



INDIANA ENVIRONMENTAL STEWARDSHIP PROGRAM ANNUAL PERFORMANCE REPORT

State Form 53475 (R7 / 2-21)

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
ENVIRONMENTAL STEWARDSHIP PROGRAM

Indiana Department of Environmental Management
Office of Program Support
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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.

This form will also be used for ESP members who are also members of the Indiana Partners for Pollution Prevention Program to recertify their membership and reaffirm their commitment to the Partners Pledge.

SECTION A FACILITY INFORMATION

Name of facility	Elanco Clinton Laboratories
Name of parent company (if applicable)	Elanco US Inc.
Street address (number and street)	10500 South State Road 63, P.O. Box 99
City / State / ZIP code	Clinton, Indiana 47842-0099
County	Vermillion
Website of facility / company	www.elanco.com
How many employees (full time equivalents) currently work at your facility?	400

CONTACT INFORMATION

Name of Primary Contact (Mr. / Mrs. / Ms. / Dr.)	John Batronis	Title	Advisor - HSE
Telephone number	(765) 832-4163	FAX number	()
Mailing address (if different from facility address)		E-mail address	john.batronis@elancoah.com
City / State / ZIP Code			
Name of Secondary Contact (Mr. / Mrs. / Ms. / Dr.)	Jason Morgan	Title	Director - HSE
Telephone number	(765) 832-4053	FAX number	()
Mailing address (if different from facility address)		E-mail address	jason.morgan@elancoah.com
City / State / ZIP Code			

REPORTING PERIOD

Reporting period dates from prior calendar year (mm/dd/yyyy – mm/dd/yyyy)	01/01/2020 - 12/31/2020
1a. Is this the fourth ESP Annual Performance Report of your membership term?	<input checked="" type="checkbox"/> Yes—If yes, answer question 1b. <input 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 checked="" 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.
2a. Are you a member of the Indiana Partners for Pollution Prevention (Partners) Program?	<input type="checkbox"/> Yes—If yes, answer question 2b. <input checked="" type="checkbox"/> No—If no, skip to the "Change in Information" section of this report.

REPORTING PERIOD (CONTINUED)

- 2b. Do you wish to recertify your Partners for Pollution Prevention (Partners) Pledge?
- ☐ Yes—If yes, please complete all sections of this annual report.
- ☐ 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: Clinton Laboratories started formulating Elanco's Clinacox® and packaging Elanco's Credelio® products in 2020.
- ☐ 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. Attended Vermillion Co. Soil & Water District Meetings, established Elanco Healthy Purpose™ web site.

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.

- ☒ Web site (<http://www.elanco.com>) ☐ Open house ☒ Meetings ☐ Press releases ☒ Other neighbor meetings and 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 26, 2020

2. Name, title, and organization of ISO 14001 EMS Lead Auditor who conducted the most recent EMS assessment: Emily Gallagher, CHMM, ERM US

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:

- | | |
|--|---|
| <input type="checkbox"/> Yes <input type="checkbox"/> No | Evidence of senior management support, commitment, and approval. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | A written environmental policy directed toward compliance, pollution prevention, and continuous improvement. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | Identification of the environmental aspects at the entity. |
| <input type="checkbox"/> Yes <input type="checkbox"/> 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. |
| <input type="checkbox"/> Yes <input type="checkbox"/> 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. |
| <input type="checkbox"/> Yes <input type="checkbox"/> 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. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | Incorporation of environmental and pollution prevention planning in the development of new products, processes, and services and modifications of existing processes. |
| <input type="checkbox"/> Yes <input type="checkbox"/> 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. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | Documentation of the implementation procedures and the results of implementation. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | Appropriate written EMS procedures. |
| <input type="checkbox"/> Yes <input type="checkbox"/> 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)

SECTION C

ENVIRONMENTAL MANAGEMENT SYSTEM ASSESSMENT
CONTINUED

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.

☐ No

5. What type of protocol was used to perform the independent EMS assessment?

☐ ISO 14001:2015 Certified audit

☐ ESP Independent Assessment Protocol

☒ Other (please specify): ERM audit protocol against HSE regulations and internal assessment guidance

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

☒ Responsible Care EMS

☐ Responsible Care 14001

☐ No

7. When was the last Senior Management review of your EMS completed?

Month / Year: 03/2021

Who headed the review (name and title)? Mark Danchek, Senior Director - Engineering, Maintenance, HSE

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: Full HSE Audit of Clinton Labs

Month(s) / Year(s): 10/2020

Who conducted the audit(s) (e.g., facility staff, corporate, third party)? Third Party - ERM US

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 on site in 2020.

10. Has your facility corrected all instances of potential environmental non-compliance and EMS non-conformance identified during your audits and other assessments?

☒ Yes—If yes, briefly summarize corrective actions taken and other improvements made as a result of your EMS assessment(s) or compliance audit(s).
See details in Attachment 1.

☐ No—If no, please explain your plans to correct these instances.

☐ No such instances identified.

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.
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).

2. Has your facility taken advantage of any ESP incentives? If so, please describe the implementation process and list additional benefits IDEM should consider.

Yes, we received an expedited Title V air permit with "flexible" language, and renewal of our NPDES permit. We have also received advance notice and schedule coordination on some IDEM inspections.

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?

Currently, the site is not pursuing ISO 14001 certification.

4. Are the ESP and/or Partners group meeting your expectations? Please provide feedback or suggestions.

Yes, ESP and Partners group meetings are meeting our expectations.

SECTION D

ADDITIONAL INFORMATION (CONTINUED)

5. If you are a member of Partners, please reaffirm your facility's or organization's pledge to the Partners and provide additional information regarding commitment to pollution prevention (P2).

Yes	No	
<input type="checkbox"/>	<input type="checkbox"/>	1. Ensure employees are aware of the facility's commitment to P2 and understand their role in implementing P2 objectives and goals in the facility.
<input type="checkbox"/>	<input type="checkbox"/>	2. Your facility has incorporated P2 planning in the development of new products, processes, and/or services.
<input type="checkbox"/>	<input type="checkbox"/>	3. Your facility established a mechanism to monitor waste generation and identify realistic P2 goals.
<input type="checkbox"/>	<input type="checkbox"/>	4. Your facility has established a process to listen and respond to stakeholder concerns.
<input type="checkbox"/>	<input type="checkbox"/>	5. Your facility makes available your general waste reduction and P2 information to members of our community, IDEM, and the Partners, if requested?
<input type="checkbox"/>	<input type="checkbox"/>	6. Your facility has participated in or conducted outreach activities that include details of your P2 efforts; please specify: _____
<input type="checkbox"/>	<input type="checkbox"/>	7. Your facility has participated in two or more Partners meetings in the last year.
<input type="checkbox"/>	<input type="checkbox"/>	8. Your facility supported the annual Pollution Prevention Conference and Trade Show. Please check all that apply: <input type="checkbox"/> Financial sponsorship <input type="checkbox"/> One or more attendees from your facility <input type="checkbox"/> Other (specify) _____

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: Land/Habitat Conserv Indicator 1: Acres Mowed	Baseline (indicate measurement unit)	Current (indicate measurement unit)	Cost Savings
Calendar year	2019	2020	NA
Actual quantity (per year)	10.2 acres	6.6 acres	Water savings have not yet been quantified.
Production unit (select one)	Earned Labor Hours Production units BKGs Production lbs. Other -- specify (e.g. Gallons, length, etc.)		
Production Quantity	8,672,897 BKGs	7,611,467 BKGs	NA
Normalization factor (Current year production ÷ Baseline year production) 0.877615			
Normalized quantity (Actual current year quantity - Actual baseline quantity) x Normalization factor -3.16 ACRES MOWED			
Briefly describe <i>how</i> you achieved improvements for environmental initiative #1 or, if relevant, any circumstances that delayed progress. Late in 2019, Clinton Laboratories employed the services of the Indianapolis office of Cardno (a global environmental and social development company) to develop a native habitat area along the front of the Clinton Labs campus. An area of 3.6 acres was planted with a native prairie seed mix in place of the fescue that had been in this area. In addition, over 750 trees (White Pine, Bald Cypress, Bur Oak, Sycamore, and River Birch) were planted in this area.			

Initiative #2

Category 2: Air toxins Indicator 2: Refrigerant Losses	Baseline (indicate measurement unit)	Current (indicate measurement unit)	Cost Savings
Calendar year	2019	2020	
Actual quantity (per year)	4445.7 lbs	1105.8 lbs	\$16,700.00 (based upon R134a @ \$5/lb)
Production unit (select one)	Earned Labor Hours Production units BKGs Production lbs. Other -- specify (e.g. Gallons, length, etc.)		
Production Quantity	8,672,897 BKGs	7,611,467 BKGs	NA
Normalization factor (Current year production ÷ Baseline year production) 0.877615			
Normalized quantity (Actual current year quantity - Actual baseline quantity) x Normalization factor -2931 lbs total refrigerants lost			
Briefly describe <i>how</i> you achieved improvements for environmental initiative #2 or, if relevant, any circumstances that delayed progress. A Clinton team developed a systemic approach that included communication of the smallest observations, increased maintenance frequency based on historical performance and implementation of simple but effective ideas to increase awareness of leaks.			

SECTION E ENVIRONMENTAL IMPROVEMENT INITIATIVE RESULTS CONTINUED			
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 environmental initiative #3 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. Initiative #1: Less water, herbicide, and fertilizer use on these 3.6 acres. Also, less carbon emissions from mowing and yard maintenance activities. Initiative #2: A 75% total reduction in refrigerant losses for all large chillers on site, resulting in a 2197-tonne reduction in CO2 Equivalent emissions.</p>			
<p>2. Are there other best management practices (BMPs) you can share correlating to your initiative(s)? Initiative #2: Maintenance frequency was increased based on historical performance (e.g., O-rings, PSVs, pipe corrosion, leak detection), and implementation of simple but effective ideas (e.g., cleaning/painting of chiller pads so oil drips were more visible). The team also made tasks easier by purchasing new leak detection units, purchasing new refrigerant recovery devices, and converting old R-11 recovery tanks to R134A.</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 these environmental improvement initiatives were attained. Initiative #2: The team's accomplishments in 2020 were outstanding, but they have more ideas for the future (e.g., Installation of a combined chilled water header would reduce the number of chillers required to be running.)</p>			
<p>4. Please provide a narrative summary of progress made toward <i>qualitative, significant</i> EMS objectives and targets, if any. These projects are part of a comprehensive strategy to reduce water and resource consumption and reduce air emissions at Clinton Laboratories.</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 next 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 20__	Future Year 20__	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 checked="" type="checkbox"/> Water Use	<input type="checkbox"/> Total water used	1,180 MM Gallons	1,100 MM Gallons	Gallons
<input 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 type="checkbox"/> Other: _____			_____
<input checked="" type="checkbox"/> Land and Habitat	<input checked="" type="checkbox"/> Land and habitat conservation	3.6 acres	6 acres	Square feet, acres
	<input type="checkbox"/> Community land revitalization			Square feet, acres
<input checked="" 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 checked="" type="checkbox"/> Air toxics	1105.8 lbs R134a	<1000 lbs R134a	Pounds, tons
	<input type="checkbox"/> Odor			European Odour Units
	<input type="checkbox"/> Radiation			Curies, Becquerels
<input checked="" type="checkbox"/> Discharges to Water	<input type="checkbox"/> Dust			Pounds, tons
	<input type="checkbox"/> COD or BOD			Pounds, tons
	<input type="checkbox"/> Toxics			Pounds, tons
	<input type="checkbox"/> Total suspended solids			Pounds, tons
	<input checked="" type="checkbox"/> Nutrients	5,658 lbs. P	<5,500 lbs. P	Pounds, tons of N or P
	<input type="checkbox"/> Sediment from runoff			Pounds, tons
<input type="checkbox"/> Non-hazardous Waste <input type="checkbox"/> Hazardous Waste	<input type="checkbox"/> Pathogens			MPN/ml, CFU/ml
	<input type="checkbox"/> Landfill			Pounds, tons
	<input type="checkbox"/> Incineration			Pounds, tons
	<input type="checkbox"/> Reused/recycled off-site			Pounds, tons, gallons
	<input type="checkbox"/> Other: _____			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 is exploring a project to recycle Membrane Bioreactor wastewater treatment plant effluent into a cooling tower system to reduce make-up water use and the need for phosphorus-based treatment chemicals. The site continues to replace mercury-vapor and florescent bulbs with LED-lighting.
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: _____

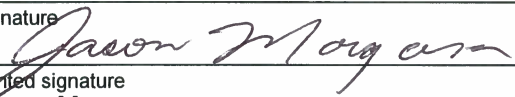
CERTIFICATION AND PLEDGE

On behalf of (name of facility) Elanco 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, Elanco U.S., Inc., 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) 05 31 2021
Printed signature Jason Morgan	Title Director - HSE

Attachment 1
Elanco Clinton Laboratories
Environmental Stewardship Program

Description of Elanco Environmental Management System Audits

Eli Lilly & Company began implementing Environmental Management Systems [EMS] more than 20 years ago, with Global EMS standards that required all sites to develop Health, Safety, and Environmental [HSE] management systems patterned after ISO 14001 standards. Following Lilly's divestiture of Elanco in March 2019, Clinton Laboratories continued to be Responsible Care Management System (RCMS) certified into 2020.

An important element of Elanco'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 Elanco'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 an Elanco corporate employee and the team members are a mix of external auditors and Elanco subject matter experts from the Global HSE organization and various Elanco 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

A comparison of each element of the IDEM Independent Assessment Protocol to Elanco's HSE management system audit protocol demonstrates that Elanco's protocol addresses all the elements of the IDEM protocol and in many respects exceeds the IDEM requirements.

The most recent HSE audit conducted at Clinton Laboratories in October 2020 was led by Ms. Emily Gallagher, CHMM., an external consultant with ERM US. There were three minor audit findings from this audit:

1. Environmental - Waste Management

It was observed that Building C-64 had three tankers staged. One tanker was labeled with only "WS100" - there was no indication of existing content hazards.

-This issue has been corrected, and procedures have been revised to ensure placards are posted when a new tanker is staged at C-64.

2. Health & Safety - Electrical Safety

Electrical disconnects were found to be blocked by equipment and/or materials in buildings C-11, C-26A, and C-77.

-This issue has been corrected for these specific areas. HSE is currently conducting a project to survey every electrical disconnect on site to ensure compliance with 1910.303(g)(1).

3. Health & Safety - Emergency Planning and Evacuation

Several portable fire extinguishers in buildings C-101, C-1, and C-11 were found to not have identification signs.

-Identification signs were posted near the identified fire extinguishers. HSE is currently conducting a project to survey every portable fire extinguisher on site to ensure compliance with 1910.157(c)(1).