



UNITED STATES
NUCLEAR REGULATORY COMMISSION

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

July 25, 2014

EA-14-076

Mr. Paul M. Loewenstein
Chairman, Radiation Safety Committee
1100 S. Grand Boulevard – Room 627
Edward A. Doisy Research Center
Saint Louis University
St. Louis, MO 63104

SUBJECT: NOTICE OF VIOLATION – ST. LOUIS UNIVERSITY; NRC ROUTINE
INSPECTION REPORT NO. 03011789/2014001(DNMS)

Dear Mr. Loewenstein:

This refers to the inspection conducted on April 7, 2014, at your St. Louis, Missouri, facility with continued in-office review through April 24, 2014. During the inspection, two apparent security violations of NRC requirements were identified. The significance of the issues and the need for lasting and effective corrective actions were discussed with you during the exit meeting on April 24, 2014. Details regarding the apparent violations were provided in NRC Inspection Report No. 03011789/2014001(DNMS) dated May 22, 2014.

In the letter transmitting the inspection report, we provided you with the opportunity to address the apparent violations identified in the report by either providing a written response or requesting a predecisional enforcement conference. In a letter dated June 24, 2014, you provided a response to the apparent violations and on July 1, 2014, you provided a supplemental response.

Based on the information developed during the inspection, and the information that you provided in your responses dated June 24 and July 1, 2014, the NRC has determined that violations of NRC requirements occurred. The first violation is cited in the Notice of Violation (Notice) in Enclosure 1 (Public) and the circumstances surrounding it are described in detail in our inspection report dated January 3, 2014. 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 mechanical failure of the door's locking mechanism. 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.

Enclosures 2 and 3 contain Sensitive
Unclassified Non-Safeguards Information.
Upon separation, this cover letter and
Enclosure 1 are decontrolled.

P. Loewenstein

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

Because your facility has not been the subject of escalated enforcement actions within the last two years, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process described in Section 2.3.4 of the Enforcement Policy. For this violation, upon identification of the issue, your staff immediately took control of the door, until your maintenance staff was able to replace the lock mechanism. Your staff also performed an immediate inventory to verify that no material was missing. As long-term corrective actions, your staff replaced the door locking mechanism with a card reader locking system. You also implemented a daily door check. On the basis of these corrective actions, the NRC determined that *Corrective Action* credit was warranted for this violation.

The NRC also identified a second security violation, but the details must be protected from unauthorized disclosure. Therefore, this violation is cited in the Notice in Enclosure 2 (Non-Public) and the circumstances surrounding it are also described in detail in our inspection report dated January 3, 2014. The violation is of concern to the NRC for the reasons stated in Enclosure 3 (Non-Public). Therefore, the violation has been categorized, in accordance with the NRC Enforcement Policy, as a Severity Level III violation.

In NRC Inspection Report No. 03011789/2014001(DNMS), the NRC described its understanding of the corrective actions taken to correct the second violation. In your responses dated June 24 and July 1, 2014, your staff described the corrective actions taken to correct the violation and to prevent recurrence. These corrective actions are also documented in Enclosure 3. Based on these corrective actions, the NRC has determined that *Corrective Action* credit is also warranted for this violation.

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 for either violation. However, significant violations in the future could result in a civil penalty. In addition, issuance of these Severity Level III violations constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations, and the date when full compliance was achieved, was adequately addressed on the docket in NRC Inspection Report No. 03011789/20140001(DNMS) dated May 22, 2014, and in your responses dated June 24 and July 1, 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 Notices. Additionally, if you choose to respond, please separate out any response to the second security violation into a separate attachment and mark your entire response "Security Related Information – Withhold from Public Disclosure under 10 CFR 2.390." In accordance with 10 CFR 2.390(b)(1)(ii), the NRC is waiving the affidavit requirements for any response to this letter. However, to the extent possible, your response, if any, should not include any personal privacy, proprietary, or safeguards information.

P. Loewenstein

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In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and Enclosure 1 will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. However, because of the Security-Related Information contained in the enclosures, and in accordance with 10 CFR 2.390, copies of Enclosures 2 and 3 will not be available for public inspection.

Additionally, Enclosures 2 and 3 must be protected from unauthorized disclosure. Security-Related Information is discussed in Regulatory Information Summary RIS-2005-031, "Control of Security-Related Sensitive Unclassified Non-Safeguards Information" (ML053480073), which is available on the NRC Web site or in ADAMS.

Sincerely,

/RA/

Cynthia D. Pederson
Regional Administrator

Docket No. 030-11789
License No. 24-00196-07

Enclosures:

1. Notice of Violation (Public)
2. Security-Related Information Notice of Violation (Non-Public)
3. Final Determination of Significance
(Non-Public)

cc w/encls: State of Missouri
Mark G. Haenchen, Radiation
Safety Officer

NOTICE OF VIOLATION

Saint Louis University
St. Louis, Missouri

Docket No. 030-11789
License No. 24-00196-07
EA-14-076

During an NRC inspection conducted on April 7, with continued in-office review through April 24, 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 April 7, 2014, the licensee did not secure from unauthorized removal or limit access to 15 millicuries of Cesium-137 located in the licensee's nuclear medicine hot lab, which is a controlled area. Specifically, the door to the lab was unlocked.

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 No. 03011789/2014001(DNMS) dated May 22, 2014, and in your letters dated June 24 and July 1, 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-14-076," 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 to this Notice, 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 <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 25th day of July, 2014

Enclosure 1

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P. Loewenstein

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System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. However, because of the Security-Related Information contained in the enclosures, and in accordance with 10 CFR 2.390, copies of Enclosures 2 and 3 will not be available for public inspection.

Additionally, Enclosures 2 and 3 must be protected from unauthorized disclosure. Security-Related Information is discussed in Regulatory Information Summary RIS-2005-031, "Control of Security-Related Sensitive Unclassified Non-Safeguards Information" (ML053480073), which is available on the NRC Web site or in ADAMS.

Sincerely,

/RA/

Cynthia D. Pederson
Regional Administrator

Docket No. 030-11789
License No. 24-00196-07

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- 3. Final Determination of Significance (Non-Public)

cc w/encls: State of Missouri
Mark G. Haenchen, Radiation
Safety Officer

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ADAMS Accession Number ML14210A023
FILE NAME: EA-14-076 St Louis University Final Action - Cover Letter & Enc 1.docx

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NAME	Lougheed	McCraw	Louden J Giessner for	Holahan ¹	Orth	Pederson
DATE	07/08/14	07/10/14	07/10/14	07/21/14	07/24/14	07/25/14

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¹ OE concurrence provided via email from K. Norman on July 21, 2014

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Letter to Paul M. Loewenstein from Cynthia D. Pederson dated July 25, 2014

SUBJECT: NOTICE OF VIOLATION – ST. LOUIS UNIVERSITY; NRC ROUTINE
INSPECTION REPORT NO. 03011789/2014001(DNMS)

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