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

July 17, 2015

EA-15-116
EN 50995
NMED No. 150223 (Closed)

Dr. Taljit Sandhu
Radiation Safety Officer
Oakwood Hospital and Medical Center
18101 Oakwood Boulevard
Dearborn, MI 48123

SUBJECT: NRC SPECIAL INSPECTION REPORT NO. 03002051/2015001(DNMS) AND NOTICE OF VIOLATION – OAKWOOD HOSPITAL

Dear Dr. Sandhu:

From April 20, 2015, through June 29, 2015, inspectors 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 seed at your facility. The NRC initiated this review after Oakwood Hospital and Medical Center (licensee) contacted the NRC Operations Center on April 20, 2015, to report the loss of the I-125 seed. Mr. Ed Harvey of my staff presented the findings of this review to you via telephone on June 29, 2015.

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 1000 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 confirm that the surgical staff's post-operation report was consistent with the radiograph of the resected specimens. This is of concern to the NRC because it increases the chance for loss or improper disposal 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 May 15, 2015, the licensee committed to implement a procedure in which pathology will confirm that the number of seeds indicated in the paperwork correlate with seeds visible in a radiograph of the specimen. If there is a discrepancy, it will be resolved with the help of the surgical staff. The licensee has also committed to surveying everything that comes in contact with the specimen before it is discarded or reused to ensure that a seed has not become accidently attached. Finally, the licensee has committed to surveying each specimen after the seeds are removed to ensure that there are no remaining seeds prior to disposal.

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, 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 Mr. Harvey of my staff if you have any questions regarding this inspection. Mr. Harvey can be reached at 630-829-9819.

Sincerely,

/RA/

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

Docket No. 030-02051
License No. 21-04515-01

Enclosure:
Notice of Violation

cc w/encl: State of Michigan

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Enclosure:
Notice of Violation

cc w/encl: State of Michigan

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NOTICE OF VIOLATION

Oakwood Hospital and Medical Center
Dearborn, Michigan
EA-15-116

License No. 21-04515-01
Docket No. 030-02051

During a U.S. Nuclear Regulatory Commission (NRC) in-office review conducted from April 20, 2015, through June 29, 2015, 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 area and that is not in storage.
>
> Contrary to the above, on April 8, 2015, Oakwood Hospital failed to maintain control and constant surveillance of a brachytherapy seed containing 0.3 millicurie of iodine-125 while it was located in a pathology lab, which is a controlled area. As a result, the licensee could not account for the brachytherapy seed upon completion of a seed removal procedure.

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-15-116" 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. 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 17th day of July 2015.

Enclosure