March 4, 2011

EA-11-010
NMED No. 100597 (CLOSED)

Mr. Eric Widner, MBA
President and Chief Executive Officer
Oakwood Hospital – Annapolis Center
33155 Annapolis Avenue
Wayne, MI 48184

SUBJECT: NOTICE OF VIOLATION – OAKWOOD HOSPITAL – ANNAPOLIS CENTER
NRC INSPECTION REPORT NO. 030-02099/2010-001(DNMS)

Dear Mr. Widner:

This refers to a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on December 14, 2010, at your Wayne, Michigan, facility, with continued in-office review through January 11, 2011. The purpose of this inspection was to review the circumstances, root cause, contributing factors, and proposed corrective actions for a medical event that occurred on December 4, 2010. In addition, the NRC staff also examined activities conducted under your license related to public health and safety as well as security. The significance of the issues, and the need for lasting and effective corrective action were discussed with you at the inspection exit meeting on January 11, 2011.

In the letter transmitting the inspection report, we provided you with the opportunity to address the apparent violations identified in the report by either attending a Predecisional Enforcement Conference or by providing a written response before we made an enforcement decision. On February 15, 2011, Ms. Dawn Baker of your staff informed Ms. Tamara Bloomer, Chief, Materials Inspection Branch, that you did not believe that either a Predecisional Enforcement Conference or a written response was necessary.

Based on the information developed during the inspection, the NRC has determined that violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report. The violations involved the administration of a diagnostic dosage that differed from the prescribed dosage by more than 20 percent and the failure to verify the quantity of byproduct material and the physical/chemical form of the dosage prior to the administration. Specifically, on December 4, 2010, a nuclear medicine technologist mistakenly gave a patient approximately 124.5 millicuries of bulk technetium-99m (Tc-99m) rather than the intended diagnostic radiopharmaceutical dose of 10 millicuries of Tc-99m Myoview™. As a result, the patient received a dose to the upper lower intestine of approximately 27 rads and a whole body equivalent dose of approximately 6 rem which exceeded the prescribed dosage by more than 20 percent, contrary to the requirements of Title 10 of the Code of Federal Regulations (10 CFR) 35.63(d). Furthermore, the technologist failed to verify the quantity of byproduct material and the physical/chemical form of the dosage prior to the administration, contrary to Condition 15 of NRC License No. 21-11457-02.

The NRC determined that the direct cause of the violations was human error by the technologist in selecting the wrong syringe from behind a radiological laboratory shield. A contributing factor was the fact that the bulk Tc-99m was received in an identical syringe such that the technician could not easily detect the difference between the two radiopharmaceuticals. The failure to ensure that the correct radiopharmaceutical was selected and the prescribed dose administered is a significant regulatory concern because the patient received a larger than expected radiation dose. Therefore, these violations have been categorized collectively in accordance with the NRC Enforcement Policy as a Severity Level III problem.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of $3,500 is considered for a Severity Level III problem. Because your facility has not been the subject of escalated enforcement action within the last two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. Credit was warranted for your corrective actions which included: (1) increasing the supervision of the technologist directly involved with the medical event; (2) instructing the nuclear medicine staff on the hospital's policies and procedures for handling doses prior to administration which included documentation of competency training; (3) implementing random staff audits to evaluate performance including assays of doses prior of administration; (4) requesting that the nuclear pharmacy dispense the hospital's standing orders of bulk Tc-99m in vials only; and (5) changing the hot lab configuration to physically separate and color-code bulk quantities of material.

Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this Severity Level III problem constitutes escalated enforcement action, which may subject you to increased inspection effort.

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to be taken to correct the violations and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 030-02099/2010-001(DNMS) and in your 15 day report submitted on December 20, 2010. Therefore, you are not required to respond to this letter 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 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 any, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. The NRC also includes significant enforcement actions on its Web site at http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions.

Sincerely,

/RA by Cynthia D. Pederson Acting for/

Mark A. Satorius
Regional Administrator

Docket No. 030-02099
License No. 21-11457-02

Enclosure:
Notice of Violation

cc w/encl: State of Michigan

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 any, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. The NRC also includes significant enforcement actions on its Web site at http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions.

Sincerely,

/RA by Cynthia D. Pederson Acting for/

Mark A. Satorius
Regional Administrator

Docket No. 030-02099
License No. 21-11457-02

Enclosure:
Notice of Violation

cc w/encl: State of Michigan

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See next page

*See previous concurrence
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OFFICE	RIII	RIII	RIII	OE	RIII	RIII
NAME	Lougheed*	Bloomer*	Louden for Boland*	Day for Zimmerman[1]	Orth	Pederson for Satorius
DATE	02/22/11	02/23/11	02/24/11	03/02/11	03/04/11	03/04/11

OFFICIAL RECORD COPY

[1] OE concurrence received via e-mail from K. Day on March 2, 2011.

Letter to Eric Widner from Mark A. Satorius, dated March 4, 2011

SUBJECT: NOTICE OF VIOLATION – OAKWOOD HOSPITAL – ANNAPOLIS CENTER
NRC INSPECTION REPORT NO. 030-02099/2010-001(DNMS)

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NOTICE OF VIOLATION

Oakwood Hospital – Annapolis Center
Wayne, Michigan

Docket No. 030-02099
License No. 21-11457-02
EA-11-010

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on December 14, 2010, with continued in-office review through January 11, 2011, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. Title 10 of the Code of Federal Regulations (10 CFR) 35.63(d) requires, in part, that, unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage differs from the prescribed dosage by more than 20 percent.

Contrary to the above, on December 4, 2010, the licensee used a dosage that differed from the prescribed dosage by more than 20 percent without being directed by an authorized user. Specifically, the licensee administered approximately 124.5 millicuries of sodium pertechnetate technetium-99m (Tc-99m) to a patient instead of the prescribed dosage of 10 millicuries of Tc-99m tetrofosmin (Myoview™), a difference in excess of 20 percent.

B. License Condition No. 15. A of NRC license No. 21-11457-02 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in an application, dated August 8, 2000.

Item 10.3 of this application lists the licensee's Laboratory Safety Rules. Item 18 requires that assayed dispensed doses must be within ±10 percent of the prescribed activity or within the prescribed activity range, unless approved by the authorized user. Item 19 requires, in part, that the licensee check the prescribed radiopharmaceutical and dosage prior to administration.

Contrary to the above, on December 4, 2010, the licensee administered material in a syringe containing sodium pertechnetate Tc-99m and failed to verify that the assayed dosage was within ±10 percent of the prescribed activity and the dispensed dose was not approved by the authorized user. Furthermore, the licensee failed to check the prescribed radiopharmaceutical and dosage prior to administration. Specifically, the licensee failed to verify that it had the correct syringe of radiopharmaceuticals which resulted in an administration of 124.5 millicuries of sodium pertechnetate Tc-99m to a patient rather than the prescribed dosage of 10 millicuries of Tc-99m Myoview™.

This is a Severity Level III problem (Section 6.3).

ENCLOSURE

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to be taken to correct the violations and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 030-02099/2010-001(DNMS) and in your 15 day report submitted on December 20, 2010. 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, EA-11-010," 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 and the Enforcement Officer, Region III, 2443 Warrenville Road, Suite 210, Lisle, IL 60532, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

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.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site 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.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 4th day of March 2011

ENCLOSURE