

STATE OF INDIANA
DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
PUBLIC NOTICE NO 20240628 – INP000739 – D
DATE OF NOTICE: June 28, 2024
DATE RESPONSE DUE: July 29, 2024

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

Minor – New:

Eli Lilly and Company - Lebanon, Permit No. INP000739, BOONE COUNTY, 1400 West 375 North, Lebanon, IN. This facility is a pharmaceutical manufacturer of bulk active ingredients and gene cell therapy products. The facility discharges 0.53 MGD of sanitary wastewater, non-process wastewater and process wastewater into the City of Lebanon POTW. Permit Manager: Heidi Etter at 317/233-4903 or hetter@idem.in.gov. Posted online at <https://www.in.gov/idem/public-notices/>.

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 5-3-9. The application and draft permit documents are available for inspection at IDEM, Office of Water Quality, Indiana Government Center North - Room 1255, 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. 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 above address.

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 circulated in at least one newspaper in the geographical area of the discharge and to those persons submitting comments and/or on the mailing list at least 30 days prior to the hearing.



INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT

We Protect Hoosiers and Our Environment.

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

Eric J. Holcomb
Governor

Brian C. Rockensuess
Commissioner

June 28, 2024

VIA ELECTRONIC MAIL

Victor M. Cruz, Senior Vice President, Corp. Engineering and Global HSE
Eli Lilly and Company
Lilly Corporate Center
Indianapolis, IN 46285

Dear Victor M. Cruz:

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

Your application and supporting documents have been reviewed and processed in accordance with rules adopted under 327 IAC 5. Enclosed is draft Industrial Wastewater Pretreatment Permit No. INP000739 which applies to the discharges associated with the pharmaceutical manufacturing facility.

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.

Please review this document carefully and become familiar with the proposed terms and conditions. Comments concerning the draft permit 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. If you have any questions concerning this proposed permit, please contact Heidi Etter at 317/233-4903 or hetter@idem.in.gov.

Sincerely,

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

cc: Boone County Health Department
Neil J. Parke, Senior Director – Engineering HSE, Eli Lilly and Company
Tony Greene, Wastewater Supervisor, Lebanon Utilities
Ryan Ottinger, Operations Manager, Lebanon Utilities
Amy Harvell, Senior Project Manager, Wessler Engineering, Inc.
Leigh Voss, IDEM
Jason Palin, IDEM



STATE OF INDIANA

DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
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.

EFFECTIVE DATE: _____

EXPIRATION DATE: _____

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.

Issued 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.
- [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.

Alternatively, a 24-hour composite sample may be obtained by an automatic sampler on an equal time interval basis over a twenty-four hour period provided that a minimum of 24 samples are taken and combined prior to analysis. The samples do not need to be flow-proportioned if the permittee collects samples in this manner.

- [5] 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.
- [6] Based on local ordinance [City of Lebanon Ordinance No. 2017-06, Section 55.307]. Note: TSS in excess of 240 mg/l, CBOD₅ in excess of 210 mg/l, FOG in excess of 100 mg/l, and Phosphorus in excess of 1 mg/l may be subject to local surcharge.
- [7] All metals shall be analyzed as Total Recoverable Metals.
- [8] Based on local ordinance [City of Lebanon Ordinance No. 2017-06 (adopted June 12, 2017)].
- [9] If the permittee collects more than one grab sample on a given day for pH, the values shall not be averaged for reporting daily maximums or daily minimums. The permittee must report the individual minimum and the individual maximum pH value of any sample during the month on the Monthly Monitoring Report form.

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	8.21 [6] Report	3.25 [6] Report	lbs/day mg/l	2 X Weekly	Grab
n-Amyl acetate	8.21 [6] Report	3.25 [6] Report	lbs/day mg/l	2 X Weekly	Grab
Ethyl acetate	8.21 [6] Report	3.25 [6] Report	lbs/day mg/l	2 X Weekly	Grab
Isopropyl acetate	8.21 [6] Report	3.25 [6] Report	lbs/day mg/l	2 X Weekly	Grab
Methylene chloride	1.19 [6] Report	0.28 [6] Report	lbs/day mg/l	2 X Weekly	Grab
4-methyl-2-pentanone	7.92 [7] Report	3.14 [7] Report	lbs/day mg/l	2 X Weekly	Grab
Isobutyraldehyde	7.92 [7] Report	3.14 [7] Report	lbs/day mg/l	2 X Weekly	Grab
n-Butyl acetate	7.92 [7] Report	3.14 [7] Report	lbs/day mg/l	2 X Weekly	Grab
Methyl formate	7.92 [7] Report	3.14 [7] Report	lbs/day mg/l	2 X Weekly	Grab
Isopropyl ether	7.92 [7] Report	3.14 [7] Report	lbs/day mg/l	2 X Weekly	Grab
Tetrahydrofuran	3.52 [7] Report	1.30 [7] Report	lbs/day mg/l	2 X Weekly	Grab
Benzene	1.15 [7] Report	0.27 [7] Report	lbs/day mg/l	2 X Weekly	Grab
Toluene	0.11 [7] Report	0.08 [7] Report	lbs/day mg/l	2 X Weekly	Grab
Xylenes	1.15 [7] Report	0.27 [7] Report	lbs/day mg/l	2 X Weekly	Grab
n-Heptane	1.15 [7] Report	0.27 [7] Report	lbs/day mg/l	2 X Weekly	Grab
n-Hexane	1.15 [7] Report	0.27 [7] Report	lbs/day mg/l	2 X Weekly	Grab
Chloroform	0.10 [7] Report	0.07 [7] Report	lbs/day mg/l	2 X Weekly	Grab

Parameter	Daily Maximum	Monthly Average	Unit	Measurement Frequency	Sample Type [4]
1,2-dichloroethane	7.92 [7] Report	3.14 [7] Report	lbs/day mg/l	2 X Weekly	Grab
Chlorobenzene	1.15 [7] Report	0.27 [7] Report	lbs/day mg/l	2 X Weekly	Grab
o-Dichlorobenzene	7.92 [7] Report	3.14 [7] Report	lbs/day mg/l	2 X Weekly	Grab
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.
- [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's 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.

Alternatively, a 24-hour composite sample may be obtained by an automatic sampler on an equal time interval basis over a twenty-four hour period provided that a minimum of 24 samples are taken and combined prior to analysis. The samples do not need to be flow-proportioned if the permittee collects samples in this manner.

- [5] 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.
- [6] Based on categorical standards [40 CFR 439.37 and 40 CFR 439.47]. The Standards are 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.
- [7] 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.
- [8] Based on local ordinance [City of Lebanon Ordinance No. 2017-06, Section 55.307]. Note: TSS in excess of 240 mg/l, CBOD₅ in excess of 210 mg/l, FOG in excess of 100 mg/l, and Phosphorus in excess of 1 mg/l may be subject to local surcharge.
- [9] If the permittee collects more than one grab sample on a given day for pH, the values shall not be averaged for reporting daily maximums or daily minimums. The permittee must report the individual minimum and the individual maximum pH value of any sample during the month on the Monthly Monitoring Report form.
- [10] Based on local ordinance [City of Lebanon Ordinance No. 2017-06 (adopted June 12, 2017)].
- [11] Closed cup flashpoint must be measured by a test method specified in 40 CFR 261.21. Regulation 40 CFR 403.5(b)(1) and the City of Lebanon SUO prohibit the discharge of pollutants that create a fire or explosive hazard, including, but not limited to wastestreams with a closed cup flashpoint below 60° C (140° F).

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	2 X Weekly	24-Hr. Total
Diethyl amine	97.62 [4] Report	38.28 [4] Report	lbs/day mg/l	2 X Weekly	Grab
Triethyl amine	97.62 [4] Report	38.28 [4] Report	lbs/day mg/l	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.
- [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.

2. ADDITIONAL DISCHARGE PROHIBITIONS

The permittee shall not allow the introduction of the following into the POTW from any location, including Outfall 001:

- a. A pollutant from any source of nondomestic wastewaters that could pass through or cause interference with the operation or performance of the POTW.
- b. A pollutant that could create a fire or explosion hazard in the POTW, including waste streams with a closed cup flashpoint of less than 140° F degrees Fahrenheit (60° C) using the test methods in 40 CFR 261.21.
- c. A pollutant that could cause corrosive structural damage to the POTW, including a discharge with pH lower than five (5.0), unless the POTW is specifically designed to accommodate such a discharge.
- d. A solid or viscous pollutant in an amount that could cause obstruction to the flow in a sewer or other interference with the operation of the POTW.
- e. A pollutant, including an oxygen demanding pollutant (such as biochemical oxygen demand) released in a discharge at a flow rate or pollutant concentration that could cause interference in the POTW.
- f. Heat in an amount that could:
 - (1) inhibit biological activity in the POTW and result in interference or damage to the POTW; or
 - (2) exceed 40° C or 104° F at the POTW treatment plant unless the commissioner, upon request of the POTW, approves alternate temperature limits.
- g. Petroleum, oil, non-biodegradable cutting oil, or products of mineral oil origin in an amount that could cause interference or pass through.
- h. A pollutant that could result in the presence of toxic gases, vapors, or fumes within the POTW in a quantity that may cause acute worker health and safety problems.
- i. A trucked or hauled pollutant, except:
 - (1) with the permission of the POTW; and
 - (2) when introduced to the POTW at a discharge point designated by the POTW.

3. AFFIRMATIVE DEFENSE

The permittee shall have an affirmative defense in any action brought against the permittee alleging a violation of the prohibitions established in Part I.A.2 of this permit if the permittee can demonstrate that:

- a. it did not know or have reason to know that its discharge, alone or in conjunction with a discharge from another source, would cause pass through or interference; and
- b. a local limit designed to prevent pass through or interference in accordance with Part I.A.2 of this permit:
 - (1) was developed for each pollutant in the permittee's discharge that caused pass through or interference, and the permittee was in compliance with each such local limit directly prior to and during the pass-through or interference; or
 - (2) was not developed for the pollutant that caused the pass through or interference, and the permittee's discharge, directly prior to and during the pass through or interference, had not changed substantially in nature or constituents from its usual discharge condition when the POTW was regularly in compliance with the applicable:
 - (A) NPDES permit requirements; and
 - (B) requirements for sewage sludge use or disposal, in the case of interference.

B. DEFINITIONS

1. Daily Discharge

The total mass of a pollutant discharged during the calendar day or, in the case of a pollutant limited in terms other than mass pursuant to 327 IAC 5-2-11(e), the average concentration or other measurement of the pollutant specified over the calendar day or any twenty-four (24) hour period that reasonably represents the calendar day for the purposes of sampling.

2. Daily Maximum (Discharge) Limitation

The maximum allowable daily discharge for any calendar day.

3. Monthly Average Discharge (Average Monthly Discharge)

The total mass or flow-weighted concentration of all daily discharges sampled or measured during a calendar month on which daily discharges are sampled and measured, divided by the number of daily discharges sampled and/or measured during such month.

4. Monthly Average (Discharge) Limitation

The highest allowable average monthly discharge for any calendar month.

5. Interference

a. "Interference" means a discharge that, alone or in conjunction with a discharge or discharges from other sources inhibits or disrupts the:

(1) treatment processes or operations;

(2) sludge processes; or

(3) selected sludge:

(A) use; or

(B) disposal methods;

of a POTW.

b. The inhibition or disruption under subsection (a) must:

(1) cause a violation of a requirement of the POTW's NPDES permit, including an increase in the magnitude or duration of a violation; or

(2) prevent the use of the POTW's sewage sludge or its sludge disposal method selected in compliance with the following statutory provisions, regulations, or permits issued thereunder or more stringent state or local regulations:

(A) Section 405 of the Clean Water Act (33 U.S.C. 1345).

(B) The Solid Waste Disposal Act (SWDA) (42 U.S.C. 6901), including:

(i) Title II, more commonly referred to as the Resource Conservation and Recovery Act (RCRA); and

(ii) the rules contained in a state sludge management plan prepared pursuant to Subtitle D of the SWDA (42 U.S.C. 6941).

(C) The Clean Air Act (42 U.S.C. 7401).

(D) The Toxic Substances Control Act (15 U.S.C. 2601).

6. Pass-through

“Pass through” means a discharge proceeding through a POTW into waters of the state in quantities or concentrations that, alone or in conjunction with a discharge or discharges from other sources, are a cause of a violation of any requirement of the POTW’s NPDES permit, including an increase in the magnitude or duration of a violation.

7. Pretreatment requirements

“Pretreatment requirements” means any substantive or procedural requirement related to pretreatment, other than a pretreatment standard, imposed on an industrial user.

8. Pretreatment standards

“Pretreatment standards” means:

- a. state pretreatment standards as established in 327 IAC 5-18-8;
- b. pretreatment standards for prohibited discharges, as established in 327 IAC 5-18-2; and
- c. national categorical pretreatment standards incorporated by reference in 327 IAC 5-2-1.5.

9. Publicly Owned Treatment Works (“POTW”)

A treatment works as defined by Section 212(2) of the Clean Water Act owned by the State or a municipality (as defined by Section 502(4) of the Clean Water Act), except that it does not include pipes, sewers or other conveyances not connected to a facility providing treatment. The term includes any devices and systems used in the storage, treatment, recycling and reclamation of municipal sewage or compatible industrial wastes. The term also includes sewers, pipes, and other conveyances only if they convey wastewater to a POTW treatment plant. “POTW” also means the municipality, as defined in Section 502(4) of the Clean Water Act, that has jurisdiction over the indirect discharges to and the discharges from such a treatment works.

C. MONITORING AND REPORTING

1. Representative Sampling

Samples and measurements taken as required herein shall be representative of the volume and nature of the entire permitted discharge.

2. Reporting

The permittee shall submit monitoring reports to the Indiana Department of Environmental Management and the City of Lebanon containing results obtained during the previous month and shall be submitted no later than the 28th day of the month following each completed monitoring period. The first report shall be submitted by the 28th day of the month following the month in which this permit becomes effective. These reports shall include, but not necessarily be limited to, the Discharge Monitoring Report (DMR) and the Monthly Monitoring Report (MMR). All reports shall be submitted electronically by using the NetDMR application, upon registration, receipt of the NetDMR Subscriber Agreement, and IDEM approval of the proposed NetDMR Signatory. Access the NetDMR website (for initial registration and DMR/MMR submittal) via CDX at: <https://cdx.epa.gov/>.

If the City of Lebanon is agreeable to receiving an electronic version of the monthly reports, copies can be sent to the City of Lebanon via NetDMR. An acceptable email address for the City of Lebanon must be provided to IDEM's Compliance Data Section. Any non-NetDMR reports sent to the City of Lebanon shall be sent to the following:

Certified Operator
City of Lebanon
802 Lafayette Avenue
Lebanon, IN 46052

The permittee shall also comply with the applicable reporting requirements of 40 CFR 403.12.

3. Monitoring Results

Requirements for test procedures shall be as follows:

- a. Test procedures identified in 40 CFR 136 shall be utilized for pollutants or parameters listed in that part, unless an alternative test procedure has been approved under 40 CFR 136.5.
- b. Where no test procedure under 40 CFR 136 has been approved, analytical work shall be conducted in accordance with the most recently approved edition of "Standard Methods for the Examination of Water and Wastewater",

published by the American Public Health Association (APHA) or as otherwise specified by the commissioner in the IWP permit.

- c. Notwithstanding subdivision a., the commissioner may specify in a permit the test procedure specified in a standard or effluent limitation guideline.

4. Recording of the Monitoring Results

For each measurement or sample taken pursuant to the requirements of this permit, including the additional monitoring described under Part I.C.5., below, the permittee shall maintain records of all monitoring information and monitoring activities, including:

- a. The date, exact place and time of sampling or measurement;
- b. The person(s) who performed the sampling or measurements;
- c. The date(s) analyses were performed;
- d. The person(s) who performed the analyses;
- e. The analytical techniques or methods used; and
- f. The results of such measurements and analyses.

5. Additional Monitoring by Permittee

If the permittee monitors any pollutant at the location(s) designated herein more frequently than required by this permit, using approved analytical methods as specified above, the results of such monitoring shall be included in the calculation and reporting of the values required in the Monthly Monitoring Report and the Discharge Monitoring Report. Such increased frequency shall also be indicated.

6. Records Retention

- a. All records of monitoring activities and results required by this permit (including all original strip chart recordings for continuous monitoring instrumentation and calibration and maintenance records) shall be retained at the permitted facility for a minimum of three (3) years. The three-year period shall be extended:
 - (1) automatically during the course of any unresolved litigation regarding the discharge of pollutants by the permittee or regarding promulgated effluent guidelines applicable to the permittee; or
 - (2) as requested by the commissioner.

- b. The permittee shall maintain and make available to IDEM, the regional administrator, and the City of Lebanon personnel, records of disposal of all wastewater generated at the site. Such records shall include, but not be limited to, flow monitoring records, flow calibration records, and the volume and destination of all wastewater hauled off-site.

7. Additional Reporting Requirements

- a. In accordance with 327 IAC 5-16-5(g), all categorical and noncategorical industrial users shall notify the POTW immediately of all discharges that could cause problems to the POTW, including any slug loadings as defined by 40 CFR 403.5(b).
- b. In accordance with 327 IAC 5-16-5(h)(2), if sampling performed by an industrial user indicates a violation, the industrial user shall notify the control authority within twenty-four (24) hours of becoming aware of the violation. The industrial user shall also repeat the sampling and analysis and submit the results of the repeat analysis to the control authority within thirty (30) days after becoming aware of the violation.

Where the control authority has performed the sampling and analysis in lieu of the industrial user, the control authority shall perform the repeat sampling and analysis unless it notifies the industrial user of the violation and requires the industrial user to perform the repeat analysis. Resampling is not required if the control authority performs sampling at the industrial user:

- (1) at a frequency of at least once per month; or
- (2) between the time when the initial sampling was conducted and the time when the industrial user or the control authority receives the results of this sampling.

D. REOPENING CLAUSE

This permit shall be modified, or, alternatively, revoked and reissued, to comply with any applicable effluent limitation or standard issued or approved under Section 307(b) of the Clean Water Act, if the effluent limitation or standard so issued or approved:

- 1. contains different conditions or is otherwise more stringent than any effluent limitation in the permit; or
- 2. controls any pollutant not limited in the permit.

The permit, as modified or reissued under this paragraph, shall also contain any other requirements of the Act then applicable.

PART II

A. RESPONSIBILITIES

1. Duty to Comply

The permittee must comply with all terms and conditions of this permit. Any permit noncompliance constitutes a violation of the Clean Water Act (CWA) and the Environmental Management Act (EMA) and is grounds for:

- a. enforcement action;
- b. permit termination, revocation and reissuance, or modification; or
- c. denial of a permit renewal application.

A permittee may claim an affirmative defense to a permit violation, however, if the circumstances of the noncompliance meet the criteria of an upset as defined in Part II.A.7, the provisions of Part I.A.3, or any defense as provided by local ordinance.

2. Right of Entry

The permittee shall allow the Commissioner of the Indiana Department of Environmental Management or the Commissioner's authorized representatives (including an authorized contractor acting as a representative of the Commissioner), upon the presentation of the credentials and such other documents as may be required by law:

- a. to enter upon the permittee's premises where a point source is located or where any records must be kept under the terms and conditions of this permit;
- b. to have access to and copy at reasonable times any records that must be kept under the terms and conditions of this permit;
- c. to inspect, at reasonable times:
 - (1) any monitoring equipment or method;
 - (2) any collection, treatment, pollution management, or discharge facilities; or
 - (3) practices required or otherwise regulated under the permit; and
- d. to sample or monitor, at reasonable times, any discharge of pollutants or internal wastestream (where necessary to ascertain the nature of a discharge of pollutants) for the purpose of evaluating compliance with the permit or as otherwise authorized.

3. Change in Discharge

If the permittee intends to add a pollutant not limited by this permit or increase discharge of a pollutant limited by this permit, the permittee must notify the receiving POTW and apply for a permit modification from the commissioner prior to commencing discharge containing the additional pollutant. The application for permit modification must:

- a. be completed on a form prescribed by the commissioner;
- b. be signed in accordance with 327 IAC 5-2-22(a); and
- c. be submitted to the commissioner no later than 120 days prior to the date that the permittee intends to commence discharge containing the additional pollutant.

4. Duty to Mitigate Adverse Impact

The permittee shall take all reasonable steps to minimize any adverse impact to the POTW or to waters of the State resulting from noncompliance with the IWP permit, including such accelerated or additional monitoring necessary to determine the nature and impact of the non-complying discharge.

5. Noncompliance Notification

- a. If the permittee does not or will not be able to comply for any reason with any discharge limitation specified in this permit, the permittee shall provide the Indiana Department of Environmental Management and the City of Lebanon with the following information in writing, within twenty-four (24) hours of becoming aware of the noncompliance.

(1) a description of the discharge and cause of noncompliance.

(2) the period of noncompliance, including exact dates and times of the noncomplying event and the anticipated time when the discharge will return to compliance.

(3) steps being taken to reduce, eliminate, and prevent recurrence of the noncomplying discharge.

The permittee may email the written notification of noncompliance to IDEM at wwreports@idem.in.gov.

- b. If the permittee has any unexpected, unintended, abnormal, or unapproved discharge from the facility into the POTW, the permittee shall comply with the spill reporting and response requirements contained in 327 IAC 2-6.1-7,

including the requirement to report the discharge to IDEM and to the receiving POTW within two hours of discovery of the discharge.

6. Spills, Reporting, Containment, and Response

Notwithstanding the permittee's obligations under Part II.A.5 of this permit, the permittee shall comply with the spill reporting, containment, and response requirements in accordance with 327 IAC 2-6.1, as applicable.

7. Upset

a. "Upset" means an exceptional incident in which there is unintentional and temporary noncompliance with any pretreatment standards or requirements in 327 IAC 5-2 because of factors beyond the reasonable control of the permittee. An upset does not include:

- (1) noncompliance to the extent caused by operational error;
- (2) improperly designed treatment facilities;
- (3) inadequate treatment facilities;
- (4) lack of preventive maintenance; or
- (5) careless or improper operation.

b. An upset shall constitute an affirmative defense to an action brought for noncompliance with the pretreatment standards or requirements if the requirements of subsection (c) are met.

c. In order to establish an affirmative defense of upset, the permittee must provide properly signed, contemporaneous operating logs, or other relevant evidence of the following facts:

- (1) An upset occurred and the permittee can identify the cause of the upset.
- (2) The facility was being operated at the time in a prudent and workmanlike manner and in compliance with applicable operation and maintenance procedures.
- (3) The permittee submitted a report, to the POTW and control authority, within twenty-four (24) hours of becoming aware of the upset or within five (5) days, if an initial verbal report of the information is given to the required authority, and the report contained the following information:

(A) A description of the indirect discharge and cause of noncompliance.

(B) The period of noncompliance, including exact dates and times or the anticipated time the noncompliance is expected to continue if it is not corrected.

(C) Steps being taken or planned for reducing, eliminating, and preventing recurrence of the noncompliance.

- d. In any enforcement proceeding, the permittee seeking to establish the occurrence of an upset shall have the burden of proof.
- e. In the usual exercise of prosecutorial discretion, the control authority may review any claims that noncompliance was caused by an upset. No determinations made in the course of the review constitute the commissioner's final action subject to judicial review. The permittee will have the opportunity for a judicial determination on any claim of upset only in an enforcement action brought for noncompliance with the pretreatment standards or requirements.
- f. The permittee shall control production or all discharges to the extent necessary to maintain compliance with the pretreatment standards or requirements upon reduction, loss, or failure of its treatment facility until the facility is restored or an alternative method of treatment is provided. This requirement applies when, among other things, the primary source of power of the treatment facility is reduced, is lost, or has failed.

8. Bypass

- a. The following definitions apply throughout this permit:
 - (1) "Bypass" means the intentional diversion of waste streams from any portion of a permittee's treatment facility.
 - (2) "Severe property damage" means substantial physical damage to property, damage to the treatment facilities that causes them to become inoperable, or substantial and permanent loss of natural resources that can reasonably be expected to occur in the absence of a bypass. Severe property damage does not mean economic loss caused by delays in production.
- b. The permittee may allow a bypass to occur if:
 - (1) it does not cause a violation of any pretreatment standard or requirement including discharge limitations contained in this permit; and
 - (2) it is for essential maintenance to assure efficient operation. These

bypasses are not subject to the provisions of Part II.A.8.c. and Part II.A.8.d. of this permit.

- c. The reporting requirements for a bypass are as follows:
- (1) If the permittee knows in advance of the need for a bypass, it shall submit prior notice to the control authority, if possible, at least ten (10) days before the date of the bypass.
 - (2) If an unanticipated bypass exceeds a pretreatment standard or requirement including discharge limitations contained in this permit, the permittee shall give oral notice to the control authority within twenty-four (24) hours from the time the permittee becomes aware of the bypass. A written submission shall also be provided to IDEM within five (5) days of the time the permittee becomes aware of the bypass. The written submission must contain the following:
 - (A) A description of the bypass and its cause.
 - (B) The duration of the bypass, including exact dates and times and the anticipated time it is expected to continue if the bypass has not been corrected.
 - (C) The steps taken or planned to reduce, eliminate, and prevent reoccurrence of the bypass.
- d. Bypass is prohibited, and an enforcement action may be taken against the permittee for a bypass unless the following are demonstrated:
- (1) The bypass was unavoidable to prevent loss of life, personal injury, or severe property damage.
 - (2) There were no feasible alternatives to the bypass, such as any of the following:
 - (A) The use of auxiliary treatment facilities.
 - (B) Retention of untreated wastes.
 - (C) Maintenance during normal periods of equipment downtime. This condition is not satisfied if adequate back-up equipment should have been installed in the exercise of reasonable engineering judgment to prevent a bypass that occurred during normal periods of equipment downtime or preventative maintenance.
 - (3) The permittee submitted notices as required under Part II.A.8.c.

(4) A planned bypass is approved in advance by IDEM after determining that the bypass will not violate Part II.A.8.d.(1) through (3).

9. Facilities Operation and Maintenance

The permittee shall at all times maintain in good working order and efficiently operate all facilities or systems (and related appurtenances) for collection and treatment that are installed or used by the permittee and necessary for achieving compliance with the terms and conditions of this permit in accordance with 327 IAC 5-2-8(9).

This provision does not act as an independent source of authority to set effluent limitations. Such limitations will be based on the design removal rates of installed treatment facilities only as required under this article. Nor should this provision be construed to require the operation of installed treatment facilities that are unessential for achieving compliance with the terms and conditions of the permit.

10. Removed Substances

Solids, sludges, filter backwash, or other pollutants removed from or resulting from treatment or control of wastewaters shall be disposed of in compliance with applicable Indiana statutes and rules, including any applicable portions of 327 IAC 6.1 and 329 IAC 10.

11. Power Failures

When a power source is used to operate wastewater treatment facilities in order to maintain compliance with the effluent limitations and prohibitions of this permit, the permittee shall either:

- a. provide an alternative power source sufficient to operate facilities utilized by the permittee to maintain compliance with the effluent limitations and conditions of this permit; or
- b. upon the reduction, loss, or failure of one or more of the primary sources of power to facilities utilized by the permittee to maintain compliance with the effluent limitations and conditions of this permit, the permittee shall halt, reduce, or otherwise control production and/or discharge in order to maintain compliance with the effluent limitations and conditions of this permit.

12. Wastewater Treatment Plant and Certified Operators

Pursuant to IC 13-18-11-11 and 327 IAC 5-23-6, a permittee's wastewater treatment plant must be under the responsible charge of an operator certified by the Commissioner in a classification corresponding to the classification of the wastewater treatment plant as determined under 327 IAC 5-23-4.

A certified operator may be designated as being in responsible charge of more than one (1) wastewater treatment plant if the requirements under 327 IAC 5-23-7(b) are met. "Operator in responsible charge" is defined at 327 IAC 5-23-2(16).

Pursuant to 327 IAC 5-23-6(4)(A), the permittee shall notify IDEM when there is a change in the person serving as the certified operator in responsible charge of the wastewater treatment facility. The notification shall be made no later than thirty (30) days after a change in the operator and submitted via e-mail to the Compliance Data Section of the Office of Water Quality at WWReports@idem.IN.gov.

13. Construction Permit

The permittee shall not construct, install, or modify any water pollution control facility except in accordance with 327 IAC 3 and IC 13-14-8-11.6. Upon completion of any construction, the permittee must notify the Compliance Evaluation Section of the Office of Water Quality in writing.

14. Containment Facilities

When cyanide or cyanogen compounds are used in any of the processes at this facility the permittee shall provide approved facilities for the containment of any losses of these compounds in accordance with the requirements of 327 IAC 2-2-1.

B. ADDITIONAL RESPONSIBILITIES

1. Effect of Permit Issuance

This permit does not affect any pretreatment requirements, including any standards or prohibitions, established by local ordinance of the City of Lebanon.

2. Permit Renewal

If the permittee wishes to continue an activity regulated by this permit after the expiration date of this permit, the permittee must apply for and obtain a new IWP permit. An application for an IWP permit must conform to the following:

- a. Be completed on a form prescribed by the commissioner;
- b. Be signed in accordance with 327 IAC 5-2-22(a);
- c. Be submitted to the commissioner no later than one hundred eighty (180) days prior to the expiration date of an existing permit if the industrial user intends to continue discharging to the POTW.

3. Permit Modification

This permit may be modified in whole or in part, revoked and reissued, or terminated during its term for cause in accordance with the pertinent provisions of 327 IAC 5-2-16. The permittee must:

- a. report to the commissioner plans for or information about any activity that has occurred or will occur that would constitute cause for modification or revocation and reissuance;
- b. comply with the existing IWP permit until it is modified or reissued; and
- c. abide by the commissioner's decision:
 - (1) to modify or revoke and reissue the permit; and
 - (2) require submission of a new application as required by 327 IAC 5-21-3.

4. Permit Transferability

- a. A permit may be transferred by the permittee to a new owner or operator only if the permit has been modified or revoked and reissued under 327 IAC 5-2-16(c)(1) or 16(e)(4), to identify the new permittee and incorporate such other requirements as may be necessary under the CWA. A permit may be transferred to another person by a permittee, without modification or revocation and reissuance being required, if the following occurs:
 - (1) The current permittee notifies the commissioner at least thirty (30) days in advance of the proposed transfer date.
 - (2) A written agreement containing a specific date for transfer of permit responsibility and coverage between the current permittee and the transferee (including acknowledgment that the existing permittee is liable for violations up to that date, and that the transferee is liable for violations from that date on) is submitted to the commissioner.
 - (3) The transferee certifies in writing to the commissioner intent to operate the facility without making such material and substantial alterations or additions to the facility as would significantly change the nature or quantities of pollutants discharged and thus constitute cause for permit modification under 327 IAC 5-2-16(d) . However, the commissioner may allow a temporary transfer of the permit without permit modification for good cause, e.g., to enable the transferee to purge and empty the facility's treatment system prior to making alterations, despite the transferee's intent to make such material and substantial alterations or additions to the facility.

- (4) The commissioner, within thirty (30) days, does not notify the current permittee and the transferee of the intent to modify, revoke and reissue, or terminate the permit and to require that a new application be filed rather than agreeing to the transfer of the permit.

5. Signature Requirements

- a. The reports required by Part I.C.2 of this Permit must be signed by one (1) of the following:
 - (1) A responsible corporate officer. As used in this subdivision, “responsible corporate officer” means:
 - (A) a president, secretary, treasurer, or vice-president of the corporation in charge of a principal business function, or any other person who performs similar policy or decision-making functions for the corporation; or
 - (B) The manager of one (1) or more manufacturing, production, or operating facilities provided the manager is authorized to make management decisions that govern the operation of the regulated facility including having the explicit or implicit duty to make major capital investment recommendations, and initiating and directing other comprehensive measures to assure long-term environmental compliance with environmental laws and regulations; the manager can ensure that the necessary systems are established or actions taken to gather complete and accurate information for permit application requirements; and where authority to sign documents has been assigned or delegated to the manager in accordance with corporate procedures.
 - (2) A general partner or proprietor or manager if the industrial user submitting the reports is a partnership or sole proprietorship, respectively.
 - (3) A duly authorized representative of the individual designated in either Part II.B.5.a.(1)(A) or Part II.B.5.a.(1)(B) of this permit if:
 - (A) the authorization is made in writing by the individual described in either Part II.B.5.a.(1)(A) or Part II.B.5.a.(1)(B) of this permit;
 - (B) the authorization specifies either an individual or a position having responsibility for the overall operation of the facility from which the industrial discharge originates, such as the position of plant manager, operator of a well, or well field superintendent, or a position of

equivalent responsibility, or having overall responsibility for environmental matters for the company; and

(C) the written authorization is submitted to the commissioner.

(4) If an authorization under subdivision (3) is no longer accurate because a different individual or position has responsibility for the overall operation of the facility or overall responsibility for environmental matters for the company, a new authorization satisfying the requirements of subdivision (3) must be submitted to the commissioner prior to or together with any reports to be signed by an authorized representative.

b. A report required by this section that relates to the actual operation of or discharge from a pretreatment facility must be prepared by or under the direction of a wastewater treatment plant operator certified under IC 13-18-11, if a certified operator is required.

6. Penalties for False Reporting

In accordance with 327 IAC 5-2-8(15), Section 309(c)(4) of the Clean Water Act (U.S.C. 1319(c)(4)) provides that any person who knowingly makes any false statement, representation, or certification in any record or other document submitted or required to be maintained under this permit, including monitoring reports or reports of compliance or noncompliance shall, upon conviction, be punished by a fine of not more than ten thousand dollars (\$10,000) per violation, or by imprisonment for not more than one hundred eighty (180) days per violation, or by both.

IC 13-30-10-1 provides that a person who knowingly or intentionally renders inaccurate or inoperative a recording device or a monitoring device required to be maintained by a permit issued by the department commits a class B misdemeanor.

7. Penalties for Tampering or Falsification

In accordance with 327 IAC 5-2-8(10), Section 309(c)(4) of the Clean Water Act (33 U.S.C. 1319(c)(4)) provides that any person who falsifies, tampers with, or knowingly renders inaccurate any monitoring device or method required to be maintained under a permit shall, upon conviction, be punished by a fine of not more than ten thousand dollars (\$10,000) per violation, or by imprisonment for not more than one hundred eighty (180) days per violation, or by both.

IC 13-30-10-1 provides that a person who knowingly or intentionally renders inaccurate or inoperative a recording device or a monitoring device required to be maintained by a permit issued by the department commits a class B misdemeanor.

8. Enforcement

- a. A violation of the pretreatment rules may:
- (1) subject a person causing or contributing to the violation to administrative or judicial enforcement proceedings, under IC 13-30-3, and the penalties provided under IC 13-30-4;
 - (2) be cause for:
 - (A) modification;
 - (B) revocation and reissuance; or
 - (C) termination;of the industrial wastewater pretreatment permit; and
 - (3) warrant the invocation of emergency procedures under IC 13-14-10.
- b. The initiation of any action in response to a violation of the pretreatment rules does not preclude initiation of any other response.
- c. A violation of the pretreatment rules includes the following:
- (1) The indirect discharge of pollutants in contravention of an applicable pretreatment standard or other applicable discharge limitation.
 - (2) The indirect discharge of pollutants without a permit from a significant industrial discharger as determined by IDEM.
 - (3) A violation of discharge limitations or other terms and conditions of the permit where an IWP permit is required under the pretreatment rules.
 - (4) Failure to comply with any other applicable pretreatment requirement.
 - (5) Failure to:
 - (A) allow entry, inspection, and monitoring by representatives of the commissioner when requested in accordance with applicable law;
or
 - (B) carry out monitoring, recording, and reporting required under this permit.

- d. It shall not be a defense for a permittee in an enforcement action that it would have been necessary to halt or reduce the permitted activity in order to maintain compliance with the conditions of the permit.

9. Oil and Hazardous Substance Liability

Nothing in this permit shall be construed to preclude the institution of any legal action or relieve the permittee from any responsibilities, liabilities, or penalties to which the permittee is or may be subject under Section 311 of the Act.

10. Property Rights

The issuance of this permit does not convey any property rights in either real or personal property, or any exclusive privileges, nor does it authorize any injury to private property or any invasion of personal rights or infringement of Federal, State, or local laws or regulations.

11. Severability

The provisions of this permit are severable and if any provision of this permit, or the application of any provision of this permit to any circumstances to held invalid, the application of such provision to other circumstances and the remainder of this permit shall not be affected thereby.



Industrial Wastewater Pretreatment (IWP)

Briefing Memo for

Eli Lilly and Company – Lebanon

Draft: June 2024

Final: TBD

Indiana Department of Environmental Management

100 North Senate Avenue
Indianapolis, Indiana 46204

(317) 232-8603

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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: New Permit
Facility Contact:	Neil J. Parke, Senior Director – Engineering HSE 317-276-7201; parke_neil_j@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 Action:	New Permit Date Application Received: February 15, 2024
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 an Industrial Wastewater Pretreatment (IWP) Permit application from Eli Lilly and Company – Lebanon on February 15, 2024. A five-year permit is proposed in accordance with 327 IAC 5-2-6(a).

The Federal Water Pollution Control Act of 1972 and subsequent amendments require a National Pollutant Discharge Elimination System (NPDES) permit for the discharge of wastewater to surface waters. Furthermore, Indiana Statute 13-15-1-2 requires a permit to control or limit the discharge of any contaminants into state waters or into a publicly owned treatment works (POTW). This proposed permit action by IDEM complies with both federal and state requirements.

In accordance with Title 40 of the Code of Federal Regulations (CFR) Sections 124.7 and 124.6, as well as Indiana Administrative Code (IAC) 327 Section 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 was prepared in order to document the factors considered in the development of IWP Permit effluent limitations. The technical basis for the Briefing Memo may consist of evaluations of prohibited discharge standards, categorical pretreatment standards, existing effluent quality, and receiving POTW limitations.

2.0 GENERAL

2.1 Facility Description

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). Pharmaceutical manufacturing of bulk active ingredients occurs at LP1. 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, oligonucleotide synthesis and purification, small molecule synthesis and purification, solvent recovery, gene cell therapy production and finishing, and warehouse operations. Other service 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 Receiving POTW

The permittee discharges to the City of Lebanon Wastewater Treatment Plant: a Class III, 5.0 MGD activated sludge treatment facility with influent and effluent flow meters, a head tank and grit structure, an anaerobic basin, four (4) oxidation ditches, three (3) secondary clarifiers, and UV disinfection facilities. Sludge treatment consists of three (3) anaerobic digesters and a centrifuge for dewatering. Dewatered and/or liquid sludge is hauled off-site.

Plant design peak flow is 15.0 MGD. The POTW also serves Hendrickson Commercial Vehicle Systems, IBC Coatings and Metals Technology, Johnson Controls, McKinley Packaging, Ken’s Foods (INP000696), Skjodt Barrett Foods (INP000684), US Cold Storage, White Castle, Kuraray MonoSol, LLC (INP000696), DS Smith (INP000698), and FGF, LLC (INP000647).

The POTW discharges to Prairie Creek (Q7,10 = 0 CFS).

2.3 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:	2,396 (2)
Process Wastestream #3:	6,418 (3)
Process Wastestream #4:	6,418 (4)
Process Wastestream #5:	1,643 (5)
Process Wastestream #6:	28,900 (6)
Process Wastestream #7:	814 (7)
Process Wastestream #8:	250 (8)
LP1 Non-Process Wastewater:	240,674 (9)
LP2 Non-Process Wastewater:	19,240 (10)
Sanitary:	22,075
Non-contact Cooling Water:	170,880
Boiler Blowdown:	24,731

- (1) Process Wastestream #1 is wastewater from Small Molecule Bulk Manufacturing.
- (2) Process Wastestream #2 is wastewater from Oligonucleotide Bulk Manufacturing.
- (3) Process Wastestream #3 is wastewater from Peptide 1 Bulk Manufacturing.
- (4) Process Wastestream #4 is wastewater from Peptide 2 Bulk Manufacturing.
- (5) Process Wastestream #5 is wastewater from Gene Cell Therapy Production and Finishing.
- (6) Process Wastestream #6 is wastewater from Solvent Recovery for Manufacturing after Ion Exchange Treatment.
- (7) Process Wastestream #7 is wastewater from the Warehouse operations.
- (8) Process Wastestream #8 is manufacturing lab support process wastewater from the Administration area.
- (9) Non-process wastewater from LP1, including soft water Multi Media Filtration and backwash from the Small Molecule Bulk Manufacturing, Oligonucleotide Bulk Manufacturing, Peptide 1 and 2 Bulk Manufacturing, Utilities, Warehouse, and Administration areas.
- (10) Non-process wastewater from LP2, including High Purity Water Generation, Municipal Water Conditioning, and Utility Mechanical wastewater.

2.4 Wastewater Pretreatment

The Eli Lilly and Company – Lebanon Campus will consist of two manufacturing sites: LP1 and LP2. Process wastewater generated at the LP1 manufacturing site, including process wastewater associated with Small Molecule Bulk Manufacturing, Oligonucleotide Bulk Manufacturing, Peptide 1 and Peptide 2 Bulk Manufacturing, solvent recovery, warehouse operations, and manufacturing lab support processes are subject to the Subpart C – Chemical Synthesis Products standards. Process wastewater generated as part of the Gene Cell Therapy Production and Finishing operations at the LP2 manufacturing site are subject to the Subpart D – Mixing/Compounding and Formulation standards.

Wastewater pretreatment at the facility includes three pH neutralization systems: one system for Utilities wastewater (LP1), 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, oligonucleotide synthesis and purification, small molecule synthesis and purification, solvent recovery, and laboratory services (LP1).

The pH neutralization system for Utilities treats wastewater from softener regeneration, Multi Media Filtration (MMF) backwash, and drains of process and HVAC cooling towers that is pumped from aqueous waste sumps in the Central Utilities Building (CUB). An aqueous waste tank with a working volume of 100,000 gallons is used to equalize the aqueous wastes coming from the aqueous waste sumps and boiler blowdown. The tank is equipped with a pH analyzer which controls the acid dosing line during recirculation of the aqueous waste into the tank.

The pH neutralization system for Gene Cell Therapy operations collects process and utility waste in a Waste Equalization Tank. From there, the waste is sent to a Waste Neutralization Tank, where anti-foaming, acid, and base dosing are provided and mixing/agitation occurs to ensure pH and temperature uniformity.

The centralized pH neutralization system consists of Aqueous Waste (AW) Tanks that handle non-solvent waste from all the manufacturing buildings and the Tank Farm area in LP1. This includes the treatment of non-process and process wastewater. No accumulated precipitation will be discharged to the sanitary sewer. The aqueous waste inlet and neutralization chemicals (sulfuric acid and caustic) are provided with dip tubes to prevent splashing and foaming. Pump recirculation is equipped with an eductor to facilitate mixing in the tank. Redundant pH analyzers are provided at the main waste discharge line and pump recirculation line to monitor the quality of the neutralized streams. The waste discharge flow is monitored at the outlet.

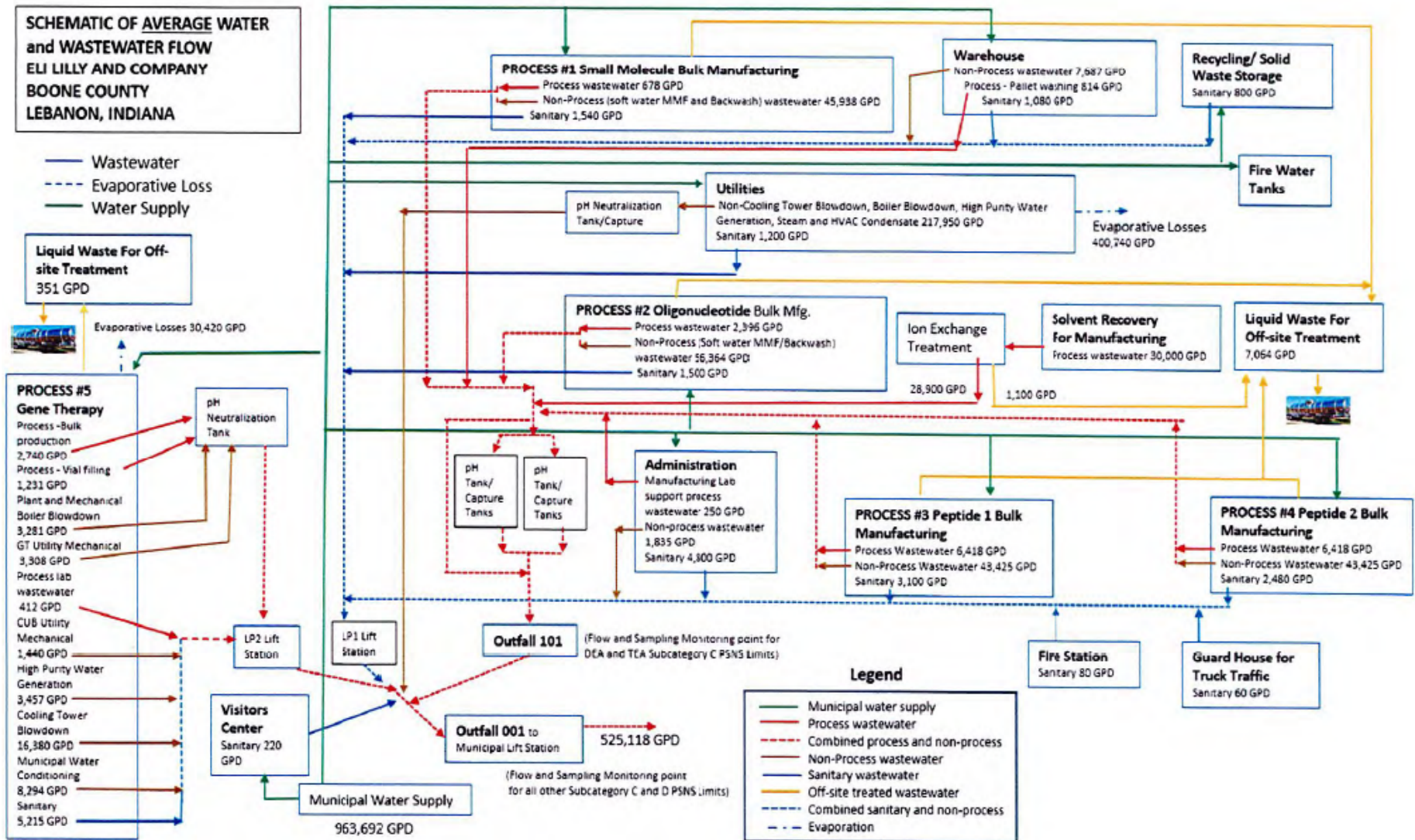
Other wastewater pretreatment conducted at the facility includes an anionic exchange treatment system that treats solvent recovery wastewater (LP1).

The aqueous stream from the solvent recovery system containing solvent impurities (and/or associated salts) is transferred to a nitrogen-blanketed holding tank. The aqueous material then flows through a “duty” bed of the chloride form of a strong base anion exchange resin. Organic solvent ions are exchanged for chloride ions during this process. When the ion exchange resin active sites approach saturation, flow is switched from the duty to the standby resin bed, and the previous duty bed is regenerated using a sodium chloride solution. The regeneration stream is collected for offsite disposal, and the previous duty bed becomes the standby bed. A caustic cleaning of the resin is performed to when the resin begins to degrade. The duty/standby functionality continues until offline analysis indicates the resin performance is degrading, due to fouling with peptide fragments. At that point, a caustic cleaning of the resin is performed to restore resin performance. The caustic cleaning stream is also disposed offsite.

Since the solvent recovery system will not be operational until late 2025, the design and definition of the anionic exchange process has not yet been fully completed and remains subject to further refinement.

A 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



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 facility is required to have a Class A-SO Operator.

2.5 Changes in Operation

This is a new IWP permit.

3.0 PERMIT HISTORY

3.1 Compliance History

This is a new IWP permit.

4.0 PERMIT DRAFT DISCUSSION

4.1 Selection of Parameters

This permit regulates the substances and parameters in the permittee's wastewater that are subject to 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. In addition, routine Closed Cup Flashpoint testing and Copper monitoring have also been added at the request of the City of Lebanon POTW.

Monitoring requirements have been included in this permit for Total Suspended Solids (TSS), Carbonaceous Biochemical Oxygen Demand (CBOD₅), Oil and Grease, Phosphorus, and Chloride as these pollutants are typically present in similar types of discharges.

The permittee has indicated they will initially discharge non-process wastewater only as construction and installation of equipment occurs and do not plan to discharge process wastewater until late 2025. This permit establishes monitoring and limitations for both scenarios: the discharge of only non-process wastewater beginning on the effective date of the permit, and the addition of process wastewater to the discharge which will occur at a future date. **The permittee must notify IDEM and the City of Lebanon at least 30 days prior to the discharge of process wastewater.**

Additionally, the discharge shall not exceed the local limits in the Sewer Use Ordinance upon entering the POTW at any time.

4.2 Selection of Limits

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.

Per 40 CFR 439.37(a), sources that discharge to a POTW with nitrification capability (defined at 40 CFR 439.2(i)) are not required to achieve the pretreatment standard for Ammonia (as N). Eli Lilly and Company provided Monthly Reports of Operation from the City of Lebanon demonstrating that the Lebanon POTW has “nitrification capability” as defined at 40 CFR 439.2(i). Data for October, November, and December 2023 shows that the municipal treatment plant removes 98.7-99.8% of the Ammonia that it receives in wastewater. Thus, the permittee is not required to achieve the pretreatment standard for Ammonia (as N).

Per 40 CFR 439.37(d), compliance with the effluent limitations for Cyanide may be achieved by certifying to the permit issuing authority that the facility’s manufacturing processes neither use nor generate cyanide. Eli Lilly and Company provided certification that Cyanide compounds are not used nor generated in a manufacturing process regulated under 40 CFR 439 Subpart C – Chemical Synthesis Products, therefore limits and monitoring for Cyanide are not required.

The remaining categorical standards have been adjusted due to the combined, non-categorical wastestreams contributing to flow at Outfall 001. The categorical process flows account for approximately 9% of the total wastestream that is discharged to the POTW – 8.7% of the total wastestream is process flows regulated under 40 CFR 439 Subpart C and 0.03% is process flows regulated under 40 CFR 439 Subpart D. Therefore, the categorical limitations have been adjusted by factoring the 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= 47,517 GPD

Total average flow of dilute wastestreams= 477,600 GPD

Average total flow= 525,117 GPD

Acetone – Daily Maximum

$$\frac{20.7 \text{ mg/l} * 47,517 \text{ GPD}}{47,517 \text{ GPD}} \times \frac{525,117 \text{ GPD} - 477,600 \text{ GPD}}{525,117 \text{ GPD}} = 1.87 \text{ mg/l}$$

Acetone – Monthly Average

$$\frac{8.2 \text{ mg/l} * 47,517 \text{ GPD}}{47,517 \text{ GPD}} \times \frac{525,117 \text{ GPD} - 477,600 \text{ GPD}}{525,117 \text{ GPD}} = 0.74 \text{ mg/l}$$

Pollutants regulated under 40 CFR 439 Subpart C only:

Total average flow of regulated wastestreams= 45,874 GPD

Total average flow of dilute wastestreams= 479,243 GPD

Average total flow= 525,117 GPD

Benzene – Daily Maximum

$$\frac{3.0 \text{ mg/l} * 45,874 \text{ GPD}}{45,874 \text{ GPD}} \times \frac{525,117 \text{ GPD} - 479,243 \text{ GPD}}{525,117 \text{ GPD}} = 0.26 \text{ mg/l}$$

Benzene – Monthly Average

$$\frac{0.7 \text{ mg/l} * 45,874 \text{ GPD}}{45,874 \text{ GPD}} \times \frac{525,117 \text{ GPD} - 479,243 \text{ GPD}}{525,117 \text{ GPD}} = 0.06 \text{ mg/l}$$

The permittee requested that the limits be expressed as mass-based limits in the IWP permit. This is applicable and 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

$$1.87 \text{ mg/l} \times 8.345 \times 0.525117 \text{ MGD} = 8.21 \text{ lbs/day}$$

Table 1 below provides the Federal Effluent Limitation Guideline 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	1.87	0.74	8.21	3.25
n-Amyl acetate	20.7	8.2	1.87	0.74	8.21	3.25
Ethyl acetate	20.7	8.2	1.87	0.74	8.21	3.25
Isopropyl acetate	20.7	8.2	1.87	0.74	8.21	3.25
Methylene chloride	3.0	0.7	0.27	0.06	1.19	0.28
Pollutants regulated under Subpart C only						
4-methyl-2-pentanone	20.7	8.2	1.81	0.72	7.92	3.14
Isobutyraldehyde	20.7	8.2	1.81	0.72	7.92	3.14
n-Butyl acetate	20.7	8.2	1.81	0.72	7.92	3.14
Methyl formate	20.7	8.2	1.81	0.72	7.92	3.14
Isopropyl ether	20.7	8.2	1.81	0.72	7.92	3.14
Tetrahydrofuran	9.2	3.4	0.80	0.30	3.52	1.30
Benzene	3.0	0.7	0.26	0.06	1.15	0.27
Toluene	0.3	0.2	0.03	0.02	0.11	0.08
Xylenes	3.0	0.7	0.26	0.06	1.15	0.27
n-Heptane	3.0	0.7	0.26	0.06	1.15	0.27
n-Hexane	3.0	0.7	0.26	0.06	1.15	0.27
Chloroform	0.1	0.03	0.009	0.003	0.04	0.01
1,2-dichloroethane	20.7	8.2	1.81	0.72	7.92	3.14
Chlorobenzene	3.0	0.7	0.26	0.06	1.15	0.27
o-Dichlorobenzene	20.7	8.2	1.81	0.72	7.92	3.14
Diethyl amine	255	100	22.28	8.74	97.62	38.28
Triethyl amine	255	100	22.28	8.74	97.62	38.28

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 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 average Chloroform mass load for all site non-process wastewater was based on the daily average non-process wastewater discharge and the 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 (MGD)	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	0.045874	N/A	0.038	0.011
Chloroform allocation for non-process wastewater	0.0157	0.0135	N/A	0.479243	0.063	0.054
Final Site Limit based on Net/Gross Calculations:					0.101	0.065

The CWF adjusted limits for Diethyl amine and Triethyl amine (Daily Max of 22.28 mg/l and Monthly Avg of 8.74 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 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	49.77	19.52	97.62	38.28
Triethyl amine	255	100	49.77	19.52	97.62	38.28

[*] Calculated using CWF with 45,874 GPD total average flow of regulated wastestreams, 189,152 GPD total average flow of dilute wastestreams, and average total flow of 235,036 GPD

4.3 Self-Monitoring Frequency

Self-Monitoring frequency is determined by the pollutants present in the permittees process and compliance history. Since this is a new IWP permit, the monitoring frequencies have been established in accordance with other similarly issued permits.

To assure compliance with the limits and terms of this permit, State rules [327 IAC 5-21-9 and 10] require the permittee to: (i) monitor the final pretreated discharge at a minimum frequency; and (ii) report the results to this agency. To fulfill this requirement, the samples must be: (i) representative of the daily discharge; and (ii) collected, preserved and analyzed using U.S. EPA-approved materials and methods.

5.0 PERMIT LIMITATIONS

5.1 Summary of Limits and Basis for Each:

Outfall 001

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.

<u>Parameter</u>	<u>Discharge Limitations</u>			<u>Monitoring Requirements</u>	
	<u>Daily Maximum</u>	<u>Monthly Average</u>	<u>Unit</u>	<u>Measurement Frequency</u>	<u>Sample Type [4]</u>
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

<u>Parameter</u>	<u>Daily Minimum</u>	<u>Daily Maximum</u>	<u>Unit</u>	<u>Measurement Frequency</u>	<u>Sample Type</u>
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.

[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.

Alternatively, a 24-hour composite sample may be obtained by an automatic sampler on an equal time interval basis over a twenty-four hour period provided that a minimum of 24 samples are taken and combined prior to analysis. The samples do not need to be flow-proportioned if the permittee collects samples in this manner.

[5] 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.

[6] Based on local ordinance [City of Lebanon Ordinance No. 2017-06, Section 55.307]. Note: TSS in excess of 240 mg/l, CBOD₅ in excess of 210 mg/l, FOG in excess of 100 mg/l, and Phosphorus in excess of 1 mg/l may be subject to local surcharge.

[7] All metals shall be analyzed as Total Recoverable Metals.

[8] Based on local ordinance [City of Lebanon Ordinance No. 2017-06 (adopted June 12, 2017)].

[9] If the permittee collects more than one grab sample on a given day for pH, the values shall not be averaged for reporting daily maximums or daily minimums. The permittee must report the individual minimum and the individual maximum pH value of any sample during the month on the Monthly Monitoring Report form.

Outfall 001

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.

Parameter	Discharge Limitations		Unit	Monitoring Requirements	
	Daily Maximum	Monthly Average		Measurement Frequency	Sample Type [4]
Flow [5]	Report	Report	MGD	1 X Daily	24-Hr. Total
Acetone	8.21 [6] Report	3.25 [6] Report	lbs/day mg/l	2 X Weekly	Grab
n-Amyl acetate	8.21 [6] Report	3.25 [6] Report	lbs/day mg/l	2 X Weekly	Grab
Ethyl acetate	8.21 [6] Report	3.25 [6] Report	lbs/day mg/l	2 X Weekly	Grab
Isopropyl acetate	8.21 [6] Report	3.25 [6] Report	lbs/day mg/l	2 X Weekly	Grab
Methylene chloride	1.19 [6] Report	0.28 [6] Report	lbs/day mg/l	2 X Weekly	Grab
4-methyl-2-pentanone	7.92 [7] Report	3.14 [7] Report	lbs/day mg/l	2 X Weekly	Grab
Isobutyraldehyde	7.92 [7] Report	3.14 [7] Report	lbs/day mg/l	2 X Weekly	Grab
n-Butyl acetate	7.92 [7] Report	3.14 [7] Report	lbs/day mg/l	2 X Weekly	Grab
Methyl formate	7.92 [7] Report	3.14 [7] Report	lbs/day mg/l	2 X Weekly	Grab
Isopropyl ether	7.92 [7] Report	3.14 [7] Report	lbs/day mg/l	2 X Weekly	Grab
Tetrahydrofuran	3.52 [7] Report	1.30 [7] Report	lbs/day mg/l	2 X Weekly	Grab
Benzene	1.15 [7] Report	0.27 [7] Report	lbs/day mg/l	2 X Weekly	Grab
Toluene	0.11 [7] Report	0.08 [7] Report	lbs/day mg/l	2 X Weekly	Grab

<u>Parameter</u>	<u>Daily</u> <u>Maximum</u>	<u>Monthly</u> <u>Average</u>	<u>Unit</u>	<u>Measurement</u> <u>Frequency</u>	<u>Sample</u> <u>Type [4]</u>
Xylenes	1.15 [7] Report	0.27 [7] Report	lbs/day mg/l	2 X Weekly	Grab
n-Heptane	1.15 [7] Report	0.27 [7] Report	lbs/day mg/l	2 X Weekly	Grab
n-Hexane	1.15 [7] Report	0.27 [7] Report	lbs/day mg/l	2 X Weekly	Grab
Chloroform	0.10 [7] Report	0.07 [7] Report	lbs/day mg/l	2 X Weekly	Grab
1,2-dichloroethane	7.92 [7] Report	3.14 [7] Report	lbs/day mg/l	2 X Weekly	Grab
Chlorobenzene	1.15 [7] Report	0.27 [7] Report	lbs/day mg/l	2 X Weekly	Grab
o-Dichlorobenzene	7.92 [7] Report	3.14 [7] Report	lbs/day mg/l	2 X Weekly	Grab
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

<u>Parameter</u>	<u>Daily</u> <u>Minimum</u>	<u>Daily</u> <u>Maximum</u>	<u>Unit</u>	<u>Measurement</u> <u>Frequency</u>	<u>Sample</u> <u>Type</u>
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.
- [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's 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.

Alternatively, a 24-hour composite sample may be obtained by an automatic sampler on an equal time interval basis over a twenty-four hour period provided that a minimum of 24 samples are taken and combined prior to analysis. The samples do not need to be flow-proportioned if the permittee collects samples in this manner.

- [5] 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.
- [6] Based on categorical standards [40 CFR 439.37 and 40 CFR 439.47]. The Standards are 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.
- [7] 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.
- [8] Based on local ordinance [City of Lebanon Ordinance No. 2017-06, Section 55.307]. Note: TSS in excess of 240 mg/l, CBOD₅ in excess of 210 mg/l, FOG in excess of 100 mg/l, and Phosphorus in excess of 1 mg/l may be subject to local surcharge.
- [9] If the permittee collects more than one grab sample on a given day for pH, the values shall not be averaged for reporting daily maximums or daily minimums. The permittee must report the individual minimum and the individual maximum pH value of any sample during the month on the Monthly Monitoring Report form.
- [10] Based on local ordinance [City of Lebanon Ordinance No. 2017-06 (adopted June 12, 2017)].
- [11] Closed cup flashpoint must be measured by a test method specified in 40 CFR 261.21. Regulation 40 CFR 403.5(b)(1) and the City of Lebanon SUO prohibit the discharge of pollutants that create a fire or explosive hazard, including, but not limited to wastestreams with a closed cup flashpoint below 60° C (140° F).

Outfall 101

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.

<u>Parameter</u>	<u>Discharge Limitations</u>			<u>Monitoring Requirements</u>	
	<u>Daily</u> <u>Maximum</u>	<u>Monthly</u> <u>Average</u>	<u>Unit</u>	<u>Measurement</u> <u>Frequency</u>	<u>Sample</u> <u>Type</u>
Flow [3]	Report	Report	MGD	2 X Weekly	24-Hr. Total
Diethyl amine	97.62 [4] Report	38.28 [4] Report	lbs/day mg/l	2 X Weekly	Grab
n-Amyl acetate	97.62 [4] Report	38.28 [4] Report	lbs/day mg/l	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.
- [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.

5.2 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.