

**CONSTRUCTION PERMIT
OFFICE OF AIR MANAGEMENT**

**Eli Lilly and Company
2010 Lilly Road
Shadeland, Indiana 47905**

is hereby authorized to construct
the replacement process tanks at the Tippecanoe Laboratories at the above location consisting of:

- (a) One (1) nominal 500 gallon general process tank, designated as tank 40-11, located in an existing building designated as T27 and controlled by existing RTOs or condenser for VOC emissions, and an existing scrubber for SO₂ emissions. CO and NO_x emissions will be controlled voluntarily by existing RTOs and scrubbers, respectively.
- (b) One (1) nominal 500 gallon general process tank, designated as tank 49-1 located in an existing building designated as T27 and controlled by existing RTOs or condenser for VOC emissions, and an existing scrubber for SO₂ emissions. CO and NO_x emissions will be controlled voluntarily by existing RTOs and scrubbers, respectively.

Tanks 40-11 and 49-1 replace the former tanks designated by the same identification numbers and permitted in OP 79-04-90-0382.

This permit is issued to the above mentioned company (herein known as the Permittee) under the provisions of 326 IAC 2-1 and 40 CFR 52.780, with conditions listed on the attached pages.

Construction Permit No.: CP-157-9245-00006	
Issued by: Paul Dubenetzky, Branch Chief Office of Air Management	Issuance Date:

Construction Conditions

General Construction Conditions

1. That the data and information supplied with the application shall be considered part of this permit. Prior to any proposed change in construction which may increase the allowable emissions, the change must be approved by the Office of Air Management (OAM).
2. That this permit to construct does not relieve the Permittee of the responsibility to comply with the provisions of the Indiana Environmental Management Law (IC 13-11 through 13-20; 13-22 through 13-25; and 13-30), the Air Pollution Control Law (IC 13-17) and the rules promulgated thereunder, as well as other applicable local, state, and federal requirements.

Effective Date of the Permit

3. That pursuant to IC 13-15-5-3, this permit becomes effective upon its issuance.
4. That pursuant to 326 IAC 2-1-9(b)(Revocation of Permits), the Commissioner may revoke this permit if construction is not commenced within eighteen (18) months after receipt of this approval or if construction is suspended for a continuous period of one (1) year or more.
5. That notwithstanding Construction Condition No. 6, all requirements and conditions of this construction permit shall remain in effect unless modified in a manner consistent with procedures established for modifications of construction permits pursuant to 326 IAC 2 (Permit Review Rules).

First Time Operation Permit

6. That this document shall also become a first-time operation permit pursuant to 326 IAC 2-1-4 (Operating Permits) when, prior to start of operation, the following requirements are met:
 - (a) The attached affidavit of construction shall be submitted to the Office of Air Management (OAM), Permit Administration & Development Section, verifying that the facilities were constructed as proposed in the application. The facilities covered in the Construction Permit may begin operating on the date the Affidavit of Construction is postmarked or hand delivered to IDEM.
 - (b) If construction is completed in phases; i.e., the entire construction is not done continuously, a separate affidavit must be submitted for each phase of construction. Any permit conditions associated with operation start up dates such as stack testing for New Source Performance Standards (NSPS) shall be applicable to each individual phase.
 - (c) Permittee shall receive an Operation Permit Validation Letter from the Chief of the Permit Administration & Development Section and attach it to this document.
 - (d) The operation permit will be subject to annual operating permit fees pursuant to 326 IAC 2-7-19 (Fees).

- (e) The Permittee has submitted their Part 70 application (**T-157-6879-00006**) on October 10, 1996, for the existing source. The equipment being reviewed under this permit shall be incorporated in the submitted Part 70 application.
7. That when the facility is constructed and placed into operation the following operation conditions shall be met:

Operation Conditions

General Operation Conditions

1. That the data and information supplied in the application shall be considered part of this permit. Prior to any change in the operation which may result in an increase in allowable emissions exceeding those specified in 326 IAC 2-1-1 (Construction and Operating Permit Requirements), the change must be approved by the Office of Air Management (OAM).
2. That the Permittee shall comply with the provisions of the Indiana Environmental Management Law (IC 13-11 through 13-20; 13-22 through 13-25; and 13-30), the Air Pollution Control Law (IC 13-17) and the rules promulgated thereunder.

Preventive Maintenance Plan

3. That pursuant to 326 IAC 1-6-3 (Preventive Maintenance Plans), the Permittee shall prepare and maintain a preventive maintenance plan, including the following information:
- (a) Identification of the individual(s) responsible for inspecting, maintaining, and repairing emission control devices.
- (b) A description of the items or conditions that will be inspected and the inspection schedule for said items or conditions.
- (c) Identification of the replacement parts which will be maintained in inventory for quick replacement.

The preventive maintenance plan shall be submitted to IDEM, OAM upon request and shall be subject to review and approval.

Transfer of Permit

4. That pursuant to 326 IAC 2-1-6 (Transfer of Permits):
- (a) In the event that ownership of tanks 40-11 and 49-1, is changed, the Permittee shall notify OAM, Permit Branch, within thirty (30) days of the change. Notification shall include the date or proposed date of said change.
- (b) The written notification shall be sufficient to transfer the permit from the current owner to the new owner.
- (c) The OAM shall reserve the right to issue a new permit.

Permit Revocation

5. That pursuant to 326 IAC 2-1-9(a)(Revocation of Permits), this permit to construct and operate may be revoked for any of the following causes:
- (a) Violation of any conditions of this permit.
 - (b) Failure to disclose all the relevant facts, or misrepresentation in obtaining this permit.
 - (c) Changes in regulatory requirements that mandate either a temporary or permanent reduction of discharge of contaminants. However, the amendment of appropriate sections of this permit shall not require revocation of this permit.
 - (d) Noncompliance with orders issued pursuant to 326 IAC 1-5 (Episode Alert Levels) to reduce emissions during an air pollution episode.
 - (e) For any cause which establishes in the judgment of IDEM, the fact that continuance of this permit is not consistent with purposes of 326 IAC 2-1 (Permit Review Rules).

Availability of Permit

6. That pursuant to 326 IAC 2-1-3(l), the Permittee shall maintain the applicable permit on the premises of this source and shall make this permit available for inspection by the IDEM or other public official having jurisdiction.

Volatile Organic Compound (VOC) Limitations

7. That the VOC emissions from the proposed replacement of the two (2) process tanks, 40-11 and 49-1 in building T27, shall be in compliance with 326 IAC 8-5-3 (Synthesized Pharmaceutical Manufacturing Operations), whenever VOC with vapor pressure over 0.5 psi (at 20 degrees Celsius), are emitted from the process tanks provided that:
- (a) The regenerative thermal oxidizers or condensers (when Eli Lilly and Company elects to control VOC emissions by condensers) operate at all times when tanks 40-11 and 49-1, in building T27, are in operation.
 - (b) When the VOC emissions from these two (2) tanks above are controlled by the condensers, the condensers shall not exceed the outlet gas temperatures, determined by 326 IAC 8-5-3(b)(1)(A), listed below:
 - 1. minus twenty-five degrees Celsius (-25°C) when condensing VOC of vapor pressure greater than forty (40) kilo Pascal (five and eight-tenths (5.8) pounds per square inch);
 - 2. minus fifteen degrees Celsius (-15°C) when condensing VOC of vapor pressure greater than twenty (20) kilo Pascal (two and nine-tenths (2.9) pounds per square inch);
 - 3. zero degrees Celsius (0°C) when condensing VOC of vapor pressure greater than ten (10) kilo Pascal (one and five-tenths (1.5) pounds per square inch);
 - 4. ten degrees Celsius (10°C) when condensing VOC of vapor pressure greater than seven (7) kilo Pascal (one (1.0) pounds per square inch);
 - 5. twenty-five degrees Celsius (25°C) when condensing VOC of vapor pressure greater than three and five-tenths (3.5) kilo Pascal (five-tenths (0.5) pounds per square inch).

Monitoring of the outlet gas temperature or other IDEM approved parameter shall be sufficient to document compliance with 326 IAC 8-5-3.

- (c) When the VOC emissions from these two (2) tanks are controlled by the existing RTOs, the existing RTO combustion chamber shall maintain a minimum operating temperature determined by a performance test to maintain at least 90% destruction, which yields an allowable VOC emission of 3.34 tons per year, of the volatile organic compounds subject to 326 IAC 8-5-3. The minimum operating temperature for the existing RTOs shall be 1500 degrees Fahrenheit. The performance test to verify the VOC control efficiency and minimum operating temperature of the existing RTOs performed under Construction Permit No. 157-2593 shall satisfy this condition.
- (d) Eli Lilly shall cover the process tanks 40-11 and 49-1, containing a volatile organic compound at any time. These covers must remain closed, unless production, sampling, maintenance, or inspection procedures require operator access.
- (e) All visible VOC equipment leaks shall be repaired as soon as possible. During operation, process operators shall inspect tanks and equipment (valves, flanges, etc.) for visible indications of leaks.

Record Keeping of Operating Parameters

- 8. That pursuant to 326 IAC 2-1-3(i)(8) and 326 IAC 8-5-3 Eli Lilly and Company shall record the following during times when volatile organic compounds are being emitted:
 - (a) The minimum operating temperature, of the existing RTOs; or
 - (b) The outlet gas temperature of the condenser or other OAM approved parameters, when the VOC emissions from either of the two (2) tanks are controlled by the condensers.

SOCHMI HON, 40 CFR 63 Subparts H and I (Pharmaceutical Processes Using Methylene Chloride)

- 9. That for tanks 40-11 and 49-1, when using Methylene Chloride, the Permittee shall comply with National Emission Standards for Organic Hazardous Air Pollutants for Equipment Leaks, 40 CFR Part 63, Subpart H, as required by the National Emission Standards for Organic Hazardous Air Pollutants for Certain Processes subject to the Negotiated Regulation for Equipment Leaks, 40 CFR Part 60, Subpart I.

Limit on the process lots

- 10. The total number of lots for processes emitting SO₂, NO_x and CO, in tanks 40-11 and 49-1, shall be limited to 100 lots or equivalent lots per year. This is based on the worst case scenario submitted by the source.

Malfunction Condition

- 11. That pursuant to 326 IAC 1-6-2 (Records; Notice of Malfunction):

- (a) A record of all malfunctions, including startups or shutdowns of any facility or emission control equipment, which result in violations of applicable air pollution control regulations or applicable emission limitations shall be kept and retained for a period of three (3) years and shall be made available to the Indiana Department of Environmental Management (IDEM), Office of Air Management (OAM) or appointed representative upon request.
- (b) When a malfunction of any facility or emission control equipment occurs which lasts more than one (1) hour, said condition shall be reported to OAM, using the Malfunction Report Forms (2 pages). Notification shall be made by telephone or facsimile, as soon as practicable, but in no event later than four (4) daytime business hours after the beginning of said occurrence.
- (c) Failure to report a malfunction of any emission control equipment shall constitute a violation of 326 IAC 1-6, and any other applicable rules. Information of the scope and expected duration of the malfunction shall be provided, including the items specified in 326 IAC 1-6-2(a)(1) through (6).
- (d) Malfunction is defined as any sudden, unavoidable failure of any air pollution control equipment, process, or combustion or process equipment to operate in a normal and usual manner. [326 IAC 1-2-39]

Record Keeping Requirements

- 12. That a log of information necessary to document compliance with operation permit condition no/s. 7, 8 and 10 shall be maintained. These records shall be kept for at least the past 36 month period and made available upon request to the Office of Air Management (OAM). This record keeping shall begin with the receipt of the valid Operating Permit Validation Letter.

Annual Emission Reporting

- 13. That pursuant to 326 IAC 2-6 (Emission Reporting), the Permittee must annually submit an emission statement for the source. This statement must be received by July 1 of each year and must comply with the minimum requirements specified in 326 IAC 2-6-4. The annual statement must be submitted to:

Indiana Department of Environmental Management
Technical Support and Modeling Section, Office of Air Management
100 North Senate Avenue, P. O. Box 6015
Indianapolis, Indiana 46206-6015

The annual emission statement covers the twelve (12) consecutive month time period starting January 1 and ending December 31.

Emergency Reduction Plans

- 14. Eli Lilly and Company has submitted a revised emergency reduction plan to OAM in January 1997. This condition has been satisfied.

MALFUNCTION REPORT

**INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR MANAGEMENT
FAX NUMBER - 317 233-5967**

**This form should only be used to report malfunctions applicable to Rule 326 IAC 1-6
and to qualify for the exemption under 326 IAC 1-6-4.**

THIS FACILITY MEETS THE APPLICABILITY REQUIREMENTS BECAUSE: IT HAS POTENTIAL TO EMIT 25 LBS/HR PARTICULATES ? _____, 100 LBS/HR VOC ? _____, 100 LBS/HR SULFUR DIOXIDE ? _____ OR 2000 LBS/HR OF ANY OTHER POLLUTANT ? _____ EMISSIONS FROM MALFUNCTIONING CONTROL EQUIPMENT OR PROCESS EQUIPMENT CAUSED EMISSIONS IN EXCESS OF APPLICABLE LIMITATION _____.

THIS MALFUNCTION RESULTED IN A VIOLATION OF: 326 IAC _____ OR, PERMIT CONDITION # _____ AND/OR PERMIT LIMIT OF _____

THIS INCIDENT MEETS THE DEFINITION OF 'MALFUNCTION' AS LISTED ON REVERSE SIDE ? Y
N

THIS MALFUNCTION IS OR WILL BE LONGER THAN THE ONE (1) HOUR REPORTING REQUIREMENT ?
Y N

COMPANY: Eli Lilly and Company PHONE NO. (765)477-4867
LOCATION: Shadeland, Indiana of Tippecanoe County
PERMIT NO. CP157-9245 AFS PLANT ID: 157-00006 AFS POINT ID: _____ INSP: _____
CONTROL/PROCESS DEVICE WHICH MALFUNCTIONED AND REASON: _____

DATE/TIME MALFUNCTION STARTED: ____/____/19____ AM / PM
ESTIMATED HOURS OF OPERATION WITH MALFUNCTION CONDITION: _____

DATE/TIME CONTROL EQUIPMENT BACK-IN SERVICE ____/____/19____ AM/PM

TYPE OF POLLUTANTS EMITTED: TSP, PM-10, SO2, VOC, OTHER: _____
ESTIMATED AMOUNT OF POLLUTANT EMITTED DURING MALFUNCTION: _____
MEASURES TAKEN TO MINIMIZE EMISSIONS: _____

REASONS WHY FACILITY CANNOT BE SHUTDOWN DURING REPAIRS: _____

CONTINUED OPERATION REQUIRED TO PROVIDE ESSENTIAL * SERVICES: _____
CONTINUED OPERATION NECESSARY TO PREVENT INJURY TO PERSONS: _____
CONTINUED OPERATION NECESSARY TO PREVENT SEVERE DAMAGE TO EQUIPMENT: _____
INTERIM CONTROL MEASURES: (IF APPLICABLE) _____

MALFUNCTION REPORTED BY: _____ TITLE: _____
(SIGNATURE IF FAXED)

MALFUNCTION RECORDED BY: _____ DATE: _____ TIME: _____

**Please note - This form should only be used to report malfunctions
applicable to Rule 326 IAC 1-6 and to qualify for
the exemption under 326 IAC 1-6-4.**

326 IAC 1-6-1

Applicability of rule

Sec. 1. The requirements of this rule (326 IAC 1-6) shall apply to the owner or operator of any facility which has the potential to emit twenty-five (25) pounds per hour of particulates, one hundred (100) pounds per hour of volatile organic compounds or SO₂, or two thousand (2,000) pounds per hour of any other pollutant; or to the owner or operator of any facility with emission control equipment which suffers a malfunction that causes emissions in excess of the applicable limitation.

326 IAC 1-2-39 “Malfunction” definition

Sec. 39. Any sudden, unavoidable failure of any air pollution control equipment, process, or combustion or process equipment to operate in a normal and usual manner. (Air Pollution Control Board; 326 IAC 1-2-39; filed Mar 10, 1988, 1:20 p.m. : 11 IR 2373)

***Essential services** are interpreted to mean those operations, such as, the providing of electricity by power plants. Continued operation solely for the economic benefit of the owner or operator shall not be sufficient reason why a facility cannot be shutdown during a control equipment shutdown.

If this item is checked on the front, please explain rationale:

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Indiana Department of Environmental Management Office of Air Management

Technical Support Document (TSD) for New Construction and Operation

Source Background and Description

Source Name: Eli Lilly and Company
 Source Location: 2010 Lilly Road, Shadeland, IN. 47905
 County: Tippecanoe
 Construction Permit No.: CP-157-9245-00006
 SIC Code: 2834 & 2879
 Permit Reviewer: Nysa L. James

The Office of Air Management (OAM) has reviewed an application from Eli Lilly and Company relating to the construction and operation of two replacement process vessels, consisting of the following equipment:

- (a) One (1) nominal 500 gallon general process tank, designated as tank 40-11, located in an existing building designated as T27, and controlled by the existing RTOs or condenser for VOC emissions, and an existing scrubber for SO₂ emissions. CO and NO_x emissions will be controlled voluntarily by existing RTOs and scrubbers, respectively.
- (b) One (1) nominal 500 gallon general process tank, designated as tank 49-1 located in an existing building designated as T27, and controlled by the existing RTOs or condenser for VOC emissions, and an existing scrubber for SO₂ emissions. CO and NO_x emissions will be controlled voluntarily by existing RTOs and scrubbers, respectively.

Tanks 40-11 and 49-1 replace the former tanks designated by the same identification numbers and permitted in OP 79-04-90-0382.

This modification does not qualify as an Exemption Qualification (1265) because this modification will cause an increase in actual emissions in the tanks due to the change in the tank sizes and method of operations.

Stack Summary

Stack ID	Operation	Height (feet)	Diameter (feet)	Flow Rate (acfm)	Temperature (°F)
T27-STK RTO 1	distillation, etc.	125	9	98,000	170
T27-STK RTO 2	distillation, etc.	125	9	98,000	125

Recommendation

The staff recommends to the Commissioner that the construction and operation be approved. This recommendation is based on the following facts and conditions:

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

A complete application for the purposes of this review was received on November 24, 1997.

Emissions Calculations

See Emissions Calculation Section (Appendix A) for detailed calculations.

Total Potential and Allowable Emissions

Indiana Permit Allowable Emissions Definition (after compliance with applicable rules, based on 8,760 hours of operation per year at rated capacity):

Pollutant	Allowable Emissions (tons/year)	Potential Emissions (tons/year)
Particulate Matter (PM)	0.0	0.0
Particulate Matter (PM10)	0.0	0.0
Sulfur Dioxide (SO ₂)	30.30	30.30
Volatile Organic Compounds (VOC)	3.34	21.78
Carbon Monoxide (CO)	19.78	19.78
Nitrogen Oxides (NO _x)	1.7	1.7
Single Hazardous Air Pollutant (HAP)	10.29	10.29
Combination of HAPs	16.28	16.28

- (a) Allowable emissions, determined from the applicability of rule 326 IAC 8-5-3, are 3.34 tons/yr (2.14 tons/yr from the stacks and 1.2 tons/yr from fugitive emissions). See Appendix A for worst case discussion.
- (b) The allowable emissions based on the rules cited are less than the potential emissions, therefore, the allowable emissions are used for the permitting determination.
- (c) Allowable emissions (as defined in the Indiana Rule) of SO₂ is greater than 25 tons per year. Therefore, pursuant to 326 IAC 2-1, Sections 1 and 3, a construction permit is required.
- (d) Allowable emissions (as defined in the Indiana Rule) of a single hazardous air pollutant (HAP) are greater than 10 tons per year and/or the allowable emissions of any combination of the HAPs are greater than 25 tons per year. Therefore, pursuant to 326 IAC 2-1, a construction permit is required.

County Attainment Status

- (a) Volatile organic compounds (VOC) are precursors for the formation of ozone. Therefore, VOC emissions are considered when evaluating the rule applicability relating to the ozone standards. Tippecanoe County has been designated as attainment or unclassifiable for ozone. Therefore, VOC emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2 and 40 CFR 52.21.
- (b) Tippecanoe County has been classified as attainment or unclassifiable for SO₂, CO, PM, and NO_x. Therefore, these emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2 and 40 CFR 52.21.

Source Status

Existing Source PSD, Part 70 or FESOP Definition (emissions after controls, based on 8,760 hours of operation per year at rated capacity and/ or as otherwise limited):

Pollutant	Emissions (ton/yr)
PM	682
PM10	682
SO ₂	5.626
VOC	5,351
CO	363
NO _x	2,834

- (a) This existing source is a major stationary source because it is in one of the 28 listed source categories and at least one regulated pollutant is emitted at a rate of 100 tons per year or more.
- (b) These emissions were based on the AIRS Facility Quick Look Report, dated July 24, 1997.

Eli Lilly and Company requested a process limitation of 100 lots per year on all process emitting SO₂, NO_x, and CO. This limitation does not requires reporting because this limitation is the worst case scenario throughput for processes emitting SO₂, NO_x, and CO.

Proposed Modification

PTE from the proposed modification (based on 8,760 hours of operation per year at rated capacity including enforceable emission control and production limit, where applicable):

Pollutant	PM (ton/yr)	PM10 (ton/yr)	SO ₂ (ton/yr)	VOC (ton/yr)	CO (ton/yr)	NO _x (ton/yr)
Proposed Modification	0.0	0.0	1.52	3.34	19.78	1.7
Contemporaneous Increases	0.0	0.0	0.0	0.0	0.0	0.0
Contemporaneous Decreases	0.0	0.0	0.0	0.0	0.0	0.0
Net Emissions	0.0	0.0	1.52	3.34	19.78	1.7
PSD or Offset Significant Level	25	15	40	40	100	40

- (a) This modification to an existing major stationary source is not major because the emissions increase is less than the PSD significant levels. Therefore, pursuant to 326 IAC 2-2, and 40 CFR 52.21, the PSD requirements do not apply.

Part 70 Permit Determination

326 IAC 2-7 (Part 70 Permit Program)

This existing source has submitted their Part 70 (T-157-6879-00006) application on October 10, 1996. The equipment being reviewed under this permit shall be incorporated in the submitted Part 70 application.

Federal Rule Applicability

40 CFR Part 60, Subpart Kb

The tanks are not subject to New Source Performance Standard, 326 IAC 12, (40 CFR Part 60.110b, Subpart Kb - Standards of Performance for Volatile Organic Liquid Storage Vessels), because these tanks are not used for VOC storage purposes.

40 CFR Part 60, Subpart VV

The tanks are not subject to New Source Performance Standard, 326 IAC 12, (40 CFR Part 60.480, Subpart VV - Standards of Performance for Equipment Leaks of VOC in the Synthetic Organic Chemical Manufacturing Industry (SOCMI)), because these tanks have a design capacity less than 1000 Mg/year.

40 CFR Part 60, Subpart III

The tanks are not subject to New Source Performance Standard, 326 IAC 12, (40 CFR Part 60.610, Subpart III, Standards of Performance for Volatile Organic Compounds (VOC) Emissions from Synthetic Organic Chemical Manufacturing Industry (SOCMI) Air Oxidation Unit Processes), because these tanks are not air oxidation units.

40 CFR Part 60, Subpart NNN

The tanks are not subject to New Source Performance Standard, 326 IAC 12, (40 CFR Part 60.660, Subpart NNN, Standards of Performance for Volatile Organic Compounds (VOC) Emissions from Synthetic Organic Chemical Manufacturing Industry (SOCMI) Distillation Operations), because these tanks are operated as batch reactors.

40 CFR Part 60, Subpart RRR

The tanks are not subject to New Source Performance Standard, 326 IAC 12, (40 CFR Part 60.700, Subpart RRR, Standards of Performance for Volatile Organic Compounds (VOC) Emissions from Synthetic Organic Chemical Manufacturing Industry (SOCMI) Reactor Processes), because these tanks are operated as batch reactors.

There are no other New Source Performance Standards (326 IAC 12) applicable to these tanks.

40 CFR Part 61

The tanks are not subject to Emissions Standards for Hazardous Air Pollutants, 326 IAC 14 and 40 CFR Part 61, because no hazardous air pollutants covered under these rules are emitted from the tanks.

40 CFR Part 63, Subpart H and I

The tanks are subject to 40 CFR 63.190(b)(5) Subpart H and I when Methylene Chloride is used in them for pharmaceutical synthesis operations. Eli Lilly will comply with these requirements, with the implementation of Eli Lilly's LDAR program, when Methylene Chloride is used in the tanks.

State Rule Applicability

326 IAC 2-6 (Emission Reporting):

This facility is subject to 326 IAC 2-6 (Emission Reporting), because the source has the potential to emit VOC, NO_x, CO, PM, or SO₂ into the ambient air at levels equal to or greater than 100 tons/yr (attainment counties). Pursuant to this rule, the owner/operator of this facility must annually submit an emission statement of the facility. The annual statement must be received by July 1 of each year and must contain the minimum requirements as specified in 326 IAC 2-6-4.

326 IAC 2-1-3.4 (New Source Toxics Control):

326 IAC 2-1-3.4 (New Source Toxics Control) does not apply to the tanks because the tanks are specifically regulated by 40 CFR Part 63 Subpart H and I (NESHAP).

326 IAC 7 (Sulfur Dioxide Emission Limitations):

This rule does not apply because the tanks are not fuel combustion facilities.

326 IAC 8-5-3 (Synthesized Pharmaceutical Manufacturing Operations):

The tanks are subject to 326 IAC 8-5-3 (b)(1), (5), and (6) because they have potential uncontrolled VOC emissions greater than 15 lb/day and are used in pharmaceutical manufacturing by chemical synthesis. The approximate control efficiency required by 326 IAC 8-5-3 (b)(1) is around 90%. VOC emissions can be controlled by using either the condensers in series with the RTO, or the RTO alone to meet the requirements of 326 IAC 8-5-3. Eli Lilly will typically use the existing RTO to control point source VOC emissions from the tank. The RTO, which has been demonstrated to achieve VOC removal efficiency in excess of 95%, will meet and exceed the requirements of 326 IAC 8-5-3 (b)(1). If the RTO cannot be used due to safety issues, an alternative control device may be used as long as the conditions of 326 IAC 8-5-3 (b)(1) are met. An analysis to demonstrate the alternative controls are acceptable controls, will be done before such alternative controls are used. In the event that the RTO is unavailable, Eli Lilly would like to continue manufacturing operations in the process tanks using other existing equipment that complies with 326 IAC 8-5-3 (b)(1).

The process tanks are equipped with tight fitting covers. As indicated by the applicant, the cover is closed at all times unless the production, sampling, inspection, or maintenance activities require access to the tank. Hence, it meets 326 IAC 8-5-3 (b)(5).

Building T-27 standard operating procedures, as indicated the applicant, is to repair all the visible equipment leaks as soon as possible. Under normal operating conditions, Eli Lilly repairs all the visible liquid leaks containing a VOC as soon as the equipment is off line long enough to complete the repair. During the operation, process operators inspect tanks and equipment (valves, flanges, etc.) for visible indications of leaks. Hence, this meets 326 IAC 8-5-3 (b)(6).

Performance Testing for the existing RTOs can be submitted by the performance testing done for CP 157-2593.

326 IAC 8-1-6 (BACT):

The requirement to reduce VOC emissions using Best Available Control Technology (BACT) does not apply to the tanks because the tanks are subject to 326 IAC 8-5-3.

No other 326 IAC 8 rules apply.

Air Toxic Emissions

Indiana presently requests applicants to provide information on emissions of the 187 hazardous air pollutants set out in the Clean Air Act Amendments of 1990. These pollutants are either

carcinogenic or otherwise considered toxic and are commonly used by industries. They are listed as air toxics on the Office of Air Management (OAM) Construction Permit Application Form Y.

- (a) This proposed modification will emit levels of air toxics greater than those that constitute major source applicability according to Section 112 of the Clean Air Act. The concentrations of these air toxics were modeled and found to be (in worst case possible) as follows:

Air Toxics and Modeled Concentrations

Pollutant	Emission Rate (lb/hr); based on allowable emission rates	Emission Rate @ 8760 hr/yr (tons/yr); based on allowable emission rates	Modeled Concentration (micrograms/m ³); based on allowable emission rates	OSHA PEL (micrograms/m ³); based on allowable emission rates	% of OSHA PEL ; based on allowable emission rates
Acetonitrile	0.24	1.07	4.3	70,000	0.01%
Carbon disulfide	0.24	1.07	4.3	20,000	0.02%
Chlorobenzene	0.24	1.07	4.3	350,000	0.00%
Dimethylformamide	0.24	1.07	4.3	30,000	0.01%
Ethylene dichloride	0.24	1.07	4.3	200,000	0.00%
Hexane	0.24	1.07	4.3	1,800,000	0.00%
Hydrochloric acid	2.349	10.29	41	7,500	0.32%
Methanol	0.24	1.07	4.3	260,000	0.06%
Methyl ethyl ketone	0.24	1.07	4.3	590,000	0.00%
Methyl isobutyl ketone	0.24	1.07	4.3	410,000	0.00%
Methyl tert-butyl ether	2.349	10.29	41	N/A	-----
Methylene chloride	2.349	10.29	41	87,000	0.05%
Toluene	0.24	1.07	4.3	751,837	0.00%
Xylene	0.24	1.07	4.3	435,000	0.00%
Glycol Ethers	0.24	1.07	4.3	N/A	-----

Methodology:

Rate in tons/yr = (rate in lbs/hr) * (hrs/yr of operation) * (1 ton/ 2000 lbs) The worst case assumption, per the applicant, is that all VOC emitted is a single organic HAP, with an average stack flow rate and temperature.

The concentrations of these air toxics were compared to the Permissible Exposure Limits (PEL) developed by the Occupational Safety and Health Administration (OSHA). The Office of Air Management (OAM) does not have at this time any specific statutory or regulatory authority over these substances.

- (b) Since it is difficult to predict the mix of compounds that will be used in tanks 40-11 and 49-1, it is assumed, per the applicant, that any one of the air toxics marked on the Form Y could be emitted as the only VOC during the entire year. This is the worst case scenario and qualifies as a major source for air toxics. The maximum emission rate (2.349 lb/hr) was calculated using the total annual point source VOC potential emission rate (10.29 tpy = 20,580 lb/yr) divided by the hours in a year (8760 hrs/ 1 yr). A similar approach was used with the inorganic air toxic Hydrochloric acid (HCL) emissions. HCL emissions (6 tons/yr) divided by the hours in a year (8760 hrs/ 1 yr) yields an emission rate of 1.37 lb/hr. The foregoing modeling calculations were based on these maximum hourly emissions of the respective air toxics.

Conclusion

The construction of this process vessels will be subject to the conditions of the attached proposed **Construction Permit No. CP-157-9245-00006**.

APPENDIX A: EMISSION CALCULATIONS

Introduction

Eli Lilly and Company has submitted an application for the replacement of tanks 40-11 and 49-1

in building T27, at Tippecanoe Laboratories located in Shadeland, Indiana. Tank volumes are not exact, and may be slightly larger due to the head shape of the tanks. The tanks are jacketed to provide heating and cooling and are equipped with agitators for mixing. It is also equipped with various ports and nozzles for charging solids, liquids, and gases into and out of the tank; sample taking; instrumentation ports; exhaust vent lines; emergency pressure relief; and hanging baffles to retard swirling of liquid contents during agitation. These tanks have sealable man ways to allow a person to enter the tanks for inspection or bulk material charging. They can be connected to other tanks or process equipment as needed.

The volatile organic compounds (VOC) from tanks 40-11 and 49-1 will be controlled by existing RTOs or existing condensers. The point source emissions from the tanks may vent directly to the RTOs, or they may first vent to scrubbers, process control condensers, vacuum sources, or through other process tanks before going to the RTOs. If venting the tanks to the RTOs would cause safety concern, the tanks may vent to an alternative air pollution control device. The condenser is used in the emission calculations because it provides the level of emission control that would be required to comply with 326 IAC 8-5-3. The control efficiency of the condenser required by this rule is approximately 90%. The actual control device normally used on the tanks will either be existing condensers in series with the existing RTOs, or the RTOs alone. The RTOs alone are designed to achieve in excess of 95% VOC reduction and therefore meets and exceeds the requirements of 326 IAC 8-5-3. Lilly would like to maintain the flexibility to use condensers or equivalent controls during RTO malfunctions, provided the condensers or equivalent controls can meet the requirements of 326 IAC 8-5-3.

The sulfur dioxide emissions from the tanks will be controlled by caustic scrubbers. Carbon Monoxide emissions from the tanks will voluntarily be controlled by the RTOs.

Process Description and Emission Calculations

The process tanks can be used in a variety of operations involved in pharmaceutical manufacturing. These operations are mainly batch in nature and include, but are not limited to: heating, cooling, distilling (atmospheric and vacuum), extracting, crystallizing, chemical synthesis, cryogenic service, and associated operations. The process used to model the emissions from tanks 40-11 and 49-1, is a worst case operating scenario designed to give maximum emissions estimates for any process that may be ran on these tanks.

Emission calculations were submitted by the applicant (Attachment A). OAM has reviewed and verified such calculations.

Emission calculations for VOC point sources from the tanks were performed by using the equations found in the EPA Guideline for Control of Volatile Organic Emissions from the Manufacture of Synthesized Pharmaceutical Products, EPA - 450/2 - 78 - 029. The various assumptions used in calculating emissions from different process activities are the same assumption that were used in previous construction permits for this source, including the latest permit, CP-157-7955 issued on May 20, 1997 as well as CP-157-3526, CP-157-4148, CP-157-4347 and CP-157-5120. To estimate the maximum potential uncontrolled and allowable VOC emissions for the tanks, acetone was used and an operating schedule of 8760 hrs/yr was assumed to get a worst case potential emissions scenario. Although acetone is not a regulated VOC, Eli Lilly and Company has opted its emissions based on acetone, which has the highest representative volatility. Since solvents with vapor pressures as high as that of acetone are not always used in the processes, the assumption used in the calculations will generate a worst case for the potential VOC emissions.

The potential uncontrolled VOC fugitive emissions were estimated by the applicant, by

multiplying the SOCMI factors for fugitive emissions by the number of each type of source. The fugitive source count for the tanks does not include any existing piping or fugitive sources that are not associated with the tanks. The duration of exposure is assumed to be 24 hours per day, 7 days per week, and 52 weeks per year.

The submitted calculations were based on 2000 gallon tanks and not 500 gallon tanks. The method and application of such calculations are the same, except for a substitution of 500 gallons in place of 2000 gallons

ATTACHMENT A:
EMISSION CALCULATIONS

Indiana Department of Environmental Management Office of Air Management

Addendum to the Technical Support Document for New Construction and Operation

Source Name: Eli Lilly and Company
Source Location: 2010 Lilly Road, Shadeland, IN. 47905
County: Tippecanoe
Construction Permit No.: CP-157-9245-00006
SIC Code: 2834 & 2879
Permit Reviewer: Nysa L. James

On January 30, 1998, the Office of Air Management (OAM) had a notice published in the Journal & Courier, Lafayette, Indiana, stating that Eli Lilly and Company had applied for a construction permit to construct and operate two (2) general process tanks with control. The notice also stated that OAM proposed to issue a permit for this installation and provided information on how the public could review the proposed permit and other documentation. Finally, the notice informed interested parties that there was a period of thirty (30) days to provide comments on whether or not this permit should be issued as proposed.

On February 27, 1998, Eli Lilly and Company submitted comments on the proposed construction permit. The summary of the comments and corresponding responses is as follows (changes are crossed out and additions are bolded for emphasis):

- Comment 1: The Notice of 30-day period for public comment, and items (a) and (b) of the authorization to construct, do not mention NO_x as one of the pollutants that the tanks have the potential to emit. As mentioned in the construction application, the potential NO_x emissions for each tank are 0.85 tons per year and these emissions will be controlled voluntarily with scrubbers.
- Response 1: OAM does realize that NO_x is released during the tanks processes. At the time of public notice, OAM only listed the air pollutant with a significant amount released into the atmosphere. The emissions of NO_x is explained in detail within the permit and technical support document.
- Comment 2: Affected Permit Section: The authorization to construct in page 1 of 10 of the proposed CP 157-9245. Also, both texts should be corrected to reflect that carbon monoxide emissions will be controlled voluntarily only by the existing RTOs (not RTOs or condensers).
- (1) In items (a) and (b) of the authorization to construct, OAM describes the volumetric capacity of the process tanks. The word "nominal" should be added before the word "capacity" to reflect that the amounts are approximate and not exact capacities.
 - (2) In items (a) and (b) of the authorization to construct, there are descriptions of the processing activities in the tanks that Lilly believes are not necessary. Also, the maximum raw material throughput included in the description is actually the average solvent charge rate for a 2,000 gallon tank used in the permit application as worst case value. Since these tanks operate in a batch mode (not continuous) the description of raw material throughput may be misleading and confusing. Lilly proposes that this language be deleted from the permit.

- (3) The sentence following item (b) of the authorization to construct states that the tank replace the former tanks in OP 79-04-90-0382. Because this operational permit contained several tanks, Lilly would like to clarify that the tanks will replace the old tanks designated with the same identification numbers as the new ones.

Proposed New Permit Language

- (a) One (1) **nominal** 500 gallon general process tank, designated as tank 40-11, located in an existing building designated as T27, ~~which will be used primarily, but not exclusively, for charging operations, with a maximum raw material throughput of 60 gallons per minute,~~ and controlled by ~~an~~ existing RTOs or condenser for VOC, ~~and CO emissions,~~ and an existing scrubber for SO2 emissions. **CO and NOx emissions will be controlled voluntarily by existing RTOs and scrubbers, respectively.**
- (b) One (1) **nominal** 500 gallon general process tank, designated as tank 49-1 located in an existing building designated as T27, ~~with a maximum raw material throughput of 60 gallons per minute,~~ and controlled by ~~an~~ existing RTOs or condenser for VOC, ~~and CO emissions,~~ and an existing scrubber for SO2 emissions. **CO and NOx emissions will be controlled voluntarily by existing RTOs and scrubbers, respectively.**

Tanks 40-11 and 49-1 replace the former tanks **designated by the same identification numbers and** permitted in OP 79-04-90-0382.

Response 2: OAM has changed accordingly in both the construction permit and the technical support document.

Comment 3: Affected Permit Section: Construction Condition 1 in page 2 of 10 and Operation Condition 1 in page 3 of 10 of the proposed CP 157-9245.

- (a) Lilly, respectfully, requests IDEM delete the first sentence of Construction and Operation Condition 1. This sentence, which incorporates by reference the information in Lilly's construction permit application into the permit, creates an obligation where the specific requirements of the Permittee are difficult to ascertain. It is not clear whether this provision renders all the statements made in the application as compliance obligations, or whether this provision creates any additional requirements on the Permittee. A permit should specifically identify all the compliance obligations on a source. If there are specific statements and information in the application that IDEM believes ought to be compliance obligations, then the permit should include specific conditions to address the information.
- (b) Moreover, including a blanket incorporation by reference statement in the permit is inconsistent with Title V permitting (The terms of this permit will eventually need to be incorporated into the Title V permit IDEM issues for Tippecanoe Laboratories). 326 IAC 2-7-5(1)(B) discourages blanket incorporation by reference, and instead requires IDEM to include specific permit conditions to incorporate portions of a permit application.
- (c) In addition, Lilly requests IDEM delete the second sentence of Construction

Condition 1 which requires IDEM approval prior to any proposed change in construction that may affect allowable emissions. This sentence is not necessary. Office of Air Management approval should be required only for changes that will increase allowable emissions, as required by 326 IAC 2-1-1.

Response 3: The data and information supplied with the application are part of this permit. The permit decision is based on the data and information provided in the application. This condition will not be deleted.

The second sentence has been amended to the following:

1. That the data and information supplied with the application shall be considered part of this permit. Prior to any proposed change in construction which may **affect increase the** allowable emissions, the change must be approved by the Office of Air Management (OAM).

Comment 4: Affected Permit Section: Construction Condition 6(e) in page 3 of 10 of proposed CP 157-9245.

Construction Condition 6(e) appears to require an update to the Tippecanoe Labs' Title V Application prior to operation of the new tanks. Also, it is not clear from this proposed language whether IDEM expects Lilly to revise the Title V application or if IDEM will automatically incorporate this new permit into the Title V application. Since Lilly understands that IDEM intends to automatically incorporate this new permit into the Title V Application, Lilly proposes that construction Condition 6(e) be deleted because it is not necessary. If IDEM's intention is that Lilly submit an amendment to its Title V application, Lilly proposes that this requirement be incorporated as an Operation Condition instead of a Construction Condition, and that if a due date must be specified for the application update, it be at least 90 days after commencement of operation of the tanks.

Response 4: This information is necessary in the permit to show that Eli Lilly and Company is in compliance with the Title V application submittal process. OAM will automatically incorporate this permit into the Title V that has been submitted by the source. Eli Lilly does not need to re-submit new Title V application forms for the units under this construction permit.

Comment 5: Affected Permit Section: Operation Condition 7 in page 4 of 10 of proposed CP 157-9245

Operation Condition 7 requires that a compliance stack test shall be performed for the condensers whenever they are being utilized to control VOC emissions. First, there is no reason to perform the stack test to determine compliance with 326 IAC 8-5-3, because that rule specifies outlet gas temperature which can be readily determined by parametric monitoring.

Moreover, there is no other VOC restriction to determine compliance with; indeed, this tank replacement does not even have an allowable VOC emission rate that requires a permit or registration. The pollutant that triggers the construction permit applicability is SO₂ and not VOCs. Therefore, the condenser stack test is not required by any rule, nor justified by any regulatory provisions.

Lilly respectfully requests that IDEM deletes the requirement of Operation Condition 7 to

perform stack test to confirm condenser performance.

Response 5: Proposed Operation Condition No. 7 has been deleted. The conditions following this condition have been renumbered.

Comment 6: Affected Permit Section: Operation Condition 8(b) (now renumbered as 7(b)) in page 5 of 10 of the proposed CP 157-9245.

Operation condition 8(b) states that the minimum operating temperature in the condensers is to be determined by a performance test to maintain at least 90% destruction efficiency. As explained in comment #5, the requirement for a stack test should be deleted. Therefore, the text of Operation Condition 8 should be modified to reflect this change.

Specifically, this new construction permit should incorporate the provision approved by IDEM in CP 157-7955, Section 7(b), that states that other IDEM approved parameters can be used to demonstrate compliance with 326 IAC 8-5-3. IDEM should include as parametric monitoring options any other alternate surrogate parameters approved by IDEM. On January 29, 1993, IDEM approved four alternate methods of condenser monitoring temperature to verify compliance with 326 IAC 8-5-3 (see copy in Appendix #1). As in previous permits, Lilly would like to have available these four options to obtain maximum operational flexibility. The options are the following as described in Lilly's December 22, 1992, letter:

- Option 1: Condenser Retrofitted with Temperature Element Inside Shell
- Option 2: Condenser with jacketed exhaust vent line
- Option 3: Condenser with extended lead temperature probe
- Option 4: Monitor condenser coolant return temperature and flow

As a summary, Lilly recommends that IDEM uses the same language in condition 7(b) of CP 157-7955 to modify condition 8(b) in the proposed permit CP-157-9245.

Operation Condition 7(b) of CP 157-7955 (page 4 of 9) is stated as follows:

“when the VOC emissions from these two (2) vessels above are controlled by the condensers, monitoring of the outlet gas temperature or other IDEM approved parameter shall be sufficient to document compliance with 326 IAC 8-5-3”

Proposed New Permit Language

Volatile Organic Compound (VOC) limitations

8. That the VOC emissions from

(b) When the VOC emissions from these two (2) tanks above are controlled by the condensers, ~~the condensers shall maintain a minimum operating temperature determined by a performance test to maintain at least 90% destruction, which yields an allowable VOC emission of 3.34 tons per year, of the volatile organic compounds subject to 326 IAC 8-5-3. The outlet gas temperature range for the condensers shall be determined by a performance test specified in Operating Condition # 7.~~ **monitoring of the outlet gas temperature or other IDEM approved parameter shall be sufficient to document compliance with 326 IAC 8-5-3.**

Response 6: Proposed Operation Condition 8(b), now renumbered as 7(b), has been amended to the following:

Volatile Organic Compound (VOC) limitations

- (b) When the VOC emissions from these two (2) tanks above are controlled by the condensers, the condensers shall ~~maintain a minimum operating temperature determined by a performance test to maintain at least 90% destruction, which yields an allowable VOC emission of 3.34 tons per year, of the volatile organic compounds subject to 326 IAC 8-5-3. The outlet gas temperature range for the condensers shall be determined by a performance test specified in Operating Condition # 7, not exceed the outlet gas temperatures, determined by 326 IAC 8-5-3(b)(1)(A), listed below:~~
1. **minus twenty-five degrees Celsius (-25°C) when condensing VOC of vapor pressure greater than forty (40) kilo Pascal (five and eight-tenths (5.8) pounds per square inch);**
 2. **minus fifteen degrees Celsius (-15°C) when condensing VOC of vapor pressure greater than twenty (20) kilo Pascal (two and nine-tenths (2.9) pounds per square inch);**
 3. **zero degrees Celsius (0°C) when condensing VOC of vapor pressure greater than ten (10) kilo Pascal (one and five-tenths (1.5) pounds per square inch);**
 4. **ten degrees Celsius (10°C) when condensing VOC of vapor pressure greater than seven (7) kilo Pascal (one (1.0) pounds per square inch);**
 2. **twenty-five degrees Celsius (25°C) when condensing VOC of vapor pressure greater than three and five-tenths (3.5) kilo Pascal (five-tenths (0.5) pounds per square inch).**

Monitoring of the outlet gas temperature or other IDEM approved parameter shall be sufficient to document compliance with 326 IAC 8-5-3.

Comment 7: Affected permit section: Operation Condition 8(c) (now renumbered as 7(c)) in page 5 of 10 of proposed CP 157-9245.

Lilly would like to request two corrections to operation condition 8(c). First, the second sentence that talks about the outlet gas temperature should be deleted because this parameter is not relevant to the RTO's.

Second, Lilly suggests that the last sentence of the condition be changed to state clearly that the recent DRE test performed on the RTO's under permit CP 157-2593 satisfies the requirements in operation condition 8(c).

New Permit Language

Volatile Organic Compound (VOC) limitations

8. That the VOC emissions from

- (c) When the VOC emissions from these two (2) tanks are controlled by the RTOs, the RTO combustion chamber shall maintain a minimum operating temperature determined by a performance test to maintain at least 90% destruction, which yields an allowable VOC emission of 3.34 tons per year, of the volatile organic compounds subject to 326 IAC 8-5-3. ~~The outlet gas temperature range for the existing RTO shall be in the range of 126-131 degrees Fahrenheit.~~ The performance test to verify the VOC control efficiency of

the RTOs ~~shall be substituted for the performance test performed in under~~ Construction Permit CP 157-2593: **shall satisfy this condition.**

Response 7: The minimum operating temperature is required to show that the control device is destructing at least 90% of the VOC emissions. The permit language has been amended as follows, 8(c) is now renumbered as 7(c):

Volatle Organic Compound (VOC) limitations

7. That the VOC emissions from

(c) When the VOC emissions from these two (2) tanks are controlled by the existing RTOs, the existing RTO combustion chamber shall maintain a minimum operating temperature determined by a performance test to maintain at least 90% destruction, which yields an allowable VOC emission of 3.34 tons per year, of the volatile organic compounds subject to 326 IAC 8-5-3. ~~The outlet gas temperature range for the RTO shall be in the range of 126-131 degrees Fahrenheit.~~ **The minimum operating temperature for the existing RTOs shall be 1500 degrees Fahrenheit.** The performance test to verify the VOC control efficiency **and minimum operating temperature** of the existing RTOs ~~shall be substituted for the performance test performed in under~~ Construction Permit CP 157-2593 **shall satisfy this condition.**

Comment 8: Affected Permit Section: Operation Condition 8(d) in page 5 of 10 of the proposed CP 157-9245

Lilly, respectfully, requests to IDEM that operation condition 8(d) be deleted because it is not necessary under the requirements of 326 IAC 8-5-3 or the PSD program. Operation condition 10 already covers the requirements applicable to the control of fugitive emissions from these tanks. Therefore there is no reason to impose the additional burden of a formal LDAR program for these tanks.

Response 8: Proposed Operation Condition 8(d) has been deleted. The conditions following this have been renumbered.

Comment 9: Affected Permit Section: Operation Condition 9(a) and (b) (now renumbered as 8 (a) and (b)) in page 6 of 10 of the proposed CP 157-9245

Operation condition 9(a) should be modified to eliminate the temperature range because it is not applicable to the RTOs, and to substitute "or" instead of "and " at the end of the sentence because these are alternative requirements. Also, in condition 9(b) the phrase "...from the two(2) tanks..." should read "...from either of the two tanks..." because it is possible that the two tanks may not run simultaneously.

Proposed New Permit Language

Record Keeping of Operating Parameters

That pursuant to 326 IAC 2-1-3(i)(8) and 326 IAC 8-5-3 Eli Lilly and Company shall...

- (a) The operating temperature ~~range, between 126-131 degrees Fahrenheit,~~ of the RTO; ~~and~~ or
- (b) The outlet gas temperature of the condenser or other OAM approved

parameters, when the VOC emissions from either of the two (2) tanks are controlled by the condensers.

Response 9: The minimum operating temperature is required by OAM because this shows that the control device is operating, at a tested temperature, to at least 90% of the VOC emissions. The Record Keeping Condition (Operating Condition No. 8) shall be changed accordingly:

- (a) The **minimum** operating temperature ~~range, between 126-131 degrees Fahrenheit,~~ of the **existing** RTOs; **and or**
- (b) The outlet gas temperature of the condenser or other OAM approved parameters, when the VOC emissions from **either of** the two (2) tanks are controlled by the condensers.

Comment 10: Affected Permit Section: second paragraph of Operation Condition 10 (now renumbered as 9) in page 6 of 10 of the proposed CP 157-9245

Lilly requests that the second paragraph of condition 10 be deleted since the HON rule is self-implementing. The Lilly Leak Detection and Repair (LDAR) procedure is a distinct entity from the HON. Imposition of the Lilly LDAR procedure is not required to comply with the HON. If this paragraph is retained at all, it should impose only the HON as at 40 CFR Part 63, Subparts H and I, and not refer to the Lilly LDAR program.

Response 10: Proposed Operation Condition 10, now renumbered as 9, has been changed accordingly to the following:

That for tanks 40-11 and 49-1, **when using Methylene Chloride**, the Permittee shall comply with National Emission Standards for Organic Hazardous Air Pollutants for Equipment Leaks, 40 CFR Part 63, Subpart H, as required by the National Emission Standards for Organic Hazardous Air Pollutants for Certain Processes subject to the Negotiated Regulation for Equipment Leaks, 40 CFR Part 60, Subpart I.

~~Lilly requests that the second paragraph of condition 10 be deleted since the HON rule is self-implementing. The Lilly Leak Detection and Repair (LDAR) procedure is a distinct entity from the HON. Imposition of the Lilly LDAR procedure is not required to comply with the HON. If this paragraph is retained at all, it should impose only the HON as at 40 CFR Part 63, Subparts H and I, and not refer to the Lilly LDAR program.~~

Comment 11: Affected Permit Section: Operation Conditions 11 in page 6 of 10 of the proposed CP 157-9245

Lilly, respectfully, requests that the requirements for SO₂ controls in operation condition 11 be deleted. Lilly requested in the permit application that the potential emissions of SO₂ be restricted by limiting the number of lots emitting SO₂ to 100 lots per tank. If this limitation is incorporated in operation condition 12 in the new permit (see Comment #13), the potential SO₂ emissions for the tanks are less than PSD significant rates, and the restrictions to the SO₂ scrubbers are not necessary and should be eliminated.

Response 11: Proposed Operation Condition No. 11 (Scrubber Operating Condition) has been deleted. The conditions following this condition have been renumbered.

Comment 12: Affected Permit Section: Operation Condition 12 (now renumbered as 10) in page 7 of 10 of the proposed CP 157-9245.

Lilly believes that operation condition 12 is confusing and not clear. Since Lilly and IDEM settled this matter in 1997 after an administrative appeal, Lilly respectfully, requests that IDEM uses identical language to the final language for condition 10(a) in CP 157-7955 issued under amendment A 157-9063 (see attached copy in Appendix # 2).

Proposed New Permit Language

Limit on the ~~production of the compounds~~ process lots

~~The Permittee shall limit the production of the compounds currently made at the plant in the equipment covered by this permit. The Permittee shall re-evaluate its Potential To Emit (PTE) estimate of SO₂, CO, VOC and NO_x and obtain OAM approval before manufacturing any product not included in the PTE calculation demonstrated in the application. That the total number of lots for processes emitting SO₂, NO_x, and CO in tanks 40-11 and 49-1 shall be limited to 100 lots or equivalent lots per tank per year.~~

Response 12: Proposed Operation Condition No.12, now renumbered as 10, has been amended as follows:

Limit on the ~~production of the compounds~~ process lots:

~~The Permittee shall limit the production of the compounds currently made at the plant in the equipment covered by this permit. The Permittee shall re-evaluate its Potential To Emit (PTE) estimate of SO₂, CO and NO_x and obtain OAM approval before manufacturing any product not included in the PTE calculation demonstrated in the application.~~ **The total number of lots for processes emitting SO₂, NO_x and CO, in tanks 40-11 and 49-1, shall be limited to 100 lots or equivalent lots per year. This is based on the worst case scenario submitted by the source.**

Comment 13: Affected permit section: Operation Condition 14 (now renumbered as 12) in page 7 of 10 of Proposed Construction Permit CP 157-9245

The title of operation condition 14 should be Record Keeping Requirements instead of "Reporting" Requirements, so please modify the section accordingly

Proposed New Permit Language:

~~Reporting~~ Record Keeping Requirements

Response 13: Proposed Operation Condition No. 14, now renumbered as 12, has been changed accordingly.

Comment 14: Affected permit section: Operation Condition 16 (now renumbered as 14) in page 8 of 10 of the proposed CP 157-9245

Operation Condition 16 requires that Lilly prepares a Emergency Reduction Plan pursuant to 326 IAC 1-5-2. Lilly wants to clarify that recent revisions of the Emergency Reduction Plan for Tippecanoe Laboratories were submitted to IDEM for approval in October 1993 and in January 1997.

Therefore, Lilly requests that operation condition 16 be deleted.

Response 14: Proposed Operation Condition No. 16, now renumbered as 14, has been amended as follows:

Emergency Reduction Plans

~~Pursuant to 326 IAC 1-5-2 (Emergency Reduction Plans; Submission):~~

- ~~(a) The Permittee shall prepare written emergency reduction plans (ERPs) consistent with safe operating procedures.~~
- ~~(b) These ERPs shall be submitted for approval to:~~

~~Indiana Department of Environmental Management
Compliance Branch, Office of Air Management
100 North Senate Avenue, P.O. Box 6045
Indianapolis, Indiana 46206-6045~~

Eli Lilly and Company has submitted a revised emergency reduction plan to OAM in January 1997. This condition has been satisfied.

Comment 15: Affected Technical Support Document (TSD) section: Source Background and Description in page 1 of 10 of Proposed Construction Permit CP 157-9245

In the Source Background and Description section, letters (a) and (b) should be modified consistent to the change proposed in Comment # 1 to the authorization to construct.

Also, the last sentence of the Source Background and Description section mentions that HEA 1265 does not apply because these are not like-kind replacements. Lilly would like to clarify that the reason HEA 1265 does not apply is because this modification will cause an increase in actual emissions in the tanks due to the change in the tank sizes and method of operations.

Proposed New TSD Language:

This modification does not qualify as an Exemption Qualification (1265) because this modification will cause an increase in actual emissions in the tanks due to the change in the tank sizes and method of operations. ~~this is a non-like replacement of tanks and therefore does not qualify for a 1265~~

Response 15: Proposed Source Background Information, on page 1 of 10 of the Technical Support Document, has been changed accordingly.

Comment 16: Affected TSD section: 40 CFR part 63, Subpart H and I in the Federal Rule Applicability section of page 4 of 10, last paragraph.

Lilly is proposing the following clarification to the first sentence in the section:

Proposed New TSD Language:

40 CFR Part 63, Subpart H and I
The tanks are subject to 40 CFR 63.190(b)(5) Subpart H and I when Methylene Chloride is used in them for pharmaceutical synthesis operations. Eli Lilly...

Response 16: Proposed Section 40 CFR part 63, Subpart H and I in the Federal Rule Applicability section of page 4 of 10, last paragraph of the TSD has been changed accordingly.

Comment 17: Affected TSD Section: Air Toxic Emissions and Modeled Concentrations, Page 6 of 10 of Proposed Construction Permit CP 157-9245.

In the submitted permit application, potential air toxic emission rates were used to determine the hazardous air pollutant emission concentrations. Lilly believes that the allowable emission rates should be used instead. Lilly therefore requests that the air toxics and modeled concentrations be changed accordingly. The data obtained using potential emission rates should be replaced with data obtained using the allowable emission rates.

Response 17: OAM has changed accordingly.

Comment 18: Affected TSD section: State Rule Applicability (326 IAC 8-5-3), page 5 of 10 of Proposed Construction Permit CP 157-9245.

Lilly, respectfully, requests that the reference to acetone in the second sentence of the first paragraph be deleted since it is irrelevant for the purpose of the requirements for condensers outlet gas temperature in 326 IAC 8-5-3.

Also, the last sentence of the section talks about the performance test of the condensers. This requirement should be eliminated by the reasons mentioned in Comment # 5.

Response 18: The last paragraph under 326 IAC 8-5-3, page 5 of 10, has been deleted because OAM has determined that performance testing is not required for the condensers. Acetone found in the second sentence of the first paragraph under 326 IAC 8-5-3, page 5 of 10, has been deleted.