

May 2, 2013

Ms. Trinka Hileman, RN, BSN, MBA
Director, Radiology and Womancare
St. Francis Medical Center
211 St. Francis Drive
Cape Girardeau, MO 63703

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03002269/13001(DNMS) AND
NOTICE OF VIOLATION – ST. FRANCIS MEDICAL CENTER

Dear Ms. Hileman:

On April 11, 2013, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at St. Francis Medical Center. 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. An exit meeting was held between Ken Lambert of my staff, and you, Ms. Curtis, and Ms. Long at the conclusion of the inspection on April 11, 2013.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff examined your compliance with the Commission's rules and regulations as well as the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, the NRC has determined that one 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 Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The violation concerned the failure to secure licensed radioactive material contained in a MEDRAD Intego PET Infusion System that was stored in the patient injection room from unauthorized access, as required by Title 10 of the Code of Federal Regulations (CFR) Part 20.1801. The violation is cited in the enclosed Notice of Violation (Notice). The NRC is citing the violation in the Notice because the inspector identified the violation.

Your staff's failure to recognize that the licensed radioactive material stored in the PET/CT patient injection room was unsecured when not under constant surveillance was the root cause of the violation. As immediate corrective action your staff moved the licensed radioactive material in to the secured hot lab.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful. You can find the Information Notice on the NRC website 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.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site 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 available to the Public without redaction.

Please feel free to contact Ken Lambert of my staff if you have any questions regarding this inspection. Mr. Lambert can be reached at (630) 829-9633.

Sincerely,

/RA/

Tamara E. Bloomer, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-02269
License No. 24-00158-03

Enclosure:
Notice of Violation

cc w/encl: State of Missouri

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Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-02269
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Enclosure: Notice of Violation

cc w/encl: State of Missouri

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NOTICE OF VIOLATION

St. Francis Medical Center
Cape Girardeau, MO

Docket No. 030-02269
License No. 24-00158-03

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on April 11, 2013, 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 (10 CFR) Part 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 11, 2013, the licensee failed to secure from unauthorized removal or limit access to four millicuries of fluorine-18 (F-18) located in the PET/CT injection room, which is a controlled area. Specifically, the licensee left the patient infusion system, containing F-18, unsecured in the injection room when the technologist took the patient to the scanning room and the injection room door was not locked.

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

Pursuant to the provisions of CFR 2.201, St. Francis Medical Center 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 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 will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, the response should not include any personal privacy, proprietary, security related, or safeguards information.

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 2nd day of May 2013.

Enclosure