



INDIANA ENVIRONMENTAL STEWARDSHIP PROGRAM ANNUAL PERFORMANCE REPORT

State Form 53475 (R5 / 2-17)
INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
ENVIRONMENTAL STEWARDSHIP PROGRAM

Indiana Department of Environmental Management
Office of Program Support
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Indianapolis, IN 46204-2251
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Please use this form if you are a member of the Indiana Environmental Stewardship Program (ESP) to report on progress toward objectives and targets AND certify ESP requirements continue to be achieved. Indiana ESP facilities must submit an Annual Performance Report (APR) by April 1st of every year, for each calendar year in which the entity has been a member for at least three (3) full months. Membership terms are renewed every four (4) years through submitting your APR. Your APR should be reviewed and signed by a senior manager at your facility prior to submittal. Once signed, e-mail the APR to IDEM at esp@idem.IN.gov. Please do not include any confidential business information in your annual performance report. Public access laws require IDEM to make the APR publicly available, which may include posting all portions of your report on the Indiana ESP Web site. If you have any questions, please contact IDEM at esp@idem.IN.gov or (800) 988-7901.

SECTION A FACILITY INFORMATION

Name of facility	Elanco Clinton Laboratories
Name of parent company (if applicable)	Eli Lilly and Company
Street address (number and street)	10500 South State Road 63, P.O. Box 99
City / State / ZIP code	Clinton, Indiana 47842-0099
Website of facility / company	http://www.lilly.com ; http://www.elanco.com

CONTACT INFORMATION

Name of Contact (Mr. / Mrs. / Ms. / Dr.)	Mr. John M Batronis		Title	Consultant - Environmental	
Telephone number	(765) 832-4163	FAX number	(765) 832-4549	E-mail address	batronisjm@elanco.com
Mailing address (if different from facility address)					
City / State / ZIP Code					

REPORTING PERIOD

Reporting period dates (mm/dd/yyyy – mm/dd/yyyy)	01/01/2017 - 12/31/2017
1a. Is this the fourth Annual Performance Report of your membership term?	
<input type="checkbox"/> Yes—If yes, answer question 1b.	
<input checked="" type="checkbox"/> No—If no, skip to the "Change in Information" section of this report.	
1b. Do you wish to renew your Indiana Environmental Stewardship Program membership?	
<input type="checkbox"/> Yes—If yes, please complete all sections of this annual report.	
<input type="checkbox"/> No—If no, please complete all sections of this annual report except for Section F.	

CHANGE IN INFORMATION

In your ESP application and, perhaps, in previous annual performance reports, you described what your facility does or makes. Have there been any changes or additions to your facility's list of products or activities?

☒ Yes—If yes, please describe them: _____
Two new products that are used for animal feedstock purposes will be produced at Clinton Laboratories - Hemicell and Lubabegron hemifumarate.

☐ No

SECTION B PUBLIC OUTREACH AND PERFORMANCE REPORTING

Why do we need this information? IDEM needs to know how environmental information was shared with the public.	What do you need to do? Describe how the facility has shared and plans to share environmental information.
Please briefly describe the activities that your facility conducted during this reporting period to interact with the community on environmental issues and to report publicly on its environmental performance. Annual community outreach meetings; Vermillion County Soil & Water Conservation District	
Please indicate which of the following methods your facility plans to use to make its ESP Annual Performance Report available to the public. Please check as many as appropriate.	
<input checked="" type="checkbox"/> Web site (http://www.lilly.com) <input type="checkbox"/> Open house <input checked="" type="checkbox"/> Meetings <input type="checkbox"/> Press releases <input checked="" type="checkbox"/> Other neighbor meetings & tours	

SECTION C**ENVIRONMENTAL MANAGEMENT SYSTEM ASSESSMENT****Why do we need this information?**

Facilities need to have implemented an EMS that meets certain criteria and use an ISO 14001 EMS Lead Auditor at least every thirty-six (36) months to assess the EMS.

What do you need to do?

Answer the following questions about your EMS.

1. What is the most recent date that an ISO 14001 EMS Lead Auditor performed an EMS assessment at your facility? October 9, 2017
2. Name, title, and organization of ISO 14001 EMS Lead Auditor who conducted the most recent EMS assessment: _____
Bradley J. Verrico, CPEA; Lead Auditor; Midland Engineering Limited, Midland, MI
3. Is the date of the most recent EMS assessment performed by an ISO 14001 EMS Lead Auditor within the past thirty-six (36) months?
- ☒ Yes—If yes, skip to Question 4.
- ☐ No—If no, please have your ISO 14001 EMS Lead Auditor complete and sign the following checklist, indicating whether or not your EMS meets the listed criteria for ESP membership:
- ☐ Yes ☐ No Evidence of senior management support, commitment, and approval.
- ☐ Yes ☐ No A written environmental policy directed toward compliance, pollution prevention, and continuous improvement.
- ☐ Yes ☐ No Identification of the environmental aspects at the entity.
- ☐ Yes ☐ No Prioritization of the environmental aspects and a determination of those aspects deemed significant considering, at the minimum, environmental impacts and applicable laws and regulations.
- ☐ Yes ☐ No Established priorities, and environmental objectives and targets for continuous improvement in environmental performance and for ensuring compliance with applicable environmental laws, regulations, and permit conditions. Objectives and targets must go beyond current legal requirements and specify the environmental media, types of pollution to be prevented or reduced, implementation activities, and projected time frames.
- ☐ Yes ☐ No An established community outreach mechanism that includes identifying and responding to community concerns; informing the community of important matters that affect the community; and reporting on the EMS, including reporting to the public on the environmental policy and significant aspects.
- ☐ Yes ☐ No Incorporation of environmental and pollution prevention planning in the development of new products, processes, and services and modifications of existing processes.
- ☐ Yes ☐ No Evidence of clear responsibility for implementation, training, monitoring, EMS maintenance, taking corrective action, and ensuring compliance with applicable environmental laws, regulations, and permit conditions.
- ☐ Yes ☐ No Documentation of the implementation procedures and the results of implementation.
- ☐ Yes ☐ No Appropriate written EMS procedures.
- ☐ Yes ☐ No An annual evaluation of the EMS with written results provided to senior management and affected employees.

Signature of ISO 14001 EMS Lead Auditor

Date (month, day, year)

4. Were any deficiencies found during the most recent EMS assessment?
- ☒ Yes—If yes, describe any deficiencies found and the corrective action taken to address each deficiency: _____
See Attachment 1 for details of three minor deficiencies that were identified, and corrective action taken.
- ☐ No
5. What type of protocol was used to perform the independent EMS assessment?
- ☐ ISO 14001:2015 Certified audit
- ☐ ISO 14001:2004 Certified audit
- ☐ ESP Independent Assessment Protocol
- ☒ Other (please specify): Responsible Care Management System (RCMS) (See Attachment 1)
6. Is the EMS certified to a recognized standard?
- ☒ Yes—If yes, what standard does the EMS follow (please provide a copy of the most recent certificate)?
- ☐ ISO 14001:2015
- ☐ ISO 14001:2004
- ☒ Responsible Care EMS
- ☐ Responsible Care 14001
- ☐ No

SECTION C	ENVIRONMENTAL MANAGEMENT SYSTEM ASSESSMENT CONTINUED
7. When was the last Senior Management review of your EMS completed? Month / Year: <u>10/2017</u> Who headed the review (name and title)? <u>Douglas A. Samuelson, Director, Site Services - Health / Safety / Environmental</u>	
8. When did your facility last conduct an internal or corporate environmental compliance audit? Do not include inspections or site visits by regulatory organizations. Scope of the compliance audit: <u>Assess the level of compliance with Environmental Requirements</u> Month(s) / Year(s): <u>04/2017</u> Who conducted the audit(s) (e.g., facility staff, corporate, third party)? <u>Lilly Corporate HSE group and external HSE EMS auditor ; Corporate (North American Env. Services)</u>	
9. Explain the emergencies experienced within the facility during the past year. Were the applicable emergency and contingency plans detailed in the EMS effective? What changes, if any, have been made to your facility's emergency or contingency plans? No actual emergencies; conducted mock disaster drill with local community, following EMS. Annual EMS review to update contact information.	
10. Has your facility corrected all instances of potential environmental non-compliance and EMS non-conformance identified during your audits and other assessments? <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <input checked="" type="checkbox"/> Yes—If yes, briefly summarize corrective actions taken and other improvements made as a result of your EMS assessment(s) or compliance audit(s). <u>All improvement opportunities from the April 2017 HSE and October 2017 RCMS audits have been implemented.</u> </div> <div style="width: 45%;"> <input type="checkbox"/> No—If no, please explain your plans to correct these instances. <input type="checkbox"/> No such instances identified. </div> </div>	

SECTION D	ADDITIONAL INFORMATION
Why do we need this information? This information will help IDEM to effectively manage the Environmental Stewardship Program.	What do you need to do? Answer the questions as completely as possible.
1. In addition to ESP, please list environmental awards received or voluntary programs participated in during the past twelve (12) months. <u>Collaboration with the DNR, pertaining to the Healthy River Initiative. Global Day of Service. Elanco's Food Resource Bank program. Partnership with Project HATCH to fight hunger and undernourishment in Central Indiana (HATCHforHunger.com).</u>	
2. Has your facility taken advantage of any ESP incentives? If so, please describe the implementation process and list additional benefits IDEM should consider. <u>Yes, we received an expedited Title V air permit with "flexible" language, and renewal of NPDES permit. Coordination on inspections.</u>	
3. If your facility was not registered to the ISO 14001 standard prior to becoming an ESP member, has ESP helped you to pursue registration? If so, how has ESP been instrumental in achieving registration? <u>Currently, the site is not pursuing ISO 14001 certification.</u>	

SECTION E	ENVIRONMENTAL IMPROVEMENT INITIATIVE RESULTS
Why do we need this information? Facilities need to share the results of the environmental improvement initiative that was pursued during the reporting period. IDEM needs to report cumulative program reduction results.	What do you need to do? Reference Section F for "Category" and "Indicator" options to complete this section. Summarize your facility's progress on achieving the initiative you identified in the application or last year's APR. For assistance, please call (800) 988-7901 or email esp@idem.IN.gov .
Initiative #1	
Category 1: <u>Energy Use</u>	
Indicator 1: <u>Boiler Feedwater Preheat</u>	
	<div style="display: flex; justify-content: space-around;"> <div>Baseline (indicate measurement unit)</div> <div>Current (indicate measurement unit)</div> <div>Cost Savings</div> </div>
Calendar year	2016
Actual quantity (per year)	0
	2017
	\$44,500
	15,120 mmBTU
	No energy savings prior to project startup.
Production unit (select one)	Earned Labor Hours Production units <input checked="" type="checkbox"/> Production lbs. Other -- specify (e.g. Gallons, length, etc.) Production days in operation
Production Quantity	172 days
	365 days
	NA
Normalization factor (Current year production ÷ Baseline year production) 2.122	
Normalized quantity (Actual current year quantity - Actual baseline quantity) x Normalization factor 32,085 mmBTU/year (\$94,400 savings)	
Briefly describe how you achieved improvements for this environmental initiative or, if relevant, any circumstances that delayed progress. <u>A project was completed to install a heat-recovery heat exchanger in the site's wastewater treatment plant to recover heat from a process wastewater to preheat boiler feedwater. Prior to project implementation, the site used once-through well water to cool this wastewater stream prior to treatment, and the well water was discharged to the plant outfall. The project startup date was 13 July 2017.</u>	

SECTION E

ENVIRONMENTAL IMPROVEMENT INITIATIVE RESULTS
CONTINUED

Initiative #2

Category 2: _____ Indicator 2: _____	Baseline (indicate measurement unit)	Current (indicate measurement unit)	Cost Savings
Calendar year			
Actual quantity (per year)			
Production unit (select one)	Earned Labor Hours Other --- specify (e.g. Gallons, length, etc.)	Production units	Production lbs.
Production Quantity			NA
Normalization factor (Current year production ÷ Baseline year production)			
Normalized quantity (Actual current year quantity - Actual baseline quantity) x Normalization factor			
Briefly describe <i>how</i> you achieved improvements for this environmental initiative or, if relevant, any circumstances that delayed progress.			

Initiative #3

Category 3: _____ Indicator 3: _____	Baseline (indicate measurement unit)	Current (indicate measurement unit)	Cost Savings
Calendar year			
Actual quantity (per year)			
Production unit (select one)	Earned Labor Hours Other --- specify (e.g. Gallons, length, etc.)	Production units	Production lbs.
Production Quantity			NA
Normalization factor (Current year production ÷ Baseline year production)			
Normalized quantity (Actual current year quantity - Actual baseline quantity) x Normalization factor			
Briefly describe <i>how</i> you achieved improvements for this environmental initiative or, if relevant, any circumstances that delayed progress.			
<p>1. Briefly describe the <i>impacts or wastes</i> eliminated resulting from the environmental initiative(s). If multiple initiatives, please indicate which specifically. Operating the heat exchanger resulted in direct energy saving from not having to combust coal or natural gas to supply steam to preheat boiler feedwater. The initiative also conserves well water, reduces water discharged from the site, and conserves electrical power required to pump the well water. Air emissions savings from the boilers were also realized as a result of the energy savings.</p>			
<p>2. Are there other best management practices (BMPs) you can share correlating to your initiative(s)? Facilities must be careful to properly size equipment during the design phase, and provisions for shutdown, lockout, and maintenance must be considered.</p>			
<p>3. If the objectives and targets associated with the environmental improvement initiative(s) were not attained, please verify continued progress toward the environmental initiative(s). If multiple initiatives, please indicate which specifically. The objectives and targets of the environmental improvement initiative were attained.</p>			
<p>4. Please provide a narrative summary of progress made toward <i>qualitative, significant</i> EMS objectives and targets, if any. This project is part of a comprehensive strategy to reduce energy consumption at Clinton Laboratories and Eli Lilly & Company by 20% by 2020.</p>			
<p>5. Please list any state, U.S. EPA, or other partnership programs to which you are reporting this data (e.g., Energy Star, Project XL). None.</p>			
<p>6. Is your entity willing to share the environmental improvement initiative(s) and its best management practices (BMPs) at the ESP Annual Meeting and/or a Partners for Pollution Prevention quarterly meeting or conference? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p>			

SECTION F

ENVIRONMENTAL IMPROVEMENT INITIATIVE

Why do we need this information?

Facilities need to show they are committed to improving their environmental performance.

What do you need to do?

Refer to the Environmental Performance Table and answer the following questions.

1. Select the appropriate boxes in the following table to indicate the category and indicator(s) that represents the environmental improvement initiative selected by your facility. For the category and indicator selected, list the baseline year (e.g., 2015) and the future year (e.g., 2016). Next, list the baseline annual quantity (e.g., 5 tons) and future annual quantity (e.g., 2 tons) you are committing to achieve by the end of the future year.

Category	Indicator	Baseline Year 2012	Future Year 2020	Unit
<input type="checkbox"/> Material Procurement	<input type="checkbox"/> Recycled content			Pounds, tons
	<input type="checkbox"/> Hazardous/toxic components			Pounds, tons
<input type="checkbox"/> Suppliers' Environmental Performance	<input type="checkbox"/> Specify indicator: _____			As specified for the particular indicator
<input type="checkbox"/> Material Use	<input type="checkbox"/> Materials used			Pounds, tons
	<input type="checkbox"/> Hazardous materials used			Pounds, tons
	<input type="checkbox"/> Ozone depleting substances used			CFC-11 equivalent pounds
	<input type="checkbox"/> Total packaging materials used			Pounds, tons
<input type="checkbox"/> Water Use	<input type="checkbox"/> Total water used			Gallons
<input checked="" type="checkbox"/> Energy Use	<input type="checkbox"/> Electricity			kWh / MWh, Btu / MMBtu
	<input type="checkbox"/> Steam			kWh / MWh, gallons, ft ³
	<input type="checkbox"/> Natural gas			Btu / MMBtu
	<input type="checkbox"/> Diesel			Gallons
	<input type="checkbox"/> Propane / LPG			Btu / MMBtu, gallons
	<input type="checkbox"/> Gasoline			Gallons
	<input type="checkbox"/> Solar			kWh / MWh
	<input type="checkbox"/> Wind			kWh / MWh
	<input type="checkbox"/> Landfill gas			Btu / MMBtu
	<input type="checkbox"/> Combined heat and power			kWh / MWh, Btu / MMBtu
	<input checked="" type="checkbox"/> Other: <u>Energy Efficiency</u>	3233 kBTU/sq ft	3101 kBTU/sq ft	kBTU/square feet
<input type="checkbox"/> Land and Habitat	<input type="checkbox"/> Land and habitat conservation			Square feet, acres
	<input type="checkbox"/> Community land revitalization			Square feet, acres
<input type="checkbox"/> Air Emissions	<input type="checkbox"/> Total GHGs			MTCO ₂ E
	<input type="checkbox"/> VOCs			Pounds, tons
	<input type="checkbox"/> NO _x , SO _x , PM _{2.5} , PM ₁₀ , or CO			Pounds, tons
	<input type="checkbox"/> Air toxics			Pounds, tons
	<input type="checkbox"/> Odor			European Odour Units
	<input type="checkbox"/> Radiation			Curies, Becquerels
	<input type="checkbox"/> Dust			Pounds, tons
<input type="checkbox"/> Discharges to Water	<input type="checkbox"/> COD or BOD			Pounds, tons
	<input type="checkbox"/> Toxics			Pounds, tons
	<input type="checkbox"/> Total suspended solids			Pounds, tons
	<input type="checkbox"/> Nutrients			Pounds, tons of N or P
	<input type="checkbox"/> Sediment from runoff			Pounds, tons
	<input type="checkbox"/> Pathogens			MPN/ml, CFU/ml
<input checked="" type="checkbox"/> Non-hazardous Waste	<input type="checkbox"/> Landfill			Pounds, tons
<input type="checkbox"/> Hazardous Waste	<input type="checkbox"/> Incineration			Pounds, tons
	<input checked="" type="checkbox"/> Reused/recycled off-site	11%	>12%	Pounds, tons, gallons
	<input checked="" type="checkbox"/> Other: <u>Waste Efficiency</u>	0.623 kg/BKG prod.	0.592 kg/BKG prod.	Pounds, tons, gallons
<input type="checkbox"/> Noise	<input type="checkbox"/> Noise			dBA
<input type="checkbox"/> Vibration	<input type="checkbox"/> Vibration			Inches per second
<input type="checkbox"/> Products	<input type="checkbox"/> Expected lifetime energy use			kWh / MWh, Btu / MMBtu
	<input type="checkbox"/> Expected lifetime water use			Gallons
	<input type="checkbox"/> Expected lifetime waste to air, water, or land from product use			Pounds, tons
	<input type="checkbox"/> Waste to air, water, or land from disposal or recovery			Pounds, tons

If you need assistance filling out the form, please contact the ESP program manager at either esp@idem.in.gov or 1-(800) 988-7901.

SECTION F

FUTURE YEAR ENVIRONMENTAL IMPROVEMENT INITIATIVE
CONTINUED

2. If the environmental improvement initiative(s) will be *qualitative* in nature, please describe. _____
Standard work practices will be defined and implemented to reduce rework/waste, and video bulletin boards will be used to promote recycling and waste-reduction initiatives.
3. What activities or process changes do you plan to undertake at your facility to accomplish your initiative (e.g., technology changes in a particular process line, employee training)? _____
The site continues to expand the use of LED-lighting to replace mercury-vapor and florescent bulbs. Ongoing efforts to maintain steam traps, identify malfunctioning traps, and reduce compressed air usage and leaks will aid in reaching the Energy Efficiency goal.
4. Does this initiative address a significant aspect in your EMS?
☒ Yes
☐ No—If no, please explain why you believe this indicator should be included as an environmental improvement initiative: _____

CERTIFICATION AND PLEDGE

On behalf of (name of facility) Eli Lilly & Company, Elanco Animal Health, Clinton Laboratories

I certify that the information contained in this Annual Performance Report and attachments is accurate to the best of my knowledge and that this facility is, to the best of my knowledge and based on reasonable inquiry, currently in compliance with all applicable federal, state, and local environmental requirements, or has a corrective action program in place to attain compliance.

We, Eli Lilly & Company, Elanco Clinton Labs, commit to maintaining the principles and goals outlined in our Environmental Management System for our facility's Indiana Environmental Stewardship Program status. We agree to strive for full compliance with all regulations promulgated by the U.S. EPA, state, or local jurisdictions. We agree to promote the Indiana Environmental Stewardship Program and to share our success stories with other facilities. We understand that we must meet the requirement of implementing one (1) new, independent environmental improvement initiative each year of membership (for a total of four (4) initiatives), that the Annual Performance Report must be submitted to IDEM by April 1st of each year, and that we must reapply to the Indiana Environmental Stewardship Program every four (4) years.

I understand that the information provided in this Annual Performance Report will be public record. I am the senior facility manager or authorized facility signatory, and fully authorized to execute this statement on behalf of the corporation or other legal entity whose facility is submitting this Annual Performance Report.

Signature

Date (month, day, year)
03-26-2018

Printed signature

Douglas A. Samuelson

Title

Director, Site Services - Health / Safety / Environmental

Attachment 1
Elanco Clinton Laboratories
Environmental Stewardship Program

Description of Eli Lilly and Company Environmental Management System Audits

Lilly began implementing Environmental Management Systems [EMS] more than 20 years ago. The Company's Global EMS standard requires all sites to develop Health, Safety, and Environmental [HSE] management systems patterned after ISO 14001 standards. The Global HSE program is Responsible Care Management System (RCMS) certified.

An important element of Lilly's Global HSE program is periodic audits of the EMS. All manufacturing sites are audited at least once every four years, and the audit includes a comprehensive review of the HSE management system.

Site audits are conducted by Lilly's Global HSE auditing group. The audit team typically consists of a lead auditor and several team members who focus on specific programs and topics. The lead auditor is a Lilly corporate employee and the team members are a mix of external auditors and Lilly subject matter experts from the Global HSE organization and various Lilly plant sites.

The EMS portion of the audit is conducted using the company's HSE management system RCMS-certified protocol, which includes over 120 questions to assure that each element of an ISO 14001 EMS is addressed and implemented. The HSE management system audit protocol includes questions on the following topics:

1. Management commitment and accountability
2. Site specific policy
3. Aspects, permits, and regulatory requirements
4. Performance objectives and targets
5. Management plans and programs
6. Management system documentation
7. Organizational structure and responsibilities
8. Training
9. Communication
10. Document control
11. Operational control
12. Emergency preparedness and response

Lilly conducted a thorough comparison of each element of the IDEM Independent Assessment Protocol to Lilly's HSE management system audit protocol and found that Lilly's protocol addresses all the elements of the IDEM protocol and in many respects it exceeds the IDEM protocol.

The most recent EMS audit conducted at Clinton Laboratories in October 2017 was led by Mr. Bradley Verrico; Lead Auditor; Midland Engineering, Ltd., an external consultant who is a Certified Professional Environmental Auditor (CPEA) and is certified and approved by BEAC to perform EMS audits. There were three minor audit findings from this audit:

1. Audit nonconformance review

The requirement to define a root cause and to review the efficacy of actions taken (based on that cause) has not been established related to audit findings.

-Lilly identified this finding in a previous internal audit, and is still working on improving this process.

2. Communication - community complaint records

There was insufficient evidence of current complaint forms being kept in the security office at the time of the audit, because the records were not available.

-The site established a system for data entry and for records retention of the completed documents.

3. Contractor training

A required record of "orientation within 5 years" could not be found for 1 of 9 sampled contractor employees.

-All overdue contractors were put back through orientation, and the site contractor safety coordinator has instituted a monthly review of the contractor orientation of long-term contractor employees with contract firms.