October 20, 2006

EA-06-188
NMED No. 060430

Ms. Maggie Fowler, R.N.
Chief Operating Officer
St. Joseph Health Center
300 First Capital Drive
St. Charles, MO 63301

SUBJECT: NOTICE OF VIOLATION (NRC SPECIAL INSPECTION REPORT NO. 030-08664/06-003(DNMS)) ST. JOSEPH HEALTH CENTER

Dear Ms. Fowler:

This refers to the special inspection conducted on July 10 and 11, 2006, by the U.S. Nuclear Regulatory Commission (NRC) at St. Joseph Health Center, St. Charles, MO, with continuing in-office review through July 25, 2006. The purpose of the inspection was to review the circumstances surrounding a medical event that occurred on June 28, 2006, and was reported to the NRC on July 3, 2006. Based upon the inspection results, several apparent violations of NRC requirements were identified, including failures to: (1) prepare a written directive before administering to a patient more than 30 microcuries (uCi) of I-131 sodium iodide (10 CFR 35.40(a)); (2) follow the licensee's and physician authorized user's instructions (10 CFR 35.27(a)(2)); and (3) notify the NRC of the occurrence of a medical event no later than the next calendar day after discovering the event (10 CFR 35.3045(a)). The NRC inspection report was provided to you on August 18, 2006.

In the letter transmitting the inspection report, we provided you the opportunity to address the apparent violations identified in the report by either attending a pre-decisional enforcement conference or by providing a written response before we made our final enforcement decision. In a letter dated September 14, 2006, you provided a written response to the apparent violations. Additional information was also provided in letters dated July 6 and 12, 2006.

Based on the information developed during the inspection and the information that was provided in the July 6 and 12, and September 14, 2006, letters, 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. In summary, on June 28, 2006, a patient was to be evaluated for hyperthyroidism using a thyroid uptake procedure. The thyroid uptake procedure, developed by your authorized user physician, specified that 15-18 uCi of I-131 sodium iodide was to be used

for that procedure. The nuclear medicine technologist performing the procedure did not review the written order from the referring physician for the thyroid uptake procedure. As a result, the technologist administered 5.4 millicuries (mCi) of I-131 sodium iodide to the patient.

Although the nuclear medicine technologist administered 5.4 mCi of I-131 sodium iodine to a patient, an authorized user physician did not prepare a written directive prior to and for this administration of greater than 30 uCi of I-131 sodium iodine, as required by 10 CFR 35.40(a), "Written Directives." The technologist, an individual working under the supervision of an authorized user physician, also failed to follow the written instructions of the licensee and authorized user when the technologist failed to take the patient's orders to the "hot lab" to prepare the dose and ensure that the drawn dose was within acceptable limits, a violation of 10 CFR 35.27, "Supervision." These violations are significant regulatory concerns and are categorized collectively in accordance with the NRC Enforcement Policy as a Severity Level III problem (Violation A).

Your staff identified this medical event on June 28, 2006, but did not notify the NRC Operations Center of the medical event until July 3, 2006. However, 10 CFR 35.3045, "Report and Notification of a Medical Event," requires an NRC licensee to notify the NRC Operations Center of a medical event no later than the next calender day following the identification of the medical event. The failure to notify the NRC of a medical event within the specified period of time may impede the NRC in assessing a significant safety issue. Therefore, the failure to notify the NRC of the medical event within the prescribed time period is categorized in accordance with the NRC Enforcement Policy at Severity Level III (Violation B).

In accordance with the Enforcement Policy, a base civil penalty in the amount of $3,250 is considered for a Severity Level III violation or problem. Because your facility has not been the subject of escalated enforcement actions 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 VI.C.2 of the Enforcement Policy. Credit was warranted for your corrective actions which consisted of: (1) revising the protocol for the administrating I-131 sodium iodide to require that a second technologist checks the dosage and related documentation; (2) requiring that technologists review the revised I-131 sodium iodide protocol during new employee orientation and during their annual competency assessment; (3) requiring that another staff member observe the first time a new technologist performs a procedure; and (4) requiring technologists to immediately review your Quality Management Policy, which includes procedures for reporting medical events to the NRC, and to review the Quality Management Policy as a part of their annual competency assessment.

Therefore, to encourage prompt 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 these Severity Level III violations constitutes escalated enforcement action, that 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 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. 030-08664/06-003(DNMS) and letters from the Licensee dated July 6 and 12 and September 14, 2006. 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, should you choose to respond, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC 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 available to the Public without redaction. The NRC also includes significant enforcement actions on its Web site at www.nrc.gov; select **What We Do**, **Enforcement**, then **Significant Enforcement Actions**.

Sincerely,

/RA/

James L. Caldwell
Regional Administrator

Docket No. 030-08664
License No. 24-15159-01

Enclosure:
Notice of Violation

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NAME	Weil		Merchant for Carpenter		Reynolds		O'Brien		Caldwell	
DATE	10/17/06		10/16/06		10/19/06		10/20/06		10/20/06	

OFFICIAL RECORD COPY

[1] Sally Merchant, OE, provided HQ concurrence by e-mail on October 17, 2006.

Letter from J. Caldwell to M. Fowler dated October 20, 2006

SUBJECT: NOTICE OF VIOLATION (NRC SPECIAL INSPECTION REPORT NO. 030-08664/06-003(DNMS)) ST. JOSEPH HEALTH CENTER

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NOTICE OF VIOLATION

St. Joseph Health Center
St. Charles, MO

Docket No. 030-08664
License No. 24-15159-01
EA-06-188

During an NRC inspection conducted from July 10 through 25, 2006, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. Violations Associated with a Medical Event

1. 10 CFR 35.40(a) requires, in part, that a written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries (uCi)).

   Contrary to the above, on June 28, 2006, a licensee nuclear medicine technologist administered I-131 sodium iodide to a patient that was greater than 30 uCi and a written directive, dated and signed by an authorized user, was not prepared. Specifically, the technologist administered 5.4 mCi of I-131 sodium iodide to a patient that was scheduled to receive 15 uCi of I-131 sodium iodide, without a written directive dated and signed by an authorized user before administering the I-131 sodium iodide dose.

2. 10 CFR 35.27(a)(2) requires, in part, that a licensee, that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user, requires the supervised individual to follow the instructions of the supervising authorized user for medical uses of byproduct material, written radiation protection procedures established by the licensee, written directive procedures, regulations of this chapter, and license conditions with respect to the medical use of byproduct material.

   The licensee's written instruction, "Out Patient Protocol," required, in part, that the technologist take the patient's orders to the hot lab to prepare the dose and enter that information into the dose computer. The technologist must ensure that the drawn dose is within acceptable limits and the dose is to be administered to the patient after all of the safeguards described in the protocol have been completed.

   Contrary to the above, on June 28, 2006, a nuclear medicine technologist, an individual under the supervision of the licensee's authorized user, failed to follow the licensee's written instructions in the "Out Patient Protocol" prior to administering 5.4 mCi of I-131 sodium iodide to a patient. Specifically, the technologist failed to take the patient's orders for a hyperthyroidism study, using 15 uCi of I-131 sodium iodide, to the hot lab and enter the patient's dose information into the department computer prior to administering 5.4 mCi of I-131 sodium iodide to the patient.

   This is a Severity Level III problem (Supplement VI).

B. Violation Associated with Timely Notification to the NRC

10 CFR 35.3045(a) requires, in part, that a licensee report any event, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material results in a dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin and the total dose delivered differs from the prescribed dose by 20 percent or more.

10 CFR 35.3045(c) requires the licensee notify the NRC Operations Center, by telephone, no later than the next calendar day after discovery of the medical event, as described in 10 CFR 35.3045(a).

Contrary to the above, on June 28, 2006, the licensee identified that a medical event had occurred and did not notify the NRC Operations Center until July 3, 2006, a period of time greater than one calendar day after the medical event was identified. Specifically, a nuclear medicine technologist administered 5.4 mCi of I-131 sodium iodide dosage to a patient instead of the prescribed 15 uCi of I-131 sodium iodide dosage resulting in the patient's thyroid receiving a dose that differed from the prescribed dose by more than 50 rems. The patient's thyroid received approximately 700 rem, a dose that differed by more than 20 percent from the prescribed dose of approximately 20 rem.

This is a Severity Level III violation (Supplement VI).

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned 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. 030-08664/06-003(DNMS) and letters from the licensee dated July 6 and 12 and September 14, 2006. 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-06-188," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555 with a copy to the Regional Administrator and the Enforcement Officer, Region III, 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, United States 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.

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 document 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.

Dated this 20th day of October 2006