



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

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

April 3, 2014

EA-14-028

Mr. Eric D. Swank
Executive Director, Research Compliance
IUPUI/Indiana University Medical Center
Radiation Safety Office
541 Clinical Drive
Indianapolis, IN 46202-5111

SUBJECT: NOTICE OF VIOLATION – IUPUI/INDIANA UNIVERSITY MEDICAL CENTER;
NRC ROUTINE INSPECTION REPORT NO. 03001609/2014001(DNMS)

Dear Mr. Swank:

This refers to the routine inspection conducted at your campus in Indianapolis, Indiana by the NRC from January 13 through 17, 2014. The purpose of the inspection was to review activities performed under your NRC license to ensure that activities were being performed in accordance with NRC requirements. During the inspection, an apparent violation of NRC requirements was identified. The significance of the issue and the need for lasting and effective corrective actions were discussed with your staff during the onsite exit meeting that was held on January 17, 2014. Details regarding the apparent violation were provided in NRC Inspection Report Nos. 03001609/2014001(DNMS) and 03009792/2014001(DNMS) dated February 13, 2014.

In the letter transmitting the inspection report, we provided you with the opportunity to address the apparent violation identified in the report by either attending a predecisional enforcement conference or by providing a written response before we made our final enforcement decision. In a letter dated March 10, 2014, you provided a written response to the apparent violation. Prior to issuance of the inspection report, you had also provided us with two electronic mail messages dated January 17 and 24, 2014, that discussed corrective actions you were considering.

Based on the information developed during the inspection and the information that you provided in your response dated March 10, 2014, the NRC has determined that a violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in the subject inspection report. Specifically, the NRC identified a violation involving your failure to secure and control radioactive material that was in storage, contrary to the requirements in Title 10 of the Code of Federal Regulations (10 CFR) 20.1801, "Security of Stored Material." The root cause of the violation was a lack of complete understanding of NRC requirements. Your staff did not recognize that having someone in a nearby room or area did not constitute maintaining control of the material. This is of significant concern to the NRC because of the chance for radioactive material to become lost or stolen, which could result in adverse impacts to the health and safety of the general public. Therefore, this violation has been categorized, in accordance with the NRC Enforcement Policy, at Severity Level III.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$3,500 is considered for a Severity Level III violation.

Because your facility has not been the subject of escalated enforcement actions within the last 2 years or two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. The NRC considered the information you provided in your March 10, 2014, letter and in your electronic mail messages dated January 17 and 24, 2014. Your immediate corrective actions were to secure all entrances at the time of inspection and remove the largest quantity of radioactive material from one laboratory and secure it under the control of the radiation safety staff. For the longer-term, you verified, via written responses from your permit holders, that they understood the need to secure licensed material and obtained their assurance that such material would be secured in the future. You also published a newsletter in February 2014 to summarize the issues and to reiterate the importance of securing licensed material. Finally, you plan on discussing the issue at the next radionuclide radiation safety committee meeting to seek additional ways to assure that licensed material is properly secured. On the basis of these corrective actions, the NRC determined that *Corrective Action* credit was warranted.

Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this Severity Level III violation constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding: (1) the reason for the violation; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was achieved is already adequately addressed on the docket in the inspection report, in your letter dated March 10, 2014, and your electronic mail messages dated January 17 and 24, 2014. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

We also acknowledge receipt of your response, dated March 10, 2014, to the Severity Level IV Notice of Violation in NRC Inspection Report Nos. 03001609/2014001(DNMS) and 03009792/2014001(DNMS). The NRC has no further questions on this issue. Your corrective actions will be examined during future inspections.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room and in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the

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NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. The NRC also includes significant enforcement actions on its Web site at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>.

Sincerely,

/RA by D. Roberts for/

Cynthia D. Pederson
Regional Administrator

Docket No. 030-01609
License No. 13-02752-03

Enclosure:
Notice of Violation

cc w/encl: State of Indiana
Mr. Mack Richard, RSO

NOTICE OF VIOLATION

IUPUI/Indiana University Medical Center
Indianapolis, Indiana

Docket No. 030-01609
License No. 13-02752-03
EA-14-028

During an NRC inspection conducted from January 13 through 17, 2014, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

Contrary to the above, on January 16, 2014, the licensee did not secure from unauthorized removal or access to licensed materials that were stored in controlled or unrestricted areas. Specifically:

1. The licensee stored radioactive material in an open fume hood, an unlocked refrigerator, and radioactive waste containers located in a laboratory whose door had been propped open, and no one was present in the room. The total quantities involved several millicurie amounts of iodine-125, calcium-45, and carbon-14.
2. The licensee stored radioactive material in refrigerators and waste containers located in a laboratory with doors that were not secured, and no one was present. The total quantities involved several millicurie amounts of sulfur-35 and tritium.

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

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report Nos. 03001609/2014001(DNMS) and 03009792/2014001(DNMS) dated February 13, 2014, your letter dated March 10, 2014, and your electronic mail messages dated January 17 and 24, 2014. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, EA-14-028," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region III, 2443 Warrenville Road, Suite 210, Lisle, IL 60532 within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

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, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at

Enclosure

<http://www.nrc.gov/reading-rm/adams.html>. Therefore, to the extent possible, your response should not include any personal privacy or proprietary information so that it can be made available to the public without redaction.

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

Dated this 3rd day of April, 2014

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NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. The NRC also includes significant enforcement actions on its Web site at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>.

Sincerely,

/RA by D. Roberts for/

Cynthia D. Pederson
Regional Administrator

Docket No. 030-01609
License No. 13-02752-03

Enclosure:
Notice of Violation

cc w/encl: State of Indiana
Mr. Mack Richard, RSO

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*See previous concurrences

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OFFICE	RIII	RIII	RIII	D:OE	RIII	RIII
NAME	Loughheed*	McCraw*	Louden* JGiessner for	Zimmerman ¹ KDay	Orth	Pederson DRoberts for
DATE	03/21/14	03/24/14	03/24/14	03/28/14	04/01/14	04/03/14

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¹ OE concurrence provided via email from K. Day on March 28, 2014