May 24, 2005

EA-05-107
NMED No. 050123

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

SUBJECT: NRC SPECIAL INSPECTION REPORT NO. 03002283/2005-001(DNMS)
ST. JOHN'S MERCY MEDICAL CENTER

Dear Mr. Stauder:

This refers to the special inspection conducted on March 15 and 16, 2005, at St. John's Mercy Medical Center, in St. Louis, Missouri, with continued NRC in-office review through April 28, 2005. The in-office review included a review of your staff's written report dated March 18, 2005, and the NRC's medical consultant's report dated April 26, 2005, on the medical event. The purpose of the inspection was to review the circumstances, root and contributing causes, and proposed corrective actions for a medical event that occurred on March 9, 2005. The enclosed report presents the results of this inspection.

The NRC contracted with a medical consultant, Edward Silberstein, M.D., to review the medical significance of this incident. Dr. Silberstein's report, dated April 26, 2005, indicated that there were no acute or subacute effects noted in the patient, but did not rule out the possibility of long-term consequences. A copy of the results of Dr. Silberstein's evaluation is enclosed.

Based on the results of this inspection, two apparent violations were identified and are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at www.nrc.gov; select **What We Do**, **Enforcement**, then **Enforcement Policy.** The apparent violations involve 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. The circumstances surrounding these apparent violations, the significance of the issues, and the need for lasting and effective corrective action were discussed with members of your staff at the preliminary exit meeting on March 16, 2005, and during the final telephone exit meeting with you on May 3, 2005. As a result, it may not be necessary to conduct a predecisional enforcement conference in order to enable the NRC to make an enforcement decision.

In addition, since your facility has not been the subject of escalated enforcement actions within the last two inspections, and based on our understanding of your corrective action, a civil penalty may not be warranted in accordance with Section VI.C.2 of the Enforcement Policy. The final decision will be based on your confirming on the license docket that the corrective actions previously described to the staff have been or are being taken.

Before the NRC makes its enforcement decision, we are providing you an opportunity to either: (1) respond to the apparent violations addressed in this inspection report within 30 days of the date of this letter, or (2) request a predecisional enforcement conference. If a conference is held, it will be open for public observation. Please contact John Madera at (630) 829-9834 within 7 days of the date of this letter to notify the NRC of your intended response.

If you choose to provide a written response, it should be clearly marked as a "Response to An Apparent Violation in Inspection Report No. 03002283/2005-001(DNMS); EA-05-107" and should include for the apparent violations: (1) the reason for the apparent violations, or, if contested, the basis for disputing the apparent violations; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance will be achieved. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in the enclosed excerpt from NRC Information Notice 96-28, "SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION," may be helpful. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required elements of the response. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a predecisional enforcement conference.

In addition, please be advised that the number and characterization of any apparent violations described in the enclosed inspection report may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response, if any, 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.

Sincerely,
/RA by G. Shear Acting for/
Marc L. Dapas, Director
Division of Nuclear Materials Safety

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

Enclosures: 1. Inspection Report
2. NRC Medical Consultant's Report
3. NRC Information Notice 96-28

cc w/encls: Robert Turco, Ph.D., Radiation Safety Officer
Bill Ross, Executive Director, Imaging Services

See Attached Distribution:

ADAMS DOCUMENT TITLE: IR 03002283/2005-001(DNMS) - ST. JOHN'S MERCY MEDICAL CENTER
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REGION III

Docket No.:	030-02283
License No.:	24-00794-03
Report No.:	030-02283/2005-001(DNMS)
Licensee:	St. John's Mercy Medical Center
Location:	615 S. New Ballas Road St. Louis, MO 63141
Dates of Inspection:	March 15-16, 2005
Date of Final Exit Meeting:	May 3, 2005
Inspector:	Darrel G. Wiedeman, Senior Health Physicist
Reviewed By:	John R. Madera, Chief Materials Inspection Branch

EXECUTIVE SUMMARY

St. John's Mercy Medical Center
St. Louis, Missouri
Inspection Report No. 03002283/2005-001(DNMS)

The purpose of the inspection was to review the circumstances, root and contributing causes, and proposed corrective actions related to a medical event that occurred on March 9, 2005, involving an oral administration of 11.2 millicuries of technetium-99^m myoview that was administered to a five-month-old child rather than the prescribed oral dosage of 0.5 millicuries of technetium-99^m sulphur colloid. The error was discovered immediately after administering the dosage to the child. The licensee staff estimated that the whole body dose to the patient is approximately 8.3 rems rather than the expected dose of 0.009 rems and the dose to the lower intestines could be as high as 58.2 rems as a result of the administration error.

The licensee concluded that the medical event would not result in adverse consequences for the patient. The NRC contracted with a medical consultant to review the medical event and determine if any adverse consequences were expected. The NRC medical consultant concluded that there were no acute or subacute effects noted in the patient, but did not rule out the possibility of long-term consequences.

To reduce the likelihood of a similar event, the licensee's proposed corrective actions included: (1) counseling the nuclear medicine technologist on the importance of following established procedures; (2) revising its written procedures to require dual verification of all dosages to be administered to children; and (3) retraining the nuclear medicine staff regarding the new procedures.

The inspector identified an apparent violation of 10 CFR 35.63(d) involving the administration of a dosage of technetium-99^m myoview that differed from the prescribed dosage by more than 20 percent. The inspector also identified an apparent violation of License Condition 20. A of NRC License No. 24-00794-03 which requires the licensee to check the assayed dosage, the patient's identification, the prescribed radionuclide, and the chemical form of the radiopharmaceutical before administering the dosage to a patient.

Report Details

1.0 Program Scope and Inspection History

License number 24-00794-03 authorizes St. John's Mercy Medical Center (licensee) to use a variety of byproduct materials for medical purposes, including diagnostic and therapeutic nuclear medicine, and sealed sources for therapy including various byproduct materials permitted by Title 10 Code of Federal Regulations (CFR) Part 30.4 for research and development. The licensee routinely performs a daily average of 20 diagnostic studies.

No violations were identified during the last and previous NRC inspections conducted on September 21, 2004, and May 9 and 10, 2001, respectively.

2.0 Sequence of Events and Licensee Investigation

a. Inspection Scope

The inspector reviewed the licensee's investigation of the medical event. The inspector also interviewed selected licensee personnel, and observed related equipment and facilities.

b. Observations and Findings

On March 9, 2005, a five-month-old child was scheduled for a routine gastric emptying study. The licensee's procedures require that the dosage be based on the child's weight. In this specific situation, the dosage was calculated by the radiopharmacist and it was determined that a dosage of 0.5 millicuries of technetium-99^{m} sulphur colloid be administered for this study. In preparation for the test, the assigned nuclear medicine technologist ordered the dosage from the radiopharmacy, then went to the hot lab to get the dosage. The technologist observed a shielded container that contained a dosage located on the hot laboratory table, and proceeded to mix the radiopharmaceutical with the baby formula.

The formula was then fed to the patient and the study began. Within minutes after starting the scan, another technologist reported that a 15.7 millicurie dosage of technetium-99^{m} myoview, prepared for an adult patient scheduled for a cardiac stress test, could not be located. It was immediately discovered that the dosage of technetium-99^{m} myoview was accidently fed to the infant patient for the gastric emptying study.

The licensee staff immediately investigated the medical event and determined that the root cause was human error involving failure to verify the radionuclide, chemical form, and the dosage prior to administering the dosage. The licensee staff routinely verify the patient's name, dosage to be administered, and chemical/physical form of the radiopharmaceutical. However, in this case, because the patient was malnourished and crying, and the patient's mother was very upset, the technologist was trying to expedite the procedure and did not remember to verify the patient's name and the information on the dosage label prior to administering the dosage.

The licensee's investigation also determined, based on the original dosage of 15.7 millicuries, the amount of radioactive material remaining in the formula bottle, and the residual radioactive material in the syringe, that the patient ingested (was administered) 11.2 millicuries of technetium-99^m. As part of the investigation, the licensee completed a dose assessment and concluded that the patient may have received a whole body dose of 8 rem and a dose to the lower intestines of approximately 58.2 rem. On March 10, 2005, the licensee determined that a medical event occurred because the total dose equivalent exceeds 5 rem to the whole body and 50 rem to the lower intestines. On March 11, 2005, the licensee staff contacted the NRC to report the medical event. The licensee's medical staff evaluated the potential adverse effects on the patient and concluded that the unintended dose to the patient would not cause an adverse biological effect.

Title 10 CFR 35.63(d) requires 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. The inspector determined that on March 9, 2005, the licensee administered a diagnostic dosage of technetium-99^m myoview to the patient that differed from the prescribed dosage by more than 20 percent. This constitutes an apparent violation of 10 CFR 35.63(d).

License Condition No. 20. A of NRC License No. 24-00794-03 requires that the licensee conduct its program in accordance with the statements, representations, and procedures contained in an application dated November 21, 2001. Item 10.4 of the application states, "we have developed rules for the safe use of radiopharmaceuticals that are appended as ATT 10.4." Attachment 10.4, Item 14, states, in part, "do not use a dose if it is more than 10 percent off from the prescribed dose. Check the patients name and identification number, the prescribed radionuclide, chemical form, and dosage before administering." The licencee's failure to (1) check the dosage; (2) the patient's identification; and (3) the prescribed radionuclide and chemical form before administering the dosage to a patient constitutes an apparent violation of License Condition No. 20. A.

c. Conclusions

The inspector determined that a medical event occurred because the licensee failed to verify the radionuclide, chemical form, and dosage prior to administering the dosage. The inspector identified an apparent violation of 10 CFR 35.63(d) because the licensee administered a dosage that differed from the prescribed dose by more than 20 percent. The inspector also identified a violation of License Condition No. 20. A that involved the licensee's failure to check the prescribed radionuclide, chemical form and dosage before administering the dosage.

3.0 Licensee Corrective Actions

a. Inspection Scope

The inspector reviewed the licensee's proposed corrective actions to preclude similar events. The inspector reviewed the licensee's 15-day report of the medical event dated March 18, 2005, and written procedures. The inspector also interviewed selected licensee personnel.

b. Observations and Findings

On March 15, 2005, the licensee identified that its written procedures did not include a requirement for dual verification of all dosages for children under the age of 18. To reduce the likelihood of a similar event, the licensee's proposed corrective actions included: (1) counseling the nuclear medicine technologist on the importance of following established procedures; (2) revising its written procedures to require dual verification of all dosages to be administered to children; and (3) retraining the nuclear medicine staff regarding the new procedures.

c. Conclusions

The inspector determined that the licensee implemented corrective actions to address the root cause of the medical event. Corrective actions to address the root cause of the event and to prevent similar incidents will be reviewed during a future NRC inspection.

4.0 Notifications and Reports

a. Inspection Scope

The inspector reviewed the licensee's notifications to the NRC Operations Center, the referring physician, and the patient's parents. In addition, the inspector reviewed the written 15-day report that was submitted to the NRC.

b. Observations and Findings

The licensee made notifications and reports of the medical event. On March 11, 2005, the licensee notified the NRC Operations Center, the patient's parents, and the patient's referring physician of the medical event. The licensee provided its written report of the medical event to the NRC in a letter dated March 18, 2005. The report included the information required by 10 CFR 35.3045(d)(1).

c. Conclusions

The licensee made all of the notifications and reports as required by 10 CFR 35.3045 within the specified time period. The written report included all of the required information.

5.0 NRC Medical Consultant's Review

The NRC staff contracted with a medical consultant, Edward Silberstein, M.D., to review the medical event and determine if any adverse health consequences were expected. Dr. Silberstein concluded that there were no acute or subacute effects noted in the patient, but did not rule out the possibility of long-term consequences.

6.0 Exit Meetings

At the completion of the onsite inspection, the inspector conducted a preliminary exit meeting with licensee management and staff. The inspector discussed the sequence of events that led to the medical event, the root and contributing causes of the medical event, and the licensee's proposed corrective actions. The licensee did not identify any

information reviewed during the inspection and proposed for inclusion in this report as proprietary in nature. The final exit meeting was subsequently conducted via telephone on May 3, 2003, with Mr. Mark Stauder and included a discussion of the apparent violations and the licensee's corrective actions.

Partial List of Persons Contacted

#* Mark Stauder, President
*William Ross, Executive Director, Imaging Services
Kerry Hollzclaw, Manager Nuclear Medicine
Tammy Sansone, Imaging Services
Connie Brenner, CNMT, Nuclear Medicine Technologist
Robert Turco, Ph.D, Radiation Safety Officer

*Denotes individuals who participated in the onsite preliminary meeting on March 16, 2005.
#*Denotes individuals who participated in the final exit meeting conducted via telephone on May 3, 2005.