



*Mitchell E. Daniels, Jr.*  
Governor

*Thomas W. Easterly*  
Commissioner

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

TO: Interested Parties / Applicant  
DATE: January 19, 2005  
RE: Eli Lilly and Company- Tippecanoe Labs / 157-20216-00006  
FROM: Paul Dubenetzky  
Chief, Permits Branch  
Office of Air Quality

### **Notice of Decision: Approval – Effective Immediately**

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

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

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

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

The filing of a petition for administrative review is complete on the earliest of the following dates that apply to the filing:

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

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

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

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



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**PART 70 OPERATING PERMIT  
OFFICE OF AIR QUALITY**

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

**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.**

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

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

Operation Permit No.: T 157-6879-00006	
Issued by: Janet G. McCabe, Assistant Commissioner Office of Air Quality	Issuance Date: 02-27-2004  Expiration Date: 02-26-2009
1st. Significant Permit Modification No.: 157-20216-00006	
Issued by: Original signed by Paul Dubenetzky, Branch Chief Office of Air Quality	Issuance Date: <b>January 19, 2005</b>

**Indiana Department of Environmental Management  
Office of Air Quality**

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

<b>Source Name:</b>	<b>Eli Lilly and Company – Tippecanoe Laboratories</b>
<b>Source Location:</b>	<b>1650 Lilly Road, Lafayette, IN, 47909</b>
<b>County:</b>	<b>Tippecanoe</b>
<b>SIC Code:</b>	<b>2833 and 2834</b>
<b>Significant Source Modification</b>	<b>173-20160-00006</b>
<b>Significant Permit Modification</b>	<b>157-20216-00006</b>
<b>Permit Reviewer:</b>	<b>Dr. Trip Sinha</b>

On December 17, 2004, Eli Lilly and Company submitted comments on the proposed Significant Source Modification No. 157-20160-00006 and Significant Permit Modification No.157-20216-00006. The summary of the comments and corresponding responses is as follows:

**Deleted items are crossed out and new additions are bolded for clarity.**

Comment 1: First, Significant Source Modification 157-20160-00006 [the letter to Lawrence J. McShane] includes four “Construction Conditions” that are normally included in pre-construction permits issued by IDEM. Since this permit modification does not authorize any construction activity, and instead revises emission control requirements, Lilly believes these conditions are not needed. We request IDEM to delete General Construction Conditions 1 through 4.

Response 1: The conditions have been deleted.

Comment 2: There is an error on Page 1 of the combined Technical Support Document for both permitting actions. In the first paragraph under the heading “History”, the text states that local exhaust ventilation systems were required to be connected to either the RTOs or the T79 fume incinerators. It is not correct to refer to the T79 fume incinerators. LEVs would have been connected only to the RTOs. Lilly requests deleting “or T79 fume incinerators” at the end of this paragraph.

Response 2: The IDEM, OAQ prefers that the Technical Support Document reflect the permit that was on public notice. Changes to the permit or technical support material that occur after the public notice are documented in this Addendum to the Technical Support Document. This accomplishes the desired result of ensuring that these types of concerns are documented and part of the record regarding this permit decision.

This Addendum to Technical Support Document becomes the part of Technical Support Document.

The IDEM, OAQ agrees that local exhaust ventilation systems were required to be connected only to the RTOs and not to the T79 fume incinerators.

Comment 3: Lilly's final comment addresses a statement in the Technical Support Document made at the end of the section entitled "Potential to Emit of Modification After Issuance". The last sentence states "This modification to revise the PSD BACT limit is considered a major modification under 326 IAC 2-2." Lilly disagrees with this statement.

A major modification under 326 IAC 2-2 is defined as a "physical change in, or change in the method of operation of, a major stationary source that would result in a significant emissions increase and a significant net emissions increase of a regulated NSR pollutant from the major stationary source." The proposal to eliminate the requirement to connect LEVs to the RTOs at Tippecanoe Laboratories will not cause a significant emissions increase. Lilly estimates the potential emission increase to be approximately 500 pounds per year.

Lilly acknowledges that a significant source modification may be the most appropriate method for revising the BACT requirement of a previously issued PSD permit. We believe, however, that using this method to revise the permit does not create a major modification under 326 IAC 2-2.

Response 3: The OAQ agrees that this change at the Tippecanoe plant is not a major modification under 236 IAC 2-2 because the revision to the Best Available Control Technology (BACT) determination results in an increase in emissions that is very small. Any change to a BACT determination established under 326 IAC 2-2 is governed by 326 IAC 2-7-10.5(f)(1). This subdivision requires that any modification subject to 326 IAC 2-2 be processed as a significant source modification.

**Indiana Department of Environmental Management  
Office of Air Quality**

**Technical Support Document (TSD) for a Prevention of Significant  
Deterioration (PSD) and Part 70 Significant Source Modification; and  
Significant Permit Modification.**

**Source Background and Description**

Source Name:	Eli Lilly and Company – Tippecanoe Laboratories
Source Location:	1650 Lilly Road, Lafayette, IN, 47909
County:	Tippecanoe
SIC Code:	2833 and 2834
Operation Permit No.:	T157-6879-00006
Operation Permit Issuance Date:	2-27-2004
Significant Source Modification No.:	157-20160-00006
Significant Permit Modification No.:	157-20216-00006
Permit Reviewer:	Dr. Trip Sinha

The Office of Air Quality (OAQ) has reviewed a source modification application from Eli Lilly and Company for the revision to the best available control technology (BACT) for production equipment exhaust systems containing greater than 50 ppm VOC and less than 50 ppm HAPs.

Followings are the operations from which VOC emissions are generated:

- (a) Open manway operations
- (b) Charging a liquid from a drum to a tank
- (c) Centrifuge emptying operations
- (d) Drum filling and drum cleaning operations
- (e) Loading wetcake into dryers

**History**

IDEM issued a Part 70 permit to The Eli Lilly and Company – Tippecanoe Laboratories on February 27, 2004. The Part 70 operation permit established Operation condition D.6.2, which required Lilly to connect and control production equipment exhaust systems (also known as local exhaust ventilation systems or “LEVs”) to the existing Regenerative Thermal Oxidizers or T79 fume incinerators.

After the issuance of the Part 70 permit, Lilly found that the cost of complying with the BACT was too high and submitted the application to remove the BACT limit established in Operation Condition D.6.2.

**Enforcement Issue**

There are no enforcement actions pending.

## Recommendation

The staff recommends to the Commissioner that the Part 70 Significant Source Modification be approved. This recommendation is based on the following facts and conditions:

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

## Emission Calculations

The calculations submitted by the applicant have been verified and found to be accurate and correct. These calculations are provided in Appendix A of this document.

## Potential To Emit of Modification

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

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

Pollutant	Potential To Emit (tons/year)
VOC	0.5
HAPs	0.5

## Justification for Modification

The Part 70 Operating permit is being modified through a Part 70 Significant Source Modification. This modification is being performed pursuant to 326 IAC 2-7-10.5(f)(1), because PSD BACT already established for LEVs, is being revised.

## County Attainment Status

The source is located in Tippecanoe County.

Pollutant	Status
PM-10	Attainment
SO <sub>2</sub>	Attainment
NO <sub>2</sub>	Attainment
Ozone	Attainment
CO	Attainment
Lead	Attainment

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

Since this type of operation is one of the 28 listed source categories under 326 IAC 2-2, the fugitive VOC emissions are counted toward determination of PSD applicability.

**Source Status**

Existing Source PSD or Emission Offset Definition (emissions after controls, based upon 8760 hours of operation per year at rated capacity and/or as otherwise limited):

Pollutant	Emissions (tons/year)
PM	>100
PM-10	>100
SO <sub>2</sub>	>100
VOC	>100
CO	>100
NO <sub>x</sub>	>100

This existing source is a major stationary source because an attainment regulated pollutant is emitted at a rate of 100 tons per year or more, and it is one of the 28 listed source categories.

**Potential To Emit of Modification After Issuance**

The table below summarizes the potential to emit, reflecting all limits, of the significant emission units after controls. The control equipment is considered federally enforceable only after issuance of this Part 70 source modification.

Process	VOC (tons/yr)	HAPs (tons/yr)
LEV System Emissions	0.5	0.5
Bulk Pharmaceutical Operations before this modification	300	
Bulk Pharmaceutical Operations After this modification	300	

- (a) There is no increase in the emission limit established for pharmaceutical bulk manufacturing operations. This modification to revise the PSD BACT limit is considered a major modification under 326 IAC 2-2.

**Federal Rule Applicability**

- (a) There is no federal new rule applicable to this modification.

**State Rule Applicability - Individual Facilities**

326 IAC 2-2-3 (BACT Requirements)

BACT Evaluation:

The existing PSD/Title V permit reflected a determination that the emission control requirements of the Pharmaceutical MACT (40 CFR 63, subpart GGG) rules, as they apply to Eli Lilly -

Tippecanoe Laboratories, are BACT for volatile organic compounds (VOCs). If the Pharmaceutical MACT rule required controls for organic hazardous air pollutants (HAPs), then the same controls were considered appropriate as BACT for VOCs. For example, all process vents with greater than 50 ppm HAP or 50 ppm VOC concentrations in the bulk pharmaceutical production buildings were required to be routed to and controlled by the source's Regenerative Thermal Oxidizers (RTOs) or T79 fume incinerators.

The permit included a provision that reflected one distinction between Pharmaceutical MACT requirements and BACT. Part 70 permit Operation condition D.6.2 allows Lilly 365 days from the effective date of the permit to connect and control LEVs containing greater than 50 ppm VOC and less than 50 ppm HAPs. The permit essentially provided a delayed BACT compliance date for the LEVs not required to be controlled under the Pharmaceutical MACT rule. The MACT rules treat LEVs as process vents that should be controlled if HAP concentrations exceed 50 ppm, however LEVs containing greater than 50 ppm of HAPs, were not provided a delayed compliance date.

The permit allowed the delayed connection of LEVs with VOC only or less than 50 ppm HAP because the emissions contained in these systems are very low and because it would take considerable time and expense to connect all the LEV systems to the RTO. LEVs are small, localized fume collection systems typically comprised of flexible duct material (also known as "elephant hoses"). They are used to collect fumes when process equipment is opened to add dry raw materials or solvents, to remove product, or to be cleaned. The projected upper bound of actual uncontrolled VOC emissions from the currently uncontrolled LEVs is approximately 500 pounds per year. At the time the permit was under development, Lilly had estimated it would cost about \$950,000 to connect these LEVs to the RTOs. Despite the extremely high cost per ton ratio that would exceed normal expectations for VOC BACT, Lilly agreed to connect these LEVs to the RTOs.

The capital costs involved in connecting the LEVs to the RTOs essentially consist of the cost for duct work and other ancillary equipment. Implementation of other feasible controls, such as condensers or carbon adsorbers, would require the purchase and installation of new emission control devices in several different areas. Total cost of that kind of project would be greater than the cost of connecting the LEVs to the existing RTO fume transport system.

U.S. EPA's RBLC data was searched, no control information was available for this type of operation.

IDEM, OAQ in consultation with U.S. EPA, has evaluated the justifications and determined that the cost effectiveness figure of 6.4 million dollars per ton is excessively.

Therefore, the operation condition D.6.2 has been replaced with the new condition.

This new condition requires if the VOC and HAPs emissions exceed the threshold of rules 40 CFR 63.1254, and 326 IAC 8-5-3(b), then the vents will be controlled by the existing RTOs.

**Deleted items are crossed out and new additions are bolded for clarity.**

D.6.2 Control Strategy for **Production Equipment Exhaust Systems** ~~VOC BPM Process Vents~~  
**[40 CFR 63.1254][326 IAC 8-5-3]** [326 IAC 2-2-3]

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

- ~~(a) — open manway operations;~~
- ~~(b) — charging a liquid from a drum to a tank;~~
- ~~(c) — centrifuge emptying operations;~~

~~(d) — drum filling and drum cleaning operations; or~~

~~(e) — loading wetcake into driers.~~

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

- (a) **Pursuant to 40 CFR 63.1254, production equipment exhaust systems containing undiluted and uncontrolled exhaust streams with HAP concentrations greater than fifty (50) ppm, HAP shall be routed to the RTO control system. The operation, inspection, and maintenance requirements for the RTO control system, and its closed - vent system, used to control emissions from these emission units are described in Section D.14 of this permit.**
- (b) **Pursuant to 326 IAC 8-5-3(b)(2), VOC emissions from production equipment exhaust systems shall not exceed thirty-three (33) pounds per day. If uncontrolled VOC emissions from a production equipment exhaust system would exceed thirty three (33) pounds per day, then the Permittee shall route VOC emissions from that production equipment exhaust system to the RTO control system. The operation, inspection, and maintenance requirements for the RTO control system, and its closed vent system, used to control emissions from these emission units are described in Section D.14 of this permit.**
- (c) **Pursuant to 326 IAC 2-2-3, VOC BACT for production equipment exhaust systems not meeting the criteria of D.6.2(a) or D.6.1(b) is no controls. If the process affiliated with a production equipment exhaust system that is not routed to the RTO control system is modified in a manner that causes the criteria in Condition D.6.2(a) or D.6.2(b) to apply, the Permittee shall connect the production equipment exhaust system to the RTO control system before beginning any operations that would cause D.6.2(a) or D.6.2(b) to be applicable.**

## Conclusion

The proposed modification shall be subject to the conditions of the attached proposed Part 70 Significant Source Modification No. 157-20160-00006 letter and Significant Permit Modification No. 157-20216-00006.