UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

August 16, 2016

Mr. Robert J. Grayhek
Director of Radiology
Saint Francis Medical Center
211 Saint Francis Drive
Cape Girardeau, MO 63703

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03002269/2016001(DNMS) AND NOTICE OF VIOLATION – SAINT FRANCIS MEDICAL CENTER

Dear Mr. Grayhek:

On June 14, 2016, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at St. Francis Medical Center in Cape Girardeau, Missouri, with continued in-office review through July 22, 2016. 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. The in-office review included a review of specifics of this case, and additional details not available at the time of the inspection. A final exit meeting was held between Dennis O'Dowd of my staff and you, Mr. Grayhek, and Mr. Gerspner, by telephone on July 22, 2016, to discuss the inspection findings.

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 website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The violation concerned the licensee's failure to sign and date a written directive for a therapeutic dosage of iodine-131 given to a patient on October 1, 2014, as required by Title 10 of the *Code of Federal Regulations* (CFR) Part 10 CFR 35.40(a). The violation is cited in the enclosed Notice of Violation (Notice). The NRC is citing the violation in the enclosed Notice because the inspector identified the violation.

The inspector determined that the root cause of the violation was an oversight by hospital staff. As corrective action, the staff involved in procedures requiring a written directive were instructed by you that they are not to proceed with the administration unless the written directive is properly signed and dated by the Authorized User (AU). This training was completed on June 17, 2016. In addition, the written directive form was improved by adding separate lines for signature and date. This revision was completed on August 1, 2016.

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 will be achieved is already adequately addressed on the docket in this letter. Therefore, you are not required to respond to this letter unless the description herein 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 Title 10 of the *Code of Federal Regulations* (CFR) 2.390 of the NRC's "Rules of Practice," a copy of this letter and your response if you choose to provide one, will be available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agency wide Documents Access 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.

Please feel free to contact Dennis O'Dowd of my staff if you have any questions regarding this inspection. Mr. O'Dowd can be reached at 630-829-9573.

Sincerely,

/RA Geoffrey Warren Acting for/

Aaron T. McCraw, 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

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 will be achieved is already adequately addressed on the docket in this letter. Therefore, you are not required to respond to this letter unless the description herein 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.

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Please feel free to contact Dennis O'Dowd of my staff if you have any questions regarding this inspection. Mr. O'Dowd can be reached at 630-829-9573.

Sincerely,

/RA Geoffrey Warren Acting for/

Aaron T. McCraw, 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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DATE	8/16/2016		8/16/2016					

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NOTICE OF VIOLATION

Saint Francis Medical Center
Cape Girardeau, Missouri

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

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on June 14, 2016, with continued in-office review through July 22, 2016, 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) Part 35.40(a) requires that a written directive must be dated and signed by an authorized user before the administration of iodine-131 (I-131) sodium iodide greater than 1.11 megabecquerels (30 microcuries).
>
> Contrary to the above, on October 1, 2014, the licensee performed an administration of 50 millicuries of I-131 sodium iodide using a written directive which had not first been dated and signed by an authorized user.

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

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 the letter transmitting this Notice. 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, IR 03002269/2016001(DNMS)" 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, within 30 days of the date of the letter transmitting this Notice.

If you choose to respond, 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. 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.

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 16th day of August 2016.