



Joseph E. Kernan
Governor

Lori F. Kaplan
Commissioner

December 30, 2004

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

TO: Interested Parties / Applicant

RE: Eli Lilly and Company -Tippecanoe Labs / 157-20160-00006

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 according to IC 13-15-6-3, 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 and IC 13-15-6-1 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, **within eighteen (18) calendar days of the mailing 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.

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
FNPER.dot 9/16/03



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

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December 30, 2004

Mr. Lawrence J. McShane
General Manager
Eli Lilly and Company – Tippecanoe Laboratories
1650 Lilly Road, Lafayette, IN, 47909

Re: 157-20160-00006
Significant Source Modification to:
Part 70 permit No.: T157-6879-00006

Dear Mr. McShane:

Eli Lilly and Company was issued Part 70 operating permit T157-6879-00006 on February 27, 2004 for its Tippecanoe Laboratories operations. An application to revise the PSD BACT limit for local exhaust ventilation systems (LEVs) was received on September 27, 2004. Pursuant to 326 IAC 2-7-10.5(f)(1) the revision to the PSD BACT for LEVs for the following emission units is approved:

- (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

Operating conditions shall be incorporated into the Part 70 operating permit as a significant permit modification in accordance with 326 IAC 2-7-10.5(f)(1) and 326 IAC 2-7-12.

Revised Operation Condition

D.6.2 Control Strategy for Production Equipment Exhaust Systems [40 CFR 63.1254][326 IAC 8-5-3] [326 IAC 2-2-3]

- (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 the RTO control system. The operation, inspection, and maintenance requirements for the RTO control system, and it's 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.1.6(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.2.6(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.

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 call (800) 451-6027, press 0 and ask for Dr. Trip Sinha or extension 3-3031, or dial (317) 233-3031.

Sincerely,
Original signed by

Paul Dubenetzky, Chief
Permits Branch
Office of Air Management

Attachments
Technical Support Document (TSD)
Appendix A

TPS
cc: File - Tippecanoe County
Tippecanoe County Health Department
Air Compliance Section Inspector – Wanda Stanfield
Compliance Data Section
Administrative and Development Section

Indiana Department of Environmental Management Office of Air Quality

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

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

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 ₂	Attainment
NO ₂	Attainment
Ozone	Attainment
CO	Attainment
Lead	Attainment

- (a) Volatile organic compounds (VOC) are precursors for the formation of ozone. Therefore, VOC emissions are considered when evaluating the rule applicability relating to the ozone standards.
- (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 ₂	>100
VOC	>100
CO	>100
NOx	>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]

~~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.

Table A-1: Summary of LEV system emission estimates [May – November 2003]

Process location/# of lots	Operation(s) involved	Solvents involved	Emissions – all lots (kilograms)
T27 Process A - 20 lots	Drum Charge	1-fluoro-2-nitrobenzene	0.083
	Drum Charge	Dimethyl sulfoxide	0.527
T27 Process B - 19 Lots	Drum Charge	t-Butanol	0.339
	Open Manway	THF	7.825
T27 Process C - 20 Lots	Drum Charge	3-pentanone	4.513
	Drum Charge	DMSO	0.188
	Drum Charge	Trimethyl orthoformate	0.860
	Open Manway Solids Charge & Liquid Packaging	Isopropyl Acetate	15.859
T27 Process D - 4 lots	Drum Charge	HMDS	0.154
	Drum Charge	Isobutyl Chloroformate	0.338
T27 Process E - 10 lots	Liquid Packaging	Anisole	0.288
T27 Process F - 50 lots	Drum Charge	Acetophenone	0.316
	Drum Charge	n-n-benzylmethylamine	0.095
	Drum Charge	Alcohol SD 3A	5.782
T27 Process G - 67 lots	Drum & Open Manway Solids Charge	Alcohol SD 3A	11.892
T27 Process H - 68 lots	Press Make up	IPA	0.148
T28 Process I - 9 lots	Drum Charge, 3 - Open Manway Solids Charges, Centrifuge operation	DMF	18.892
T28 Process J - 25 lots	Open Manway Solids Charge	Alcohol SD 3A	0.435
	Handy Dandy Unloading	THF	10.857
T28 Process K - 57 lots	Open Manway Solids Charge	DMSO	0.056
T28 Process L - 62 lots	Drum Charge	Formic Acid 98%	0.169
	Charge Funnel Solids Addition	Amyl Acetate	0.074
T29 Process M - 77 lots	Drum Charge	HMDS	23.588
T100 Process N - 15 lots	Drum Charge	Methyl Chlorodifluoroacetate	0.035
	Drum Charge	Isopropyl Acetate	0.140
	Liquid Packaging	Heptane	1.056
T100 Process O - 15 lots	Drum Charge & Liquid Packaging	Isopropyl Acetate	0.280
T100 Process P - 15 lots	Drum Charge & Liquid Packaging	DMI	0.001
Total			104.79 kg

* Table does not include processes that were evaluated but do not have VOC emissions.
 105 kg * 2.2 lb/kg = 231 lbs VOC per six months
 231 lbs VOC per six months * 2 = 462 lbs/year
 462 lbs/year + 10% contingency factor = 508 lbs/year = baseline emission rate

Table B-1 Summary of LEV system control cost estimates

Direct Installation Costs

Foundations and Supports	\$29,500
Auxiliaries: Purchases (Details Below)	\$1,108,500
Auxiliaries: Ductwork Installation	\$687,000
Handling and Erection	\$88,000
Piping	\$0
Insulation and Painting	\$5,000
Electrical	\$65,000
Site Preparation	\$121,000

Direct Install Subtotal **\$2,104,000**

Indirect Installation Costs

Engineering	\$470,000
Lost Production	\$0
Construction and Field Exp.	\$30,000
Contractor Fees	\$0
Start-up and Performance Tests	\$75,000
Over-all Contingency	\$400,000
Working Capital	\$0
Other (Owner Labor Costs)	\$150,000

Indirect Install Cost Subtotal **\$1,125,000**

Total Project Cost **\$3,229,000**

Details of Capital Purchases for Auxiliaries

T27

4 fans	\$20,000
2 filtration units	\$18,000
4 fume extraction arms	\$17,000
duct materials	\$128,000
Miscellaneous equipment	\$17,000

T28

2 fans	\$10,000
2 fume extraction arms	\$8,500
duct materials	\$77,000
fume hoods	\$62,000
Miscellaneous equipment	\$9,000

T99

1 fan	\$5,000
8 filtration units	\$70,000
duct materials	\$44,000
fume hoods	\$100,000
Miscellaneous equipment	\$5,000

T100

7 fans	\$35,000
2 filtration units	\$18,000
2 fume extraction arms	\$8,500
duct materials	\$148,000
fume hoods	\$227,000
Miscellaneous equipment	\$17,500

Instrumentation \$14,000

Sales Tax \$50,000

Purchased. Equip. Subtotal \$1,108,500