

STATE OF INDIANA
DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
PUBLIC NOTICE NO: 20260603– INP000739 – D
DATE OF NOTICE: June 3, 2026
DATE RESPONSE DUE: July 6, 2026

The Office of Water Quality proposes the following DRAFT IWP PERMIT:

MINOR – MODIFICATION:

Eli Lilly and Company - Lebanon, Permit No. INP000739, BOONE COUNTY, 1400 West 375 North, Lebanon, IN. The facility operates as a pharmaceutical manufacturer of bulk active ingredients and gene cell therapy products. The permittee requests a modification of their existing industrial wastewater pretreatment (IWP) permit to include updated discharge flows and effluent limitations due to the expansion of operations at the site. The facility discharges sanitary wastewater, non-process wastewater, and process wastewater to the City of Lebanon POTW. With the expansion, the facility proposes to have a new average daily discharge flow of about 0.6 MGD and a maximum discharge of 0.8 MGD to the City of Lebanon POTW.

The Eli Lilly and Company – Lebanon Campus will consist of two manufacturing operations, discussed herein as Lebanon Project 1 (LP1) and Lebanon Project 2 (LP2). Eli Lilly and Company requests that the IWP permit be modified to include updated discharge flows and effluent limitations due to the expansion of their Lebanon site (LP1X Expansion). This expansion includes the addition of the Small Molecule 2 Process and enlargement of the Peptide 2 Process.

Pharmaceutical manufacturing of bulk active ingredients occurs at LP1/LP1X. These bulk active pharmaceutical ingredients are manufactured by chemical synthesis and will be shipped off-site for formulation into final products for patient use. At LP2, gene cell therapy products are manufactured and finished into final products for patient use.

Manufacturing processes and support operations conducted on-site that produce wastewater include peptide synthesis and purification, small molecule synthesis and purification, solvent recovery, gene cell therapy production and finishing, and warehouse operations. The oligonucleotide facility mentioned in the 2024 permit was removed from the site. Other services and activities conducted on-site that generate wastewater include utilities (such as cooling systems, boilers, water softening, high purity water generation), laboratory services, administrative services with a cafeteria, and sanitary wastewater from occupied buildings. The plant normally operates 24 hours/day, 7 days/week.

The waste flows from chemical synthesis and mixing/compounding and formulation are subject to the Categorical Pretreatment Standards for New Source Pharmaceutical Manufacturing Point Source Category, Subpart C – Chemical Synthesis Products [40 CFR 439.37] and Subpart D – Mixing/Compounding and Formulation [40 CFR 439.47] operations. The standards are concentration-based (mg/l).

Permit Manager: Heidi Etter, 317/233-4903, hetter@idem.in.gov. Posted online at <https://www.in.gov/idem/public-notice/>.

PROCEDURES TO FILE A RESPONSE

You are hereby notified of the availability of a 30-day public comment period regarding the referenced draft permit, in accordance with 327 IAC 5-21-11. The application and draft permit documents are available for inspection at IDEM, Office of Water Quality, Indiana Government Center North – 12th Floor, 100 N. Senate Ave, Indianapolis, IN 46204 from 9:00 a.m. until 4:00 p.m., Monday thru Friday, (copies 10¢ per page). The Draft Permit is posted online on the above-referenced IDEM public notice web page. A courtesy copy has also been sent via email to the local County Health Department. Electronic copies of any supplemental documents (beyond what is posted with this notice on IDEM's public notice web pages) are also available by contacting the permit manager. Please tell others whom you think would be interested in this matter. For more information about public participation including your rights & responsibilities, please see <https://www.in.gov/idem/public-notices/>. You may want to consult our online Citizens' Guide to IDEM: <https://www.in.gov/idem/resources/citizens-guide-to-idem/>.

Comments: The proposed decision to issue a permit is tentative. Interested persons are invited to submit written comments on the draft permit. All comments must be delivered to IDEM or postmarked no later than the Response Due Date noted to be considered in the decision to issue a final permit. Deliver or mail all requests or comments to the attention of the Permit Manager at the following address:

Indiana Dept. of Environmental Management
Office of Water Quality, Industrial NPDES Permits Section
Attn: Ms. Heidi Etter, Permit Manager
100 N Senate Ave., IGCN 12th Floor
Indianapolis, IN 46204-2251

Alternatively, you may submit comments regarding the draft permit modification via email to Hetter@idem.IN.gov.

To Request a Public Hearing: Any person may request a public hearing. A written request must be submitted to the above address on or before the Response Due Date. The written request shall include: the name and address of the person making the request, the interest of the person making the request, persons represented by the person making the request, the reason for the request and the issues proposed for consideration at the hearing. The Department will determine whether to hold a public hearing based upon the comments and the rationale for the request. Public Notice of such a hearing will be posted on IDEM's web site and will be transmitted to those persons submitting comments and/or on the mailing list at least 30 days prior to the hearing.



INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT

100 N. Senate Avenue • Indianapolis, IN 46204
(800) 451-6027 • (317) 232-8603 • Fax (317) 233-6647 • www.idem.in.gov

Mike Braun
Governor

Clint Woods
Commissioner

June 3, 2026

VIA ELECTRONIC MAIL

Christopher R. Langan, Senior Vice President – Lebanon API Site Head
Eli Lilly and Company
Lilly Corporate Center
Indianapolis, IN 46285

Dear Christopher R. Langan:

Re: IWP Permit No. INP000739
Draft Permit Modification
Eli Lilly and Company – Lebanon
Lebanon, IN – Boone County

Your request for a permit modification has been reviewed and processed in accordance with rules adopted under 327 IAC 5. The enclosed Pages 1, 2, 4, 5, and 7 of 26 are intended to replace the corresponding pages of your existing IWP Permit No. INP000739. An accompanying Briefing Memo itemizes and explains the rationale for the revisions.

Pursuant to IC 13-15-5-1, IDEM will publish the draft permit document online at <https://www.in.gov/idem/public-notice/>. Additional information on public participation can be found in the "Citizens' Guide to IDEM", available at <https://www.in.gov/idem/resources/citizens-guide-to-idem/>. A 30-day comment period is available to solicit input from interested parties, including the public.

Please review this draft permit modification and associated documents carefully to become familiar with the proposed terms and conditions. Comments concerning the draft permit modification should be submitted in accordance with the procedure outlined in the enclosed public notice form. We suggest that you meet with us to discuss major concerns or objections you may have with the draft permit modification.

Questions concerning this draft permit modification may be addressed to Heidi Etter of my staff, at 317/233-4903 or by email at hetter@idem.in.gov.

Sincerely,

Richard Hamblin, Chief
Industrial NPDES Permits Section
Office of Water Quality

Enclosures

cc: Boone County Health Department
Matthew Gentry, Mayor, City of Lebanon
Ryan Ottinger, Operations Manager, Lebanon Utilities
Edward Stehno, HSE Advisor – Environmental, Eli Lilly and Company
Neil J. Parke, Senior Director – Engineering HSE, Eli Lilly and Company

Visit on.in.gov/survey or scan the QR code to provide feedback.

We appreciate your input!



STATE OF INDIANA

DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
AMENDED AUTHORIZATION TO DISCHARGE UNDER THE
INDUSTRIAL WASTEWATER PRETREATMENT PROGRAM

INDUSTRIAL WASTEWATER PRETREATMENT (IWP) PERMIT

In accordance with 327 IAC 5-21 and IDEM's permitting authority under IC 13-15, **Eli Lilly and Company – Lebanon** (hereinafter referred to as the permittee) is authorized to discharge, from the facility located at 1400 West 375 North, Lebanon, Indiana into the **City of Lebanon Publicly Owned Treatment Works (POTW)**, in accordance with the effluent limitations, monitoring requirements, and other conditions set forth in Parts I and II hereof.

The permit, as issued on **August 23, 2024**, is hereby amended, as contained herein. The amended provisions shall become effective _____. All terms and conditions of the permit not modified at this time remain in effect. Further, any existing condition or term affected by the amendments will remain in effect until the amended provisions become effective. This permit and the authorization to discharge, as amended, shall expire at midnight **October 31, 2029**.

NOTE: In order to receive authorization to discharge beyond the date of expiration, the permittee must submit a renewal IWP permit application to the Industrial NPDES Permit Section in the Office of Water Quality, no later than one hundred and eighty (180) days prior to the date this permit expires. Failure to do so will result in expiration of the authorization to discharge.

Signed on _____ for the Indiana Department of Environmental Management.

Jerry Dittmer, Chief
Permits Branch
Office of Water Quality

PART I

A. EFFLUENT LIMITATIONS AND MONITORING REQUIREMENTS

1. During the period beginning on the effective date of this permit and lasting until the discharge of any process wastewater [1], the permittee is authorized to discharge from Outfall 001 in accordance with the terms and conditions of this permit. The table below summarizes the permit limits at the designated sample site Outfall 001 [2][3]. This outfall is located at the point of discharge to the POTW and contains non-process and sanitary wastestreams. Such discharge shall be limited and monitored by the permittee as specified below:

Table 1

Parameter	Discharge Limitations		Monitoring Requirements		
	Daily Maximum	Monthly Average	Unit	Measurement Frequency	Sample Type [4]
Flow [5]	Report	Report	MGD	1 X Daily	24-Hr. Total
TSS [6]	Report	Report	mg/l	1 X Monthly	24-Hr. Comp.
CBOD ₅ [6]	Report	Report	mg/l	1 X Monthly	24-Hr. Comp.
Oil and Grease [6]	Report	Report	mg/l	1 X Monthly	Grab
Phosphorus [6]	Report	Report	mg/l	1 X Monthly	24-Hr. Comp.
Chloride	Report	Report	mg/l	1 X Monthly	24-Hr. Comp.
Copper [7]	0.2 [8]	Report	mg/l	1 X Monthly	24-Hr. Comp.

Table 2

Parameter	Quality or Concentration		Monitoring Requirements		
	Daily Minimum	Daily Maximum	Units	Measurement Frequency	Sample Type
pH [9]	6.0 [8]	9.0 [8]	s.u.	1 X Daily	Grab

- [1] The permittee must notify IDEM and the City of Lebanon at least 30 days prior to the discharge of process wastewater regulated under federal categorical standards under 40 CFR 439.
- [2] Outfall 001 shall be designated as the combined wastestreams at the point of discharge to the POTW.
- [3] The discharge shall not exceed the local limits in the Sewer Use Ordinance upon entering the POTW.
- [4] A "24-hour composite sample" means a sample consisting of at least 3 individual flow-proportional samples of wastewater, consisting of aliquots withdrawn throughout the 24-hour discharge period. The aliquots may be: (i) uniform aliquots withdrawn at uniform flow intervals; (ii) flow-proportional aliquots withdrawn at uniform time intervals; or (iii) for batch discharge, uniform aliquots

2. During the period beginning immediately upon commencement of discharge of any process wastewater [1], the permittee is authorized to discharge from Outfall 001 in accordance with the terms and conditions of this permit. The table below summarizes the permit limits at the designated sample site Outfall 001 [2][3]. This outfall is located at the point of discharge to the POTW and contains combined process, non-process, and sanitary wastestreams. Such discharge shall be limited and monitored by the permittee as specified below:

Table 1

Parameter	Discharge Limitations		Monitoring Requirements		
	Daily Maximum	Monthly Average	Unit	Measurement Frequency	Sample Type [4]
Flow [5]	Report	Report	MGD	1 X Daily	24-Hr. Total
Acetone	8.08 [6] Report	3.20 [6] Report	lbs/day mg/l	2 X Weekly	Grab [12]
n-Amyl acetate	8.08 [6] Report	3.20 [6] Report	lbs/day mg/l	2 X Weekly	Grab [12]
Ethyl acetate	8.08 [6] Report	3.20 [6] Report	lbs/day mg/l	2 X Weekly	Grab [12]
Isopropyl acetate	8.08 [6] Report	3.20 [6] Report	lbs/day mg/l	2 X Weekly	Grab [12]
Methylene chloride	1.17 [6] Report	0.27 [6] Report	lbs/day mg/l	2 X Weekly	Grab [12]
4-methyl-2-pentanone	7.80 [7] Report	3.09 [7] Report	lbs/day mg/l	2 X Weekly	Grab [12]
Isobutyraldehyde	7.80 [7] Report	3.09 [7] Report	lbs/day mg/l	2 X Weekly	Grab [12]
n-Butyl acetate	7.80 [7] Report	3.09 [7] Report	lbs/day mg/l	2 X Weekly	Grab [12]
Methyl formate	7.80 [7] Report	3.09 [7] Report	lbs/day mg/l	2 X Weekly	Grab [12]
Isopropyl ether	7.80 [7] Report	3.09 [7] Report	lbs/day mg/l	2 X Weekly	Grab [12]
Tetrahydrofuran	3.47 [7] Report	1.28 [7] Report	lbs/day mg/l	2 X Weekly	Grab [12]
Benzene	1.13 [7] Report	0.26 [7] Report	lbs/day mg/l	2 X Weekly	Grab [12]
Toluene	0.11 [7] Report	0.08 [7] Report	lbs/day mg/l	2 X Weekly	Grab [12]
Xylenes	1.13 [7] Report	0.26 [7] Report	lbs/day mg/l	2 X Weekly	Grab [12]
n-Heptane	1.13 [7] Report	0.26 [7] Report	lbs/day mg/l	2 X Weekly	Grab [12]
n-Hexane	1.13 [7] Report	0.26 [7] Report	lbs/day mg/l	2 X Weekly	Grab [12]
Chloroform	0.11 [7] Report	0.08 [7] Report	lbs/day mg/l	2 X Weekly	Grab [12]

Parameter	Daily Maximum	Monthly Average	Unit	Measurement Frequency	Sample Type [4]
1,2-dichloroethane	7.80 [7] Report	3.09 [7] Report	lbs/day mg/l	2 X Weekly	Grab [12]
Chlorobenzene	1.13 [7] Report	0.26 [7] Report	lbs/day mg/l	2 X Weekly	Grab [12]
o-Dichlorobenzene	7.80 [7] Report	3.09 [7] Report	lbs/day mg/l	2 X Weekly	Grab [12]
TSS [8]	Report	Report	mg/l	1 X Monthly	24-Hr. Comp.
CBOD ₅ [8]	Report	Report	mg/l	1 X Monthly	24-Hr. Comp.
Oil and Grease [8]	Report	Report	mg/l	1 X Monthly	Grab
Phosphorus [8]	Report	Report	mg/l	1 X Monthly	24-Hr. Comp.
Chloride	Report	Report	mg/l	1 X Monthly	24-Hr. Comp.

Table 2

Parameter	Quality or Concentration		Monitoring Requirements		
	Daily Minimum	Daily Maximum	Units	Measurement Frequency	Sample Type
pH [9]	6.0 [10]	9.0 [10]	s.u.	1 X Daily	Grab
Closed Cup Flashpoint	140.0° [10][11]	-----	°F	2 X Weekly	Grab

- [1] The permittee must notify IDEM and the City of Lebanon at least 30 days prior to the discharge of process wastewater regulated under federal categorical standards under 40 CFR 439.
- [2] Outfall 001 shall be designated as the combined wastestreams at the point of discharge to the POTW.
- [3] The discharge shall not exceed the local limits in the Sewer Use Ordinance upon entering the POTW.
- [4] A “24-hour composite sample” means a sample consisting of at least 3 individual flow-proportional samples of wastewater, consisting of aliquots withdrawn throughout the 24-hour discharge period. The aliquots may be: (i) uniform aliquots withdrawn at uniform flow intervals; (ii) flow-proportional aliquots withdrawn at uniform time intervals; or (iii) for batch discharge, uniform aliquots withdrawn from uniform batch volumes. A flow-proportioned composite sample may be obtained by:
- (1) recording the discharge flow rate at the time each individual sample is taken,
 - (2) adding together the discharge flow rates recorded from each individual sampling time to formulate the “total flow” value,
 - (3) the discharge flow rate of each individual sampling time is divided by the total flow value to determine its percentage of the total flow value,
 - (4) then multiply the volume of the total composite sample by each individual sample’s percentage to determine the volume of that individual sample which will be included in the total composite sample.

3. During the period beginning immediately upon commencement of discharge of any process wastewater [1], the permittee is authorized to discharge from Outfall 101 in accordance with the terms and conditions of this permit. The table below summarizes the permit limits at the designated sample site Outfall 101 [2]. This outfall is located after the centralized pH neutralization system. Such discharge shall be limited and monitored by the permittee as specified below:

Table 1

Parameter	Discharge Limitations		Monitoring Requirements		
	Daily Maximum	Monthly Average	Unit	Measurement Frequency	Sample Type
Flow [3]	Report	Report	MGD	1 X Daily	24-Hr. Total
Diethyl amine	96.05 [4] Report	37.67 [4] Report	lbs/day mg/l	2 X Weekly	Grab [5]
Triethyl amine	96.05 [4] Report	37.67 [4] Report	lbs/day mg/l	2 X Weekly	Grab [5]

- [1] The permittee must notify IDEM and the City of Lebanon at least 30 days prior to the discharge of process wastewater regulated under federal categorical standards under 40 CFR 439.
- [2] Outfall 101 shall be designated as the combined wastestreams from the centralized pH neutralization system prior to discharge to the POTW via Outfall 001.
- [3] The flow must be measured and recorded using valid flow measurement devices, not estimated. The flow monitoring device must be calibrated at least once every twelve (12) months.
- [4] Based on categorical standards [40 CFR 439.37]. The Standard is concentration-based (mg/l). Pursuant to *Development Document for Final Effluent Limitations Guidelines and Standards for the Pharmaceutical Manufacturing Point Source Category* (EPA 821-R-98-005, July 1998), the limits are expressed as mass-based limits.
- [5] The permittee must collect a minimum of two grab samples over a twenty-four hour period on a given day for this parameter, the values shall be averaged for reporting daily maximums or daily minimums on the Monthly Monitoring Report form.



Industrial Wastewater Pretreatment (IWP)

Briefing Memo for

Eli Lilly and Company – Lebanon

Draft modification: May 2026

Final modification: TBD

Indiana Department of Environmental Management

100 North Senate Avenue

Indianapolis, Indiana 46204

(317) 232-8603

Toll Free (800) 451-6027

www.idem.IN.gov

Permittee:	Eli Lilly and Company – Lebanon 1400 West 375 North Lebanon, Indiana 46052
Existing Permit Information:	Permit Number: INP000739 Expiration Date: October 31, 2029
Facility Contact:	Edward Stehno, HSE Advisor – Environmental (463) 269-5797, Edward.Stehno@Lilly.com
Facility Location:	1400 West 375 North Lebanon, Indiana 46052 Boone County
Receiving POTW:	City of Lebanon WWTP 802 Lafayette Avenue Lebanon, Indiana 46052 NPDES Permit #IN0020818
Proposed Permit Action:	Modify
Source Category	Industrial Pretreatment
Permit Writer:	Heidi Etter (317) 233-4903 hetter@idem.in.gov

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1.0 INTRODUCTION

The Indiana Department of Environmental Management (IDEM) received a request from Eli Lilly and Company on December 8, 2025 to modify Industrial Wastewater Pretreatment (IWP) Permit INP000739. The current five-year permit was issued with an effective date of November 1, 2024 in accordance with 327 IAC 5-2-6(a).

In accordance with Title 40 of the Code of Federal Regulations (CFR) Sections 124.7 and 124.56, as well as Indiana Administrative Code (IAC) 327 Article 5, development of a Statement of Basis, or Briefing Memo, is required for NPDES permits. This document fulfills the requirements established in those regulations.

This Briefing Memo identifies the basis for this modification to the permit and the modified pages of the permit issued on August 23, 2024.

2.0 PERMIT MODIFICATION

2.1 Modification Request

The Eli Lilly and Company – Lebanon Campus will consist of two manufacturing operations, discussed herein as Lebanon Project 1 (LP1) and Lebanon Project 2 (LP2). Eli Lilly and Company requests that the IWP permit be modified to include updated discharge flows and effluent limitations due to the expansion of their Lebanon site (LP1X Expansion). This expansion includes the addition of the Small Molecule 2 Process and enlargement of the Peptide 2 Process.

Pharmaceutical manufacturing of bulk active ingredients occurs at LP1/LP1X. These bulk active pharmaceutical ingredients are manufactured by chemical synthesis and will be shipped off-site for formulation into final products for patient use. At LP2, gene cell therapy products are manufactured and finished into final products for patient use.

Manufacturing processes and support operations conducted on-site that produce wastewater include peptide synthesis and purification, small molecule synthesis and purification, solvent recovery, gene cell therapy production and finishing, and warehouse operations. The oligonucleotide facility mentioned in the 2024 new permit was removed from the site. Other services and activities conducted on-site that generate wastewater include utilities (such as cooling systems, boilers, water softening, high purity water generation), laboratory services, administrative services with a cafeteria, and sanitary wastewater from occupied buildings. The plant normally operates 24 hours/day, 7 days/week.

The waste flows from chemical synthesis and mixing/compounding and formulation are subject to the Categorical Pretreatment Standards for New Source Pharmaceutical Manufacturing Point Source Category, Subpart C – Chemical Synthesis Products [40 CFR 439.37] and Subpart D – Mixing/Compounding and Formulation [40 CFR 439.47] operations. The standards are concentration-based (mg/l).

2.2 IDEM's Proposed Modification

IDEM agrees to modify the permit to address the expansion of the Eli Lilly and Company – Lebanon Campus. Changes to the discharge flows, wastewater pretreatment, and permitted limitations are described below.

2.2.1. Updated Discharge Description

The permittee discharges wastewaters from the following sources to the POTW:

<u>Source</u>	<u>Flow (GPD)</u>
Process Wastestream #1:	678 (1)
Process Wastestream #2:	497 (2)
Process Wastestream #3:	6,418 (3)
Process Wastestream #4:	4,995 (4)
Process Wastestream #5:	1,643 (5)
Process Wastestream #6:	32,300 (6)
Process Wastestream #7:	250 (7)
LP1/LP1X Non-Process Wastewater:	224,354 (8)
LP2 Non-Process Wastewater:	19,240 (9)
Sanitary:	96,315
Non-Contact Cooling Water:	113,966
Boiler Blowdown:	119,459
HVAC Condensate:	6,100

- (1) Process Wastestream #1 is wastewater from Small Molecule 1 Bulk Manufacturing at LP1.
- (2) Process Wastestream #2 is wastewater from Small Molecule 2 Bulk Manufacturing at LP1X.
- (3) Process Wastestream #3 is wastewater from Peptide 1 Bulk Manufacturing at LP1.
- (4) Process Wastestream #4 is wastewater from Peptide 2 Bulk Manufacturing at LP1X.

- (5) Process Wastestream #5 is wastewater from Gene Cell Therapy Production and Finishing at LP2.
- (6) Process Wastestream #6 is wastewater from Solvent Recovery at LP1/LP1X.
- (7) Process Wastestream #7 is manufacturing lab support process wastewater from the Administration area at LP1/LP1X.
- (8) Non-process wastewater from LP1/LP1X, including soft water Multi Media Filtration and backwash from the Small Molecule 1 and 2 Bulk Manufacturing, Peptide 1 and 2 Bulk Manufacturing, Utilities, Warehouse, and Administration areas.
- (9) Non-process wastewater from LP2, including High Purity Water Generation, Municipal Water Conditioning, and Utility Mechanical wastewater.

2.2.2. Updated Wastewater Pretreatment Description

Wastewater pretreatment at the facility includes three pH neutralization systems: one system for Utilities wastewater (LP1/LP1X), one for wastewater associated with Gene Cell Therapy operations (LP2), and a centralized pH neutralization system for all process wastewater from peptide synthesis and purification, small molecule synthesis and purification, solvent recovery, and laboratory services (LP1/LP1X).

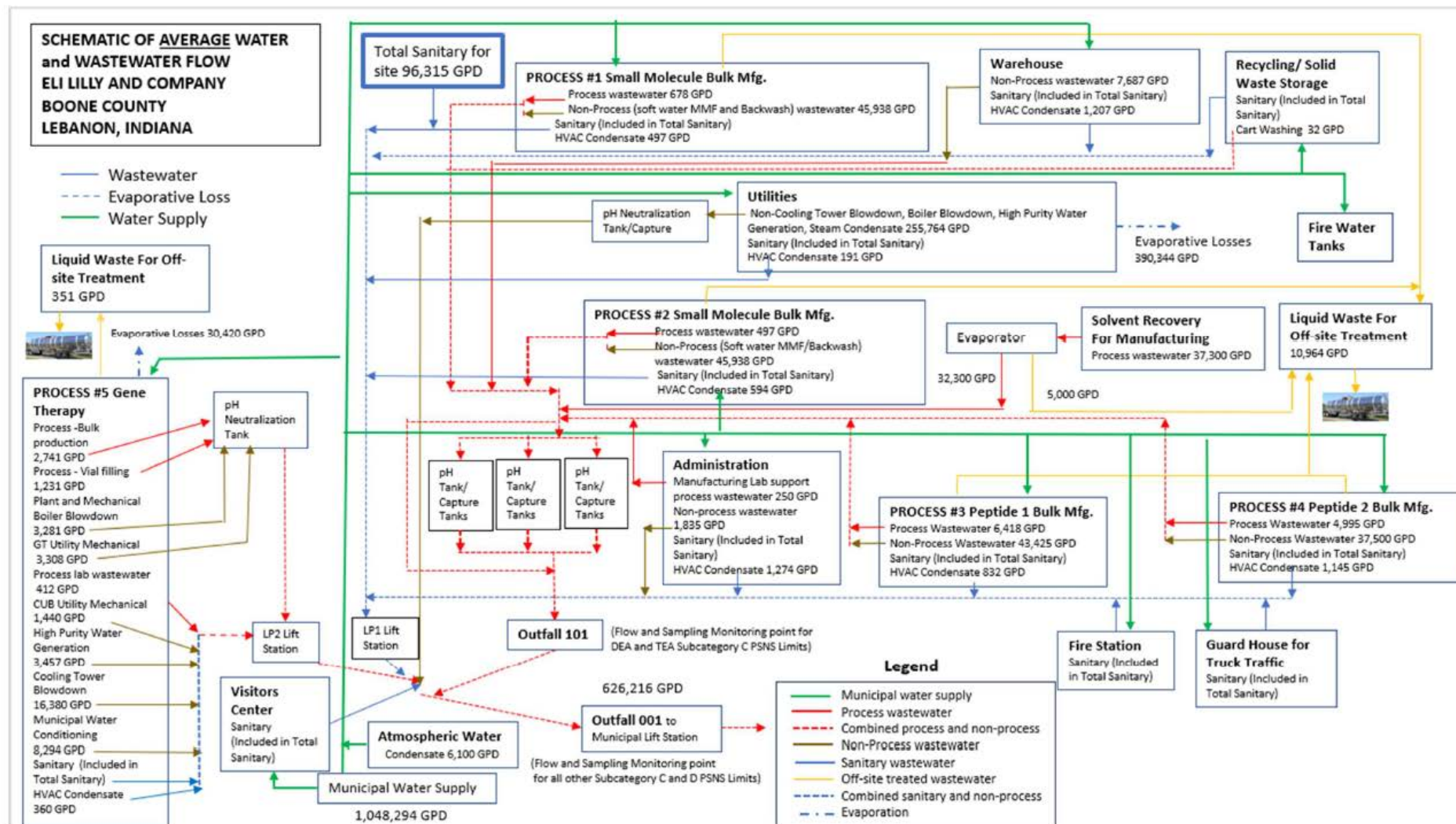
Eli Lilly and Company was issued a permit to construct improvements to the industrial pretreatment system (Permit Approval No. 25500R) on December 17, 2025. These improvements include the addition of a third tank for the centralized pH neutralization system and a LaserFlow sensor to Outfall 001.

Additionally, an evaporator will be used instead of an anionic exchange treatment system to treat solvent recovery wastewater at LP1/LP1X.

The permittee shall have the wastewater treatment facilities under the responsible charge of an operator certified by the Commissioner in a classification corresponding to the classification of the wastewater treatment plant as required by IC 13-18-11-11 and 327 IAC 5-23-6. Based on information supplied by the permittee, the classification of the treatment system has not changed. The facility is still required to have a Class A-SO Operator.

An updated flow diagram of average water and wastewater generation and disposal has been included in Figure 1.

Figure 1: Average Water and Wastewater Generation and Disposal Flow Diagram



2.2.3. Updated Limit Calculations

The permittee's process wastewater discharge must comply with New Source Pharmaceutical Manufacturing Point Source Category, Subpart C – Chemical Synthesis Products [40 CFR 439.37] and Subpart D – Mixing/Compounding and Formulation [40 CFR 439.47] standards that apply at the end of process and any existing local ordinance limits that apply at the end of pipe.

As provided in the permit effective November 1, 2024, the facility is not required to achieve the pretreatment standard for Ammonia (as N) per 40 CFR 439.37(a), and limits and monitoring are not required for Cyanide per 40 CFR 439.37(d).

The remaining categorical standards have been adjusted due to the combined, non-categorical wastestreams contributing to flow at Outfall 001. With the expansion of LP1, the categorical process flows now account for approximately 7.5% of the total wastestream that is discharged to the POTW – 7.2% of the total wastestream is process flows regulated under 40 CFR 439 Subpart C and 0.3% is process flows regulated under 40 CFR 439 Subpart D. Therefore, the categorical limitations have been adjusted by factoring the updated percentage process flow to the total wastestream using the Combined Wastestream Formula (CWF) below.

C_T = Adjusted concentration limit

C_i = Categorical Pretreatment Standard

F_i = Avg. flow of regulated wastestream = GPD (taken from application)

F_D = Avg. flow of dilute wastestream = GPD (taken from application)

F_T = Avg. total flow = GPD

$$C_T = \frac{C_i * F_i}{F_i} \times \frac{F_T - F_D}{F_T}$$

Example Calculations:

Pollutants regulated under 40 CFR 439 Subpart C and D:

Total average flow of regulated wastestreams= 46,782 GPD

Total average flow of dilute wastestreams= 579,434 GPD

Average total flow= 626,216 GPD

Acetone – Daily Maximum

$$\frac{20.7 \text{ mg/l} * 46,782 \text{ GPD}}{46,782 \text{ GPD}} \times \frac{626,216 \text{ GPD} - 579,434 \text{ GPD}}{626,216 \text{ GPD}} = 1.55 \text{ mg/l}$$

Acetone – Monthly Average

$$\frac{8.2 \text{ mg/l} * 46,782 \text{ GPD}}{46,782 \text{ GPD}} \times \frac{626,216 \text{ GPD} - 579,434 \text{ GPD}}{626,216 \text{ GPD}} = 0.61 \text{ mg/l}$$

Pollutants regulated under 40 CFR 439 Subpart C only:

Total average flow of regulated wastestreams= 45,138 GPD

Total average flow of dilute wastestreams= 581,078 GPD

Average total flow= 626,216 GPD

Benzene – Daily Maximum

$$\frac{3.0 \text{ mg/l} * 45,138 \text{ GPD}}{45,138 \text{ GPD}} \times \frac{626,216 \text{ GPD} - 581,078 \text{ GPD}}{626,216 \text{ GPD}} = 0.22 \text{ mg/l}$$

Benzene – Monthly Average

$$\frac{0.7 \text{ mg/l} * 45,138 \text{ GPD}}{45,138 \text{ GPD}} \times \frac{626,216 \text{ GPD} - 581,078 \text{ GPD}}{626,216 \text{ GPD}} = 0.05 \text{ mg/l}$$

The permittee requested that the limits be expressed as mass-based limits in the IWP permit. This is consistent with guidance from the *Development Document for Final Effluent Limitations Guidelines and Standards for the Pharmaceutical Manufacturing Point Source Category* (EPA 821-R-98-005, July 1998). The equation below was used to convert the adjusted concentration-based limits to mass-based limits:

$$\text{Mass – Based Value (lbs/day)} = \text{mg/l} \times 8.345 \times \text{process flow (MGD)}$$

Example Calculations:***Acetone – Mass-Based Daily Maximum***

$$1.55 \text{ mg/l} \times 8.345 \times 0.626216 \text{ MGD} = 8.08 \text{ lbs/day}$$

Table 1 below provides the Federal Effluent Guideline (FEG) limitation for each pollutant, the adjusted limitations utilizing the Combined Wastestream Formula provided above, and the corresponding mass-based limitation that is applicable.

Table 1. Summary of Categorical Standards and Adjusted Limits at Outfall 001

	FEG (mg/l)		Adjusted Limits (CWF) (mg/l)		Adjusted Limits (CWF) (lbs/day)	
	Daily Max	Monthly Avg	Daily Max	Monthly Avg	Daily Max	Monthly Avg
Pollutants regulated under Subpart C and D						
Acetone	20.7	8.2	1.55	0.61	8.08	3.20
n-Amyl acetate	20.7	8.2	1.55	0.61	8.08	3.20
Ethyl acetate	20.7	8.2	1.55	0.61	8.08	3.20
Isopropyl acetate	20.7	8.2	1.55	0.61	8.08	3.20
Methylene chloride	3.0	0.7	0.22	0.05	1.17	0.27
Pollutants regulated under Subpart C only						
4-methyl-2-pentanone	20.7	8.2	1.49	0.59	7.80	3.09
Isobutyraldehyde	20.7	8.2	1.49	0.59	7.80	3.09
n-Butyl acetate	20.7	8.2	1.49	0.59	7.80	3.09
Methyl formate	20.7	8.2	1.49	0.59	7.80	3.09
Isopropyl ether	20.7	8.2	1.49	0.59	7.80	3.09
Tetrahydrofuran	9.2	3.4	0.66	0.25	3.47	1.28
Benzene	3.0	0.7	0.22	0.05	1.13	0.26
Toluene	0.3	0.2	0.02	0.01	0.11	0.08
Xylenes	3.0	0.7	0.22	0.05	1.13	0.26
n-Heptane	3.0	0.7	0.22	0.05	1.13	0.26
n-Hexane	3.0	0.7	0.22	0.05	1.13	0.26
Chloroform	0.1	0.03	0.007	0.002	0.04	0.01
1,2-dichloroethane	20.7	8.2	1.49	0.59	7.80	3.09
Chlorobenzene	3.0	0.7	0.22	0.05	1.13	0.26
o-Dichlorobenzene	20.7	8.2	1.49	0.59	7.80	3.09
Diethyl amine	255	100	18.38	7.21	96.05	37.67
Triethyl amine	255	100	18.38	7.21	96.05	37.67

Per 40 CFR 403.15, the Categorical Pretreatment Standards may be adjusted to reflect the presence of pollutants in the Industrial User's intake water in accordance with this section. The applicable Standard will be calculated on a "net" basis (adjusted to reflect credit for pollutants in the intake water) if the requirements of 40 CFR 403.15(b) are met. The permittee has demonstrated that the control system it purposes or uses to meet applicable categorical Pretreatment Standards would, if properly installed and operated, meet the Standards in the absence of pollutants in the intake waters.

The permittee reported in the IWP permit modification application that the 2022 Drinking Water Measurements for Chloroform provided by the City of Lebanon ranged from 11.4 to 15.7 ug/L and averaged 13.5 ug/L. The daily maximum Chloroform mass load for all site non-process wastewater was based on the daily average non-process wastewater discharge and the daily maximum Chloroform present in the city water (15.7 ug/L) and added to the Pretreatment Standards for New Sources (PSNS) limit for process wastewater.

The monthly average Chloroform mass load for all site non-process wastewater was based on the daily average non-process wastewater discharge and the daily average Chloroform present in the city water (13.5 ug/L) and added to the Pretreatment Standards for New Sources (PSNS) limit for process wastewater.

Table 2. “Net” Limits for Chloroform

Parameter	Daily Max mg/l)	Monthly Avg (mg/l)	Daily Avg Process Flow (	Daily Avg Non-Process Flow (MGD)	Daily Max Mass Limit (lbs/day)	Monthly Avg Mass Limit (lbs/day)
Chloroform PSNS Limit for process wastewater	0.1	0.03	0.045138	N/A	0.038	0.011
Chloroform allocation for non-process wastewater	0.0157	0.0135	N/A	0.581078	0.076	0.065
Final Site Limit based on Net/Gross Calculations:					0.114	0.077

The CWF adjusted limits for Diethyl amine and Triethyl amine (Daily Max of 18.38 mg/l and Monthly Avg of 7.21 mg/l) are below the analytical detection limits for these pollutants and thus the adjusted limits may not be used at Outfall 001.

To address this, the permittee has elected to continue to take samples for these pollutants at Outfall 101, located after the centralized pH neutralization system and before combination with additional dilute wastestreams, rather than end-of-pipe at Outfall 001. Since there is still a combination of non-process and process wastewater at Outfall 101, the CWF was applied using regulated and dilute wastestream flows at that sample site. This resulted in CWF adjusted limits for Diethyl amine and Triethyl amine that are above the analytical detection limits for these pollutants at Outfall 101.

As was done at Outfall 001, CWF adjusted limits at Outfall 101 were converted from concentration-based to mass-based limits.

Table 3. Summary of Categorical Standards and Adjusted Limits at Outfall 101

	FEG (mg/l)		Adjusted Limits (CWF) (mg/l)*		Adjusted Limits (CWF) (lbs/day)	
	Daily Max	Monthly Avg	Daily Max	Monthly Avg	Daily Max	Monthly Avg
Diethyl amine	255	100	50.60	19.84	96.05	37.67
Triethyl amine	255	100	50.60	19.84	96.05	37.67

* Calculated using CWF with 45,138 GPD total average flow of regulated wastestreams, 182,354 GPD total average flow of dilute wastestreams, and average total flow of 227,492 GPD.

2.2.4. Changes to the Permit

The calculated limits provided in Table 1 of Section 2.2.3. above, except the limits for Chloroform, have replaced the existing limits in Part I.A.2, Table 1 of the permit. The limits calculated for Chloroform in Table 2 of Section 2.2.3. above have replaced the limits for Chloroform in Part I.A.2, Table 1 of the permit. The calculated limits for Diethyl amine and Triethyl amine provided in Table 3 of Section 2.2.3. above have replaced the existing limits for those pollutants in Part I.A.3, Table 1 of the permit.

In addition to the requested permit modification to address the expansion of the Lebanon site, a needed change was identified during the drafting of this modification. The following clarification, italicized and underlined below, has been added to Footnote [1] of Parts I.A.1, 2, and 3 of the permit:

[1] The permittee must notify IDEM and the City of Lebanon at least 30 days prior to the discharge of process wastewater *regulated under federal categorical standards under 40 CFR 439.*

This is an important detail to add as part of “process” wastewater associated with the small bulk scale gene cell therapy is not subject to the federal categorical standards and this could be the first “process” wastewater that the facility may generate. Eli Lilly has provided that this wastewater does not use any of the specific substances in Table 1 of Part I.A.2 of the permit. With the revised language, the facility is anticipating to provide a 30-day notice in advance of a discharge of wastewater subject to the federal categorical limits.

3.0 Permit Processing/Public Comment

Pursuant to IC 13-15-5-1, IDEM will publish the draft permit document online at <https://www.in.gov/idem/public-notices/>. Additional information on public participation can be found in the "Citizens' Guide to IDEM", available at <https://www.in.gov/idem/resources/citizens-guide-to-idem/>. A 30-day comment period is available to solicit input from interested parties, including the public.