the applicable facilities. Only 326 IAC 1-6-3(a)(1) is limited, in that it requires identification of the personnel in charge of only the emission control equipment, and not any other facility equipment. The commissioner may require changes in the maintenance plan to reduce excessive malfunctions in any control device or combustion or process equipment under 326 IAC 1-6-5.

No changes were made to the Condition D.5.8.

Comment 21:

D.5.9 – Volatile Organic Compounds (VOC)
Lilly requests that Section D.5.9 be changed in the LTC Title V permit to provide better clarification.

D.5.9 Volatile Organic Compounds (VOC)

Source emissions shall be calculated by mass balance, by appropriate unit operation emissions estimation procedures (e.g., Appendix B of "Control of Volatile Organic emissions from Manufacture of Synthesized Pharmaceutical Products," EPA-450/2-78-029), or by other generally accepted methods (e.g., AP-42 emission factors), as approved by the Commissioner ~~to determine compliance with D.5.3~~.

Response to Comment 21:

Condition D.5.3 sets the VOC emissions limit that makes PSD requirements not applicable. Condition D.5.9 specifies determination of compliance with that particular limit. No changes were made to the Condition D.5.9.

Comment 22:

D.5.11 – Instrument Specifications
Lilly requests the addition of the terms "as required by Condition D.5.10" in Condition D.5.11, in order to clarify the scope of this requirement.

Response to Comment 22:

In order to clarify which instruments this condition is addressing, the following changes were made to Condition D.5.11:

D.5.11 Instrument Specifications [326 IAC 2-1.1-11] [326 IAC 2-7-5(3)] [326 IAC 2-7-6(1)]

(a) The instrument employed for the measurement of temperature **as required by Conditions D.5.6 and D.5.10** shall have a scale such that the expected normal reading shall be no less than five percent (5%) of full scale and be accurate within plus or minus 2.5°C.

(b) The instrument employed for the measurement of flowrate **as required by Condition D.5.10** shall be accurate within plus or minus ten percent (10%) of design flow rate.

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

Comment 23:

D.5.13 – Reporting Requirements
Lilly requests the modification to Section D.5.13 as shown below in order to eliminate redundancy with Condition C.17 and other terms of the permit.

D.5.13 Reporting Requirements

(a) **The permittee shall submit a** ~~A~~ **semi-annual** ~~quarterly~~ summary of the information to document compliance with Condition D.5.3 ~~shall be submitted to the addresses listed in Section C - General Reporting Requirements, of this permit, within thirty (30) days after the end of the quarter being reported. The report submitted by the Permittee does require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34)~~.

(b) **Reports t**~~T~~o document compliance with D.5.4~~, the Permittee shall submit reports as~~ are described in Condition E.2.4 ~~for fugitive emission components in VOC service~~.

Response to Comment 23:

For quarterly versus semi-annual reporting (Condition D.5.13(a)), see Response to Comment 11.

Condition D.5.13(a) has been revised.

The reports required in D.5.13(b) are described (items to be included in the report, frequency, etc.) in Condition E.2.4, but not required specifically by Condition E.2.4. The requirement in Condition E.2.4 applies to equipment subject to the Pharmaceutical NESHAP. Condition D.5.13(b) applies to equipment in VOC service in the BHI area and specifies a reporting requirement to document compliance with Condition D.5.4. Therefore, no change was made to Condition D.5.13(b).

D.5.13 Reporting Requirements

(a) A quarterly summary of the information to document compliance with Condition D.5.3 shall be submitted **according** to ~~the addresses listed in~~ Section C - General Reporting Requirements, of this permit~~, within thirty (30) days after the end of the quarter being~~

~~reported. The report submitted by the Permittee does require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34)~~.

(b) To document compliance with **Condition** D.5.4, the Permittee shall submit reports as described in Condition E.2.4 for fugitive emission components in VOC service.

.....

Comment 24:

D.6 - Descriptive Box
Lilly requests the deletion of the phrase "with condensers to control VOC emissions" in the Section D.6 Facility Description in order to correct erroneous information. B130 does not have any condensers or any other control devices for VOC emissions control.

Response to Comment 24:

The following change was made to the Section D.6 Facility Description:

SECTION D.6 FACILITY CONDITIONS

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

(f) Building 130 Complex (buildings 130, 135 and 136) consisting of laboratories and manufacturing of bulk pharmaceutical products (Building 130) through chemical synthesis ~~with condensers to control VOC emissions~~.

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

Comment 25:

Lilly requests that the changes below be incorporated into the LTC Title V air permit. First, Lilly requests modifying the language in Section D.6.3 in order to clarify that the allowable emissions are based on the equation in the permit term. Second, Lilly requests that the phrase "and will operate at all times this facility is in operation" because the scrubber is integral to the process.

D.6.3 Particulate [326 IAC 6-3-2]

Pursuant to 326 IAC 6-3-2 (Particulate Emission Limitations for Manufacturing Processes), the allowable particulate emission rate from the ~~TKB265~~ urea prills unloading operation **shall be in accordance with the particulate emission rate established by the equation below. The urea prills unloading operation ~~(~~located in Building 130 complex~~)~~** shall not exceed 27.0 pounds per hour when operating at a process weight rate of 16.7 tons per hour. The scrubber for **the urea prills unloading process** ~~Emission Unit ID # TK-265 is an integral part of to the urea prill unloading process and will operate at all times this facility is in operation~~.

Response to Comment 25:

IDEM, OAQ, and OES agree that an integral scrubber, by definition, is in operation at all times when the process equipment is in operation. However, the scrubber is needed to ensure that the urea prills unloading operation will be in compliance with the limit established by the equation in 326 IAC 6-3-2. Therefore, the statement that the scrubber will operate at all times the unloading is in operation needs to remain in the condition. The following changes were made to the Condition D.6.3:

D.6.3 Particulate [326 IAC 6-3-2]

Pursuant to 326 IAC 6-3-2 (Particulate Emission Limitations for Manufacturing Processes), the allowable particulate emission rate from the ~~TKB265~~ urea prills unloading operation ~~(~~located in Building 130~~)~~ shall **meet the particulate emission rate established by the equation below. The urea prills unloading operation shall** not exceed 27.0 pounds per hour when operating at a process weight rate of 16.7 tons per hour. ~~The~~ **A** scrubber ~~for Emission Unit ID # TK-265~~ is ~~an~~ integral ~~part of~~ **to** the urea prill unloading process and will operate at all times this facility is in operation.

Comment 26:

D.7.5 Preventative Maintenance Plan
Lilly requests the deletion of the requirement in Section D.7.5 to prepare and implement a Preventive Maintenance Plan for the HEPA filtration system since the HEPA filter is integral to the process and the uncontrolled particulate matter emissions are extremely low (0.006 lb/hr). [Lilly disagrees with the statement on page 34 of the Technical Support Document that the potential particulate emissions from the dryer are 1.187 lb/hr. Because the HEPA filter system is part of the process, the potential emissions from the PC100 dryer should be considered the emissions that occur after the HEPA filter system.] The allowable particulate matter emissions for this facility is 0.551 lb/hr, and Lilly is able to operate this system using the integral HEPA filter system well below this emission rate. Lilly believes that there is little or no environmental benefit compared to the cost of implementing a Preventive Maintenance Plan for emission units with particulate matter emissions below insignificant activity thresholds. It is Lilly's understanding that IDEM is not requiring Preventive Maintenance Plans for sources with low levels of emissions before controls. Requiring a PMP for a low emitting source is inconsistent with the May 15, 1996 IDEM compliance monitoring guidance document where IDEM stated its intention to require compliance monitoring plans and Preventive Maintenance Plans only for higher-emitting sources.

Response to Comment 26:

Particulate emissions from Building the PC100 dryer are minimal. Therefore, a requirement to maintain and implement a Preventive Maintenance Plan for the HEPA filter or the dryer is not being included in this permit. The following change was made to Condition D.7.5:

D.7.5 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 carbon block condenser controlling VOC emissions ~~and the integral HEPA filter controlling PM emissions in PC100~~.

Comment 27:

Lilly requests the deletion of Condition D.7.7 for the same reasons described above in our request to delete the Preventive Maintenance Plan for the PC100 HEPA filtration system in Condition D.7.5. The cost of implementing this compliance monitoring term is even greater than the cost of implementing a Preventive Maintenance Plan. Not only is there a cost to conduct the inspections, there is additional cost to create a system to ensure the inspections take place, and to verify the inspections took place. Lilly believes these additional costs are not justified when the HEPA filter system must operate in order for the process to operate. It is in Lilly's financial interest to keep the HEPA filter system in good operating condition so that normal production operations may take place.

Response to Comment 27:

Particulate Matter emissions from the PC100 dryer are minimal; therefore, compliance monitoring will not be required for the integral HEPA filter. Condition D.7.7 has been deleted. The subsequent Section D.7 conditions have been renumbered.

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

~~D.7.7 Particulate Matter (PM)~~

~~The Permittee shall perform inspections once per batch on the HEPA filter in PC100 to demonstrate that the filter is in operation and controlling particulate emissions.~~

Comment 28:

D.7.7 (formerly D.7.8) - Record Keeping Requirements
Lilly requests the deletion of the requirement to keep records of PC100 HEPA filter inspections in Condition D.7.8. If the requirement to conduct the inspection is removed, the requirement to keep records of the inspection should also be removed.

Response to Comment 28:

Since the requirement to perform the inspections has been removed, the associated record keeping requirement has also been removed. The following changes were made to Condition D.7.7 (formerly D.7.8):

D.7.~~8~~**7** Record Keeping Requirements

(a) The Permittee shall maintain the following records to document compliance with D.7.3 and D.7.5:

(1) Input of VOC per month.
(2) Twelve month rolling VOC input.

Records necessary to demonstrate compliance shall be available within 30 days of the end of each twelve month period.

~~(b)~~ ~~The Permittee shall maintain once per batch records of the inspections of the HEPA filter in PC100.~~

~~(c)~~**(b)** Records required to be kept by 40 CFR 63, Subpart GGG are described in Sections E.1, E.2, and E.3 of this permit.

~~(d)~~**(c)** To document compliance with Condition D.7.5, the Permittee shall maintain records of inspections prescribed by the Preventive Maintenance Plan.

~~(e)~~**(d)** All records shall be maintained in accordance with Section C - General Record Keeping Requirements.

Comment 29:

D.7.8 (formerly D.7.9) Reporting Requirements
Lilly requests modifying Condition D.7.8(a) as shown below in order to eliminate redundancy with Condition C.17(d) and other terms of the permit.

D.7.8 Reporting Requirements

(a) **Permittee shall submit a** ~~A~~ **semi-annual** ~~quarterly~~ summary of the information to document compliance with Condition D.7.3 ~~shall be submitted to the addresses listed in Section C - General Reporting Requirements, of this permit, within thirty (30) days after the end of the quarter being reported. The report submitted by the Permittee does require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34)~~.

Response to Comment 29:

For quarterly versus semi-annual reporting, see Response to Comment 11.

The following changes were made to the Condition D.7.8 (formerly D.7.9):

D.7.~~9~~**8** Reporting Requirements

(a) A quarterly summary of the information to document compliance with Condition D.7.3 shall be submitted ~~to the addresses listed in~~ **according to** Section C - General Reporting Requirements, of this permit ~~within thirty (30) days after the end of the quarter being reported. The report submitted by the Permittee does require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34)~~.

.....

Comment 30:

D.8.5 Preventative Maintenance Plan, D.8.7 Particulate Matter, and D.8.8 Record Keeping Requirements Lilly requests the deletion of the provisions requiring Preventive Maintenance Plans, compliance monitoring inspections, and recordkeeping of compliance monitoring inspections for the PC1 HEPA filter system. This request is based on the same reasons provided in the request to delete these requirements from Section D.7 of the permit for PC100 operations. Similarly, Lilly disagrees with the statement on page 35 of the Technical Support Document that potential particulate matter emissions from PC1 are 0.618 lb/hr because this is the emission rate before the integral HEPA system. Potential particulate matter emissions from PC1 are less than the allowable emissions of 0.551 lb/hr.

Response to Comment 30:

Particulate emissions from the PC1 dryer are minimal. Therefore, requirements to maintain and implement a Preventive Maintenance Plan for PC1 and to perform compliance monitoring are not being included in this permit. The following changes were made to Conditions D.8.5, D.8.7, and D.8.8. The remaining D.8 Conditions have been renumbered.

~~D.8.5 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 granulation and drying process in PC 1. and the integral HEPA filter controlling PM emissions.~~

Compliance Determination Requirements

D.8.~~6~~**5** Volatile Organic Compounds (VOC)

To demonstrate compliance with Condition D.8.3, VOC input shall be calculated by mass balance or by appropriate unit operation emissions estimation procedures (e.g., Appendix B of "Control of Volatile Organic emissions from Manufacture of Synthesized Pharmaceutical Products," EPA-450/2-78-029).

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

~~D.8.7 Particulate Matter (PM)~~

~~The Permittee shall perform inspections once per batch on the HEPA filter in PC1 to ensure that the filter is in operation and controlling particulate emissions.~~

D.8.~~8~~**6** Record Keeping Requirements

(a) The Permittee shall maintain the following records to document compliance with D.8.3 and D.8.6:

(1) Input of VOC per month.
(2) Twelve month rolling VOC input.

Records necessary to document compliance shall be available within 30 days of the end of each twelve month period.

~~(b) The Permittee shall maintain once per batch records of the inspections of the HEPA filter in PC1.~~

~~(c) To document compliance with Condition D.8.5, the Permittee shall maintain records of inspections prescribed by the Preventive Maintenance Plan.~~

~~(d)~~**(b)** Records required to be kept by 40 CFR 63, Subpart GGG are described in Sections E.1, E.2, and E.3 of this permit.

Comment 31:

D.8.7 (formerly D.8.9) Reporting Requirements
Lilly requests modifying Condition D.8.7 (formerly D.8.9) as shown below in order to eliminate redundancy with Condition C.17 and other terms of the permit.

D.8.7 Reporting Requirements

(a) **Permittee shall submit a** ~~A~~ **semi-annual** ~~quarterly~~ summary of the information to document compliance with Condition D.8.3 ~~shall be submitted to the addresses listed in Section C - General Reporting Requirements, of this permit, within thirty (30) days after the end of the quarter being reported. The report submitted by the Permittee does require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34)~~.

Response to Comment 31:

Regarding quarterly versus semi-annual reporting, see Response to Comment 11.

The following changes were made to Condition D.8.7 (formerly D.8.9).

D.8.~~9~~**7** Reporting Requirements

(a) A quarterly summary of the information to document compliance with Condition D.8.3 shall be submitted ~~to the addresses listed in~~ **according to** Section C - General Reporting Requirements, of this permit~~, within thirty (30) days after the end of the quarter being reported. The report submitted by the Permittee does require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34)~~.

.....

Comment 32:

Lilly requests addition of a permit term that reflects the requirements of 326 IAC 8-3-5, which applies to cold cleaner degreasers without remote solvent reservoirs. The LTC site has cold cleaner degreasers without remote solvent reservoirs, and so, the permit must include the appropriate regulatory language. Current Condition D.9.2 should be renumbered to D.9.3.

Addition of this language will enable Lilly to install both cold cleaner degreasers equipped with or without remote solvent reservoirs pursuant to the advance approval of modification provisions currently in D.9.2 of the permit.

Furthermore, the Technical Support Document description of the cold cleaner degreasers on page 36 is incorrect. All of the degreasers are listed as having remote solvent reservoirs. This is not correct. The correct information is shown below.

Degreasers

Bldg / Floor	Type	Installation Date	Remote Solvent Reservoir	Open Top	Conveyorized
105/1	Cold Cleaner Degreaser	1980 - 1990	No	No	No
110/1	Cold Cleaner Degreaser	After 1990	Yes	No	No
142/1	Cold Cleaner Degreaser	After 1990	No	No	No
194/X	Cold Cleaner Degreaser	After 1990	No	No	No
152/1 Machine shop	Cold Cleaner Degreaser	After 1990	No	No	No
152/1 Material Handling Shop	Cold Cleaner Degreaser	1980 – 1990	Yes	No	No
194/1	Cold Cleaner Degreaser	After 1990	Yes	No	No
195/1	Cold Cleaner Degreaser	After 1990	No	No	No
314/1	Cold Cleaner Degreaser	After 1990	No	No	No
325/1	Cold Cleaner Degreaser	After 1990	Yes	No	No
358/B	Cold Cleaner Degreaser	After 1990	No	No	No

Response to Comment 32:

The changes to the description of the cold cleaner degreasers is noted. However, as stated on Page 1 of this Addendum to Technical Support Document, " The Technical Support Document (TSD) will remain as it originally appeared when published. Changes to the permit or technical support material that occur after the permit has published for public notice are documented in this Addendum to the Technical Support Document. This accomplishes the desired result of ensuring that these types of concerns are documented and part of the record regarding this permit decision."

In order to include all applicable requirements for equipment existing at the source, the requirements of 326 IAC 8-3-5, applicable to the cold cleaner degreasers without remote solvent reservoirs, existing as of January 1, 1980 in Clark, Elkhart, Floyd, Lake, Marion, Porter or St. Joseph counties, or constructed after July 1, 1990, located in any county, have been added into a new Condition D.9.2. The former Condition D.9.2 was renumbered. The following changes were made to Section D.9:

D.9.2 Volatile Organic Compounds (VOC) (Cold Cleaner Degreaser Operation and Control)[326 IAC 8-3-5]

(a) Pursuant to 326 IAC 8-3-5(a) (Cold Cleaner Degreaser Operation and Control), the owner or operator of cold cleaner degreasers without remote solvent reservoirs existing as of January 1, 1980, located in Clark, Elkhart, Floyd, Lake, Marion, Porter or St. Joseph counties, or constructed after July 1, 1990, located in any county, shall ensure that the following requirements are met:

(1) Equip the degreaser with a cover. The cover must be designed so that it can be easily operated with one (1) hand if:

(A) The solvent volatility is greater than two (2) kiloPascals (fifteen (15) millimeters of mercury or three-tenths (0.3) pounds per square inch) measured at thirty-eight degrees Celsius (38^{o} C) (one hundred degrees Fahrenheit (100^{o} F));
(B) The solvent is agitated; or
(C) The solvent is heated.

(2) Equip the degreaser with a facility for draining cleaned articles. If the solvent volatility is greater than four and three-tenths (4.3) kiloPascals (thirty-two (32) millimeters of mercury or six-tenths (0.6) pounds per square inch) measured at thirty-eight degrees Celsius (38°C) (one hundred degrees Fahrenheit (100^{o} F)), then the drainage facility must be internal such that articles are enclosed under the cover while draining. The drainage facility may be external for applications where an internal type cannot fit into the cleaning system.

(3) Provide a permanent, conspicuous label which lists the operating requirements outlined in subsection (b).

(4) The solvent spray, if used, must be a solid, fluid stream and shall be applied at a pressure which does not cause excessive splashing.

(5) Equip the degreaser with one (1) of the following control devices if the solvent volatility is greater than four and three-tenths (4.3) kiloPascals (thirty-two (32) millimeters of mercury or six-tenths (0.6) pounds per square inch) measured at thirty-eight degrees Celsius (38°C) (one hundred degrees Fahrenheit (100°F)), or if the solvent is heated to a temperature greater than forty-eight and nine-tenths degrees Celsius (48.9°C) (one hundred twenty degrees Fahrenheit (120°F)):

(A) A freeboard that attains a freeboard ratio of seventy-five hundredths (0.75) or greater.
(B) A water cover when solvent is used is insoluble in, and heavier than water.
(C) Other systems of demonstrated equivalent control such as a refrigerated chiller of carbon adsorption. Such systems shall be submitted to the U.S. EPA as a SIP revision.

(b) Pursuant to 326 IAC 8-3-5(b) (Cold Cleaner Degreaser Operation and Control), the owner or operator of a cold cleaning facility construction shall ensure that the following operating requirements are met:

(1) Close the cover whenever articles are not being handled in the degreaser.

(2) Drain cleaned articles for at least fifteen (15) seconds or until dripping ceases.

(3) Store waste solvent only in covered containers and prohibit the disposal or transfer of waste solvent in any manner in which greater than twenty percent (20%) of the waste solvent by weight could evaporate.

D.9.2**3** Advance Approval of Modifications [326 IAC 2-7-5(16)]

The Permittee may modify any existing degreasing operation, replace any existing degreasing operation, or add a new degreasing operation without a source modification approval required by 326 IAC 2-7-10.5 or a permit revision required by 326 IAC 2-7-12 or 326 IAC 2-7-11 provided the following requirements are satisfied:

Comment 33:

D.10.2 National Emission Standards for Hazardous Air Pollutants for Stationary Reciprocating Internal Combustion Engines Requirements
Lilly requests the following changes to term D.10.2. The initial notifications have been submitted, and this requirement is no longer applicable to the Lilly Technology Center.

D.10.2 National Emission Standards for Hazardous Air Pollutants for Stationary Reciprocating Internal Combustion Engines Requirements [40 CFR Part 63, Subpart ZZZZ] [326 IAC 20-82] [40 CFR 63.6590] [40 CFR 63.6645]

Permittee has satisfied the notification requirements of the RICE MACT and no other conditions apply. ~~Pursuant to 40 CFR 63.6645(d), the permittee shall submit the initial notification, which shall include the information in §63.9(b)(2)(i) through (v), and a statement that the stationary RICE, Emission Units Generators A, B, and C have no additional requirements, and explain the basis of the exclusion. The notification for the Generators A and B shall be submitted no later than 120 days after this permit issuance date, and for the new Generator C - no later than 120 days after its start up date.~~

Response to Comment 33:

The Permittee submitted the initial notification on May 19, 2006. Therefore, since the requirements of this condition have been met, the condition is no longer necessary. Condition D.10.2 has been removed and all subsequent D.10 conditions have been renumbered.

~~D.10.2 National Emission Standards for Hazardous Air Pollutants for Stationary Reciprocating Internal Combustion Engines Requirements [40 CFR Part 63, Subpart ZZZZ] [326 IAC 20-82] [40 CFR 63.6590] [40 CFR 63.6645]~~

~~Pursuant to 40 CFR 63.6645(d), the permittee shall submit the initial notification, which shall include the information in §63.9(b)(2)(i) through (v), and a statement that the stationary RICE, Emission Units Generators A, B, and C have no additional requirements, and explain the basis of the exclusion. The notification for the Generators A and B shall be submitted no later than 120 days after this permit issuance date, and for the new Generator C - no later than 120 days after its start up date.~~

Comment 34:

D.10.3 (formerly D.10.4) Preventative Maintenance Plan
Lilly requests the deletion of term D.10.3 (formerly D.10.4). This term is not needed since no control devices are required for the generators.

Response to Comment 34:

See Response to Comment 20. No changes were made to the Permit.

Comment 35:

D.10.4 (formerly D.10.5) Record Keeping Requirements
Lilly requests the deletion of term D.10.4(b) (formerly D.10.5(b). This term is redundant with Condition C.16.

Response to Comment 35:

The following changes were made to Condition D.10.4 (formerly D.10.5):

D.10.**4**~~5~~ Record Keeping Requirements

(a) To document compliance with Condition D.10.3, the Permittee shall maintain records of actual hours of operation for each of the Generators A, B, and C. Records shall be taken monthly and shall be complete and sufficient to establish compliance with the time of operation limit established in Condition D.10.3. Records necessary to demonstrate compliance shall be available within 30 days of the end of each compliance period.

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

Comment 36:

D.10.5 (formerly D.10.6) Reporting Requirements
Lilly requests changing term D.10.5 (formerly D.10.6) as shown below. This change eliminates redundancy with Condition C.17.

D.10.5 Reporting Requirements

The permittee shall submit a ~~A~~ **semi-annual** ~~quarterly~~ summary of the information to document compliance with Condition D.10.3 ~~shall be submitted to the addresses 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 calendar quarter being reported. The report submitted by the Permittee does require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34)~~.

Response to Comment 36:

For quarterly versus semi-annual reporting, see Response to Comment 11.

The following changes were made to the Condition D.10.6:

D.10.**5**~~6~~ Reporting Requirements

A quarterly summary of the information to document compliance with Condition D.10.3 shall be submitted ~~to the addresses listed in~~ **according to** 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 calendar quarter being reported. The report submitted by the Permittee does require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).~~

Comment 37:

E.1.2 Pharmaceutical NESHAP Monitoring and Compliance Demonstration Requirement
Lilly requests the deletion of the "a" division in E.1.2. This term is not needed since there is no "b" division.

Response to Comment 37:

The following change was made to the Condition E.1.2:

~~(a)~~ ~~900~~ / 1800 kg Compliance Option and 93% / 98% Reduction Option:
.....

Comment 38:
Lilly requests the deletion of term E.3.3(a). This term is not needed as LTC does not have any control devices with wastewater.

Response to Comment 38:

40 CFR 63.1256(d)(4)(i) and (ii) clarifies that for containers, improper work practice includes, but is not limited to, leaving open any access hatch or other opening when such hatch or opening is not in use and control equipment failure includes, but is not limited to, any time a cover or door has a gap or crack, or is broken. 40 CFR 63.1256(e)(2)(i) and (ii) clarifies that for individual drain systems improper work practice includes, but is not limited to, 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 and control equipment failure includes, but is not limited to, any time a joint, lid, cover, or door has a gap or crack, or is broken. Pursuant to 40 CFR 63.1256(d)(5), except as provided in paragraph (i) of this section (referring to 40 CFR 63.1256), when an improper work practice or a control equipment failure is identified, first efforts at repair shall be made no later than 5 calendar days after identification and repair shall be completed within 15 calendar days after identification. 40 CFR 1256(i) discusses when delay of repair is allowed. The record keeping requirements outlined in Condition E.3.3(a) describe the records that shall be maintained to document the reasons that the delay of repair was necessary. These records would need to be maintained if the Permittee delays repair of the items described in 40 CFR 63.1256(d)(4)(i) and (ii) and 40 CFR 63.1256(e)(2)(i) and (ii), which includes gap, cracks or breaks of doors, joints, lids or covers. While doors, joints, lids and covers might not be thought of as traditional ”control devices”, these items are considered “control equipment” for the purposes of the delay of repair conditions. Since this type of equipment, joints, doors, lids and/or covers, does exist in the wastewater area at the source, IDEM, OAQ and OES have determined that paragraph (a) of Condition E.3.3 should remain in the permit. No change has been made to Condition E.3.3.

Comment 39:

Appendices
Lilly requests the addition of a reporting sheet for the Vanco process in the appendices. Vanco originally had a reporting sheet but the public notice version did not have a reporting sheet with it.

Response to Comment 39:

The following Report form was added to the Permit:

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY
COMPLIANCE DATA SECTION
and
INDIANAPOLIS OFFICE OF ENVIRONMENTAL SERVICES
AIR QUALITY MANAGEMENT SECTION

Part 70 Quarterly Report

Source Name: Eli Lilly and Company - Lilly Technology Center
Source Address: 1555 South Harding Street, Indianapolis, IN 46221
Mailing Address: Eli Lilly and Company, Lilly Corporate Center, Indianapolis, IN 46285
Part 70 Permit No.: T097-6846-00072
Facility: VANCO
Parameter: VOC Limit: less than 40 tons per twelve (12) consecutive month period with compliance determined at the end of each month

QUARTER: _____ **YEAR:** _____

Month	Column 1	Column 2	Column 1 + Column 2
	This Month	Previous 11 Months	12 Month Total
Month 1			
Month 2			
Month 3			

No deviation occurred in this quarter.

Deviation/s occurred in this quarter.
Deviation has been reported on:

Submitted by:
Title / Position:
Signature:
Date:
Phone:

Comment 40:

Technical Support Document – Source Definition
Technical Support Document – Compliance Requirements

On page 1 of the Technical Support Document, IDEM, OAQ and OES state that LTC has the same SIC code as LCC. This is not correct, as LCC has the SIC code of 8731, which corresponds to the NAICS code of 54171. Thus, Lilly requests that the following changes shown below be incorporated into the TSD:

On page 38 of the Technical Support Document, IDEM, OAQ and OES characterize five different monitoring methods as "compliance monitoring" requirements under the permit. Lilly disagrees with this characterization, and instead believes items (a), (b), (c), and (d) on pages 38-39 should be characterized as "compliance determination" methods. Each of these methods are required by the Pharmaceutical MACT rules, and they are considered direct measurements of compliance. If there are any instances where the measured results do not meet the regulatory requirements, then Lilly would be considered to be out of compliance with the regulations and the permit, unless otherwise exempted or excused [for example if a malfunction occurred]. Lilly requests the TSD be revised to include the correct characterization of these monitoring methods.

Response to Comment 40:

The correction to the SIC Code for the Eli Lilly Corporate Center is noted. However, as stated on Page 1 of this Addendum to Technical Support Document, "the Technical Support Document (TSD) will remain as it originally appeared when published."

Items (a), (b), (c), and (d) on pages 38-39 of the technical support document are identified in the Pharmaceutical Mact (40 CFR 63, Subpart GGG) as Monitoring Requirements and are outlined in 40 CFR 63.1258. Therefore, these items are covered in the Compliance Monitoring section of the Technical Support Document. The methods are required by Subpart GGG; therefore, IDEM, OAQ and OES have the requirements listed in the Emission Limitations and Standards portion of the appropriate E Sections of the Operating Permit. In the Technical Support Document they are listed in the Compliance Requirements section of the document and are identified as compliance monitoring only because of the title of the 40 CFR 63.1258.

Upon further review of the draft permit, IDEM, OAQ and OES have made the following changes:

IDEM, OAQ and OES Change 1:
Phone numbers for IDEM, OAQ's Compliance Data Section have been updated as shown below in Condition B.14 and on the Emergency Occurrence Report.

IDEM, OAQ
Telephone No.: 1-800-451-6027 (ask for Office of Air Quality, Compliance Branch) or,
Telephone No.: 317-233-~~5674~~ **0178** (ask for Compliance Branch)
Facsimile No.: 317-233-~~5967~~ **6865**

IDEM, OAQ and OES Change 2:
The location of the phrase "on a rolling five (5) year basis" has been moved for further clarification in Condition B.20(a)(5):

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

(a) (5) The Permittee maintains records**, on a rolling five (5) year basis,** 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, and OES in the notices specified in 326 IAC 2-7-20(b)(1), (c)(1), and (e)(2).

IDEM, OAQ and OES Change 3:

To be more accurate, the following rule citation changes have been made to Condition B.21:

B.21 Source Modification Requirement [326 IAC 2-7-10.5] [326 IAC 2-3-2] **[326 IAC 2-2-2]**

(a) A modification, construction, or reconstruction is governed by the requirements of 326 IAC 2 and 326 IAC 2-7-10.5.

(b) Any modification at an existing major source is governed by the requirements of **326 IAC 2-2-2 and/or** 326 IAC 2-3-2.

Indiana Department of Environmental Management
Office of Air Quality
and
Indianapolis Office of Environmental Services

Technical Support Document (TSD) for a Part 70 Operating Permit

Source Background and Description

Source Name:	**Eli Lilly and Company - Lilly Technology Center**
Source Location:	**1555 South Harding Street, Indianapolis, IN 46221**
County:	**Marion**
SIC Code:	**2834, 2833**
Operation Permit No.:	**T097-6846-00072**
Permit Reviewer:	**Amanda Hennessy / Boris Gorlin**

The Office of Air Quality (OAQ) and the Indianapolis Office of Environmental Services (OES) have reviewed a Part 70 permit application from Eli Lilly and Company - Lilly Technology Center relating to the operation of a pharmaceutical research, development and manufacturing facility.

Source Definition

OAQ and OES determined that this source:

(a) is not contiguous or adjacent to the Lilly Corporate Center (097-00019) located at the corner of McCarty and Delaware Street (greater than 2 miles apart);

(b) has the same SIC code as the Lilly Corporate Center;

(c) is under common control and ownership with the Lilly Corporate Center; and

(d) although some intellectual information is shared between the two locations, no physical product is transferred between the two locations; therefore, there is no support relationship.

Therefore, due to the distance and lack of a support relationship, the two locations will be considered two (2) separate sources.

Permitted Emission Units and Pollution Control Equipment

The source consists of the following permitted emission units and pollution control devices:

(a) A chemical development pilot plant facility and laboratories (identified as Building 110) used to develop new chemical processes and to produce new pharmaceutical compounds for subsequent use in toxicology studies and clinical trial research, with Modules A, B, C, D, E, 30 gallon A, 30 gallon B, Solids Containment and D-wing, and with process condensers.

(b) Manufacture of bulk pharmaceutical products (Building 358) by:

(1) protein isolation with a carbon adsorber for VOC and HAP control with laboratory support;

(2) through chemical synthesis or non-synthesized processes;

(c) Manufacture of vancomycin (VANCO) by isolation (base) and purification (HPLC) with a condenser for VOC and HAP control located in Building 348.

(d) The BHI area consists of five buildings (building 132, 133, 134, 142 and 138) where manufacturing of bulk pharmaceutical products through chemical synthesis takes place using condensers and a scrubber as VOC control.

(e) Building 130 Complex (buildings 130, 135 and 136) consisting of laboratories and manufacturing of bulk pharmaceutical products through chemical synthesis.

(f) Dry pharmaceutical manufacturing, identified as PC100 and located in Building 100, with processes including milling, mixing, granulation, sieving, microwave drying, compression, and filling and with a carbon block condenser on the dryer for VOC control and a HEPA filter for particulate control which is integral to the room.

(g) Dry pharmaceutical manufacturing, identified as PC1 and located in Building 328, with processes including milling, mixing, granulation, sieving, drying, compression, and filling, with a HEPA filter for particulate control which is integral to the dryer, and a scrubber for VOC control.

(h) Two (2) peak diesel generators, one (1) Model number DFHD, identified as Generator A, and one Model number DFJD, identified as Generator B, both located at the Building 141 (B141), constructed, respectively, in 1999 and 2004, with a maximum capacity of 1,350 HP each, using no control, and exhausting to stack B141 Generator A.

(i) One (1) peak diesel generator, Model number DQKC, identified as Generator C, located at the Building 141 (B141), constructed in 2006, with a maximum capacity of 2,700 HP, using no control, and exhausting to stack B141 Generator C.

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

The following emission units 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]:

(a) An outside storage tank area (Tank Farm North) with the storage tanks holding raw material and waste solvents.

(b) Laboratories, identified as Building 135. (This equipment is combined with the permitted equipment in the Building 130 Complex in the D section of the permit and in the State Applicability section of this TSD.)

(c) Equipment installed in Building 130 in 1981, 1982, 1984 and 1985. (This equipment is combined with the permitted equipment in the D section of the permit and in the State Applicability section of this TSD.)

(d) Equipment installed in PC 1 (Building 328) in 1983, 1986, and 1989. (In 1991, a permit was issued for tablet formulation in PC 1. This permit was updated in 1995. This equipment is combined with the permitted equipment in the D section of the permit and in the State Applicability section of this TSD.)

Insignificant Activities

The source also consists of the following insignificant activities, as defined in 326 IAC 2-7-1(21):

(a) 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.

(b) The following VOC and HAP storage containers:

(1) Storage tanks with capacity less than or equal to 1,000 gallons and annual through puts less than 12,000 gallons.

(2) Vessels storing lubricating oils, hydraulic oils, machining oils, and machining fluids.

(c) Application of oils, greases, lubricants or other nonvolatile materials applied as temporary protective coatings.

(d) Degreasing operations that do not exceed 145 gallons per 12 months, except if subject to 326 IAC 20-6. [326 IAC 8-3]

(e) Cleaners and solvents characterized as follows:
(1) having a vapor pressure equal to or less than 2 kPa; 15mm Hg; or 0.3 psi measured at 38 degrees C (100^{o}F) or;
(2) having a vapor pressure equal to or less than 0.7 kPa; 5mm Hg; or 0.1 psi measured at 20 degrees C (68^{o}F),
the use of which for all cleaners and solvents combined does not exceed 145 gallons per 12 months.

(f) Closed loop heating and cooling systems.

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

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

(i) Noncontact cooling tower systems with the following: forced and induced draft cooling tower system not regulated under a NESHAP.

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

(k) Heat exchanger cleaning and repair.

(l) Process vessel degassing and cleaning to prepare for internal repairs.

(m) Paved and unpaved roads and parking lots with public access. [326 IAC 6-4]

(n) Asbestos abatement projects regulated by 326 IAC 14-10.

(o) 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.

(p) 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.

(q) Blowdown for any of the following: sight glass; boiler; compressors; pumps; and cooling tower.

(r) On-site fire and emergency response training approved by the department.

(s) Emergency generators as follows: Diesel generators not exceeding 1600 horsepower.

(t) Stationary fire pumps.

(u) Purge double block and bleed valves.

(v) Filter or coalescer media changeout.

(w) Laboratories as defined in 326 IAC 2-7-1(21)(D).

(x) Research and development activities as defined in 326 IAC 2-7-1(21)(E).

(y) Any unit emitting greater than 1 pound per day but less than 5 pounds per day or 1 ton per year of a single HAP:
  (1) Loading and unloading of raw materials and wastes into tank trucks and/or rail cars. There are at least two of these installations. Emissions include methanol and acetonitrile.
  (2) Equipment cleaning. Emissions include methanol.

(z) Any unit emitting greater than 1 pound per day but less than 12.5 pounds per day or 2.5 tons per year of any combination of HAPs.
  (1) Optimization and testing of developmental fermentation processes in fermenters less than or equal to 6,000 liter capacity. This description applies to a minimum of ten fermenters. The emissions include methanol.
  (2) Manufacturing in fermenters less than 40,000 liters. This applies to at least four fermenters. Emissions include methanol.
  (3) Filtration of fermentation broths in lots less than 2,000 liters. This description applies to a minimum of three installations. The emissions include methanol.
  (4) Processing in development area portable tanks, less than 500 liters. This description applies to a minimum of two tanks. The emissions include methanol.
  (5) Hydrogenation equipment less than 50 gallons located in developmental area. This description applies to a minimum of two installations. The emissions include methanol and methylene chloride.

(aa) Activities with emissions equal to or less than insignificant thresholds:
  (1) Optimization, testing, and manufacturing with fermentors. Emissions less than 5 pounds per hour and 25 pounds per day particulate matter and 3 pounds per hour and 15 pounds per day of VOC.
  (2) Testing of cartridge filters used as part of fermentation and sterile area operations. Emissions are less than 3 pounds per hour and 15 pounds per day of VOC.
  (3) Equipment cleaning. Emissions are less than 3 pounds per hour and 15 pounds per day of VOC.
  (4) Pilot plant equipment used in optimization of the purification of potential

manufacturing fermentation processes. Emissions are less than 3 pounds per hour and 15 pounds per day of VOC.

(5) Printing operations for product identification. Emissions are less than 3 pounds per hour and 15 pounds per day of VOC.

(6) Fluid bed dryers in dry products manufacturing. Emissions are less than 5 pounds per hour and 25 pounds per day particulate matter.

(7) Process equipment or storage tanks which contain a VOC with a vapor pressure less than 0.1 mm Hg.

Existing Approvals

The source has been operating under previous approvals including, but not limited to, the following:

Operating Permits

(a) 8109, issued on May 16, 1984 for B348 Evaporator 24;

(b) 8163, issued on July 9, 1984 for B348 Tanks 14-17;

(c) 8303, issued on November 29, 1984 for B348 Evaporator 21;

(d) 8304, issued on November 29, 1984 for B348 Evaporator 22;

(e) 8305, issued on November 29, 1984 for B348 Evaporator 23

(f) 8306, issued on November 29, 1984 for B348 Evaporator (wall);

(g) 8307, issued on November 29, 1984 for B348 Ventilation Room;

(h) 8308, issued on November 30, 1984 for B140/P/D5, PCA14 (Bldg 100);

(i) 8309, issued on November 30, 1984 for B140/P/D7, PCA16 (Bldg 100);

(j) 8310, issued on November 30, 1984 for B100/P/F6, EF4;

(k) 8311, issued on November 30, 1984 for B100/P/F6, EF9 (Bldg 100);

(l) 8312, issued on November 30, 1984 for B100 ST3/D15;

(m) 8783, issued on April 22, 1986, for Vanco 348 Facility;

(n) 0072-1, issued on July 15, 1987 for Building 130;

(o) 890073-01, issued on September 8, 1989 for equipment in Building 334 (replaced by CP950073-03 issued on May 17, 1995);

Construction Permits

(p) 11043, issued on September 13, 1985 for Vanco 348;

(q) 890073-03, issued on November 17, 1989 for B348: Tanks 19 and 20;

(r) 910072-01, issued on October 2, 1991 for BHI 132 Facility;

(s) 920073-01, issued on August 14, 1992 for 358 Pilot Plant;

(t) 097-3341, issued on July 27, 1994 for 110 RACT Plan;

(u) 950073-03, issued on November 6, 1995 for LTC Emergency Generators;

(v) 950073-02, issued on January 5, 1995 for PC1: 328 Facility;

(w) 950073-01, issued on January 5, 1995 for PC100 Facility;

(x) 950073-03, issued on May 17, 1995 for Vancomycin Processing (revoked);

(y) A097-5322, issued on February 20, 1996 for 110 RACT Plan Amendment;

(z) 960072-01, issued on February 29, 1996 for Glucagon 130 Facility;

(aa) A072-0001, issued on June 1, 1996 for Buildings 132 and 138

(bb) 960073-01, issued on July 10, 1996 for Emergency Generator (314);

(cc) 960073-01, issued on September 25, 1996 for 358 Pilot Plant;

(dd) A0970072-02, issued on December 10, 1997, for 110 RACT Plan Amendment;

(ee) A0970072-03, issued on March 12, 1999, 110 RACT Plan Amendment;

(ff) 097-12128, issued on May 2, 2001, for Building 110 RACT Plan Amendment;

(gg) 097-12605-00072, issued on September 10, 2001, for modification to Building 130;

(hh) 097-22049-00072, issued on March 10, 2005, for modification of two (2) existing diesel generators (peak Generators A and B, Building 141, formerly emergency generators), and construction of one (1) new peak diesel generator (Generator C, Building B184).

All conditions from previous approvals were incorporated into this Part 70 permit except the following:

(a) Minor Source Modification 097-12605-00072, issued on September 10, 2001, permit Condition D.1.1(b):

D.1.1 Particulate Matter (PM) [326 IAC 6-3-2 (Process Operations: Particulate Emission Limitation)] [326IAC 2-2 (Prevention of Significant Deterioration)]

(b) The PM emissions from the complex B130 shall be limited to less than 100 tons per year, such that 326 IAC 2-2 requirements do not apply.

Reason not incorporated:

In 2001, the Permittee modified Building 130 by adding and modifying existing equipment in Building 130 for the production of KPB and the support of KPB production and rGlucagon production. The VOC emission increase from this modification was 37.5 tons per year and the PM emissions increase was negligible. These increases were below the 326 IAC 2-2 significant level threshold. In the minor source modification, a limit of 100 tons per year of PM was taken so that 326 IAC 2-2 did not apply. However, B130 PM potential emissions were/are 8.13 tons per year and source-wide PM potential emissions were/are less than 100 tons per year. Since potential emissions are less than 100 tons

per year, no limit is needed. Therefore, this limit has not been carried over.

(b) Certificate of Operation 0072-1, issued on July 15, 1987, entire permit.

Reason not incorporated:

The equipment listed and process described in this Certificate of Operation has either been removed from the source or moved to another area of the source. If the equipment has been moved to another area of the source, it is included in a permit for that area of the source. Since this equipment is no longer located in this building, this Certificate is no longer applicable.

(c) Construction Permit 960072-01, issued on February 29, 1996, Conditions 3, 4, and 6.

Reason not incorporated:

In this construction permit, emissions were limited to less than 15 pounds per day so that the requirements of 326 IAC 8-5-3 and 326 IAC 8-1-6 were not applicable. The limits in Condition 3 are not necessary because potential emissions from each emission unit in this process are less than 15 pounds per day and less than 25 tons per year. Therefore, Condition 3, Condition 4 (recordkeeping to demonstrate compliance with the limit in Condition 3), and Condition 6 (leak repair) are not necessary.

(d) Amendment 097-12128-00072, issued on May 2, 2001, which amended Condition 5 of CP 097-3341-00072 (second sentence only).

Reason not incorporated:

The condition stated “These records shall be kept for at least the past 36 month period and made available upon request to the Office of Air Quality”. Title V provisions require the Permittee to keep records for five (5) years. Therefore, the requirement to keep the records for 36 months is not being incorporated into the Title V permit. However, the rest of the condition is being carried over into the Title V permit.

(e) CP-910072-01, issued on October 2, 1991 and Amended by A072-0001 on June 3, 1997 Condition 7a.

Reason not incorporated:

The requirement to maintain a record of any startup, shutdown or malfunction period as outlined in the permit is no longer necessary. The Permittee must keep those records as part of the requirements of 40 CFR 63, Subpart GGG.

(f) CP960073-01, issued September 25, 1996, for Building 358, Conditions 3, 5, 8,10, and 12.

Reason not incorporated:

The potential to emit of VOC from Building 358 is no longer greater than 25 tons per year due to equipment changes. Since the PTE of VOC from Building 358 is no longer greater than 40 tons per year, the limit (Condition 3) is no longer necessary. This limit and all related compliance demonstration and recordkeeping requirements have not been carried over into this Part 70 permit.

Since issuance of the CP0960073-01, the 40 CFR 63, Subpart GGG was promulgated. It contains requirements for leak detection and repair work practices previously included in the Lilly LDAR Program. Therefore, this permit is replacing the Lilly LDAR Program required by CP960073-01 (Conditions 5 and 12b) with the requirements of 40 CFR 63, Subpart GGG.

(g) CP910072-01, issued October 2, 1991, for Building 132 which replaced 890072-01, and which was Amended by A072-0001 on June 3, 1997, Condition 6 and 7b.

Reason incorporated differently:

The Permittee has requested that the Leak Detection and Repair requirements (Conditions 6 and 7b) no longer refer to the Lilly LDAR program. Equipment subject to this condition shall no longer be required to follow the Lilly LDAR program but shall be required to follow the LDAR requirements of 40 CFR 63, Subpart GGG. "In VOC service" was, under CP960073-01 and Amendment A072-0001, understood to mean "containing a stream containing greater than or equal to ten (10) percent VOC by weight." Therefore, all pumps, valves, and flanges in the BHI area, which contains a stream containing greater than or equal to ten (10) percent VOC by weight, are subject to 40 CFR 63.1255 (Subpart GGG). Equipment not in organic HAP service 300 hours or more during the calendar year is not subject to monitoring requirements of 40 CFR, Subpart GGG.

(h) CP 930072-01, issued July 16, 1993, for Building 110 Modules E and F - entire permit

Reason not incorporated:

This construction permit was superseded by CP097-3341, issued on July 27, 1994.

Air Pollution Control Justification as an Integral Part of the Process

The following determination was made in Minor Source Modification 097-12605-00072, issued on September 10, 2001:

The company has submitted the following justification such that the Scrubber Emission Unit ID TK-265, controlling emissions from urea prills pneumatic unloading process into the storage tank TK-265, be considered as an integral part of the process:

(a) The Scrubber is a vital part of the process because without it the Tank's vent would be immediately clogged preventing pneumatic unloading operation;

(b) The urea prills collected in the Scrubber are recycled and used in the process.

OES has evaluated the justifications and agreed that the Scrubber Emission Unit ID # TK-265, will be considered as an integral part of the urea prills pneumatic unloading process. Therefore, the permitting level will be determined using the potential to emit after the Scrubber.

The following determinations were made during the Title V review process:

The scrubber on the urea prill unloading process in B132 (in the BHI area) is an integral part of the process because of the same situation as for Scrubber Emission Unit ID TK-265 described above in Minor Source Modification 097-12605-00072. The line would become immediately clogged preventing pneumatic unloading if the scrubber was not in place.

The HEPA filter on the dryer in PC1 is integral to the process because the purpose of the HEPA filter is to maintain product quality. The purpose of the HEPA filter is not related to controlling air pollution from the granulation process. Over the last ten years, EPA has put forth the following questions that sources should use to determine whether equipment should be considered inherent and/or integral to the process when calculating potential to emit:

(a) Is the primary purpose of the equipment to control air pollution?
(b) Where the equipment is recovering product, how do the cost savings from the product recovery compare to the cost of the equipment?
(c) Would the equipment be installed if no air quality regulations are in place?

The source has stated that the main purpose for the HEPA filter is to ensure product quality and that the air used in the drying operations is free of contamination. Therefore, for potential to emit calculations, the HEPA filter on the granulation and drying process in PC100 will be considered inherent to the process.

The HEPA filter on the dryer in PC100 is integral to the room in which the process takes place for the same reasons that the HEPA filter in PC1 is integral. The purpose of the HEPA filter is to maintain product quality. The purpose of the HEPA filter is not related to controlling air pollution from the granulation process.

Enforcement Issue

There are no enforcement actions pending. All previously unpermitted emission units described in the list of emission units identified through the Title V Compliance Transition Program (See the Section of this Technical Support Document identified as Unpermitted Emission Units and Pollution Control Equipment Identified Through the Title V Compliance Transition Program) meet the requirements of IC 13-7-7 and non-rule policy document AIR-000-NPD. This proposed permit is intended to satisfy the requirements of the construction permit rules.

Recommendation

The staff recommends to the Commissioner that the Part 70 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 8, 1996. There was no notice of completeness letter mailed to the source. Updates to the application were received on April 20, 1998 (Amendment A), on December 10, 1998 (Amendment B), in July, 2003 (Amendment C), on August 16, 2004 (Amendment D), December 6, 2004 (Amendment E), February 7, 2005, and March 17, 2005.

Potential To Emit

Pursuant to 326 IAC 2-1.1-1(16), Potential to Emit is defined as Athe 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, the department, or the appropriate local air pollution control agency.@

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

Pollutant	Potential To Emit (tons/year)
PM	less than 100
PM-10	less than 100
SO_2	less than 100
VOC	greater than 100
CO	less than 100
NO_x	less than 100

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

HAPs	Potential To Emit (tons/year)
acetonitrile	greater than 10
Combined HAPs	greater than 25

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

(b) The potential to emit (as defined in 326 IAC 2-1.1-1(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.

(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 and Emission Offset applicability.

Actual Emissions

The following table shows the actual emissions from the source. This information reflects 2004 OAQ emission data.

Pollutant	Actual Emissions (tons/year)
PM	none reported
PM-10	none reported
SO_2	none reported
VOC	43.17
CO	none reported
NO_x	none reported
methylene chloride	0.74 tons
chlorine	0.17 tons

Potential to Emit After Issuance

The table below summarizes the potential to emit, reflecting all limits, of the significant emission units after controls. (See next page)

	Potential to Emit (tons/year unless otherwise indicated)						
Process/facility	PM	PM-10	SO_2	VOC	CO	NO_X	HAPs
Building 110				10[1]			
Building 358				24.1			
Building 132	47.2 lb/hr			<40[2]			
Building 130	27 lb/hr[3]			<15 lb/day[5]			
VANCO				BACT[6] and <40[7]			
PC100				<25[4]			
PC1				<25[4]			
Building 135							
Tank Farm North							
Total Emissions	<100		<100	>100	<100	<100	>25 combined >10 individual

1 Part of source specific RACT plan pursuant to CP 097-3341, Amendment A097-5322, Amendment A0970072-02, Amendment A0970072-03, Amendment 097-13792-00072, Amendment 097-13924-00072, Amendment 097-12128, 326 IAC 8-1-5 and 326 IAC 8-5-3

2 Limit to make 326 IAC 2-2 not applicable pursuant to CP910072-01 and updated in this permit.

3 Limit pursuant to 326 IAC 6-3-2.

4 Limit pursuant to 326 IAC 8-1-6.

5 Limit or potential from each emission unit to make 326 IAC 8-5-3 not applicable.

6 BACT pursuant to 326 IAC 8-1-6, consists of routing EV116 vapors to an after condenser.

7 Limit to make 326 IAC 2-2 not applicable.

County Attainment Status

The source is located in Marion County.

Pollutant	Status
PM10	Attainment
PM2.5	Nonattainment
SO_2	Maintenance Attainment
NO_2	Attainment
1-Hour Ozone	Maintenance Attainment
8-Hour Ozone	Basic Nonattainment
CO	Maintenance Attainment
Lead	Maintenance Attainment

(a) Volatile organic compounds (VOC) and Nitrogen Oxides (NOx) are regulated under the Clean Air Act (CAA) for the purposes of attaining and maintaining the National Ambient Air Quality Standards (NAAQS) for ozone. Therefore, VOC and NOx emissions are considered when evaluating the rule applicability relating to the ozone standards. Marion County has been designated as nonattainment for the 8-hour ozone standard. Therefore, VOC and NOx emissions were reviewed pursuant to the requirements of the Emission Offset Rules.

(b) Marion County has been classified as nonattainment for PM2.5 in 70 FR 943 dated January 5, 2005 and effective April 5, 2005. Until U.S. EPA adopts specific New Source Review rules for PM2.5 emissions, it has directed states to regulate PM10 emissions as surrogate for PM2.5 emissions pursuant to the Non-attainment New Source Review requirements. See the State Rule Applicability for the source section.

(c) Marion County has been classified as attainment or unclassifiable in Indiana for all other criteria pollutants. Therefore, these emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2. See the State Rule Applicability for the Source Section.

(d) 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 and Emission Offset 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

(a) This source has emission units which used to be subject to the recordkeeping requirements of the New Source Performance Standard, 326 IAC 12, (40 CFR 60.110b, Subpart Kb), because they are volatile organic liquid storage tanks that construction, modification or reconstruction commenced after July 23, 1984 and they have capacity greater than 40 cubic meters. However, on October 15, 2003, 40 CFR 60.110b was amended such that storage vessels with a capacity less than or equal to 75 cubic meters used to store volatile organic liquids, volatile organic liquid storage vessels with a capacity greater than or equal to 151 cubic meters storing a liquid with a maximum true vapor pressure less than 3.5 kilopascals, and volatile organic liquid storage vessels with a capacity less than 151 cubic meters but greater than 75 cubic meters storing a liquid with a maximum true vapor pressure less than 15 kilopascals are not subject to 40 CFR 60, Subpart Kb. The revised 40 CFR 60, Subpart Kb was adopted in 326 IAC 1-1-3 by reference, and became effective on November 13, 2005.

The table below outlines the applicability level for each tank:

Tank ID	Location	Capacity (cubic meters)	Maximum True Vapor Pressure (kPa)	Subject to Subpart Kb
TFT508	130	75.71	3.74	No
TFT512	130	75.71	2.81	No
TFT512A	130	108.57	2.81	No
TFT514	130	75.71	2.59	No
TK682	130	75.71	3.05	No
TK683	130	75.71	3.05	No
5061	BHI	150.66	2.81	No
5331	BHI	94.64	5.34	No
TK 201	VANCO	75.71	1.4	No
TK 202	VANCO	75.71	0.266	No
TK 203	VANCO	75.71	0.03	No
TK 204	VANCO	75.71	0.04	No
TK 205	VANCO	75.71	0.04	No

All other tanks at this source have a capacity less than 75 cubic meters.

There are tanks at this source with capacity greater than 75 cubic meters and less than 151 cubic meters but with maximum true vapor pressure less than 15 kPa. There are no tanks at this source with capacity greater than 75 cubic meters and less than 151 cubic meters that store a liquid with a maximum true vapor pressure greater than 15 kPa. There are no tanks at this source with capacity greater than 151 cubic meters. Therefore, no 40 CFR 60, Subpart Kb requirements are included for the tanks located at this source.

(b) The requirements of 40 CFR 60, Subparts VV, III, NNN, and RRR (Synthetic organic chemical manufacturing) are not included in this permit. 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, 40 CFR 60.617, 40 CFR 60.667 or 40 CFR 60.707.

(c) This source is identified as the type of facility subject to the National Emission Standards for Hazardous Air Pollutants (NESHAPs), 40 CFR 61, Subpart FF, which applies to benzene waste operations. However, the total annual benzene quantity from facility waste is less than 10 megagrams per year (11 tons per year) and therefore, the source is exempt from the specific requirements of 40 CFR 61, Subpart FF. [40 CFR 61.342(a)]

(d) The requirements of 40 CFR 61, Subpart V are not included in this permit. However, B358 is following 40 CFR 61, Subpart V LDAR program as a result of streamlining. This source is not subject to any other standard in Part 61 which refers to Subpart V. Pursuant to 40 CFR 61.240, Subpart V applies to equipment at sources after the date of promulgation of a specific subpart in Part 61. In addition, pursuant to 40 CFR 63.1255(a)(2), equipment subject to 40 CFR 63, Subpart GGG that is also subject to either 40 CFR 60 and/or 40 CFR 61 will be required to comply only with the provisions of 40 CFR 63, Subpart GGG.

(e) This source is subject to the requirements of 40 CFR 61, Subpart M because this source may perform renovation or demolition activity which may involve the removal of regulated asbestos containing material. The source must comply with the requirements of 40 CFR 61.145(a), (b) and/or (c) depending on the type of demolition or renovation activity that is occurring.

(f) The requirements of 40 CFR 63, Subpart I and 326 IAC 20-12, which applies to pharmaceutical production processes using carbon tetrachloride or methylene chloride, are not included in this permit. The source does not have any pharmaceutical production processes using carbon tetrachloride or methylene chloride.

(g) The requirements of 40 CFR 63, Subpart F (National Emission Standards for Organic Hazardous Air Pollutants from the Synthetic Organic Chemical Manufacturing Industry) are not included in this permit. The source does not manufacture as a primary product one or more of the chemicals listed in 40 CFR 63.100(b)(1)(i) or (b)(1)(ii) or use as a reactant or manufacture as a product, or co-product, one or more of the organic hazardous air pollutants listed in 40 CFR 63, Subpart F Table 2.

(h) The requirements of 40 CFR 63, Subpart T (National Emission Standards for Halogenated Solvent Cleaning) are not included in this permit. The source does not use a solvent containing methylene chloride, perchloroethylene, trichloroethylene, 1, 1, 1-trichloroethylene, carbon tetrachloride, or chloroform or any combination of these halogenated HAP solvents, in a total concentration greater than five percent (5%) by weight as a cleaning and/or drying agent in an individual batch vapor, in-line vapor, in line cold and batch cold solvent cleaning machine.

(i) The requirements of 40 CFR 63, Subpart FFFF (National Emission Standards for Miscellaneous Organic Chemical Production and Processes) are not included in this permit. All the facilities that would otherwise be subject to Subpart FFFF are subject to 40 CFR 63, Subpart GGG (Pharmaceutical Production MACT).

(j) This requirements of 40 CFR 64 Compliance Assurance Monitoring are not included in this permit. Since this source applied for a Part 70 permit prior to April 20, 1998 (initial Part 70 permit application was submitted on October 8, 1996) and has not yet applied for a renewal of a Part 70 permit, compliance assurance monitoring would only apply to “large pollutant specific emissions units” upon submittal of a significant permit revision for that large pollutant specific emissions unit. There are no “large pollutant specific emission units” as defined in 40 CFR 64.5 located at this source, and the Permittee has not submitted a significant permit revision for a large pollutant specific emissions unit.

(k) This source has facilities that are subject to the National Emission Standards for Hazardous Air Pollutants, 326 IAC 14, (40 CFR 63, Subpart GGG) for Pharmaceuticals Production. Subpart GGG is applicable to facilities at major sources (as defined in 40 CFR 63.2) that process, use or produce HAP in the manufacture of a pharmaceutical product.

The provisions of 40 CFR 63 Subpart A - General Provisions, which are incorporated as 326 IAC 20-1-1, apply to the facilities described in this section except when otherwise specified in 40 CFR 63 Subpart GGG.

(l) National Emission Standards for Hazardous Air Pollutants for Stationary Reciprocating Combustion Engines (40 CFR 63, Subpart ZZZZ)

(1) The diesel Generators A, B, and C are, each, are subject to the National Emission Standards for Hazardous Air Pollutants for Stationary Reciprocating Internal Combustion Engines (40 CFR 63, Subpart ZZZZ), which is incorporated by reference as 326 IAC 20-82. Existing Generators A and B, and new Generator C are limited by stationary RICE, operating (limited to) less than 100 hours per year each (see State Rule Applicability Section).

(2) Pursuant to 40 CFR 63.6590(b), the Permittee is subject only to the requirements in 40 CFR 63.6645 (d) for this facility.

(3) Pursuant to 40 CFR 63.6645(d), the permittee shall submit the initial notification, which shall include the information in 40 CFR 63.9(b)(2)(i) through (v), and a statement that the stationary RICE, Emission Units Generators A, B, and C have no additional requirements, and explain the basis of the exclusion (for example, that it operates occasionally with limited operation hours, less than 100 hours per year each). The notification for the Generators A and B shall be submitted no later than 120 days after this permit issuance date, and for the new Generator C - no later than 120 days after its start up date.

(4) The provisions of 40 CFR 63 Subpart A – General Provisions, which are incorporated as 326 IAC 20-1-1, apply to the facility described in this section except when otherwise specified in 40 CFR 63 Subpart ZZZZ.

Source Wide - applicability

(a) Process vent requirement 40 CFR 63.1254(a)(4) is not included in this permit because the source does not use a centralized combustion control device (CCCD).

(b) The source does not have any bypass lines where a vent could bypass a control device required by this rule, therefore, all requirements related to bypass lines are not included in this permit.

(c) The source does not currently have any storage tanks larger than 75 cubic meters with a vapor pressure greater than or equal to 13.1 kPa and no storage tanks larger than 38 cubic meters with a vapor pressure greater than or equal to 13.1 kPa. Therefore, currently, the storage tank requirements of Subpart GGG are not included in this permit.

(d) The source does not currently have any liquid streams in open systems, therefore, the requirements of 40 CFR 63.1252(f) are not included in this permit.

(e) Pursuant to the preamble to the rule published in the Federal Register on September 21, 1998, closed individual drain systems are equivalent to hard piping.

(f) The source does not have any surface impoundments, therefore the wastewater requirements for surface impoundments are not included in this permit.

(g) The source does not have any oil water separators, therefore, the wastewater requirements for oil water separators are not included in this permit.

(h) There are no inspection requirements under 40 CFR 63.1258(h) included in this permit.

Individual Facility - applicability

(a) Building 110 is not subject to 40 CFR 63, Subpart GGG because it is a research and development facility. Pursuant to 40 CFR 63.1250(d), research and development facilities are exempted from the requirements of Subpart GGG.

(b) The source does not use supplemental gases added to the vents or manifolds for control devices complying with the alternative standard, therefore, the requirements of 40 CFR 63.1258(b)(5)(ii) are not included.

(c) There are no control devices on any wastewater tanks or containers subject to the requirements of 40 CFR 63.1256(b) through (f). Therefore, the requirements of 40 CFR 63.1256(h) are not applicable to any equipment at this source.

(d) **Process Vents Standards**
Each process in Building 358, the VANCO area, the BHI area, the Building 130 Complex, PC1 and PC100 shall comply with one of the following standards. Notification of a change in the compliance method for any process shall be reported according to the procedures of 40 CFR 63.1260(h).

(1) **900 / 1800 kg Compliance Option:**
[40 CFR 63.1254(a)(2) and(3)]

(A) Actual HAP emissions from the sum of all process vents within a process (as defined in 40 CFR 63.1251) must not exceed 900 kilograms (kg) in any 365 day period.
(B) Actual HAP emissions from the sum of all process vents at the source within processes complying with the 900 kilogram limit in 40 CFR 63.1254(a)(2)(i) are limited to a maximum of 1,800 kilogram in any 365 day period.
(C) Emissions from vents that are subject to the requirements of 40 CFR 63.1254(a)(3) and emissions from vents that are controlled in accordance with the alternative limit in 40 CFR 63.1254(c) shall be excluded from the sums calculated above.
(D) The Permittee may switch from compliance with 40 CFR 63.1254(a)(2) to compliance with 40 CFR 63.1254(a)(1) only after at least one year of operation in compliance with 40 CFR 63.1254(a)(2).

(2) **93% / 98% Reduction Compliance Option**
[40 CFR 63.1254(a)(1) and (3)]

(A) Uncontrolled HAP emissions from the sum of all process vents within a process that are not subject to 40 CFR 63.1254(a)(3) shall be reduced by 93 percent or greater by weight or any one or more vents within a process may be controlled in accordance with any of the following procedures:

(i) To outlet concentrations less than or equal to 20 ppmv as TOC and less than or equal to 20 ppmv as hydrogen halides and halogens; OR
(ii) By a control device specified in 40 CFR 63.1257(a)(4).

(B) If the uncontrolled HAP emissions from any process vent exceed 25 tons per year and the flow-weighted average flowrate (FR_a) calculated using

Equation 1 in 40 CFR 63.1254(a)(3) is less than or equal to the flowrate index (FRI) calculated using Equation 2 of 40 CFR 63.1254(a)(3), then the Permittee must either:

(i) Reduce uncontrolled HAP emissions from that process vent by 98 percent or in accordance with any of the procedures in 40 CFR 63.1254(a)(1)(ii)(A) through (D); OR
(ii) As an alternative to the 98% reduction in (i) above, the Permittee may comply with the provisions in 40 CFR 63.1254(a)(3)(ii)(A), (B), or (C).

(e) **Monitoring and Compliance Demonstration Requirements:**
Each process in Building 358, the VANCO area, the BHI area, PC1 and PC100 shall comply with the following based on the compliance option chosen.

(1) **900 / 1800 kg Compliance Option and 93% Reduction Option:**

(A) For control devices that control vent streams totaling less than 1 ton per year HAP emissions, before control, the Permittee shall verify daily that the control device is operating properly. If the control device is used to control batch process vents alone or in combination with other streams, the verification may be on a per batch basis. This verification shall include, but not be limited to, a daily or per batch demonstration that the unit is working as designed. Measurements taken for this verification are not considered continuous monitoring systems.

(B) For condensers that control vent streams totaling greater than 1 ton per year HAP emissions, before control:

(i) The Permittee shall establish the maximum condenser outlet temperature as a site-specific operating parameter.
(ii) The Permittee shall measure and record the outlet gas temperature at least every 15 minutes during the period in which the condenser is functioning in achieving HAP removal.
(iii) The temperature monitoring device must be accurate to within ∀ 2 percent of the temperature measured in degrees Celsius or ∀ 2.5 degrees Celsius whichever is greater.
(iv The temperature monitoring device must be calibrated annually.
(v) Averaging periods for the site-specific operating parameters shall be established according to 40 CFR 63.1258(b)(2)(i) through (iii).
(vi) The site specific operating parameters shall be set pursuant to 40 CFR 63.1258(b)(3).
(vii) The outlet gas temperature continuous monitoring system must meet all applicable requirements of 40 CFR 60.8.

(C) For scrubbers that control vent streams totaling greater than 1 ton per year HAP emissions, before control:

(i) The Permittee shall establish a minimum scrubber liquid flow rate or pressure drop as a site-specific operating parameter. If the scrubber uses a caustic solution to remove acid emissions, the Permittee shall establish a minimum pH of the effluent scrubber liquid as a site-specific operating parameter.
(ii) The Permittee shall measure and record either the scrubber liquid flow rate or pressure drop every 15 minutes during the

period in which the scrubber is functioning in achieving HAP removal. If the scrubber uses a caustic solution to remove acid emissions, the Permittee shall monitor the pH of the effluent scrubber liquid at least once per day.

(iii) The monitoring device(s) used to determine the pressure drop shall be certified by the manufacturer to be accurate to within a gage pressure of ∀ 10 percent of the maximum pressure drop measured.

(iv) The monitoring device(s) used for measurement of scrubber liquid flow rate shall be certified by the manufacturer to be accurate within ∀ 10 percent of the design scrubber liquid flow rate.

(v) The monitoring device(s) shall be calibrated annually.

(vi) The site specific operating parameters shall be set pursuant to 40 CFR 63.1258(b)(3).

(vii) The outlet gas temperature continuous monitoring system must meet all applicable requirements of 40 CFR 63.8.

(D) For regenerative carbon adsorbers that control vent streams totaling greater than 1 ton per year HAP emissions, before control:

(i) Establish the following regeneration cycle characteristics under worst-case conditions, as defined in 40 CFR 63.1257(b)(8)(i):

(a) Minimum regeneration frequency (i.e. , operating time since last regeneration);

(b) Minimum temperature to which the bed is heated during regeneration;

(c) Maximum temperature to which the bed is cooled, measured within 15 minutes of completing the cooling phase; and

(d) Minimum regeneration stream flow.

(ii) Monitor and record the following regeneration cycle characteristics for each regeneration cycle:

(a) Regeneration frequency (operating time since end of last regeneration);

(b) Temperature to which the bed is heated during regeneration;

(c) Temperature to which the bed is cooled, measured within 15 minutes of the completion of the cooling phase; and

(d) Regeneration stream flow.

(iii) Use a temperature-monitoring device that is accurate to within ∀2 percent of the temperature measured in degrees Celsius or ∀2.5EC, whichever is greater.

(iv) Use a regeneration stream flow monitoring device capable of recording the total regeneration stream flow to within ∀10 percent of the established value (i.e., accurate to within ∀10 percent of the reading.)

(v) Calibrate the temperature and flow monitoring devices annually.

(vi) Conduct an annual check for bed poisoning in accordance with manufacturer=s specifications.

(E) Pursuant to 40 CFR 63.1258(c), the Permittee shall demonstrate continuous compliance with the 900 and 1,800 kilogram per year emission limits by calculating daily 365 day rolling summations of emissions.

(f) **LDAR Requirements**

Each process in Building 358, the VANCO area, the BHI area, the Building 130 Complex, PC1 and PC100 shall comply with the following standards as applicable. Pursuant to 40 CFR 63.1255(a), the LDAR provisions in 40 CFR 63.1255 apply to pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, instrumentation systems, control devices, and closed-vent systems that are intended to operate in organic hazardous air pollutant service 300 hours or more during the calendar year. Equipment to which these requirements apply shall be identified such that it can be distinguished readily from equipment that is not subject to these requirements. Identification does not require physical tagging of the equipment. If changes are made to the affected source subject to the leak detection requirements, equipment identification for each type of component shall be updated, if needed, within 90 calendar days, or by the next Periodic Report following the end of the monitoring period for that component, whichever is later.

When each leak is detected by visual, audible, or olfactory means, or by monitoring as described in 40 CFR 63.180(b) or (c), a weatherproof and readily visible identification, marked with the equipment identification number, shall be attached to the leaking equipment. The identification on a valve in light liquid or gas/vapor service may be removed after it has been monitored as specified in 40 CFR 63.1255(e)(7)(iii) and no leak has been detected during follow-up monitoring. The identification on equipment except on a valve in light liquid or gas/vapor service may be removed after it has been repaired.

(1) The following process components in VOHAP/ VOC service shall comply with design standards, shall be operated in accordance with work practice standards or shall undergo periodic monitoring in accordance with the provisions cited below. Periodic monitoring shall be performed in accordance with 40 CFR 60, Appendix A, Method 21 and 40 CFR 63.1255(b)(4)(v) and 40 CFR 63.1255(a)(11)(iv).

(A) Pumps in light liquid service shall be operated in accordance with the standard at 40 CFR 63.1255(c);
(B) Compressors shall be operated in accordance with the standards at 40 CFR 63.1255(b)(3);
(C) Pressure relief devices in gas/vapor service shall be operated in accordance with the standard at 40 CFR 63.1255(b)(3);
(D) Sampling connection systems shall be operated in accordance with the standard at 40 CFR 63.1255(b)(3);
(E) Open ended valves or lines shall be operated in accordance with the standard at 40 CFR 63.1255(d);
(F) Valves in gas/vapor and light liquid service shall be operated in accordance with the standard at 40 CFR 63.1255(e);
(G) Closed-vent systems and control devices used to comply with LDAR shall be operated in accordance with the standard at 40 CFR 63.1255(b)(4)(ii);
(H) Agitators in gas/vapor and light liquid service shall be operated in accordance with the standard at 40 CFR 63.1255(c);
(I) 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 40 CFR 63.1255(b)(3); and

(J) Connectors in gas/vapor and light liquid service shall be operated in accordance with the standard at 40 CFR 63.1255(b)(4)(iii).

(2) As an alternative to complying with (1) above, except (1)(G), system components may comply with 40 CFR 63.1255(b)(4)(iv).

(3) Pursuant to 40 CFR 63.1255(b)(3), which references 40 CFR 63.179 (Alternative means of emission limitation: Enclosed-vented process units), process units enclosed in such a manner that all emissions from equipment leaks are vented through a closed-vent system to a control device meeting the requirements of 40 CFR 63.172 and 40 CFR 1255(b)(4)(ii) are exempted from the requirements of 40 CFR 63.163 through 171, and 40 CFR 63.173 through 174 as referenced by 40 CFR 63.1255. The enclosure shall 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 (1)(G).

(4) Alternative means of emission limitations not already included in 40 CFR 63.1255 may be approved in accordance with 40 CFR 63.1255(b).

(5) The following equipment is exempt from the monitoring requirements as specified in 40 CFR 63.1255(f)(1)(i) through (iv) provided the Permittee meets the requirements specified in 40 CFR 63.1255(f)(2), (3) or (4) as applicable. All equipment must be assigned to a group of processes.

(A) Equipment that is designated as unsafe to monitor or unsafe to inspect pursuant to 40 CFR 63.1255(f)(2);
(B) Equipment that is difficult to monitor or difficult to inspect pursuant to 40 CFR 63.1255(f)(3); and
(C) Connectors that are inaccessible, ceramic, or ceramic-lined pursuant to 40 CFR 63.1255(f)(4).

(6) The following facilities are not subject to the LDAR standards in 40 CFR 63.1255:

(A) Research and development facilities, activities, and equipment [40 CFR 63.1250(d)];
(B) Components on transportation equipment and containers (e.g., railroad cars, tanker trucks and drums);
(C) Utilities and non-process lines [40 CFR 63.1255(a)(5)];
(D) Bench scale processes [40 CFR 63.1255(a)(6)];
(E) Equipment in vacuum service [40 CFR 63.1255(a)(8)];
(F) Waste components;
(G) Equipment that is in HAP service but that is in such service less than 300 hours per calendar year [40 CFR 63.1255(a)(10)]; and
(H) Closed loop heat exchange systems [40 CFR 63.1255(a)(5)].

(g) **Waste Water Requirements**

The Permittee shall determine the characteristics of each wastewater stream at each Point of Determination to determine if a wastewater stream is an affected wastewater stream by one of the means below:

(1) The Permittee shall comply with the provisions of 40 CFR 63.1257(e)(1) to determine the annual average concentrations and annual load of partially soluble and soluble HAP compounds; OR

(2) The Permittee shall designate the wastewater stream as meeting the criteria to be an affected wastewater stream. If the Permittee chooses to designate a wastewater stream, the Permittee shall comply with 40 CFR 63.1256(a)(1)(ii)(A) and (B) and is not required to determine the annual average concentration or load for each designated wastewater stream for the purposes of designation.

(3) For each wastewater tank that receives, manages, or treats affected wastewater or a residual removed from affected wastewater, the Permittee shall operate and maintain a fixed roof.

(A) The Permittee may install any wastewater tanks that meet the three criteria below without modifying this section of the permit:

(B) wastewater tanks with a capacity less than seventy five (75) cubic meters,

(C) wastewater tanks with a capacity greater than seventy five (75) cubic meters and less than one hundred fifty one (151) cubic meters and a maximum true vapor pressure less than thirteen and one tenth (13.1) kPa; or

(C) wastewater tanks with a capacity greater than one hundred fifty one (151) cubic meters and a maximum true vapor pressure less than five and two tenths (5.2) kPa.

(4) The Permittee may not install any wastewater tanks that meet the two criteria below without modifying this section of the permit.

(A) wastewater tanks with a capacity greater than seventy five (75) cubic meters and less than one hundred fifty one (151) cubic meters and a maximum true vapor pressure greater than thirteen and one tenth (13.1) kPa; or

(B) wastewater tanks with a capacity greater than one hundred fifty one (151) cubic meters and a maximum true vapor pressure greater than five and two tenths (5.2) kPa.

(5) If the contents of a wastewater tank are heated, treated by means of an exothermic reaction, or sparged, the Permittee must demonstrate that the total soluble and partially soluble HAP emissions from the wastewater tank are no more than five (5) percent higher than the emissions would be if the contents of the wastewater tank were not heated, treated by an exothermic reaction or sparged. This demonstration shall be included in the operating scenario.

(6) For each wastewater tank that receives, manages, or treats wastewater, a residual removed from wastewater, a recycled wastewater, or a recycled residual removed from wastewater, the Permittee shall comply with the inspection requirements in 40 CFR 63.1258(g), as applicable.

(7) For each container that receives, manages, or treats affected wastewater or a residual removed from affected wastewater, the Permittee shall:

(A) The Permittee shall operate and maintain a cover on each container used to handle, transfer, or store affected wastewater or a residual removed from affected wastewater in accordance with 40 CFR 63.1256(d)(1)(i)

through (iii);

(B) Pumping affected wastewater or a residual removed from affected wastewater into a container with a capacity greater than or equal to 0.42 cubic meters shall be conducted in accordance with 40 CFR 63.1256(d)(2)(i) and (ii).

(C) Except as provided in 40 CFR 63.1256(i), when an improper work practice or a control equipment failure is identified, first efforts at repair shall be made no later than five (5) calendar days after identification and repair shall be completed within fifteen (15) calendar days after identification.

(8) For each individual drain system that receives or manages affected wastewater or a residual removed from affected wastewater, the Permittee shall comply with the requirements of 40 CFR 63.1256(e)(4)(i) through (iii). Except as provided in 40 CFR 63.1256(i), when a gap, hole or crack is identified in a joint or cover, first efforts at repair shall be made no later than five (5) calendar days after identification, and repair shall be completed within fifteen (15) calendar days after identification.

(9) The Permittee shall comply with the wastewater treatment requirements by transferring affected wastewater streams or a residual removed from such a wastewater to an offsite treatment operation in accordance with 40 CFR 63.1256(a)(5).

(10) The Permittee shall comply with the requirements of 40 CFR 63.1256(a)(4)(i) through (iv) for maintenance wastewater containing partially soluble or soluble HAP listed in 40 CFR 63, Subpart GGG Tables 2 and 3. Maintenance wastewater is exempt from all other provisions of 40 CFR 63, Subpart GGG.

(11) Delay of repair of equipment for which a control equipment failure or a gap, crack, tear, or hole has been identified, is allowed only in accordance with the provisions of 40 CFR 63.1256(i). Repair of this equipment shall occur by the end of the next shutdown.

(12) For each wastewater tank, container, and individual drain system that receives, manages, or treats wastewater, a residual removed from wastewater, a recycled wastewater, or a recycled residual removed from wastewater, the Permittee shall comply with the inspection requirements in Table 7 of 40 CFR 63, Subpart GGG, as applicable.

(h) **Recordkeeping Requirements**

(1) The Permittee shall keep records of each operating scenario, which demonstrates compliance with 40 CFR 63, Subpart GGG.

(2) The Permittee shall keep the current and superseded versions of the startup, shutdown and malfunction plan onsite, as specified in 40 CFR 63.6(e)(3)(v). The Permittee shall keep the startup, shutdown and malfunction records specified in 40 CFR 63.1259(a)(3)(i) through (iii).

(3) For control devices that control vent streams totaling less than 1 ton per year HAP emissions, before control, the Permittee shall keep records of the daily verifications that each control device is operating properly.

(4) For each process using the 900 / 1800 kg Compliance Option, the Permittee shall

keep daily records of the rolling annual total emissions

(5) For each condenser or scrubber controlling vent streams totaling greater than 1 ton per year HAP emissions, before control, the Permittee shall keep records of outlet gas temperature, scrubber liquid flow rate, and pressure drop as applicable.

(6) For each process using continuous monitoring systems, the Permittee shall maintain continuous monitoring system records specified in 40 CFR 63.10(c)(1) through (14). Pursuant to 40 CFR 63.1259(b)(3), the Permittee shall maintain records documenting the completion of calibration checks and maintenance of continuous monitoring systems.

(7) Pursuant to 40 CFR 63.1259(b)(5), the Permittee shall keep records of the following, as appropriate:

(A) The number of batches per year for each batch process;
(B) The operating hours per year for continuous processes;
(C) Standard batch uncontrolled and controlled emissions for each process;
(D) Actual uncontrolled and controlled emissions for each nonstandard batch;
(E) A record whether each batch operated was considered a standard batch;.

(8) The Permittee shall keep a schedule or log of each operating scenario updated daily or, at a minimum, each time a different operating scenario is put into operation.

(9) The Permittee shall keep a description of worst-case operating conditions as required in 40 CFR 63.1257(b)(8).

(10) The Permittee shall keep records of all maintenance performed on the air pollution control equipment.

(11) Records relating to leak detection and repair shall be kept in accordance with 40 CFR 63.1255(g).

(12) The following records relating to wastewater shall be kept:

(A) The Permittee shall keep records documenting decisions to use a delay of repair due to unavailability of parts, as specified in 40 CFR 63.1256(i).
(B) For transfers of affected wastewater streams or residuals removed from an affected wastewater stream in accordance with 40 CFR 63.1256(a)(5), the Permittee shall keep a record of the notice sent to the treatment operator stating that the wastewater stream or residual contains organic HAP which are required to be managed and treated in accordance with the provisions 40 CFR 63, Subpart GGG.
(C) A record, as applicable, that each waste management unit inspection required by 40 CFR 63.1256(b) through (f) was performed.

(i) **Reporting Requirements**

(1) The Permittee shall submit semiannual Periodic Reports. When a new operating scenario has been operated since the last Periodic report, quarterly reports shall be submitted.

(2) The Permittee must submit a report 60 days before the scheduled implementation date of either any change in the activity covered by the Precompliance report or a change in the status of a control device from small to large.

(3) Whenever a process change is made or there is a change in any of the information submitted in the Notification of Compliance Status Report (other than those changes covered in (2) above), the Permittee shall submit the following information with the next Periodic report:

(A) A brief description of the process change;
(B) A description of any modifications to standard procedures or quality assurance procedures;
(C) Revisions to any of the information reported in the original Notification of Compliance Status Report;
(D) Information required by the Notification of Compliance Status Report for changes involving the addition of processes or equipment.

(4) The Permittee shall prepare startup, shutdown, and malfunction reports as outlined in 40 CFR 63.1260(i).

(5) Reporting relating to leak detection and repair shall be conducted in accordance with 40 CFR 63.1255(h).

Pursuant to 40 CFR 63.1252(a), the Permittee may open a safety device at any time conditions require it to avoid unsafe conditions.

State Rule Applicability - Entire Source

326 IAC 1-6-3 (Preventive Maintenance Plan)

Pursuant to 326 IAC 2-7-5(13)(A), Part 70 permits must require that the source maintain preventive maintenance plans (PMPs) as described in 326 IAC 1-6-3.

Based on OAQ and OES review:

(a) a PMP is not required for any equipment in Building 110.

(b) a PMP is required for the carbon adsorber in Building 358 because a NESHAP applies. A PMP is not required for other equipment in Building 358 because LDAR is already required for this equipment under 40 CFR 63, Subpart GGG and there is no preventive maintenance that can be done to prevent excess emissions.

(c) a PMP is not required for Tank Farm North.

(d) a PMP is required for emission units and control devices in the BHI area that are subject to Synthesized Pharmaceutical Manufacturing Operations [326 IAC 8-5-3]. A PMP is not required for other equipment in the BHI area because LDAR is already required for this equipment under 40 CFR 63, Subpart GGG and there is no preventive maintenance that can be done to prevent excess emissions.

(e) a PMP would normally be required for Building 130 because a NESHAP applies; however, other than LDAR, there is no preventive maintenance that can be done to prevent excess emissions on the emission units in the processes in Building 130. Therefore, since LDAR is required for this equipment through the Pharmaceutical NESHAP, no PMP will be required for the units in this building.

(f) a PMP is required for the condenser in VANCO because a NESHAP applies. A PMP is not required for other equipment in VANCO because LDAR is already required for this equipment under 40 CFR 63, Subpart GGG and there is no preventive maintenance that

can be done to prevent excess emissions.

(g) a PMP is not required for Building 135.

(h) a PMP is not required for Building 136.

326 IAC 1-5-2 (Emergency Reduction Plans)

The source submitted an Emergency Reduction Plan (ERP) in 1996 and submitted and updated ERP in 1999. The ERP has been verified to fulfill the requirements of 326 IAC 1-5-2 (Emergency Reduction Plans).

326 IAC 2-1.1-5

Marion County has been classified as nonattainment for PM2.5. In a memo dated April 5, 2005, the U.S. EPA has directed states to regulate PM10 emissions as surrogate for PM2.5 emissions pursuant to the Non-attainment New Source Review requirements until the U.S. EPA promulgates implementation rules for PM2.5. The potential to emit of PM10 of this source is less than 100 tons per year. Therefore, the source is not major under nonattainment new source review.

326 IAC 2-2

This source is one of the listed source types, but does not have the potential to emit PM-10, CO, NO_2, or SO_2 greater than 100 tons per year. Therefore, pursuant to 326 IAC 2-2, the source is not a major source under PSD.

326 IAC 2-3

This source has potential emissions of VOC greater than 100 tons per year. Therefore, pursuant to 326 IAC 2-3, it is a major source. However, the source was constructed prior to the effective date of the rule and no construction or modifications to this source have resulted in a significant emissions increase as defined in 326 IAC 2-3. See State Rule Applicability - Individual facilities for additional information on modifications at the source.

326 IAC 2-4.1

This source is a major source of HAPs and is regulated by a MACT standard issued under Section 112(d) of the Clean Air Act, the provisions of Section 112(g) of the Clean Air Act Amendments of 1990 as implemented at 40 CFR 63, Subpart GGG. All modifications at this source since the effective date of July 27, 1997 are subject to 40 CFR 63, Subpart GGG. Therefore, pursuant to 326 IAC 2-4.1-1(b)(2), this rule is not applicable.

326 IAC 2-6 (Emission Reporting)

Since this source is required to have an operating permit under 326 IAC 2-7, Part 70 Permit Program, this source is subject to 326 IAC 2-6 (Emission Reporting). In accordance with the compliance schedule in 326 IAC 2-6-3, an emission statement must be submitted triennially by July 1 beginning in 2005 and every 3 years after. The emission statement shall contain, at a minimum, the information specified in 326 IAC 2-6-4.

326 IAC 5-1 (Opacity Limitations)

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

(a) Opacity shall not exceed an average of thirty percent (30%) any one (1) six (6) minute averaging period as determined in 326 IAC 5-1-4.

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

continuous opacity monitor) in a six (6) hour period.

326 IAC 6-4 (Fugitive Dust Emissions)

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.

326 IAC 6.5 (Particulate Emissions Limitations)

This rule does not apply to this source because the potential to emit of particulate is less than one hundred (100) tons per year, actual particulate emissions are less than ten (10) tons per year, and it is not a specifically listed source in 326 IAC 6.5-6 (Marion County).

326 IAC 6-5-1 (Fugitive Particulate Matter Emission Limitations)

In the original application, the source submitted potential fugitive particulate matter emissions as 30.23 tons per year. This number was calculated using a silt loading of 3 g/m3 which is for worst case conditions (conditions that do not apply to the roads at this source). In July of 2003 new fugitive dust calculations were submitted to more accurately reflect the road type and use at the source (a silt loading of 0.4 g/m3 was proposed and OES agreed). The potential fugitive particulate matter emissions from automobile traffic is calculated as 21.5 tons per year. Since potential fugitive particulate matter emissions are less than 25 tons per year and no fugitive PM emission units were added since 1985, the source is not subject to the requirement to submit a Fugitive Dust Control Plan under 326 IAC 6-5-3.

State Rule Applicability - Individual Facilities

Building 110

326 IAC 2-2 and 326 IAC 2-3

In 2004, Marion County was designated as nonattainment for ozone under the 8-hour standard. Therefore, all modifications prior to June 15, 2004 were reviewed under PSD (326 IAC 2-2). Modifications taking place after June 15, 2004, were reviewed under Emission Offsets (326 IAC 2-3).

In 1987, the Permittee installed modules A, B, C, and D in Building 110. Potential emissions from these processes (18.9 tpy of VOC) were less than significant pursuant to 326 IAC 2-2 (the significant emissions increase level for a VOC major PSD source is 40 tons per year). An installation permit was issued by the City of Indianapolis.

In 1993, the Permittee installed module E in Building 110. Potential emissions from this process (14.3 tpy) were less than significant pursuant to 326 IAC 2-2 (the significant emissions increase level for a VOC major PSD source is 40 tons per year). A construction permit was issued by the City of Indianapolis. Pursuant to this construction permit (CP 930072-01), the source shall install chilled water condensers on all dryers and process modules equipped with vacuum pumps. This permit was superseded by CP097-3341; therefore, this requirement was not carried over into the Part 70 operating permit. See also Existing Approvals section.

326 IAC 6-3-2

Particulate emissions are not expected from any process or facility in Building 110; therefore, 326 IAC 6-3-2 is not applicable.

326 IAC 8-1-5 and 8-5-3

Pursuant to CP 097-3341 (the site specific RACT plan issued on July 27, 1994), Amendment A097-5322 issued on February 20, 1996, Amendment A0970072-02 issued on December 10, 1997, Amendment A0970072-03 issued on March 12, 1999, Amendment 097-13792-00072 issued on January 30, 2001, Amendment 097-13924-00072 issued on February 20, 2001,

Amendment 097-12128 issued on May 2, 2001, 326 IAC 8-1-5, 326 IAC 8-5-3, and 40 CFR 52.770(c)(157), effective January 7, 2005, the following shall be met:

(a) The volatile organic compound (VOC) emissions from the pilot plant in Building 110 shall be limited to less than 10 tons per twelve (12) consecutive month period rolled on a monthly basis.

(b) The primary reactor condensers shall operate during reactor venting, material transfer, distillation, and storage of filtrates in reactors, which are transferred from the filters. The primary reactor condensers working fluid inlet temperature shall be -10 degrees C or colder for mixtures that will not freeze at -10 degrees C (includes most non-aqueous streams).

(c) The applicant shall submit a quarterly certification that the condensers were operating at all times as required by the condition (b) above. If exceptions to this occur, the Permittee shall note the exception, indicate what caused the exception, and how it was corrected.

(d) The emission units which have the potential to emit VOC greater than 15 pounds per day shall comply with the requirements of 326 IAC 8-5-3(b)(3) through (6) in addition to the site-specific RACT plan requirements in (a), (b), and (c) above.

(1) Pursuant to 326 IAC 8-5-3(b)(3), the Permittee shall provide a vapor balance system or equivalent control that is at least 90% effective in reducing emissions from truck or railcar deliveries to storage tanks which have the potential to emit VOC greater than 15 pounds per day and with capacities greater than seven thousand five hundred (7,500) liters (two thousand (2,000) gallons) that store VOC with vapor pressures greater than twenty-eight (28) kiloPascals (four and one-tenth (4.1) pounds per square inch) at 20 degrees C.

(2) Pursuant to 326 IAC 8-5-3(b)(3), the Permittee shall install a pressure / vacuum conservation vents set at plus or minus two-tenths (∀0.2) kiloPascals on all storage tanks which have the potential to emit VOC greater than 15 pounds per day and that store VOC with vapor pressures greater than ten (10) kiloPascals (one and five-tenths (1.5) pounds per square inch) at 20 degrees C, unless a more effective control system is used.

(3) Pursuant to 326 IAC 8-5-3(b)(4), the Permittee shall enclose all centrifuges, rotary vacuum filters, and other filters for the emission units which have the potential to emit VOC greater than 15 pounds per day having an exposed liquid surface, where the liquid contains VOC and exerts a total VOC vapor pressure of three and five-tenths (3.5) kiloPascals (five-tenths (0.5) pounds per square inch) or more at 20 degrees C.

(4) Pursuant to 326 IAC 8-5-3(b)(5), the Permittee shall install covers on all inprocess tanks containing a volatile organic compound at any time for the emission units which have the potential to emit VOC greater than 15 pounds per day. These covers must remain closed, unless production, sampling, maintenance, or inspection procedures require operator access.

(5) Pursuant to 326 IAC 8-5-3(b)(6), the Permittee shall, for the emission units which have the potential to emit VOC greater than 15 pounds per day, repair all leaks from which a liquid, containing VOC, can be observed running or dripping. The repair shall be completed the first time the equipment is off line for a period of time long enough to complete the repair.

Building 358

326 IAC 2-2 and 326 IAC 2-3

In 2004, Marion County was designated as nonattainment for ozone under the 8-hour standard. Therefore, all modifications prior to June 15, 2004 were reviewed under PSD (326 IAC 2-2). Modifications taking place after June 15, 2004, were reviewed under Emission Offsets (326 IAC 2-3).

Pursuant to CP 960073-01, issued on September 25, 1996, which replaced 920073-01, issued on August 14, 1992, annual VOC emissions from point and fugitive sources (including insignificant activities) were limited to less than 40 tons per twelve (12) month consecutive period with compliance determined at the end of each month such that 326 IAC 2-2 did not apply. However, the potential to emit of VOC from Building 358 has been reduced from 86.4 tons per year to 24.1 tons per year. This reduction is a result of equipment changes. Some of the equipment modules in B358 have been reconfigured to process only aqueous materials and no longer are capable of processing solvents. Therefore, the limit from CP 960073-01 to keep emissions less than 40 tons per year such that 326 IAC 2-2 did not apply is no longer necessary.

Eli Lilly submitted information on March 17, 2005 indicating that two steps of the r-glucagon manufacturing process from the Building 130 complex are being moved to B358. The potential to emit of this equipment is 0.32 tons per year of VOC and 0.008 tpy of a single (and combined) HAP. Therefore, this is not a major modification under 326 IAC 2-3.

326 IAC 6-3-2 (Particulate Emission Limitations for Manufacturing Processes)

There are no emission units with a potential to emit particulates located in Building 358.

326 IAC 8-1-6 [BACT]

(a) Pursuant to CP 960073-01, issued on September 25, 1996, which replaced 920073-01, and 326 IAC 8-1-6, the Permittee shall employ Best Available Control Technology (BACT). Equipment subject to this requirement is listed in the following table:

B358 equipment subject to BACT (CP 960073-01)					
Bldg.	**Stack/Vent ID**	**Emission Unit ID**	**Equipment Description**	**Maximum Capacity**	**UOM**
358	COL-2121	COL-2121	100 cm column	500 L	Liters
358	TK-4101	TK-4101	TANK	10000 L	Liters
358	TK-4111	TK-4111	TANK	10000 L	Liters
358	TK-4121	TK-4121	TANK	5000 L	Liters
358	TK-4131	TK-4131	TANK	5000 L	Liters
358	TK-4141	TK-4141	TANK	2500 L	Liters
358	TK-4151	TK-4151	TANK	2500 L	Liters
358	LYPH-1611	LYPH-1611	Freeze Dryer	N/A	N/A
358	TK-4201	TK-4201	TANK	10000 L	Liters
358	TK-4211	TK-4211	TANK	10000 L	Liters
358	TK-4221	TK-4221	TANK	5000 L	Liters
358	TK-4231	TK-4231	TANK	5000 L	Liters
358	TK-4241	TK-4241	TANK	2500 L	Liters
358	TK-4251	TK-4251	TANK	2500 L	Liters
358	TK-1961	TK-1961	Haz. Waste tank	4000 G	Gallons
358	TK-1962	TK-1962	Haz. Waste tank	200 G	Gallons
358	TK-1963	TK-1963	Haz. Waste tank	200 G	Gallons
358	TK-1964	TK-1964	Haz. Waste tank	200 G	Gallons
358	TK-1965	TK-1965	Haz. Waste tank	200 G	Gallons

BACT for Building 358 consists of the following:

(1) BACT for all point sources of VOC in aggregate shall be a reduction of emissions by 95%, or to a level of 0.20 pounds per hour, whichever is less stringent, by applying air pollution control equipment.

(2) BACT for fugitive emissions shall be a Leak Detection and Repair (LDAR) in accordance with 40 CFR Subpart GGG for process components and 40 CFR Subpart DD for waste components.

Subpart GGG indicates that a source subject to both GGG and I (which imposes the provisions of Subpart H) may comply with Subpart I by complying with the requirements in Subpart GGG. Therefore, the EPA considers compliance with Subpart I (which imposes the provisions of Subpart H) equivalent to compliance with Subpart GGG for process components (from the arrival of raw materials to the Pharmaceutical Production MACT point of determination (POD)). All process components in Building 358 subject to BACT from CP 960073-01 (identified in the table above) that have the potential to emit fugitive emissions and contain VOC streams greater than 10% by weight will follow the LDAR requirements of 40 CFR, Subpart GGG instead of the Lilly LDAR Program.

Pursuant to 40 CFR 63.691(b), equipment leaks subject to Subpart DD shall be controlled in accordance with the requirements of 40 CFR 61, Subpart V or 40 CFR 63, Subpart H. Therefore, given these compliance options (40 CFR 63, Subpart H was the basis for the Lilly LDAR program as identified in the original BACT determination), IDEM and OES are replacing the Lilly LDAR Program for waste components (all equipment after the Pharmaceutical Production MACT point of determination (POD)) with the LDAR requirements of the 40 CFR Subpart DD. All waste components in Building 358 subject to BACT from CP 960073-01 (identified in the table above) that have the potential to emit fugitive emissions and contain VOC streams greater than 10% by weight will follow the LDAR requirements of Subpart DD instead of the Lilly LDAR Program.

(b) The two steps of the r-glucagon process that were added to B358 in 2005 are not subject to 326 IAC 8-1-6 because they do not have the potential to emit 25 tons per year of VOC and they would be subject to 326 IAC 8-5-3.

326 IAC 8-5-3

The requirements of 326 IAC 8-5-3 do not apply to the bio-synthetic production processes equipment in Building 358 since the equipment is not manufacturing pharmaceutical products by chemical synthesis.

The two steps of the r-glucagon process that were added to B358 in 2005 are used to produce pharmaceutical products by chemical synthesis. The potential emissions of this equipment are less than 15 pounds per day. Therefore, pursuant to 326 IAC 8-5-3(a), the requirements of 326 IAC 8-5-3 are not applicable to this equipment at this time.

326 IAC 8-9-1

The volatile organic liquid storage vessels located in Building 358 are not subject to the requirements of 326 IAC 8-9-1 because they are not located in Clark, Floyd, Lake or Porter County.

BHI area (Buildings 132, 133, and 138)

326 IAC 2-2 and 326 IAC 2-3

In 2004, Marion County was designated as nonattainment for ozone under the 8-hour standard. Therefore, all modifications prior to June 15, 2004 were reviewed under PSD (326 IAC 2-2). Modifications taking place after June 15, 2004, were reviewed under Emission Offsets (326 IAC 2-

3).

The Construction Permit CP910072-01 was issued on October 2, 1991, to install equipment in Insulin manufacturing Building 132, Acetone Recovery Building 133 and Tank Farm Building 138. In 1997 an amendment, A072-0001, was issued and replaced Condition 6 of CP910072-01. At the time these permits were issued, these buildings were given a limit of 38 tons of VOC per year. Since this permit was issued, acetone is no longer considered a VOC under the Clean Air Act, and therefore, the Acetone Recovery Building 133 no longer has any VOC emissions. The Tank Farm Building 138 has been modified and no longer has any VOC emissions. Therefore, this allowable emission limit has been changed to less than 40 tons per 12 consecutive month period for Building 132 to make 326 IAC 2-2 not applicable.

The construction permit CP 910072-01 required fugitive emissions for VOC streams greater than 10% by weight to implement the ALilly LDAR Program@ which was approved by IDEM. The Lilly LDAR Program was modeled after the LDAR requirements in 40 CFR 63, Subpart H (the HON).

This permit replaces requirements of the Lilly LDAR Program required by the CP 9100072-01 with LDAR requirements of the 40 CFR Subpart GGG. Subpart GGG indicates that a source subject to both GGG and I (which imposes the provisions of Subpart H) may comply with Subpart I by complying with the requirements in Subpart GGG. Because of this compliance option in the rule, 40 CFR 63, Subpart GGG leak detection requirements are at least as stringent as the 40 CFR 63, subpart I (which imposes the provisions of Subpart H). Since the ALilly LDAR Program@ was modeled after 40 CFR 63, Subpart H, it follows that 40 CFR 63, Subpart GGG is equivalent in stringency with the Lilly LDAR Program.@ The only difference is that 40 CFR 63, Subpart GGG applies only to systems in organic hazardous air pollutant service 300 hours or more during the calendar year while the construction permit leak detection and repair requirements applied to VOC streams greater than 10% by weight. Therefore, this Part 70 Operating permit includes the leak detection and repair requirements of Subpart GGG for streams not only in organic hazardous air pollutant service, but also pumps, flanges and valves that contain VOC streams greater than 10% by weight. Equipment in organic hazardous air pollutant service less than 300 hours during the calendar year are exempt from monitoring requirements.

326 IAC 6-3-2

Particulate emissions are only expected from the urea prill unloading process in Building 132. No other activities in the BHI area are expected to emit particulate. Therefore, pursuant to 326 IAC 6-3-1(a) and 326 IAC 6-3-1.5, this rule is not applicable to other facilities in the BHI area.

The urea prills unloading operation is subject to 326 IAC 6-3-2 because it has the potential to emit particulate in the production of a product. Particulate from the urea prills unloading operation shall be limited by the following:

> Interpolation and extrapolation of the data for the process weight rate in excess of 60,000 pounds per hour shall be accomplished by use of the equation:
>
> $E = 55.0\ P^{0.11} - 40$, where E = rate of emission in pounds per hour; and
> P = process weight rate in tons per hour

Based on an unloading rate of 1000 kg/min (66 tons per hour, the process weight limit is 47.2 pounds per hour [55 * (66^0.11)-40 = 47.2]. The potential hourly emissions from the urea prill unloading operation are 32.6 pounds per hour (EIIP 0-01-040-03). Therefore, this facility is in compliance with the emission limit.

326 IAC 8-1-6 (New Source General Emission Reduction Requirements)

Since the equipment in this area is covered by the source category regulated in 326 IAC 8-5-3, 326 IAC 8-1-6 does not apply.

326 IAC 8-5-3

The manufacture of pharmaceutical products by chemical synthesis takes place in the BHI area. Therefore, pursuant to 326 IAC 8-5-3(a), all facilities emitting volatile organic compounds that have the potential to emit fifteen (15) pounds per day are subject to the requirements of 326 IAC 8-5-3:

(a) Pursuant to 326 IAC 8-5-3(b)(1), volatile organic compound emissions from all reactors, distillation operations, crystallizers, centrifuges, and vacuum dryers shall be controlled by surface condensers or equivalent controls as outlined in 326 IAC 8-5-3(b)(1)(A) through (C).

(b) Pursuant to 326 IAC 8-5-3(b)(2), volatile organic compound emissions from all air dryers and production equipment shall be reduced by at least 90% if emissions are three hundred thirty (330) pounds per day or more of VOC or to thirty three (33) pounds per day or less if emissions are less than three hundred thirty (330) pounds per day of VOC.

(c) Pursuant to 326 IAC 8-5-3(b)(3)(A), the Permittee shall provide a vapor balance system or equivalent control that is at least 90% effective in reducing emissions from truck or railcar deliveries to storage tanks, which have the potential to emit VOC greater than 15 pounds per day and which have capacities greater than seven thousand five hundred (7,500) liters (two thousand (2,000) gallons) that store VOC with vapor pressures greater than twenty-eight (28) kiloPascals (four and one-tenth (4.1) pounds per square inch) at 20 degrees C.

(d) Pursuant to 326 IAC 8-5-3(b)(3)(B), the Permittee shall install a pressure / vacuum conservation vents set at plus or minus two-tenths (0.2) kiloPascals on all storage tanks which have the potential to emit VOC greater than 15 pounds per day and that store VOC with vapor pressures greater than ten (10) kiloPascals (one and five-tenths (1.5) pounds per square inch) at 20 degrees C, unless a more effective control system is used.

(e) Pursuant to 326 IAC 8-5-3(b)(4), the Permittee shall enclose all centrifuges, rotary vacuum filters, and other filters which have the potential to emit VOC greater than 15 pounds per day and which have an exposed liquid surface, where the liquid contains VOC and exerts a total VOC vapor pressure of three and five-tenths (3.5) kiloPascals (five-tenths (0.5) pounds per square inch) or more at 20 degrees C.

(f) Pursuant to 326 IAC 8-5-3(b)(5), the Permittee shall install covers on all inprocess tanks which have the potential to emit VOC greater than 15 pounds per day and which contain a volatile organic compound at any time. These covers must remain closed, unless production, sampling, maintenance, or inspection procedures require operator access.

(g) Pursuant to 326 IAC 8-5-3(b)(6), the Permittee shall, for the emission units which have the potential to emit VOC greater than 15 pounds per day, repair all leaks from which a liquid, containing VOC, can be observed running or dripping. The repair shall be completed the first time the equipment is off line for a period of time long enough to complete the repair.

326 IAC 8-9-1

The volatile organic liquid storage vessels located in Building 132 (BHI) are not subject to the requirements of 326 IAC 8-9-1 because they are not located in Clark, Floyd, Lake or Porter County.

Buildings 130 and 135

326 IAC 2-2 and 326 IAC 2-3

In 2004, Marion County was designated as nonattainment for ozone under the 8-hour standard. Therefore, all modifications prior to June 15, 2004 were reviewed under PSD (326 IAC 2-2). Modifications taking place after June 15, 2004, were reviewed under Emission Offsets (326 IAC 2-3).

In 1996, the Permittee modified Building 130 by adding an rGlucagon purification and manufacturing process. VOC emissions from equipment subject to 326 IAC 8-5-3 were limited to less than 15 pounds per day such that 326 IAC 8-5-3 did not apply. Emissions from this modification were less than 40 tons per year and were not significant pursuant to 326 IAC 2-2. The HPLC operation, added to VANCO in Building 348 in 1996, was a separate project and is considered unrelated to the rGlucagon purification and manufacturing process. Even while these two changes were within 12 months of each other, PSD was not triggered.

In 2001, the Permittee modified Building 130 by adding and modifying existing equipment in Building 130 for the production of KPB and the support of KPB production and rGlucagon production. This modification did not significantly increase emissions pursuant to 326 IAC 2-2. The equipment added in Minor Source Modification 097-12605-00072, issued on September 10, 2001, had a potential to emit of VOC of 16.2 tons per year (including debottlenecking increases from existing equipment) and negligible potential to emit of PM and PM10. Source wide potential VOC emissions are greater than 100 tons per year, therefore, the source was major for PSD at the time of the modification. Since the potential to emit VOC was less than 40 tons per year, this was not a major modification under PSD (326 IAC 2-2) for VOC. In the minor source modification, a limit of 100 tons per year of PM was taken so that 326 IAC 2-2 did not apply. This limit is not necessary. PM and PM10 potential emissions (from existing equipment in B130) were/are 8.13 tons per year and potential PM and PM10 emissions from the new equipment were negligible. This modification PM and PM10 emission increases were below the 326 IAC 2-2 significant thresholds. Therefore, this 100 ton per year limit is not being carried over.

Potential emissions of all PSD regulated pollutants, including fugitives, from equipment installed in Building 135 in 1984 and 1989, were below than 326 IAC 2-2 significant thresholds. The Permittee, a PSD listed source category, was major for PSD - therefore, significant emissions increase thresholds for the Permittee were: VOC - 40 tpy, PM - 25 tpy, PM10 - 15 tpy, NOx - 40 tpy, SO2 - 40 tpy. At the time of these modifications, Marion County was designated as attainment for ozone, therefore, VOC emissions were reviewed pursuant to 326 IAC 2-2 PSD.

326 IAC 6-3-2 (Particulate Emission Limitations for Manufacturing Processes)

The storage tank TK-265 urea prills unloading operation is subject to 326 IAC 6-3-2 because it has the potential to emit particulate in the production of a product. Pursuant to minor source modification 097-12605-00072 issued on September 10, 2001, the particulate from the tank TK-265 urea prills unloading operation shall be limited by the following:

> Interpolation of the data for the process weight rate up to sixty thousand (60,000) pounds per hour shall be accomplished by use of the equation:
>
> $E = 4.10\ P^{0.67}$ where E = rate of emission in pounds per hour and
> P = process weight rate in tons per hour

Based on an unloading rate of 16.7 tons per hour, the process weight limit is 27.0 pounds per hour. [4.10 * 16.7^0.67 = 27.0] The potential hourly emissions from the scrubber (determined to be integral to the process in the minor source modification, 097-12605-00072, issued on September 10, 2001) are 5.95 pounds per hour. Therefore, TK-265 is in compliance with the emission limit.

326 IAC 8-1-6 (New Source General Emission Reduction Requirements)

Since Building 130 is regulated by 326 IAC 8-5-3, 326 IAC 8-1-6 does not apply.

No facility in Building 135 was constructed after January 1, 1980, has the potential to emit 25 tons per year or more, and is not regulated by other provisions of Article 8.

326 IAC 8-5-3 (Miscellaneous Operations: Synthesized Pharmaceutical Manufacturing)

(a) While the manufacture of pharmaceutical products by chemical synthesis takes place in Building 130, all emission units have emissions less than 15 pounds per day. Therefore, the control requirements of 326 IAC 8-5-3 do not apply to any emission units in Building 130.

(b) No manufacturing of pharmaceutical products by chemical synthesis takes place in Building 135, therefore, 326 IAC 8-5-3 is not applicable to any facilities in Building 135.

VANCO - located in Buildings 334 and 348

326 IAC 2-2 and 326 IAC 2-3

In 2004, Marion County was designated as nonattainment for ozone under the 8-hour standard. Therefore, all modifications prior to June 14, 2004 were reviewed under PSD (326 IAC 2-2). Modifications taking place after June 15, 2004, were reviewed under Emission Offsets (326 IAC 2-3).

In 1985, the source submitted an application to install the HPLC process in Building 348. The City of Indianapolis issued an installation permit (11043) in September of 1985 and a construction Permit (8783) in April of 1986. Emissions from the equipment (approximately 1.6 tons per year) were less than the significant thresholds in 326 IAC 2-2.

In 1989 the source installed equipment in Building 334. The City of Indianapolis issued an Installation Permit (890073-01) on September 8, 1989. Emissions from this project (seven tons per year) were less than the significant thresholds in 326 IAC 2-2.

In 1995, the source modified Building 334. The City of Indianapolis issued a Construction Permit (950073-03) in May of 1995 to replace the installation permit and permit new equipment. Emissions from this project (< 25 tons per year) were less than the significant thresholds in 326 IAC 2-2. This Construction Permit (950073-03) was revoked when acetone was delisted as a VOC. Since acetone is no longer a regulated VOC, the permit was no longer necessary for this equipment. Equipment in this building no longer emits VOC.

In September of 1996, the source submitted an application to add a High Pressure Liquid Chromatography (HPLC) operation in Building 348. (See the first paragraph in this section for information on approvals received for Building 348 prior to this modification). The application indicated that the HPLC operation was subject to the requirements of 326 IAC 8-1-6 (this process is not manufacturing pharmaceutical products by chemical synthesis and therefore, not regulated by 326 IAC 8-5-3). The source submitted a best available control technology (BACT) analysis (in September 1996 with the HPLC application) and proposed that the evaporator vapors be vented through a series of condensers to recover the acetonitrile. The BACT analysis showed that the condensers would meet the BACT requirements in 326 IAC 8-1-6. After control emissions from this modification (14.7 tpy) were less than the significant thresholds in 326 IAC 2-2 and nonattainment new source review. Therefore, compliance with BACT renders 326 IAC 2-2 and nonattainment new source review not applicable. The City of Indianapolis issued a letter on October 28, 1996 indicating that the application had been received and indicated that the control equipment as outlined in the BACT application would satisfy the BACT requirements and that the VOC emissions increase would not trigger PSD. The letter then stated that the changes would be incorporated into the source=s Title V Permit. The rGlucagon purification and manufacturing process that was added to Building 130 was unrelated to this project, therefore, PSD was not triggered.

On July 28, 2003, OES received a streamlining application to streamline BACT, pursuant to 326 IAC 2-7-24, after April 2, 2007 with a requirement from 40 CFR 63, Subpart GGG that becomes applicable on April 2, 2007. This Subpart GGG requirement is more stringent than the current BACT requirement. The future Subpart GGG requirement is a 98% reduction in VHAP from EV116. Since this process uses acetonitrile, which is both a VOC and a HAP, a 98% reduction in HAP is equivalent to a 98% reduction in VOC. The source has no plans to switch to a different solvent. Therefore, after April 2, 2007 (or when the unit is reconstructed or replaced if prior to April 2, 2007), the Permittee will be required to achieve 98% control of HAP from EV116 pursuant to 40 CFR 63.1254(a)(3)(ii)(3) and (4). If the Permittee chooses to switch to a different solvent, they must obtain the approval of IDEM and OES before making the change. The BACT record keeping and reporting requirements are equivalent to the MACT record keeping and reporting requirements and will be streamlined in the permit.

326 IAC 6-3-2 (Particulate Emission Limitation)

No particulate is expected to be emitted from the processes in the VANCO area.

326 IAC 8-1-6

In 1996, the source added a new emission unit which had the potential to emit greater than 25 tons per year of VOC and was not regulated by any other provision in Article 8. Therefore, the source has to reduce VOC emission using best available control technology (BACT).

IDEM and OES have determined that BACT for the HPLC operation in Building 348 will consist of routing of the evaporator vapors through an after condenser to achieve 95% control. Compliance Determination for BACT has been streamlined with the requirements of 40 CFR 63, Subpart GGG. For a summary of the BACT analysis and review, see Appendix A of this TSD.

After April 2, 2007 (or upon reconstruction or replacement if earlier than April 2, 2007), the requirements of BACT for the HPLC operation will be streamlined with the requirements of 40 CFR 63.1254(a)(3)(ii)(A)(3) and (4) which requires the Permittee to route all vapors from EV 116 to a condenser that achieves a 98% reduction in HAP.

326 IAC 8-5-3

There are no processes in these buildings that manufacture pharmaceutical products by chemical synthesis. Therefore, the requirements of 326 IAC 8-5-3 do not apply to the processes in the VANCO area.

PC100

326 IAC 8-1-6 (New Source General Emission Reduction Requirements)

Pursuant to CP 950073-01 issued on January 5, 1995, the uncontrolled VOC emissions from the PC100 Facility shall be less than 25 tons each 12 month period with compliance determined at the end of each month. This limit makes the requirements of 326 IAC 8-1-6 not applicable. CP 950073-01 required that the Permittee submit reports within 60 days after the end of the quarter being reported. In order to keep all reporting requirements on the same schedule, the Permittee has requested that this be changed to requiring reports to be submitted within thirty (30) days after the end of the quarter being reported.

326 IAC 6-3-2 (Particulate Emission Limitation)

The dryer in PC100 is part of the manufacturing process and has the potential to emit particulate matter (from non-combustion activities) and, therefore, is subject to the requirements of 326 IAC 6-3-2. The dryer has a dry capacity of 58.3 pounds per hour.

Pursuant to 326 IAC 6-3-2(e)(2) (Particulate Emission Limitations for Manufacturing Processes), the allowable particulate emission rate from manufacturing processes with a process weight rate

less than 100 pounds per hour shall be 0.551 pounds per hour. Since the dryer has a process weight rate less than 100 pounds per hour, the dryer is limited to particulate emissions less than 0.551 pounds per hour.

Compliance Demonstration:
Potential particulate emissions from the dryer are 1.187 pounds per hour. Therefore, the HEPA filter must be in operation and controlling particulate emissions at all times the dryer is in operation.

326 IAC 8-5-3

No manufacturing of pharmaceutical products by chemical synthesis takes place in PC100, therefore, the requirements of 326 IAC 8-5-3 are not applicable to the facilities in PC100.

PC1 (Building 328)

326 IAC 2-2

All equipment in PC 1 installed prior to CP 910073-01 was insignificant and did not require a permit. CP 950073-02, issued on January 5, 1995 replaced CP 910073-01.

326 IAC 6-3-2 (Particulate Emission Limitations)

The dryer in PC1 is part of the manufacturing process and has the potential to emit particulate matter (from non-combustion activities) and, therefore, is subject to the requirements of 326 IAC 6-3-2. The dryer has a dry capacity of 31 pounds per hour.

Pursuant to 326 IAC 6-3-2 (Particulate Emission Limitations for Manufacturing Processes), the allowable particulate emission rate from the dryer shall not exceed 0.551 pounds per hour when operating at a process weight rate of less than 100 pounds per hour.

Compliance Demonstration:
Potential emissions from the microwave dryer are 0.616 pounds per hour. Therefore, the HEPA filter on the room must be in operation and controlling emissions from the dryer at all times the dryer is in operation.

326 IAC 8-1-6 (New Source General Emission Reduction Requirements)

Pursuant to CP 950073-02 issued on January 5, 1995, the uncontrolled VOC emissions from the tablet formulation process in Building 328 (PC1) shall be less than 25 tons each 12 month period with compliance determined at the end of each month. This limit makes the requirements of 326 IAC 8-1-6 not applicable. CP 950073-02 required that the Permittee submit reports within 60 days after the end of the quarter being reported. In order to keep all reporting requirements on the same schedule, the Permittee has requested that this be changed to requiring reports to be submitted within thirty (30) days after the end of the quarter being reported.

326 IAC 8-5-3

No manufacturing of pharmaceutical products by chemical synthesis takes place in PC1 (Building 328), therefore, the requirements of 326 IAC 8-5-3 are not applicable to the facilities in PC 1.

Tank Farm North

326 IAC 2-2 and 326 IAC 2-3

In 2004, Marion County was designated as nonattainment for ozone under the 8-hour standard. Therefore, all modifications prior to June 14, 2004 were reviewed under PSD (326 IAC 2-2). Modifications taking place after June 15, 2004, were reviewed under Emission Offsets (326 IAC 2-3).

The total potential VOC emissions, including fugitives, from Tank Farm North, installed in 1985,

were less than significance levels pursuant to 326 IAC 2-2.

326 IAC 8-1-6

No facility in this area was/is: new after January 1, 1980, has the potential to emit 25 tons per year or more, and is not regulated by other provisions of Article 8, therefore, no facility in this are is subject to 326 IAC 8-1-6.

326 IAC 8-9-1

The volatile organic liquid storage vessels located in the tank farm are not subject to the requirements of 326 IAC 8-9-1 because they are not located in Clark, Floyd, Lake or Porter County.

326 IAC 12

326 IAC 12 incorporates the rules of 40 CFR 60 by reference. In the March 1, 2005 Indiana Register, the Indiana Air Pollution Control Board published a Proposed Rule Notice to adopt in 326 IAC 1-1-3 (CFR References) the July 1, 2004 Code of Federal Regulations (CFR) version in order to incorporate all Federal Rule revisions to the CFR through July 1, 2004. The proposed rule became effective November 13, 2005.

There are no tanks at this source with a capacity greater than 75 cubic meters but less than 151 cubic meter that store a liquid with a maximum true vapor pressure greater than 15 kPa. There are no tanks at this source with a capacity greater than 151 cubic meters. Therefore, 40 CFR Part 60, Subpart Kb and 326 IAC 12 are not included in this permit.

Degreasers

Bldg / Floor	Type	Installation Date	Remote Solvent Reservoir	Open Top	Conveyorized
142/1	Cold Cleaner Degreaser	After 1990	Yes	No	No
151/1	Cold Cleaner Degreaser	After 1990	Yes	No	No
152/1	Cold Cleaner Degreaser	1980 - 1990	Yes	No	No
194/1	Cold Cleaner Degreaser	After 1990	Yes	No	No
325/1	Cold Cleaner Degreaser	After 1990	Yes	No	No
314/1	Cold Cleaner Degreaser	After 1990	Yes	No	No
195/1	Cold Cleaner Degreaser	After 1990	Yes	No	No
358/B	Cold Cleaner Degreaser	After 1990	Yes	No	No
105/1	Cold Cleaner Degreaser	1980 - 1990	Yes	No	No
143/1	Cold Cleaner Degreaser	After 1990	Yes	No	No

326 IAC 8-3 (Organic Solvent Degreasing Operations)

Pursuant to 326 IAC 8-3-1, the degreasers at this source are subject to the requirements of 326 IAC 8-3-2 because they were constructed after January 1, 1980. The degreasers are not subject to the requirements of 326 IAC 8-3-4 because the degreasers are not conveyorized. The degreasers are not subject to the requirements of 326 IAC 8-3-3 because they are not open top vapor degreasers. The degreasers are not subject to the requirements of 326 IAC 8-3-5 through 8-3-7 because they are cold cleaner degreasers that have remote solvent reservoirs.

Pursuant to 326 IAC 8-3-2 (Cold Cleaner Operation), the Permittee shall:

(a) Equip the cleaner with a cover;

(b) Equip the cleaner with a facility for draining cleaned parts;

(c) Close the degreaser cover whenever parts are not being handled in the cleaner;

(d) Drain cleaned parts for at least fifteen (15) seconds or until dripping ceases;

(e) Provide a permanent, conspicuous label summarizing the operation requirements;

(f) Store waste solvent only in covered containers and not dispose of waste solvent or transfer it to another party, in such a manner that greater than twenty percent (20%) of the waste solvent (by weight) can evaporate into the atmosphere.

Peak Diesel Generators A, B, and C

326 IAC 2-3 (Emission Offset)

(a) Time of operation of each of the Generators A, B, and C shall be limited to less than 99 hours per 12 consecutive month period, with compliance determined at the end of each month.

(b) NOx emission from each of the Generators A and B shall be limited to less than 32.40 pounds per hour; NOx emission from the Generator C shall be limited to less than 64.80 pounds per hour.

Compliance with these limits shall render requirements of 326 IAC 2-3 not applicable.

326 IAC 2-4.1 (Major Sources of Hazardous Air Pollutants (HAP))

The operation of Generators A, B, and C will emit less than ten (10) tons per year for a single HAP and less than twenty-five (25) tons per year for a combination of HAPs. Therefore, 326 IAC 2-4.1 does not apply.

326 IAC 6.5-1-2 (Particulate Emissions Limitations)

This rule does not apply to Generators A, B, and C because the source's potential to emit of particulate is less than one hundred (100) tons per year, actual particulate emissions are less than ten (10) tons per year, and it is not a specifically listed source in 326 IAC 6.5-6 (Marion County).

326 IAC 7-1 (Sulfur Dioxide Emission Limitations)

This rule does not apply to the Generators A, B, and C because the potential to emit SO_2 from each emission unit is less than twenty five (25) tons per year or ten (10) pounds per hour.

326 IAC 8-1-6 (New facilities; general reduction requirements)

This rule does not apply to the Generators A, B, and C because the potential VOC emissions are less than twenty five (25) tons per year per unit.

326 IAC 20-82 (Stationary Reciprocating Internal Combustion Engines)

The source is subject to 326 IAC 20-82 Stationary Reciprocating Internal Combustion Engines. 326 IAC 20-82 incorporates by reference 40 CFR 63 Subpart ZZZZ. The Permittee shall comply with the provisions of 40 CFR 63 Subpart ZZZZ as detailed in the Federal Rule Applicability Determination section above.

Compliance Requirements

Permits issued under 326 IAC 2-7 are required to ensure that sources 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 and OES, 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 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.

Compliance monitoring plans for demonstrating compliance are as follows under Rule 326 IAC 2-7-5(3) which requires all permitted sources to demonstrate that all emitting units are in continuos compliance with all Aapplicable requirements@ as defined by 326 IAC 2-7-1(6). Compliance is demonstrated by taking sufficient measurements of emissions or operating parameters or by gathering other data.

Based on IDEM and OES=s review, compliance monitoring requirements applicable to this source are as follows:

(a) Pursuant to 40 CFR 63, the carbon adsorber in Building 358 (complying with the alternative compliance option) has applicable compliance monitoring conditions as specified below:

(1) Establish the following regeneration cycle characteristics under worst-case conditions, as defined in 40 CFR 63.1257(b)(8)(i):

(A) Minimum regeneration frequency (i.e. operating time since last regeneration);
(B) Minimum temperature to which the bed is heated during regeneration;
(C) Maximum temperature to which the bed is cooled, measured within 15 minutes of completing the cooling phase; and
(D) Minimum regeneration stream flow.

(2) Monitor and record the following regeneration cycle characteristics for each regeneration cycle:

(A) Regeneration frequency (operating time since end of last regeneration);
(B) Temperature to which the bed is heated during regeneration;
(C) Temperature to which the bed is cooled, measured within 15 minutes of the completion of the cooling phase; and
(D) Regeneration stream flow.

(3) Use a temperature-monitoring device that is accurate to within ∀2 percent of the temperature measured in degrees Celsius or ∀2.5EC, whichever is greater.

(4) Use a regeneration stream flow monitoring device capable of recording the total regeneration stream flow to within 10 percent of the established value (i.e., accurate to within 10 percent of the reading.)

(5) Calibrate the temperature and flow monitoring devices annually.

(6) Conduct an annual check for bed poisoning in accordance with manufacturer's specifications.

(b) Pursuant to 40 CFR 63, Subpart GGG, for any control devices that control vent streams totaling less than 1 ton per year HAP emissions, before control, and using the 93% / 98% or 900 / 1800 kg compliance options, the Permittee shall verify daily that the control device is operating properly. If the control device is used to control batch process vents alone or in combination with other streams, the verification may be on a per batch basis. This verification shall include, but not be limited to, a daily or per batch demonstration that the unit is working as designed.

This monitoring condition is necessary because it is required by the NESHAP to demonstrate continuous compliance.

(c) Pursuant to 40 CFR 63, Subpart GGG, for any condensers that control vent streams totaling greater than 1 ton per year HAP emissions, before control and using the 93% / 98% or 900 / 1800 kg compliance options, the Permittee shall:

(2) The Permittee shall establish the maximum condenser outlet temperature at which the 93% reduction is achieved as a site-specific operating parameter.
(3) The Permittee shall measure and record the outlet gas temperature at least every 15 minutes during the period in which the condenser is functioning in achieving HAP removal.
(4) The temperature monitoring device must be accurate to within ∀2 percent of the temperature measured in degrees Celsius or ∀2.5 degrees Celsius whichever is greater.
(5) The temperature monitoring device must be calibrated annually.

This monitoring condition is necessary because it is required by the NESHAP to demonstrate continuous compliance.

(d) For scrubbers that control vent streams totaling greater than 1 ton per year HAP emissions, before control:

(1) The Permittee shall establish a minimum scrubber liquid flow rate or pressure drop at which the 93% reduction is achieved as a site-specific operating parameter. If the scrubber uses a caustic solution to remove acid emissions, the Permittee shall establish a minimum pH of the effluent scrubber liquid at which the 93% reduction is achieved as a site-specific operating parameter. The minimum scrubber flow rate or pressure drop shall be based on the conditions anticipated under worst-case conditions, as defined in 40 CFR 63.1257(b)(8)(i).
(2) The Permittee shall measure and record either the scrubber liquid flow rate or pressure drop every 15 minutes during the period in which the scrubber is functioning in achieving HAP removal. If the scrubber uses a caustic solution to remove acid emissions, the Permittee shall monitor the pH of the effluent scrubber liquid at least once per day.

(3) The monitoring device(s) used to determine the pressure drop shall be certified by the manufacturer to be accurate to within a gage pressure of ∀10 percent of the maximum pressure drop measured.

(4) The monitoring device(s) used for measurement of scrubber liquid flow rate shall be certified by the manufacturer to be accurate within ∀10 percent of the design scrubber liquid flow rate.

(5) The monitoring device(s) shall be calibrated annually.

This monitoring condition is necessary because it is required by the NESHAP to demonstrate continuous compliance.

(e) The Permittee shall perform inspections once per batch on the HEPA filter in PC1 to ensure that the filter is in operation and controlling particulate emissions. The Permittee shall keep records of the inspections.

(f) The Permittee shall perform inspections once per batch on the HEPA filter in PC100 to ensure that the filter is in operation and controlling particulate emissions. The Permittee shall keep records of the inspections.

Conclusion

The operation of this stationary pharmaceutical research, development and manufacturing operation shall be subject to the conditions of the attached proposed **Part 70 Permit No. T097-6846-00072.**

Appendix A

326 IAC 8-1-6 BACT ANALYSIS
High Pressure Liquid Chromatography Operation in Building 348

Background

Source Name:	Eli Lilly and Company - Lilly Technology Center (LTC)
Source Location:	1555 South Harding Street, Indianapolis, IN 46221
County:	Marion
SIC Code:	2833, 2834
Operating Permit No.:	T097-6846-00072
Permit Reviewer:	AH

In 1996, Eli Lilly and Company applied for a Construction Permit for a High Pressure Liquid Chromatography (HPLC) operation in Building 348 at the Eli Lilly Technology Center. This operation did not fall under the Synthesized Pharmaceutical rule in 326 IAC 8-5-3. All emission units except for Evaporator 116 and total fugitive sources had potential emissions less than 25 tons per year. Potential emissions for the Evaporator 116 were greater than 25 tons per year at maximum design capacity. Potential emissions from fugitive sources were approximately 7.88 tons per year. Therefore, Evaporator 116 was subject to the requirements of 326 IAC 8-1-6.

Eli Lilly=s application included a BACT analysis for vapors from Evaporator 116 (EV116).

The Indiana Department of Environmental Management, Office of Air Quality (IDEM, OAQ) and the City of Indianapolis, Office of Environmental Services (OES) conduct BACT analysis in accordance with the *"Top-Down@ Best Available Control Technology Guidance Document* outlined in the 1990 draft USEPA *New Source Review Workshop Manual*, which outlines the steps for conducting a top-down BACT analysis. Those steps are listed below:

(a) Identify all potentially available control options;

(b) Eliminate technically infeasible control options;

(c) Rank remaining control technologies by control effectiveness;

(d) Evaluate the most effective controls and document the results; and

(e) Select BACT.

Also, in accordance with the ATop-Down@ Best Available Control Technology Guidance Document outlined in the 1990 draft U.S EPA New Source Review Workshop Manual, 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. Such reductions are necessary to demonstrate that the emissions remaining after application of BACT will not cause or contribute to air pollution thereby protecting public health and the environment.

The City of Indianapolis and the Indiana Department of Environmental Management agreed with Lilly=s BACT determination for EV116 and issued a letter indicating that the revision would be incorporated into the Title V permit for Eli Lilly=s Technology Center. This appendix addresses the BACT analysis and completes the requirement to incorporate the revision into the Title V permit.

Calculations

ID	Emission Unit	Potential Emissions			
		pounds per hour	pounds per day	pounds per year	tons per year
T-201	Receipt of Raw Solvent	0.09	2.15	783	0.4
T-202	Intermediate Storage	0.06	1.48	542	0.27
T-203	Intermediate Storage	0.01	0.17	62	0.03
T-15	ACN Makeup	0.2	4.82	1761	0.88
T-21	10% ACN Transfer	< 0.01	0.07	24	0.01
T-16	30% ACN Transfer	< 0.01	0.10	38	0.02
T-19	Main Stream Collection	< 0.01	0.06	22	0.01
T-20	Main Stream Transfer	0.01	0.12	44	0.02
T-18	Main Stream Collection	< 0.01	0.06	22	0.01
T-22	10% ACN	< 0.01	0.07	24	0.01
T-107	10% ACN	0.01	0.13	47	0.02
T-108	5% ACN	< 0.01	0.09	34	0.02
T-109	30% ACN	< 0.01	0.08	31	0.02
T-120	Waste ACN	< 0.01	0.02	7	< 0.01
T-204	Waste ACN	0.01	0.23	83	0.04
T-205	Waste ACN	0.01	0.23	83	0.04
EV-116	**Evaporator Vacuum Pump (before control)**	**22.88**	**549.17**	**200,448**	**100**
	Evaporator Vacuum Pump (after control)	**1.14**	**27.46**	**10,022**	**5**
Fugitive	valves, flanges, pumps, etc.	1.80	43.17	15,758	7.88
Total Emissions Before Controls			**602.22**	**219,813**	**109.7**
Total Emissions After Controls			**80.51**	**29,387**	**14.7**

BACT Analysis

Step One - Identify all potentially available control options:

IDEM, OAQ and OES searched EPA=s RACT/BACT/LAER Clearinghouse (RBLC) and Indiana=s Air Permits to identify sources with emissions similar to this source. The search identified that for similar processes (and similar size vent stream) condensers were determined to be BACT. For similar processes pulling vents from multiple sources (dissimilar size vent stream) thermal oxidizers or other combustion methods were also found to be BACT.

EPA=s Reasonably Available Control Technology (RACT) Standards for synthesized pharmaceutical manufacturing facilities require the use of surface condensers with an outlet gas temperature of 10EC (50EF) or less. EV116 is not subject to this RACT standard, but is a similar process.

Eli Lilly and Company identified the following control methods:

(a) Destruction of VOC via combustion
(b) Reclamation via adsorption
(c) Reclamation via absorption (scrubbing)
(d) Combination of carbon adsorption with recuperative thermal incineration
(e) Reclamation via condensation
(f) No add on control

Step Two - Eliminate technically infeasible control options

(a) Destruction of VOC via combustion. The waste stream from EV116 has a very low air flow rate and has a highly variable VOC concentration. Therefore, supplemental air would be required in order to provide a proper control system. In addition the variable VOC concentration would require varying levels of supplemental fuel to be self-sustaining. Therefore, this option has been determined to be technically infeasible for this waste stream.

(b) Reclamation via adsorption. A fixed bed system has been determined to be technically infeasible for this waste stream because fixed bed systems require a minimum air flow rate of 2,000 scfm. Replaceable carbon cartridge systems may be feasible for low air flow applications. Acetonitrile, the VOC of concern in this application, has a very low affinity for activated carbon (low molecular weight, higher polarity, and low volatility). The inlet temperature of the waste stream in this application would be very high. The low air flow rate and high temperature could lead to carbon fires. Therefore, due to the low affinity of acetonitrile for activated carbon and the chance of carbon fires, the use of activated carbon is technically infeasible for this waste stream. In addition, adsorption would result in the creation of additional solid waste, which would require treatment and/or disposal.

(c) Reclamation via absorption (scrubbing). A system utilizing absorption would generate large volumes of liquid waste and would require the purchase of a suitable absorption solvent. Therefore, this option has been determined to be technically infeasible for this waste stream.

(d) Combination of carbon adsorption with recuperative thermal incineration. Using a carbon adsorption process before incineration would eliminate the problem of requiring supplemental fuel. However, the other problems (the low affinity of acetonitrile for activated carbon, the chance of carbon fires, generation of solid waste and the highly variable VOC concentration in the waste stream) would remain. Therefore, this option

has been determined to be technically infeasible.

(e) Reclamation via condensation. An after-condenser is a feasible option for this waste stream.

(f) No add on control. The use of no control is a feasible option for this waste stream.

Step Three - Rank remaining control technologies by control effectiveness

(e) An after condenser would condense 95% of the organic material contained in the waste air stream.

(f) Using no additional control would reduce emissions 0%.

Step Four - Evaluate the most effective controls and document the results

Of the technically feasible options, the after condenser yields the greatest reduction in VOC emissions. An after condenser alone can attain 95% control. Due to moisture in the air stream, control levels significantly higher than 95% cannot be attained with the after condenser alone. To attain a control level of 98% for this air stream (98% control is the level to which this area would have to be controlled starting in 2007 under 40 CFR 63, Subpart GGG), a heat exchanger would need to be added.

When the BACT application was submitted in 1996, the source provided no cost estimates, indicating that an after condenser was a cost effective control method for this waste stream at that time and proposing that BACT be equivalent to 95%.

Tables A, B, C, D, E, and F summarize the costs that would be associated with adding a heat exchanger (in June of 2005) to attain 98% control for the next two years. The economic lifetime of the heat exchanger was determined to be two years since the source has plans to remove this equipment prior to April 2007. This is consistent with previous EPA determinations in situations where the life of the equipment is short due to source specific situations. The Permittee has requested that BACT be streamlined into an applicable NESHAP requirement after April 2007. The NESHAP requirement, which becomes applicable to this process in April 2007 would require 98% control for this process. Therefore, even if the Permittee does not remove the equipment by April 2007, they will be required to attain 98% control regardless of cost effectiveness.

Table G shows the annualized incremental cost effectiveness of adding the heat exchanger to attain the additional control (from 95% to 98%) over the next two years.

A. Direct Capital Costs (continued)			
Item*		**Cost Estimate**	**Reference/Source of Cost Estimate**
Direct Installation Costs			
7.	Foundations and Supports	$350	Central IN Cost Est.- Piping
8.	Auxiliaries (duct work, fittings - include only the equipment which would not be necessary if the facility was not controlled)	$0	
9.	Handling and Erection	$0	
10.	Piping	$450	Central IN Cost Est.- Piping
11.	Insulation and Painting	$4320	Central IN Cost Est. – Subcontractors
12.	Electrical	$5000	Instrumentation Cost Est.
13.	Site Preparation	$1500	Central IN Cost Est. - Subcontractors, tank cleaning

14.	Other (please specify)		
15.	**Direct Installation Costs Subtotal** (Sum of Items 7, 8, 9, 10, 11, 12, 13, and 14)	**$11620**	
16.	**DIRECT CAPITAL COSTS SUBTOTAL** (Sum of Items 6 and 15)	**$15140**	

B. Indirect Installation Costs			
Item*		**Cost Estimate**	**Reference/Source of Cost Estimate**
1.	Engineering and Supervision	$16,900	Instrumentation Cost Est., Engineering Cost Est.
2.	Construction and Field Expenses	$10082	Central IN Cost Est.
3.	Contractor Fees	$321	Central IN Cost Est.- Incentive Potential
4.	Start-up and Performance Tests	$2000	Instrumentation Cost Est., Engineering Cost Est.
5.	Over-all Contingencies	**$936**	Central IN Cost Estimate plus contingencies for engineering and instrumentation*
6.	**INDIRECT INSTALLATION COSTS SUBTOTAL** (Sum of Items 1, 2, 3, 4, 5, 6, 7, and 8)	**$30,239**	

***** Contingencies determined as **3%** of cost subtotal. This is based on Central IN Cost Estimate contingency figures in recognition of risk and changes in scope of the project.

C. Capital Cost Summary		
1.	**Total Capital Investment Subtotal** (Sum of Table A, Item 16 and Table B, Item 9)	**$15,140 + $30,239= $45,379**
2.	**Capital Recovery Factor**	.57619
a.	Interest Rate	10%
b.	Economic Lifetime	2 years*
3.	**CAPITAL RECOVERY COST**	**$ 26,147**

* The economic lifetime of the heat exchanger was determined to be two years since the source has plans to remove this equipment prior to April 2007. This is consistent with previous EPA determinations in situations where the life of the equipment is short due to source specific situations. The Permittee has requested that BACT be streamlined into an applicable NESHAP requirement after April 2007. The NESHAP requirement, which becomes applicable to this process in April 2007 would require 98% control for this process. Therefore, even if the Permittee does not remove the equipment by April 2007, they will be required to attain 98% control regardless of cost effectiveness.

D. Direct Annual Costs			
Item*		**Cost Estimate**	**Reference/Source of Cost Estimate**
1.	Operating Labor (Itemize below)		
2.	Maintenance Labor (Itemize below)		
Annual cleaning		$1000	Average maintenance costs for cleaning current heat exchanger
Annual temperature transmitter PM		$125	Average annual PM cost
3.	Materials (Itemize below)		
4.	Utilities (Itemize below)		
5.	Waste Treatment and Disposal (Itemize below)		
ACN waste - hazardous		$150	Calculation assuming 200 gal/yr @ $0.75/gal for disposal
6.	Replacement Parts (Itemize below)		
7.	Other (please specify)		

D. Direct Annual Costs			
8.	**DIRECT ANNUAL COSTS SUBTOTAL** (Sum of Items 1, 2, 3, 4, 5, 6, and 7)	**$1275**	

E. Total Annual Cost Summary	
1. Direct Annual Costs Subtotal from Table D, Item 8	**$1275**
2. Indirect Annual Costs Subtotal from Table E, Item 4	**$0**
3. Recovery Credits Subtotal from Table F, Item 4	**$0**
4. TOTAL ANNUAL COST SUBTOTAL (Item 1 plus Item 2 Minus Item 3)	**$1275**

F. Total Annualized Cost Summary	
1. **Capital Recovery Cost** from Table C, Item 3	**$26,147**
2. **Total Annual Cost Subtotal** from Table G, Item 4	**$1275**
3. **TOTAL ANNUALIZED COST**(TAC)(Sum of Items 1 and 2)	**$27,422**

G. Incremental Cost Effectiveness			
1.	Baseline Emissions Rate (tons per year) (currently 95% control)		2.60
	2.	Post-BACT Emissions Rate (tons per year) (would be 98% control)	1.04
	(5)	Total Pollutant Removed (tons per year) (Difference of Item 1 and Item 2)	1.56
4.	**AVERAGE COST EFFECTIVENESS OF BACT OPTION** ($/ton of pollutant removed) (Divide Table H, Item 3 by Table I, Item 3)		**$17,578**

The average cost effectiveness of adding the heat exchanger (**$17,578** per ton) as presented in Table G is the average cost effectiveness of the incremental impact of adding the heat exchanger. This was determined by taking the annual cost of the heat exchanger and dividing it by the incremental increase in emission reductions obtained by adding the heat exchanger. The cost of the condenser was not included since the condenser is in place and attaining 95% control.

Step Five - Select BACT

At a cost of **$17,578** per ton of VOC controlled, adding the heat exchanger to attain the additional 3% is cost prohibitive for this portion of the project.

BACT for the Vanco chrom process is 95% control via the condenser. Compliance will be determined in the same way that compliance with 40 CFR Subpart GGG is determined. The compliance determination requirements of Subpart GGG for condensers include:

(a) The Permittee shall establish the maximum condenser outlet temperature as a site-specific operating parameter.

(b) The Permittee shall measure and record the outlet gas temperature at least every 15 minutes during the period in which the condenser is functioning in achieving HAP removal.

(c) The temperature monitoring device must be accurate to within ± 2 percent of the temperature measured in degrees Celsius or ± 2.5 degrees Celsius whichever is greater.

(d) The temperature monitoring device must be calibrated annually.

(e) Averaging periods for the site-specific operating parameters shall be established according to 40 CFR 63.1258(b)(2)(i) through (iii).

(f) The site specific operating parameters shall be set pursuant to 40 CFR 63.1258(b)(3).

(g) The outlet gas temperature continuous monitoring system must meet all applicable requirements of 40 CFR 60.8.

This determination is not inconsistent with previous BACT determinations for similar equipment. See Table H below for a brief summary of other BACT determinations for similar processes.

H. Other Similar BACT Determinations					
Company / Location	**Year Issued**	**Process Description**	**Emission Limits**	**Control Required**	**Comments**
The Upjohn Company	1994	Expansion of HF Chemistry	94.7%	Refrigerated Condenser	Not identified as a BACT determination in the Database. Identified as: Other – Case by Case.
Cargill	1995	Citric Acid Solvent Extractor	90% control	condenser	
Pfizer	1996	Tablet Coater	95%	Catalytic Oxidizer	
Eli Lilly and Company, Lilly Technology Center	Proposed in this analysis	Vanco HPLC process (Building 148W)	Proposed: 95% control	condenser	

The RACT/BACT/LAER Clearinghouse database did not include cost effectiveness information for any of the determinations identified in Table H. Therefore, IDEM, OAQ and OES were not able to compare the cost to attain the incremental control to other similar projects.