

DATE: July 18, 2008

TO: Interested Parties / Applicant

RE: Eli Lilly and Company, Lilly Technology Center / T097-25463-00072

FROM: Timothy J. Method
Environmental Coordinator



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 13-17-3-4 and 326 IAC 2, this permit modification 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 13-15-7-3 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 Environmental Adjudication, 100 North Senate Avenue, Government Center North, Room 501, Indianapolis, IN 46204, **within fifteen (15) days of the receipt of this notice**. The filing of a petition for administrative review is complete on the earliest of the following dates that apply to the filing:

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

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

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

Pursuant to 326 IAC 2-7-18(d), any person may petition the U.S. EPA to object to the issuance of a Title V operating permit 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 impracticable 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 Office of Air Quality, Permits Branch at (317) 233-0178. Callers from within Indiana may call toll-free at 1-800-451-6027, ext. 3-0178.

Enclosures



Air Quality Hotline: 317-327-4AIR | knozone.com

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



July 18, 2008

Mr. Brian R. Brown
Eli Lilly & Company, Lilly Technology Center
Lilly Corporate Center
Indianapolis, IN 46285

Certified Mail: 7008 0150 0003 5219 4001

Re: T097-25463-00072
First Significant Permit Modification to
Part 70 No.: T097-6846-00072

Dear Mr. Brown:

Eli Lilly & Company, Lilly Technology Center was issued a permit on October 31, 2006 for a stationary pharmaceutical manufacturing and research and development facility. A letter requesting changes to this permit was received on April 13, 2007. On May 19, 2008, IDEM OAQ and OES received an application for a significant permit modification to modify BACT requirements for the Building 358 (B358) secondary waste tank identified as Tank 1961 (TK-1961). This request was assigned Permit No. T097-26575-00072, and was combined with this permit action. Pursuant to the provisions of 326 IAC 2-7-12 a significant permit modification to this permit is hereby approved as described in the attached Technical Support Document.

The modification consists of changes to the permit language pertaining to 40 CFR 63, Subpart GGG, National Emission Standards for Pharmaceutical Manufacturing, to reflect the existing bypass valve in the carbon bed adsorber located in Building 358, as well as changes to Section D.2.3 to address TK-1961.

All other conditions of the permit shall remain unchanged and in effect. Please find attached a copy of the revised permit.

This decision is subject to the Indiana Administrative Orders and Procedures Act - IC 4-21.5-3-5. If you have any questions on this matter, please contact Monica Doyle at (317) 327-2846, or mdoyle@indygov.org.

Sincerely,

ORIGINAL SIGNED BY

Timothy J. Method
Environmental Coordinator
Department of Public Works

Attachments
mmd

cc: U.S. EPA, Region V
Mindy Hahn, IDEM OAQ
Matt Mosier, OES Compliance



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Department of Public Works
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PART 70 OPERATING PERMIT

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT (IDEM) OFFICE OF AIR QUALITY (OAQ) and INDIANAPOLIS OFFICE OF ENVIRONMENTAL SERVICES (OES)

**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	
Original Signed by, Nisha Sizemore, Chief Permits Branch Office of Air Quality	Issuance Date: October 31, 2006
Original Signed by, Felicia A. Robinson, Administrator Office of Environmental Services	Expiration Date: October 31, 2011
First Significant Permit Modification: 097-25463-00072	Sections revised: D.2, E.1
Issued by: ORIGINAL SIGNED BY Timothy J. Method Environmental Coordinator Department of Public Works	Issuance Date: July 18, 2008 Expiration Date: October 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.

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 PM 2.5 Attainment for all other criteria pollutants
Source Status:	Part 70 Permit Program Major Source under PSD Minor Source under Nonattainment NSR 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) 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) An outside storage tank area (Tank Farm North) with the storage tanks holding raw material and waste solvents.
- (g) 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.
- (h) 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°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°F);
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 13-15-3-3. 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 responsible 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
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

and

Indianapolis Office of Environmental Services (OES)
Air Compliance
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 responsible official as defined by 326 IAC 2-7-1(34).

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

-
- (a) If required by specific condition(s) in Section D of this permit, the Permittee shall prepare and maintain Preventive Maintenance Plans (PMPs) within ninety (90) days after issuance of this permit, including the following information on each facility:
 - (1) Identification of the individual(s) responsible for inspecting, maintaining, and repairing emission control devices;
 - (2) A description of the items or conditions that will be inspected and the inspection schedule for said items or conditions; and
 - (3) Identification and quantification of the replacement parts that will be maintained in inventory for quick replacement.

If, due to circumstances beyond the Permittee's control, the PMPs cannot be prepared and maintained within the above 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
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

and

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

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

- (b) The Permittee shall implement the PMPs, including any required record keeping, as necessary to ensure that failure to implement a PMP does not cause or contribute to an exceedance of any limitation on emissions or potential to emit.
- (c) A copy of the PMPs shall be submitted to IDEM, OAQ, 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 responsible official as defined by 326 IAC 2-7-1(34).
- (d) To the extent the Permittee is required by 40 CFR Part 60/63 to have an Operation, Maintenance, and Monitoring (OMM) Plan for a unit, such Plan is deemed to satisfy the PMP requirements of 326 IAC 1-6-3 for that unit.

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

- (a) An emergency, as defined in 326 IAC 2-7-1(12), is not an affirmative defense for an action brought for noncompliance with a federal or state health-based emission limitation.
- (b) An emergency, as defined in 326 IAC 2-7-1(12), constitutes an affirmative defense to an action brought for noncompliance with a technology-based emission limitation if the affirmative defense of an emergency is demonstrated through properly signed, contemporaneous operating logs or other relevant evidence that describe the following:
 - (1) An emergency occurred and the Permittee can, to the extent possible, identify the causes of the emergency;
 - (2) The permitted facility was at the time being properly operated;
 - (3) During the period of an emergency, the Permittee took all reasonable steps to minimize levels of emissions that exceeded the emission standards or other requirements in this permit;
 - (4) For each emergency lasting one (1) hour or more, the Permittee notified IDEM, OAQ, 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
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

and

Indianapolis Office of Environmental Services (OES)
Air Compliance
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 responsible official as defined by 326 IAC 2-7-1(34).

- (6) The Permittee immediately took all reasonable steps to correct the emergency.
- (c) In any enforcement proceeding, the Permittee seeking to establish the occurrence of an emergency has the burden of proof.
- (d) This emergency provision supersedes 326 IAC 1-6 (Malfunctions). This permit condition is in addition to any emergency or upset provision contained in any applicable requirement.
- (e) IDEM, OAQ, 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
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

and

Indianapolis Office of Environmental Services (OES)
Air Compliance
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 responsible official as defined by 326 IAC 2-7-1(34).

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

B.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 responsible official as defined by 326 IAC 2-7-1(34).
- (b) This permit shall be reopened and revised under any of the circumstances listed in IC 13-15-7-2 or if IDEM, OAQ, 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 responsible official as defined by 326 IAC 2-7-1(34).

Request for renewal shall be submitted to:

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

and

Indianapolis Office of Environmental Services (OES)
Air Permits
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
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251
- and
- Indianapolis Office of Environmental Services (OES)
Air Permits
2700 South Belmont Avenue
Indianapolis, IN 46221
- Any such application shall be certified by the responsible official as defined by 326 IAC 2-7-1(34).
- (c) The Permittee may implement administrative amendment changes addressed in the request for an administrative amendment immediately upon submittal of the request.
[326 IAC 2-7-11(c)(3)]

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
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

and

Indianapolis Office of Environmental Services (OES)
Air Permits
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
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

and

Indianapolis Office of Environmental Services (OES)
Air Permits
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
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

and

Indianapolis Office of Environmental Services (OES)
Air Compliance
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
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

and

Indianapolis Office of Environmental Services (OES)
Air Compliance
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 responsible 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
MC 61-50 IGCN 1003
Indianapolis, Indiana 46204-2251

and

Indianapolis Office of Environmental Services (OES)
Air Compliance
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(II)) 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(II))

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 responsible official as defined by 326 IAC 2-7-1(34).
- (b) The report required in (a) of this condition and reports required by conditions in Section D 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
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

and

Indianapolis Office of Environmental Services (OES)
Air Compliance
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(II)) 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
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

and

Indianapolis Office of Environmental Services (OES)
Air Compliance
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 ($\pm 2\%$) 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
MC 61-53 IGCN 1003
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 Building 358 (shown in the table below) 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-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:
 - (1) Return the purged process fluid directly to the process line;
 - (2) Collect and recycle the purged process fluid;
 - (3) Be designed and operated to capture and transport the purged process fluid to a control device;
 - (4) Collect, store, and transport the purged process fluid to a SOCMH/HON waste management unit (40 CFR Part 63, Subpart G) operated according to the provisions which apply to Group 1 wastewater streams, or to a treatment, storage, or disposal facility subject to 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
 - (5) 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. 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 [Reserved]

This section has been intentionally reserved and left blank.

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 [Reserved]

This section has been intentionally reserved and left blank.

SECTION D.8

FACILITY OPERATION CONDITIONS [Reserved]

This section has been intentionally reserved and left blank

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° C) (one hundred degrees Fahrenheit (100° 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°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 or 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

<p>Facility Description [326 IAC 2-7-5(15)]:</p> <p>(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.</p> <p>(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.</p>
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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
MC 61-53 IGCN 1003
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.10.2, 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.10.2. 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.10.2 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]

- (a) 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 $\pm 2.5^{\circ}\text{EC}$, 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.
- (b) Pursuant to 40 CFR 63.1252 for closed vent systems that contain bypass lines, the Permittee shall:
 - (1) Comply with the requirements of 40 CFR 63, Subpart GGG, Table 4.
 - (2) Install, calibrate, maintain, and operate a flow indicator that determines whether vent stream flow is present at least once every 15 minutes. Records shall be maintained as specified in §63.1259(i)(6)(i). The flow indicator shall be installed at the entrance to any bypass line that could divert the vent stream away from the control device to the atmosphere.

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.
- (k) The Permittee shall keep records for each closed vent system that contains bypass lines as specified in 40 CFR 63.1259(i)(6)(i).

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 nonreparable;
 - (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
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251
Phone: 317-233-0178
Fax: 317-233-6865**

and

**INDIANAPOLIS OFFICE OF ENVIRONMENTAL SERVICES
AIR COMPLIANCE**

**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 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: **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 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 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".	
<input type="checkbox"/> NO DEVIATIONS OCCURRED THIS REPORTING PERIOD.	
<input type="checkbox"/> THE FOLLOWING DEVIATIONS OCCURRED THIS REPORTING PERIOD	
Permit Requirement (specify permit condition #)	
Date of Deviation:	Duration of Deviation:
Number of Deviations:	
Probable Cause of Deviation:	
Response Steps Taken:	
Permit Requirement (specify permit condition #)	
Date of Deviation:	Duration of Deviation:
Number of Deviations:	
Probable Cause of Deviation:	
Response Steps Taken:	

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

Form Completed By:

Title/Position:

Date:

Phone:

Attach a signed certification to complete this report.

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
and
Indianapolis Office of Environmental Services**

Technical Support Document (TSD) for a Part 70 Significant Permit Modification

Source Description and Location	
--	--

Source Name:	Eli Lilly and Company, Lilly Technology Center
Source Location:	1555 South Harding Street, Indianapolis, IN
County:	Marion County
SIC Code:	2834, 2833
Operation Permit No.:	T097-6846-00072
Significant Permit Modification No.:	097-25463-00072
Permit Reviewer:	Monica Doyle

Existing Approvals

The source is operating under the following approvals:

- (a) Initial Title V, T097-6846-00072, issued on October 31, 2006,
- (b) Administrative Amendment, T097-24610-00072, issued on August 1, 2007.

The source historically has operated under the following approvals:

- (c) 8109, issued on May 16, 1984 for B348 Evaporator 24;
- (d) 8163, issued on July 9, 1984 for B348 Tanks 14-17;
- (e) 8303, issued on November 29, 1984 for B348 Evaporator 21;
- (f) 8304, issued on November 29, 1984 for B348 Evaporator 22;
- (g) 8305, issued on November 29, 1984 for B348 Evaporator 23
- (h) 8306, issued on November 29, 1984 for B348 Evaporator (wall);
- (i) 8307, issued on November 29, 1984 for B348 Ventilation Room;
- (j) 8308, issued on November 30, 1984 for B140/P/D5, PCA14 (Bldg 100);
- (k) 8309, issued on November 30, 1984 for B140/P/D7, PCA16 (Bldg 100);
- (l) 8310, issued on November 30, 1984 for B100/P/F6, EF4;
- (m) 8311, issued on November 30, 1984 for B100/P/F6, EF9 (Bldg 100);
- (n) 8312, issued on November 30, 1984 for B100 ST3/D15;
- (o) 8783, issued on April 22, 1986, for Vanco 348 Facility;
- (p) 0072-1, issued on July 15, 1987 for Building 130;
- (q) 890073-01, issued on September 8, 1989 for equipment in Building 334 (replaced by CP950073-03 issued on May 17, 1995);

Construction Permits

- (r) 11043, issued on September 13, 1985 for Vanco 348;
- (s) 890073-03, issued on November 17, 1989 for B348: Tanks 19 and 20;
- (t) 910072-01, issued on October 2, 1991 for BHI 132 Facility;
- (u) 920073-01, issued on August 14, 1992 for 358 Pilot Plant;
- (v) 097-3341, issued on July 27, 1994 for 110 RACT Plan;
- (w) 950073-03, issued on November 6, 1995 for LTC Emergency Generators;
- (x) 950073-02, issued on January 5, 1995 for PC1: 328 Facility;
- (y) 950073-01, issued on January 5, 1995 for PC100 Facility;
- (z) 950073-03, issued on May 17, 1995 for Vancomycin Processing (revoked);
- (aa) A097-5322, issued on February 20, 1996 for 110 RACT Plan Amendment;
- (bb) 960072-01, issued on February 29, 1996 for Glucagon 130 Facility;
- (cc) A072-0001, issued on June 1, 1996 for Buildings 132 and 138
- (dd) 960073-01, issued on July 10, 1996 for Emergency Generator (314);
- (ee) 960073-01, issued on September 25, 1996 for 358 Pilot Plant;
- (ff) A0970072-02, issued on December 10, 1997, for 110 RACT Plan Amendment;
- (gg) A0970072-03, issued on March 12, 1999, 110 RACT Plan Amendment;
- (hh) 097-12128, issued on May 2, 2001, for Building 110 RACT Plan Amendment;
- (ii) 097-12605-00072, issued on September 10, 2001, for modification to Building 130;
- (jj) 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).

County Attainment Status

The source is located in Marion County

Pollutant	Designation
SO ₂	Better than national standards.
CO	Attainment effective February 18, 2000, for the part of the city of Indianapolis bounded by 11 th Street on the north; Capitol Avenue on the west; Georgia Street on the south; and Delaware Street on the east. Unclassifiable or attainment effective November 15, 1990, for the remainder of Indianapolis and Marion County.
O ₃	Attainment effective October 19, 2007, for the 8-hour ozone standard. ¹
PM ₁₀	Unclassifiable effective November 15, 1990.
NO ₂	Cannot be classified or better than national standards.
Pb	Attainment effective July 10, 2000, for the part of Franklin Township bounded by Thompson Road on the south; Emerson Avenue on the west; Five Points Road on the east; and Troy Avenue on the north. Attainment effective July 10, 2000, for the part of Wayne Township bounded by Rockville Road on the north; Girls School Road on the east; Washington Street on the south; and Bridgeport Road on the west.

Pollutant	Designation
	The remainder of the county is not designated.
¹ Attainment effective October 18, 2000, for the 1-hour ozone standard for the Indianapolis area, including Marion County, and is a maintenance area for the 1-hour ozone National Ambient Air Quality Standards (NAAQS) for purposes of 40 CFR 51, Subpart X*. The 1-hour designation was revoked effective June 15, 2005. Basic Nonattainment effective April 5, 2005 for PM2.5.	

- (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 emissions and NOx emissions are considered when evaluating the rule applicability relating to ozone.

On November 8, 2007, a temporary emergency rule took effect redesignating Marion County to attainment for the eight-hour ozone standard. The Indiana Air Pollution Control Board has begun the process for a permanent rule revision to incorporate these changes into 326 IAC 1-4-1. The permanent revision to 326 IAC 1-4-1 should take effect prior to the expiration of the emergency rule. Therefore, VOC emissions and NOx emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2. See the State Rule Applicability – Entire Source section.

- (b) Marion County has been classified as nonattainment for PM2.5 in 70 FR 943 dated January 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 PM10, SO₂, NO₂, CO, and Lead. 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
 This type of operation is one of the twenty-eight (28) listed source categories under 326 IAC 2-2 or 326 IAC 2-3, and there is an applicable New Source Performance Standard that was in effect on August 7, 1980, specifically 40 CFR Part 60, Subpart Y, fugitive emissions are counted toward the determination of PSD and Emission Offset applicability.

Source Status

The table below summarizes the potential to emit of the entire source, prior to the proposed modification, after consideration of all enforceable limits established in the effective permits:

Pollutant	Emissions (tons/year)
PM	<100
PM10	<100
SO ₂	<100
VOC	>100
CO	<100
NO _x	<100

- (a) This existing source has potential emissions of VOC greater than 100 tons per year. Therefore, pursuant to 326 IAC 2-2 the source is a major source.
- (b) These emissions are based upon the Part 70 Permit Application.

The table below summarizes the potential to emit HAPs for the entire source, prior to the

proposed modification, after consideration of all enforceable limits established in the effective permits:

HAPs	Potential To Emit (tons/year)
acetonitrile	greater than 10
Combined HAPs	greater than 25

This existing source is a major source of HAPs, as defined in 40 CFR 63.41, because HAP emissions are greater than ten (10) tons per year for a single HAP and greater than twenty-five (25) tons per year for a combination of HAPs. Therefore, this source is a major source under Section 112 of the Clean Air Act (CAA).

Actual Emissions

The following table shows the actual emissions from the source. This information reflects the 2004 Office of air Quality (OAQ) and Indianapolis Office of Environmental Services (OES) 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

Description of Proposed Modification

Lilly submitted an application indicating that they had recently discovered that the Building 358 control device, the carbon bed adsorber, has a bypass valve in the system. Emissions would only go through the bypass valve when there are unsafe conditions in the control device and during maintenance and shutdown. The source has not done modifications to the emission unit or control device, and potential emissions will not be affected.

A second application was received on May 19, 2008, to address BACT applicability for the secondary waste tank identified as Tank 1961 (TK-1961). This application was assigned tracking number 097-26565-00072, and was combined with this permit action.

Pursuant to 326 IAC 2-7-12(b)(E), this modification does not fit the definition of a minor permit modification, therefore it is a significant permit modification.

Enforcement Issues

There are no pending enforcement actions by OES, however the U.S. EPA issued a Finding of Violation in March, 2007, to the source regarding LDAR violations of the NESHAP for Pharmaceutical Production (40 CFR 63, Subpart GGG).

Permit Level Determination – PSD

Pursuant to 326 IAC 2-2, this permit modification does not fit the definition of "project", therefore it is not major for PSD because there is no physical change or change in the method of operation.

Federal Rule Applicability Determination

The following portions of 40 CFR 63, Subpart GGG are being added to reflect the applicable requirements for the Building 358 control device.

§ 63.1252 Standards: General.

Each owner or operator of any affected source subject to the provisions of this subpart shall control HAP emissions to the level specified in this section on and after the compliance dates specified in §63.1250(f). Initial compliance with the emission limits is demonstrated in accordance with the provisions of §63.1257, and continuous compliance is demonstrated in accordance with the provisions of §63.1258.

(a) *Opening of a safety device.* Opening of a safety device, as defined in §63.1251, is allowed at any time conditions require it to do so to avoid unsafe conditions.

(b) *Closed-vent systems.* The owner or operator of a closed-vent system that contains bypass lines that could divert a vent stream away from a control device used to comply with the requirements in §§63.1253, 63.1254, and 63.1256 shall comply with the requirements of Table 4 to this subpart and paragraph (b)(1) or (2) of this section. Equipment such as low leg drains, high point bleeds, analyzer vents, open-ended valves or lines, rupture disks and pressure relief valves needed for safety purposes are not subject to this paragraph.

(1) Install, calibrate, maintain, and operate a flow indicator that determines whether vent stream flow is present at least once every 15 minutes. Records shall be maintained as specified in §63.1259(i)(6)(i). The flow indicator shall be installed at the entrance to any bypass line that could divert the vent stream away from the control device to the atmosphere.

§ 63.1259 Recordkeeping requirements.

(i) *Records of inspections.* The owner or operator shall keep records specified in paragraphs (i)(1) through (9) of this section.

(6) For each vapor collection system or closed-vent system that contains bypass lines that could divert a vent stream away from the control device and to the atmosphere, the owner or operator shall keep a record of the information specified in either paragraph (i)(6)(i) or (ii) of this section.

(i) Hourly records of whether the flow indicator specified under §63.1252(b)(1) was operating and whether a diversion was detected at any time during the hour, as well as records of the times and durations of all periods when the vent stream is diverted from the control device or the flow indicator is not operating.

State Rule Applicability Determination

This permit modification does not result in any changes in State Rule applicability.

Compliance Determination and Monitoring Requirements

Permits issued under 326 IAC 2-7 are required to ensure that sources can demonstrate compliance with all applicable state and federal rules on a continuous basis. All state and federal rules contain compliance provisions, however, these provisions do not always fulfill the requirement for a 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 Determination Requirements are included in the permit. The Compliance Determination Requirements in Section D of the permit are those conditions that are found directly within state and federal rules and the violation of which serves as grounds for enforcement action.

If the Compliance Determination Requirements are not sufficient to demonstrate continuous compliance, they will be supplemented with Compliance Monitoring Requirements, also in Section

D of the permit. Unlike Compliance Determination Requirements, failure to meet Compliance Monitoring conditions would serve as a trigger for corrective actions and not grounds for enforcement action. However, a violation in relation to a compliance monitoring condition will arise through a source's failure to take the appropriate corrective actions within a specific time period.

- (a) The Building 358 control device, the carbon bed adsorber, has applicable compliance monitoring conditions as specified below:

Install, calibrate, maintain, and operate a flow indicator that determines whether vent stream flow is present at least once every 15 minutes. Records shall be maintained as specified in §63.1259(i)(6)(i). The flow indicator shall be installed at the entrance to any bypass line that could divert the vent stream away from the control device to the atmosphere.

These monitoring conditions are necessary because they apply to the bypass valve in the carbon bed adsorber.

Proposed Changes

The changes listed below have been made to Part 70 Operating Permit No. T097-6846-00072. Deleted language appears as ~~strike throughs~~ and new language appears in **bold**:

1. The applicable requirements of 40 CFR 63, Subpart GGG are being added to E.1.2 and E.1.3. The existing reporting requirements in condition E.1.4 accommodate any reporting applicable to the bypass line.

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

...

- (b) Pursuant to 40 CFR 63.1252 for closed vent systems that contain bypass lines, the Permittee shall:**

- (1) Comply with the requirements of 40 CFR 63, Subpart GGG, Table 4.**
- (2) Install, calibrate, maintain, and operate a flow indicator that determines whether vent stream flow is present at least once every 15 minutes. Records shall be maintained as specified in §63.1259(i)(6)(i). The flow indicator shall be installed at the entrance to any bypass line that could divert the vent stream away from the control device to the atmosphere.**

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

...

- (k) The Permittee shall keep records for each closed vent system that contains bypass lines as specified in 40 CFR 63.1259(i)(6)(i).**

2. On November 8, 2007, a temporary emergency rule took effect redesignating Marion County to attainment for the eight-hour ozone standard. Condition A.1 is being modified as follows:

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.

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
Part 70 Permit Program
Source Status: ~~Minor~~ **Major** Source under PSD and
Minor Source under Nonattainment NSR
~~Major Source under Emission Offsets~~
Major Source, Section 112 of the Clean Air Act
1 of 28 Source Categories

3. On May 19, 2008, IDEM OAQ and OES received an application for a Significant Permit Modification to Title V Permit No. T097-6846-00072 to modify BACT requirements for the Building 358 (B358) secondary waste tank identified as Tank 1961 (TK-1961). The source stated that the potential to emit for TK-1961 was estimated to be 2.8 tons per year of VOC.

The source cited that pursuant to 326 IAC 8-1-6, and 326 IAC 1-2-27, TK-1961 is an individual facility which does not have the potential to emit twenty-five (25) tons or more of VOC per year, therefore, BACT was incorrectly applied to this tank. The potential to emit VOC for TK-1961 was aggregated with the combined potential to emit for all other emission units in Building 358.

Therefore, Section D.2.3 is being modified as follows:

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 (**shown in the table below**) 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-1964	TK-1964	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

Conclusion and Recommendation

This proposed modification shall be subject to the conditions of the attached proposed Part 70 Significant Permit Modification No. 097-25463-00072. The staff recommends to the Administrator that this Part 70 Significant Permit Modification be approved.