



**UNITED STATES  
NUCLEAR REGULATORY COMMISSION**

REGION III  
2443 WARRENVILLE ROAD, SUITE 210  
LISLE, IL 60532-4352  
February 28, 2012

EA-11-286

Ms. Annie Shaynak  
Interim Executive Director, Cancer Center  
St. Vincent Hospital and Health  
Care Center  
2001 West 86th Street  
Indianapolis, IN 46240-0970

**SUBJECT: NOTICE OF VIOLATION – ST. VINCENT HOSPITAL AND HEALTH CARE CENTER; NRC INSPECTION REPORT NO. 03001579/2011-001(DNMS) AND INVESTIGATION REPORT NO. 3-2012-001**

Dear Ms. Shaynak:

This refers to a U.S. Nuclear Regulatory Commission (NRC) routine inspection conducted on September 19 and 20, 2011, at your Anderson, Fishers, and Indianapolis, Indiana facilities, with continued in-office review through November 2, 2011. The purpose of the inspection was to determine whether activities authorized under your license were conducted safely and in accordance with NRC requirements.

During the on-site inspection, your staff provided information to the inspectors regarding a report entitled, "Self-Identified Regulatory Violation." The report documented a September 7, 2011, incident in which an individual who was not an authorized user or acting under the supervision of an authorized user administered licensed material to a patient. NRC Inspection Report No. 03001579/2011-001, issued on November 10, 2011, stated that you would be informed by separate correspondence of the results of NRC's deliberation on the matter.

Additionally, the NRC initiated an investigation by the NRC's Office of Investigations (OI) to determine if willfulness was associated with this incident. The investigation began on October 11, 2011, and was completed on December 22, 2011.

Based on the information developed during the inspection and the investigation, the NRC has determined that a willful violation of NRC requirements occurred. Specifically, a physician performing a mapping procedure administered technetium-99m – macroaggregated albumin (Tc-99m MAA) after a nuclear medicine technician informed the physician that he was not an authorized user on the St. Vincent license. The physician was not acting under the supervision of an authorized user. Willful violations are, by definition, of concern to the NRC because its regulatory program is based on licensees and its employees acting with integrity. However, the NRC recognizes the very low safety significance of the underlying violation and that your staff identified the violation and took prompt and significant remedial actions to prevent recurrence. Therefore, this violation has been categorized at Severity Level IV and is being cited in the enclosed Notice of Violation (Notice).

The NRC has concluded that information regarding the reasons for the violation, the corrective actions taken and planned to be taken to correct the violation and prevent recurrence, and the

A. Shaynak

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date when full compliance was achieved, is already adequately addressed on the docket in NRC Inspection Report No. 03001579/2011-001(DNMS), and in an electronic mail message submitted by your Radiation Safety Officer on February 8, 2012. These documents are available in the NRC's Agencywide Documents Access and Management System (ADAMS) under Accession Numbers ML11319A062 and ML120470043. 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.

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 any, will be made available electronically for public inspection in the NRC Public Document Room or from ADAMS which is accessible from the 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 Patrick L. Loudon for/***

Anne T. Boland, Director  
Division of Nuclear Materials Safety

Docket No. 030-01579  
License No. 13-00133-02

Enclosure:  
Notice of Violation

cc w/encl: State of Indiana

## NOTICE OF VIOLATION

St. Vincent Hospital and Health Care Center  
Ann Arbor, Michigan

Docket No. 030-01579  
License No. 13-00133-02  
EA-11-286

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on September 19 and 20, 2011, with continued in-office review through November 2, 2011, and an investigation conducted from October 11 through December 22, 2011, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

License Condition 12 of Amendment No. 129 of License No. 13-00133-02 requires, in part, that licensed material only be used by or under the supervision of certain named individuals.

Contrary to the above, on September 7, 2011, a physician used technetium-99m, a licensed material, and the physician was not a named individual on NRC License No. 13-00133-02, nor was the physician under the supervision of a named individual.

This is a Severity Level IV violation (Section 6.3).

The NRC has concluded that information regarding the reasons for the violation, the corrective actions taken and planned to be taken to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in NRC Inspection Report No. 03001579/2011-001(DNMS), and in an electronic mail message submitted on February 8, 2012.

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-11-286," 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, U.S. 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 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>. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards 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 28th day of February 2012

date when full compliance was achieved, is already adequately addressed on the docket in NRC Inspection Report No. 03001579/2011-001(DNMS), and in an electronic mail message submitted by your Radiation Safety Officer on February 8, 2012. These documents are available in the NRC's Agencywide Documents Access and Management System (ADAMS) under Accession Numbers ML11319A062 and ML120470043. 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.

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 any, will be made available electronically for public inspection in the NRC Public Document Room or from ADAMS which is accessible from the 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 Patrick L. Loudon for/*

Anne T. Boland, Director  
Division of Nuclear Materials Safety

Docket No. 030-01579  
License No. 13-00133-02

Enclosure:  
Notice of Violation

cc w/encl: State of Indiana

DISTRIBUTION:  
See next page

\*See previous concurrences

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OFFICE	RIII	RIII	RIII	OGC
NAME	Lougheed*	Bloomer*	Heck	Klukan Scott <sup>1</sup>
DATE	02/14/12	02/14/12	02/16/12	02/24/12
OFFICE	FSME	OE	RIII	RIII
NAME	White for Satorius <sup>2</sup>	Day for Zimmerman <sup>3</sup>	Orth	PLLouden for Boland
DATE	02/17/12	02/24/12	02/27/12	02/28/12

**OFFICIAL RECORD COPY**

<sup>1</sup> OGC "No Legal Objection received via e-mail from B. Klukan on February 24, 2012

<sup>2</sup> FSME concurrence received via e-mail from K. Day on February 24, 2012

<sup>3</sup> OE concurrence received via e-mail from K. Day on February 24, 2012.

Letter to Annie Shaynak from Anne T. Boland dated February 28, 2012

SUBJECT: NOTICE OF VIOLATION – ST. VINCENT HOSPITAL & HEALTH CARE CENTER; NRC INSPECTION REPORT NO. 03001579/2011-001(DNMS) AND INVESTIGATION REPORT NO. 3-2012-001

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