

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Eli Lilly and Company
Lilly Corporate Center
Indianapolis, IN 46285

2. NRC/REGIONAL OFFICE

Region III
U. S. Nuclear Regulatory Commission
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

REPORT NUMBER(S) 2016001

3. DOCKET NUMBER(S)

030-04330

4. LICENSE NUMBER(S)

13-01133-02

5. DATE(S) OF INSPECTION

OCTOBER 12-14, 2016

LICENSEE:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:



- ☒ 1. Based on the inspection findings, no violations were identified.
- ☐ 2. Previous violation(s) closed.
- ☐ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, to exercise discretion, were satisfied.

Non-cited violation(s) were discussed involving the following requirement(s):

- ☐ 4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.
(Violations and Corrective Actions)

Statement of Corrective Actions

I hereby state that, within 30 days, the actions described by me to the Inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE	DATE
LICENSEE'S REPRESENTATIVE			
NRC INSPECTOR	Ryan Craffey		10/14/16
BRANCH CHIEF	Aaron McCraw		10/19/16

Docket File Information

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3. DOCKET NUMBER(S) 030-04330	4. LICENSE NUMBER(S) 13-01133-02	5. DATE(S) OF INSPECTION October 12-14, 2016
6. INSPECTION PROCEDURES USED 87126	7. INSPECTION FOCUS AREAS All	

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 04612	2. PRIORITY 5	3. LICENSEE CONTACT Trenton Mays - RSO	4. TELEPHONE NUMBER (317) 276-2747
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☒ Main Office Inspection Next Inspection Date: 10/12/2021

☒ Field Office Inspection Lilly Technology Center, Tippecanoe Labs

☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an unannounced routine inspection of a pharmaceutical company authorized to use byproduct material for research and development, in analytical instrumentation, fixed gauges, and other uses at locations in Indianapolis, Clinton, Greenfield, and Lafayette, Indiana. At the time of the inspection, the licensee had approximately 50 authorized users of unsealed material (mostly H-3, C-14, S-35, and I-125), including one that performed radiosynthesis of I-125 compounds. The licensee utilized two incinerators for H-3 and C-14 waste: one the premises of the Lilly Corporate Center (LCC), and one at Evonik Corporation's Tippecanoe Laboratories (TL) in Lafayette. The remainder of waste was disposed of via sanitary sewerage, held for decay in storage or transferred to a waste broker. The licensee also possessed fixed gauges containing Cs-137 at its Clinton Labs, and had recently begun using trace amounts of C-14 in one lab at the Lilly Technology Center (LTC). The licensee decommissioned the last active lab at its Elanco Animal Health division in Greenfield in mid-2014, and had not yet conducted any principal activities at its Materials Center in Indianapolis. However, the licensee intended to retain authorization for both of these locations in anticipation of future use. In addition to its radiation safety staff, the licensee enlisted the services of an on-site contractor to perform routine surveys, as well as interns to audit labs, and a consulting service to audit the radiation safety program.

PERFORMANCE OBSERVATIONS: The inspector toured areas of LCC, LTC and TL to observe the conduct of licensed activities, interview staff, and evaluate measures for materials security, hazard communication, and exposure control. The inspector also observed waste incinerations at LCC and TL, observed the licensee's response to a minor spill of S-35 at LCC, and conducted independent surveys. The licensee's staff demonstrated and discussed the implementation of procedures for radioiodinations, animal use, disposal via sanitary sewerage, package receipt, area surveys, bioassays, radiation safety training, waste processing, effluent monitoring and decommissioning. The inspector reviewed a selection of records related to these topics, in addition to records of personnel dosimetry, periodic audits and authorized user approvals. The inspector also reviewed extensive closeout surveys for the last active lab in Greenfield. Based on these records, the lab appeared to be acceptable for unrestricted use. The inspector also continued the NRC's review of EN 45127 (NMED 100344) regarding the discovery of 26 loose tritium exit light tubes in May 2009. The inspector verified that licensee still possessed these tubes in secure storage. The licensee intends to dispose of them in the next year, as the cost of doing so has fallen substantially. The NRC intends to close this event once it receives confirmation of their proper disposal. No violations of significance were identified as a result of this inspection.