UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352
November 28, 2014

Mr. Chris Lang, CEO
Cass Regional Medical Center
2800 Rock Haven Road
Harrisonville, MO 64701

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03029723/2014001(DNMS) AND NOTICE OF VIOLATION – CASS REGIONAL MEDICAL CENTER

Dear Mr. Lang:

On November 5, 2014, inspectors from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your facility in Harrisonville, Missouri. 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 Mr. Zahid Sulaiman and Mr. Ken Lambert of my staff and Mr. Brent Probasco, Ms. Julie German, and Mr. Les Warner of your staff on November 5, 2014, 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 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 ensure that an authorized user date and sign a written directive prior to the administration of iodine-131 sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries), as required by Title 10 of the *Code of Federal Regulations* (CFR) Section 35.40(a) and License Condition 12.B of NRC License No. 24-20234-02. Specifically, an individual who was not listed as an authorized user on your NRC license signed and dated a written directive for a hyperthyroidism treatment procedure on April 21, 2014. The violation is cited in the enclosed Notice of Violation (Notice). The NRC is citing the violation in the Notice because the inspectors identified the violation.

The inspectors determined the root cause of the violation was an individual's misunderstanding that an authorized user qualified under another NRC license can prescribe, sign, and date the written directive under your license. As corrective actions to restore compliance and to prevent recurrence, staff training was completed on November 14, 2014, on the requirement that only

individuals listed as authorized users on the license may date and sign written directives, and your staff committed to submitting a license amendment, by December 2014, to include all individuals who may perform authorized user activities at its facility.

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 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 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'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. 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 Mr. Sulaiman of my staff if you have any questions regarding this inspection. Mr. Sulaiman can be reached at 630-829-9752.

Sincerely,

/RA/

Aaron T. McCraw, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-29723
License No. 24-20234-02

Enclosure: Notice of Violation

cc w/encl: State of Missouri
Vandana Halder, M.D., RSO

individuals listed as authorized users on the license may date and sign written directives, and your staff committed to submitting a license amendment, by December 2014, to include all individuals who may perform authorized user activities at its facility.

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 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 Mr. Sulaiman of my staff if you have any questions regarding this inspection. Mr. Sulaiman can be reached at 630-829-9752.

Sincerely,

/RA/

Aaron T. McCraw, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-29723
License No. 24-20234-02

Enclosure: Notice of Violation

cc w/encl: State of Missouri
Vandana Halder, M.D., RSO

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DATE	11/25/14		11/28/14		11/28/14			

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NOTICE OF VIOLATION

Cass Regional Medical Center
Harrisonville, MO

Docket No. 030-29723
License No. 24-20234-02

During an NRC inspection conducted on November 5, 2014, a 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) 35.40(a) requires, in part, that a written directive be dated and signed by an authorized user before the administration of iodine-131 sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries).
>
> License Condition 12.B. of NRC License No. 24-20234-02 lists the individuals who are authorized users on the license and the specific type of medical use for which they are authorized.
>
> Contrary to the above, on April 21, 2014, the licensee failed to have an individual listed on the license as an authorized user for medical uses under 10 CFR 35.300 date and sign a written directive before the administration of 1,106 MBq (29.9 millicuries) of iodine-131 sodium iodide to a patient. Specifically, the written directive was signed by an individual who was not listed as an authorized user on NRC License No. 24-20234-02.

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 NRC letter transmitting this Notice of Violation (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," 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 in 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. 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.

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.

Dated this 28TH day of November, 2014.