



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

REGION III  
2443 WARRENVILLE RD. SUITE 210  
LISLE, IL 60532-4352  
October 29, 2014

EA-14-153  
EN 50232  
NMED 140341(Closed)

Mr. Stanley D. Hampton, M.S.  
Corporate Radiation Safety Officer  
Eli Lilly and Company  
Lilly Corporate Center  
Indianapolis, IN 46285

SUBJECT: NRC SPECIAL INSPECTION REPORT NO. 99990003/2014008(DNMS) AND  
NOTICE OF VIOLATION – ELI LILLY AND COMPANY

Dear Mr. Hampton:

On September 4, 2014, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a special inspection at your office in Indianapolis, Indiana, with continued in-office review through October 15, 2014. The purpose of the inspection was to review the circumstances surrounding the licensee's report of the loss of three tritium exit signs discovered on June 26, 2014. The purpose of the in-office review was to evaluate the case history of the licensee's reports of previously lost tritium exit signs. Mr. Edward Kulzer of my staff conducted a telephonic exit meeting with you on October 15, 2014, to discuss the inspection findings. The enclosed inspection report presents the results of the inspection (Enclosure 2).

Based on the results of this inspection, the NRC has determined that a Severity Level IV violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The violation involved the licensee's failure to properly transfer and/or dispose of generally licensed devices in accordance with Title 10 of the *Code of Federal Regulations* (CFR) Part 31.5(c)(8)(i). The violation is cited in the enclosed Notice of Violation (Notice) (Enclosure 1). The NRC is citing the violation in the Notice because the violation was identified as a result of an event.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. Because the NRC has previously identified a similar violation at your facility, the NRC is requesting that your response include how your corrective actions to this violation will be more effective in preventing recurrence of a similar violation in the future. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be useful in preparing your response. You can find the Information Notice on the NRC website's at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html>. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

S. Hampton

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In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction.

We will gladly discuss any questions you have concerning this correspondence.

Sincerely,

*/RA/*

Aaron T. McCraw, Chief  
Materials Inspection Branch  
Division of Nuclear Materials and Safety

Docket No. 999-90003  
License No. General Licensee

cc: State of Indiana

S. Hampton

- 2 -

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction.

We will gladly discuss any questions you have concerning this correspondence.

Sincerely,

*/RA/*

Aaron T. McCraw, Chief  
Materials Inspection Branch  
Division of Nuclear Materials and Safety

Docket No. 999-90003  
License No. General Licensee

cc: State of Indiana

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## NOTICE OF VIOLATION

Eli Lilly and Company  
Indianapolis, Indiana

Docket No. 999-90003  
License No. General Licensee

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on September 4, 2014, with continued in-office review through October 15, 2014, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

Title 10 of the *Code of Federal Regulations* (CFR) 31.5.(c)(8)(i) requires, in part, that any person who acquires, receives, possesses, uses or transfers byproduct material in a device pursuant to a general license shall transfer or dispose of the device containing byproduct material only by export as provided by paragraph (c)(7) of this section, by transfer to another general licensee as authorized in paragraph (c)(9) of this section, or to a person authorized to receive the device by a specific license.

Contrary to the above, on or around June 5, 2014, the licensee disposed of three self-luminous exit signs containing hydrogen-3. This disposal was made to a person who did not hold a specific license pursuant to 10 CFR Parts 30 and 32 or from an Agreement State to receive the devices, and the exception in 10 CFR 31.5(c)(9) did not apply. Specifically, the devices were disposed of to a local waste disposal company which was unlicensed to receive the devices.

This is a Severity Level IV violation (Section 6.7).

Pursuant to the provisions of CFR 2.201, Eli Lilly and Company is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include: (1) the reason for the violation, or if contested, the basis for disputing the violation or severity level; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance was or will be achieved. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

Your response to this Notice will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction.

Enclosure 1

Notice of Violation

-2-

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 29<sup>TH</sup> day of October, 2014.

**U.S. Nuclear Regulatory Commission  
Region III**

Docket No.	99990003
License No.	General Licensee
Report No.	99990003/2014008(DNMS)
EA No.	EA-14-153
Licensee:	Eli Lilly and Company
Facility:	Lilly Corporate Center 639 S. Delaware St Indianapolis, Indiana 46225
Inspection Dates:	September 4, 2014, with continued in-office review through October 15, 2014
Exit Meeting Date:	October 15, 2014
Inspector:	Edward Kulzer, Health Physicist
Approved By:	Aaron T. McCraw, Chief Materials Inspection Branch Division of Nuclear Materials Safety

## **EXECUTIVE SUMMARY**

### **Eli Lilly and Company NRC Inspection Report 99990003/2014008(DNMS)**

An inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a special inspection on September 4, 2014, in response to the licensee's report of the loss of three tritium exit signs, each containing over 10 Curies of tritium (Event Number (EN) 50232). On June 27, 2014, Eli Lilly and Company, the licensee, reported to the NRC Headquarters Operations Center, the loss of three tritium exit signs that had been disposed of improperly with supplemental information provided in a written report dated July 24, 2014.

Specifically, during the week of June 5, 2014, as a result of an area demolition, the licensee's renovation contractor placed the three tritium exits signs in plastic bags and put them in a demolition debris dumpster. The dumpster was then removed by a local waste disposal company and taken to a nearby landfill for disposal. The licensee discovered that the signs were missing during an equipment inventory taken after the completion of the renovation on June 26, 2014.

During the inspection, the inspector identified a Severity Level IV violation of Title 10 of the *Code of Federal Regulations* (CFR) 31.5(c)(8)(i) concerning the licensee's failure to transfer or dispose of generally licensed devices in a manner authorized by the regulation. This is considered a repeat violation, because the NRC identified a similar violation following a review of the loss of 16 tritium exit signs by the licensee that was reported on January 17, 2011 (EN 46547).

As of the date of this inspection report, the corrective actions to prevent recurrence were: (1) that the on-site contractor building engineer, or his designee, will log and record all tritium signs present and compare it with the inventory maintained by the licensee's Radiation Safety staff prior to the commencement of project work; (2) sign removal will be performed by the on-site contractor building engineer, or his designee, prior to the demolition contractor's arrival; and, (3) the licensee's Radiation Safety staff will work with maintenance organizations across its Indianapolis facilities, to communicate the learning, and encourage similar processes be developed within all organizations.

Because this is a repeat violation, the NRC has requested that the licensee provide a written response detailing how the aforementioned corrective actions, as well as any additional actions, taken to prevent recurrence of a similar violation will be more effective than previous corrective actions that were taken to prevent recurrence of a similar violation.

## **REPORT DETAILS**

### **1 Program Overview**

The licensee is authorized under 10 CFR 31.5 to possess generally licensed devices. The licensee has over 3,300 generally licensed exit signs at its facilities listed in the NRC's General License Tracking System (GLTS).

On January 17, 2011, the licensee reported the loss of 16 tritium exit signs to the NRC Headquarters Operations Center, with a written report that followed on February 14, 2011. In its acknowledgement of the written response on March 18, 2011, the NRC identified a Severity Level IV violation of 10 CFR 31.5(c) for the licensee's failure to transfer or dispose of generally licensed devices only by transfer to persons holding a specific license to receive the devices pursuant to 10 CFR Parts 30 and 32 or from an Agreement State. The NRC dispositioned the violation as a Non-Cited Violation because the violation was self-identified, non-repetitive, non-willful, and prompt corrective actions were taken, consistent with Section 2.3.2 of the NRC Enforcement Policy.

### **2 Events surrounding the loss of three tritium exit signs.**

#### **2.1 Inspection Scope**

On September 4, 2014, the inspector conducted a special inspection to review the facts and circumstances that surrounded the licensee's report of the loss of three tritium exit signs during the week of June 5, 2014, by interviewing licensee staff and reviewing actions taken by the licensee to investigate the loss of the three exit signs.

#### **2.2 Observations and Findings**

During the week of June 5, 2014, the licensee had a contractor perform chemical decontamination of an area in Building 82, used as chemical laboratories, located at 1249 South White River Parkway, Indianapolis, Indiana. The onsite contractor went beyond the scope of the work for the project, and demolished walls and ceiling of the area, removing and inadvertently disposing of three tritium exit signs as part of their demolition. Two of the exit signs contained approximately 17 Curies of tritium at the time of the loss, and the other contained approximately 11 Curies.

On June 26, 2014, during an equipment inventory taken after the renovation, the licensee discovered that the exit signs were missing and determined that the exit signs had been improperly disposed of during the renovation project. On June 27, 2014, the licensee contacted NRC Headquarters Operations Center to report the loss of the exit signs.

Immediately following the discovery of the loss, the licensee performed wipe tests of the work areas and did not detect any tritium contamination. As a result, the licensee did not project any doses to the contract workers, who would be considered members of the public for comparison to regulatory limits. The licensee contacted the landfill to determine if the dumpsters were still awaiting disposition on the grounds. The landfill



reported that the contents of the dumpsters in question had already been buried under approximately 15 feet of other garbage and earth. The landfill advised the licensee that no attempt should be made to recover the signs.

During the September 4, 2014, inspection, the inspector identified a Severity Level IV violation of Title 10 of the *Code of Federal Regulations* (CFR) 31.5(c)(8)(i) concerning the licensee's failure to transfer or dispose of generally licensed devices in a manner authorized by the regulation. Because the NRC had determined that a similar violation had previously occurred in 2011, as mentioned above, the NRC considered this a repeat violation.

The licensee determined and the inspector agreed that the cause of the event and violation was that the contract company's supervisors did not provide adequate oversight of their workers during sign removal, despite having been previously trained and proper tritium exit sign disposal. Other contributing factors included the lack of involvement of radiation safety staff during the process, and the oversight of the signs during a pre-planning safety checklist.

As of the date of this inspection report, the corrective actions to prevent recurrence were: (1) that the on-site contractor building engineer, or his designee, will log and record all tritium signs present and compare it with the inventory maintained by the licensee's Radiation Safety staff prior to the commencement of project work; (2) sign removal will be performed by the on-site contractor building engineer, or his designee, prior to the demolition contractor's arrival; and, (3) the licensee's Radiation Safety staff will work with maintenance organizations across its Indianapolis facilities, to communicate the learning, and encourage similar processes be developed within all organizations.

Because this is a repeat violation, the NRC has requested that the licensee provide a written response detailing how the aforementioned corrective actions, as well as any additional actions, taken to prevent recurrence of a similar violation will be more effective than previous corrective actions that were taken to prevent recurrence of a similar violation.

### 2.3 Conclusions

The inspector identified a repeat violation of 10 CFR 31.5(c)(8)(i) for the licensee's failure to transfer or dispose of the three tritium exit signs in an authorized manner.

## 3 **Reporting the Event**

### 3.1 Inspection Scope

The inspector reviewed the reporting of the event of the loss of the three exit signs by interviewing the licensee's staff and evaluating the required 30-day written report documenting the lost signs.

### 3.2 Observations and Findings

On June 26, 2014, the licensee became aware of the fact that three of the generally licensed tritium exit signs that were listed to the licensee in the NRC's GLTS could not be accounted for. On June 27, 2014, the licensee reported the loss of the three exit signs to the NRC Headquarters Operations Center. The inspector determined that the licensee met all initial reporting requirements.

The licensee provided the required 30-day report dated July 24, 2014, and amended report dated August 7, 2014. The inspector reviewed all of the documentation and determined that it included all required information in accordance with 10 CFR 20.2201(b)(1). A copy of the licensee's initial written report can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) under Accession Number ML14209B000. The amended report can be found under Accession Number ML14225A406.

### 3.3 Conclusions

The NRC inspector did not identify and violations concerning the licensee's telephonic and written reports.

## **4 Exit Meeting Summary**

The NRC inspector presented the inspection findings via telephone on October 15, 2014. The licensee did not identify any documents or processes reviewed by the inspector as proprietary. The licensee acknowledged the findings presented.

### **LIST OF PERSONNEL CONTACTED**

# Stanley D. Hampton, Corporate Radiation Safety Officer

# Participated in the telephonic exit meeting on October 15, 2014.

### **INSPECTION PROCEDURES USED**

87103: Materials Licensees Involved in an Incident or Bankruptcy Filing