



## Materials Inspection Report

<b>1. Licensee/Location Inspected:</b>  Eli Lilly and Company Lilly Corporate Center 893 South Delaware Street Indianapolis, IN 46285  Report Number(s) 2022-001	<b>2. NRC/Regional Office</b>  Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352
---	--

<b>3. Docket Number(s)</b> 030-04330	<b>4. License Number(s)</b> 13-01133-02	<b>5. Date(s) of Inspection</b> August 24, 2022
---	--	--

**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. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements, and were assessed at Severity Level IV, in accordance with the NRC Enforcement Policy.

A. 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, corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy were satisfied.  
 (Non-cited violation(s) was/were discussed involving the following requirement(s))

B. The following violation(s) is/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 AND DATE
LICENSEE'S REPRESENTATIVE		
NRC INSPECTOR	Ryan Craffey	 <small>Digitally signed by Ryan J. Craffey Date: 2022.09.08 15:11:36 -04'00'</small>
BRANCH CHIEF	Michael Kunowski	Michael A. Kunowski <small>Digitally signed by Michael A. Kunowski Date: 2022.09.12 09:12:43 -05'00'</small>



### Materials Inspection Record

1. Licensee Name: Eli Lilly and Company		2. Docket Number(s): 030-04330		3. License Number(s) 13-01133-02	
4. Report Number(s): 2022-001			5. Date(s) of Inspection: August 24, 2022		
6. Inspector(s): Ryan Craffey		7. Program Code(s): 03611	8. Priority: 5	9. Inspection Guidance Used: IP 87126	
10. Licensee Contact Name(s): Trent Mays, MS, CHP - RSO		11. Licensee E-mail Address: t.mays@lilly.com		12. Licensee Telephone Number(s): 317-276-2747	
13. Inspection Type:		14. Locations Inspected:		15. Next Inspection Date (MM/DD/YYYY):	
<input type="checkbox"/> Initial <input checked="" type="checkbox"/> Routine <input type="checkbox"/> Announced <input type="checkbox"/> Non-Routine <input checked="" type="checkbox"/> Unannounced		<input checked="" type="checkbox"/> Main Office <input type="checkbox"/> Field Office <input type="checkbox"/> Temporary Job Site <input type="checkbox"/> Remote		08/24/2027 <input checked="" type="checkbox"/> Normal <input type="checkbox"/> Extended <input type="checkbox"/> Reduced <input type="checkbox"/> No change	

16. Scope and Observations:

Eli Lilly and Company was a pharmaceutical company authorized to use byproduct material for research and development, instrument calibration, and in gauging, analytical, and static elimination devices at its Corporate Center (LCC) and Technology Center (LTC) in Indianapolis, Indiana. The licensee was also authorized to dispose of licensed materials by incineration at Evonik Corporation's Tippecanoe Laboratories (TL) in Lafayette, Indiana. At the time of the inspection, the licensee had 17 active authorized users at LCC who used microcurie quantities of radiolabeled compounds (primarily H-3, C-14, and I-125) for protein binding and metabolism studies; none at present performed radiosynthesis or iodinations. The licensee performed three incinerations per year of low-level radioactive waste at TL, which consisted primarily of short-lived waste from LCC decayed in storage to background prior to transfer to TL. No material was currently in use at LCC. The licensee did not possess any gauging devices; however, the licensee still had around 1,800 generally-licensed tritium exit signs, down from over 5,000 previously, after the licensee committed to use only non-tritium exit signs in renovations and new construction.

The inspector toured LCC, visiting five labs and the radioactive waste storage area. All areas were adequately posted, and all licensed material (including DIS waste) was adequately secured and accounted for. The inspector performed independent surveys of these areas; no residual contamination or exposures in excess of regulatory limits to members of the public were noted. The inspector observed the conduct of laboratory surveys by radiation safety staff, discussed the handling and use of radiolabeled compounds with authorized users, and observed demonstrations of package receipt and survey meter calibrations by radiation safety staff. All staff were knowledgeable of radiation protection principles, licensee procedures, and regulatory requirements.

The inspector reviewed a selection of radiation safety program records, including external audits of the radiation safety program, authorized user approvals, area survey results, personnel dosimetry reports, and records of material use and accountability, incinerations, sewer disposals, and air effluent monitoring.

No violations of NRC requirements were identified as a result of this inspection.