



**Docket File Information**  
**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

1. LICENSEE/LOCATION INSPECTED:  Eli Lilly and Company Radiation Safety Office: Mail Drop 2123, MCC20 Lilly Corporate Center Indianapolis, Indiana 46285  REPORT NUMBER(S) 2011-001	2. NRC/REGIONAL OFFICE  Region IV U. S. Nuclear Regulatory Commission 612 E. Lamar Boulevard, Suite 400 Arlington, TX 76011-4125
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3. DOCKET NUMBER(S) 030-04330	4. LICENSE NUMBER(S) 13-01133-02	5. DATE(S) OF INSPECTION 09/21-23/11
6. INSPECTION PROCEDURES USED 87126	7. INSPECTION FOCUS AREAS 03.01-03.07	

**SUPPLEMENTAL INSPECTION INFORMATION**

1. PROGRAM CODE(S) 3611	2. PRIORITY 5	3. LICENSEE CONTACT Stanley Hampton, RSO	4. TELEPHONE NUMBER (317) 276-7862
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Main Office Inspection                      Next Inspection Date:                      09/2016

Field Office Inspection    *2500 INNOVATION Way, Greenfield, IN, 1971 W. Davis Road, Greenfield, IN*

Temporary Job Site Inspection

**PROGRAM SCOPE**

Eli Lilly is and Research and Development (R&D) broad scope licensee with approximately 90 principal investigators (PI) and 600 authorized users (AU). Most of the research is performed at the headquarters office in Indianapolis. The licensee uses C-14, H-3, I-131, and P-32. All entrances to facilities, receipt area for radioactive material (RAM), RAM storage areas, DIS room, waste room were secured to prevent unauthorized entry. The licensee's transportation logs were reviewed and were in compliance with Department of Transportation requirements. 70 percent of the licensee's shipments are exempt quantity and on rare occasions they might ship up to a Yellow II. The licensee used appropriate shielding consistent with operating procedures in the labs and storage areas. The licensee has calibrated radiation instrumentation in each laboratory to monitor the radiation levels. The radiation safety staff has contractors that perform the laboratory area surveys and wipes. The survey frequency can be daily, weekly, monthly, or semi-annual and is determined by the most restrictive nuclide and its maximum possession limit in each lab. They have a room with several liquid scintillation counters. The wipe and leak tests samples are taken to this room. They have computer software that tracks the vials per AU and lab. The licensee has procedures in place for when an area survey or wipe test result triggers their action level. Lilly has a dosimetry program and the frequency in which the AU's exchange the dosimeters is dependent on nuclide and quantity of RAM used per experiment. They have one AU performing iodination.

**Performance Observations**

The inspector reviewed the dosimetry records of the AU performing iodination. The individual was significantly below NRC limits. For the past two years, the licensee has been using a computer software program (HP assist) that allows them to streamline different processes, including AU's ordering of RAM, tracking of inventory and limits per lab, license inventory, and tracking radiation training. Inspector reviewed the PI and AU selection process and reviewed several applications. The licensee uses a review checklist similar to NRC NUREG-1556 Volume 11 Appendix C to name PI's and AU's on the license. Inspectors interviewed numerous AU and PI's. All individuals had adequate knowledge and training to ensure the radiation safety program was operated appropriately. Inspector reviewed a representative sample of records, such as inventory, leak test, biannual refresher training, bioassay results, waste logs, package receipt, dosimetry, effluent release, area surveys. Annual audits were reviewed and are performed by an an independent contractor.

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(Continued)

The inspector reviewed circumstances surrounding the discovery of 26 tritium exit tubes in a conference room drawer in July 2009 (NRC Event 45127). The tubes are double bagged and secured in a locked cabinet within a controlled access room. The licensee is searching for a viable disposal route. The event is still open and the licensee has not received any communication from the NRC.

No safety concerns identified.

Note to inspector: Lilly has a policy for 2500 Innovation Way stating the NRC cannot begin an inspection until a representative from the Radiation Staff is present.