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

February 19, 2016

EA-16-032
EN 51668
NMED No. 160039 (Closed)

Dr. Andre Strzembosz
Radiation Safety Officer
SSM Health St. Clare Hospital - Fenton
1015 Bowles Avenue
Fenton, Missouri 63026

SUBJECT: NRC SPECIAL INSPECTION REPORT NO. 03002368/2016001(DNMS) AND NOTICE OF VIOLATION – SSM HEALTH ST. CLARE HOSPITAL - FENTON

Dear Dr. Strzembosz:

From January 20, 2016, through February 9, 2016, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted an in-office review of the circumstances surrounding the loss of one iodine-125 (I-125) brachytherapy calibration seed at your facility. The NRC initiated this review after SSM Health St. Clare Hospital (licensee) contacted the NRC Operations Center on January 20, 2016, to report the loss of the I-125 seed. Mr. Zahid Sulaiman of my staff presented the findings of this review to Mr. Mark Pohlman, Medical Physicist of your staff via telephone on February 9, 2016.

During this in-office review, 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. The in-office review consisted of interviews with personnel and examination of information provided by you to the NRC.

Based on the results of the in-office review and the information you provided, the NRC has determined that a 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 control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage, as required by Title 10 of the *Code of Federal Regulations* (CFR) 20.1802. 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 NRC is citing the violation at Severity Level IV due to the low safety significance associated with the small amount of material; the fact that the quantity was less than 1,000 times the 10 CFR Part 20, Appendix C value; and the isolated nature of the loss.

The NRC has determined that the root cause of the violation was failure to inspect the bottle to verify that the I-125 seed is returned to the bottle after the calibration and at the end of the prostate implant procedures. This is of concern to the NRC because it increases the chance for loss of I-125 seeds, which could result in adverse impacts to the health and safety of the general public. As corrective actions to address recurrence of the event and to prevent a similar violation in the future, per your letter dated January 20, 2016, the licensee committed to implement the following procedures: (1) mandate the use of reverse action forceps when sealed source seeds being removed from the pig; (2) the bottle will be inspected to verify it contains the calibration seed, when the seed is returned to the bottle after calibration; (3) the practice of "pushing-out" seeds from unused needles into the pig in the operating room suite will no longer be practiced; it will be done in the hot lab; and (4) the calibration source stored in the pig will remain in the hot lab.

The NRC has concluded that information regarding the root cause of the violation, the corrective actions planned to correct the violation and address its recurrence, and the date when full compliance was or 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 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, any 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. 030-02368
License No. 24-11858-01

Enclosure:
Notice of Violation

cc w/encl: State of Missouri

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
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Docket No. 030-02368
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Enclosure:
Notice of Violation

cc w/encl: State of Missouri

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OFFICE	RIII-DNMS		RIII-EICS		RIII-DNMS		RIII	
NAME	ZSulaiman:ps		RSkokowski		AMcCraw			
DATE	2/17/2016		2/18/2016		2/19/2016			

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NOTICE OF VIOLATION

SSM Health St. Clare Hospital - Fenton
Fenton, Missouri

License No. 24-11858-01
Docket No. 030-02368
EA-16-032

During a U.S. Nuclear Regulatory Commission (NRC) in-office review conducted from January 20, 2016, through February 9, 2016, 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) 20.1802 requires that the licensee control and maintain constant surveillance of licensed material that is in a controlled or unrestricted areas and that is not in storage.
>
> Contrary to the above, SSM Health St. Clare Hospital - Fenton failed to maintain control and constant surveillance of a brachytherapy calibration seed, model 6711, containing 0.359 millicurie of iodine-125, while it was in a controlled area and was not in storage. Specifically, on December 22, 2015, during inventory and collection of seeds for shipment back to the vendor for disposal, the licensee discovered the brachytherapy calibration seed was missing.

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

The NRC has concluded that information regarding the reason for the violation, the corrective actions planned to correct the violation and prevent recurrence, and the date when full compliance was or will be achieved is already adequately addressed on the docket in the letter transmitting this Notice. Therefore, you are not required to respond to this Notice 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 are required to submit a written statement or explanation pursuant to 10 CFR 2.201. If you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, EA-16-032" 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 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 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, and 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 19th day of February 2016.

Enclosure