August 25, 2005

EA-05-107
NMED No. 050123

Mark S. Stauder
President
St. John's Mercy Medical Center
615 South New Ballas Road
St. Louis, MO 63141

SUBJECT: NOTICE OF VIOLATION
(NRC SPECIAL INSPECTION REPORT NO. 03002283/2005-001(DNMS))

Dear Mr. Stauder:

On March 11, 2005, your staff notified the U.S. Nuclear Regulatory Commission (NRC) that a medical event occurred on March 9, 2005, when an infant was administered a dosage of 11.2 millicuries of technetium-99m tetrofosmin instead of the prescribed dosage of 0.5 millicuries of technetium-99m sulphur colloid. A special inspection was conducted on March 15 and 16, with additional in-office review continuing through May 3, 2005, to determine the circumstances surrounding the medical event. Two apparent violations of NRC requirements (10 CFR 35.63(d) and License Condition No. 20. A. of your NRC license) were identified during the inspection. The apparent violations concerned the use of technetium-99m in an amount that differed from the prescribed dosage by more than 20 percent, without approval of an authorized user, and the failure to check the identity of the patient and the radiopharmaceutical prior to administering the dosage.

In a letter dated May 25, 2005, transmitting the inspection report, we provided you the opportunity to address the apparent violations identified in the report by either attending a predecisional enforcement conference or providing a written response before we made our final enforcement decision. On May 31, 2005, you declined the opportunity to address the apparent violations by attending a predecisional enforcement conference, and in a letter dated June 21, 2005, you provided a written response to the apparent violations. This supplemented an earlier response that you provided on March 18, 2005.

Based on the information developed during the inspection and the information that you provided in your March 18 and June 21, 2005, 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 the violations are described in detail in the inspection report. In summary, a nuclear medicine technician (NMT) administered to an infant an unauthorized dosage of 11.2 millicuries of technetium-99m tetrofosmin instead of the authorized dosage of 0.5 millicuries of technetium-99m sulphur colloid. The NMT administered the dosage without checking the identity of the patient or confirming the radiopharmaceutical to be administered.

The dosage of technetium-99m sulphur colloid was prescribed for a diagnostic gastric study of the infant. The dosage of technetium-99m tetrofosmin was intended for an adult cardiac myocardial perfusion examination.

The administration of a dosage in excess of 20 percent of the prescribed dosage, without the approval of an authorized user, and the failure to check the patient's identity and dosage information are significant safety issues, as demonstrated, in part, by the NRC medical consultant's recommendation that a pediatric gastroenterologist monitor the infant for cancer for an extended period of time. The NRC medical consultant's report was provided to you in our letter, dated May 24, 2005. Therefore, the violations are categorized collectively in accordance with the NRC Enforcement Policy as a Severity Level III problem. The current Enforcement Policy is included on the NRC's Web site at www.nrc.gov; select **What We Do, Enforcement**, then **Enforcement Policy**.

In accordance with the Enforcement Policy, a base civil penalty in the amount of $3,250 is considered for a Severity Level III problem. Because the licensee has not been the subject of escalated enforcement actions within the past 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. The NRC determined that credit was warranted for your corrective actions which included: (1) counseling and retraining the NMT on the importance of following established procedures; (2) revising current procedures to require that two individuals verify the dosage to a pediatric patient before administering the dosage; (3) requiring that a form is prepared indicating the patient and dosage information prior to preparing a pediatric dosage; (4) training the NMTs on the changes to the procedures; (5) scheduling in-service training during November 2005 to reenforce the immediate training; and (6) monitoring compliance with the proper implementation of the procedural changes at quarterly quality assurance meetings.

Therefore, to encourage prompt identification 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, that may subject you to increased inspection effort.

The NRC has concluded that information regarding the reasons 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. 03002283/2005-001(DNMS) and your March 18 and June 21, 2005, letters. Therefore, you are not required to respond to this letter unless the description in your response 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 and its enclosure, 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, if you choose to respond, 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**.

Please contact John Madera, Chief, Materials Inspection Branch at telephone number (630) 829-9834 if you have any questions.

Sincerely,

/RA Geoffrey E. Grant for/

James L. Caldwell
Regional Administrator

Docket No. 030-02283
License No. 24-00794-03

Enclosure: Notice of Violation

cc w/encl: John Arnold, Chairman of the Board
St. John's Mercy Medical Center
615 New Ballas Road
St. Louis, MO 63141

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NAME	Weil		Berson		Reynolds		Schwartz[1]	
DATE	08/23/05		08/23/05		08/24/05		08/22/05	

OFFICE	OE	E	RIII	E	RIII	E		
NAME	Nolan[1]		O'Brien		Grant for Caldwell			
DATE	08/22/05		08/25/05		08/25/05			

OFFICIAL RECORD COPY

[1]Concurrence from HQ in 8/22/05 e-mail from M. Schwartz, OE, to Ken O'Brien, RIII

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NOTICE OF VIOLATION

St. John Mercy Medical Center
St. Louis, Missouri

Docket No. 030-02283
License No. 24-00794-03
EA-05-107

During an NRC inspection conducted on March 15 and 16, with in-office review through May 3, 2005, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. 10 CFR 35.63(d) provides that unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent.

License Condition No. 20. A. of NRC License No. 24-00794-03 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in an application, dated November 21, 2001.

Attachment 10.4 to the November 21, 2001, application, Section 14, "Safe Use of Radiopharmaceuticals," provides, in part, that the licensee not use a dose that is more than 10 percent different from the prescribed dose, except for prescriptions of less than 30 microcuries.

Contrary to the above, on March 9, 2005, the licensee administered to an infant a dosage of 11.2 millicuries of technetium-99m tetrofosmin instead of the prescribed dosage of 0.5 millicuries of technetium-99m sulphur colloid, a dosage in excess of 30 microcuries and more than 20 percent different from the prescribed dose.

B. License Condition No. 20. A. of NRC License No. 24-00794-03 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in an application, dated November 21, 2001.

Section 14, Attachment 10.4 to the November 21, 2001, application, also provides that the licensee check the patient's name and identification number and the prescribed radionuclide, chemical form, and dosage before administering the dosage to the patient.

Contrary to the above, on March 9, 2005, the licensee administered to an infant a dosage of 11.2 millicuries of technetium-99m tetrofosmin instead of the prescribed dosage of 0.5 millicuries of technetium-99m sulphur colloid and failed to check the patient's name and identification number and the prescribed radionuclide, chemical form, and dosage before administering the dosage to the patient.

This is a Severity Level III problem (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. 03002283/2005-001(DNMS) and your March 18 and June 21, 2005, letters.

However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description in your response 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-05-107," 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 Enforcement Officer, Region III, 2443 Warrenville Road, Suite 210, Lisle, IL 60532-4352, within 30 days of the date of the letter transmitting this Notice of Violation.

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.

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.

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

Dated this 25th day of August 2005.