MERCY
ST. JOHN'S MERCY
MEDICAL CENTER

June 21, 2005

Marc L. Dapas, Director
United States Nuclear Regulatory Commission
Region III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

RE: Response to An Apparent Violation in Inspection Report No. 03002283/2005-001 (DNMS); EA-05-107

Dear Mr. Dapas:

Please see the attached written response in reference to the Medical Event that occurred on March 9, 2005. Although it is unfortunate that this incident occurred, St. John's Mercy Medical Center required four verification procedures to keep an incident such as this from happening. When the Medical Event did occur, the hospital responded appropriately and timely by conducting its own investigation and reporting the event to the proper administrative authority. St. John's Mercy Medical Center has subsequently implemented a dual verification procedure to require proper dosage and reduce the likelihood of such an event reoccurring.

As you stated, we have rated highly during previous inspections and believe we have an overall safe and effective program here at St. John's Mercy Medical Center.

Please let me know if you need additional information or need to discuss anything further with me.

Respectfully Submitted,

Mark S. Stauder
Co-President

/ch

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314-569-6000 ph.

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"Response to An Apparent Violation in Inspection Report No. 03002283/2005-001(DNMS); EA-05-107".

1. **The reason for apparent violations:**
On March 9, 2005, a 5-month-old child was scheduled to have a gastric emptying study performed. Based upon our standard protocol, the patient was calculated to receive a dosage of 0.5 milliCuries of technetium-99m sulphur colloid by oral administration mixed with the baby's formula. Soon after the imaging procedure was started, it was discovered that the patient was given 11.2 milliCuries technetium-99m tetrafosmin (Myoview), which was prepared for an adult patient scheduled for a cardiac myocardial perfusion examination. St. John's Mercy Medical Center requires by policy that four standard items of identification be reviewed prior to the administration of a radiopharmaceutical. The medical event occurred because:

    a. the technologist failed to verify the proper dosage by reviewing the standard items of identification listed below prior to administering the agent:
        - the patient's name
        - identification number (birth date or medical record number)
        - radiopharmaceutical
        - dosage

    and

    b. the dose administered differed from the prescribed dose by more than 20%.

2. **The corrective steps that have been taken and the results achieved:**
    a. Counseling and retraining of the nuclear medicine technologists on the importance of following established procedures. Completed March 11, 2005.
    b. Revising written procedures to require dual verification of all doses to be administered to children. Completed March 16, 2005 (a copy of the revised policy is attached). This is in addition to the standard four items of identification which were previously used to verify dosage as described in #1 above.
    c. Retraining of Nuclear Medicine staff regarding the new procedure. Discussed changes with staff on March 16, 2005.
    Additionally, St. John's Mercy Medical Center has reviewed changes at department meetings on April 6 and May 25, 2005.
    In-service given to staff by Radiation Safety Office Personnel on May 11 and May 20, 2005 to include all technologists.
    Since March 16, 2005, 63 pediatric procedures have been performed using the procedure described above without any errors.

3. **The corrective steps that will be taken to avoid further violations:**
    a. Follow up in-service will be given in November to review the procedure changes that were made and the NRC recommendations and requirements regarding the safe use of radiopharmaceuticals. This will be followed by annual in-service reviews regarding same.
    b. Pediatric form has been added that includes the patient's name and birth date, the injection technologist, the radiopharmacy technologist, and the calculations for determining the patient's weight in kilograms. It is a requirement that this form be filled out and given to the technologist in the radiopharmacy before the dose is prepared. This new form was implemented after the April 6, 2005 departmental meeting. A copy of the form is attached for your review.
    c. The Nuclear Medicine department will monitor compliance of the above procedure changes at the quarterly Quality Assurance meeting by tracking the use of pediatric forms for each pediatric patient.

4. **The date when full compliance will be achieved:**
    All corrective steps were implemented by April 6, 2005. There will be a follow up in-service in November, 2005 to ensure continued compliance with St. John's Mercy Medical Center's policies and procedures to ensure dosage verification and the administration of proper dosage to patients.

On page 5 of Dr. Silberstein's report, number X states: "Current Status of Patient; the primary physician whose name is on the requisition, Dr. Naseer, cannot be located by St. Louis telephone information or by the St. John's Mercy Medical Center operator." The physician on the requisition should be Dr. Lynda M. Brady, telephone number: 314-996-0006.

CATEGORY: NUCLEAR MEDICINE

TITLE: SAFE USE OF RADIOPHARMACEUTICALS

1. Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.

2. Wear disposable gloves at all times while handling radioactive materials.

3. Before leaving the area, monitor your hands and clothing for contamination in a low background area with a low range survey meter.

4. Use syringe shields for routine preparation of patient dosages and administration to patients, except in those circumstances in which their use is contraindictated (e.g., recessed veins, infants). In these exceptional cases, consider the use of other protective methods such as remote delivery of the dose (e.g., through use of a butterfly valve).

5. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.

6. Do not store food, drink, or personal effects in areas where radioactive material is stored or used.

7. Wear personal monitoring devices at all times while in areas where radioactive materials are used or stored. These devices should be worn as prescribed by the Radiation Safety Officer. When not being worn to monitor occupational exposures, personnel monitoring devices should be stored in the work place in a designated low background areas.

8. Wear a finger exposure exposure monitor during the elution of generators, during the preparation, assay and injection of radiopharmaceuticals, and when holding patients during procedures.

9. Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.

10. Never pipette by mouth.

11. Perform removable contamination surveys as directed in ATT 10.12 Area Surveys. If necessary, decontaminate or secure the area for decay.

12. Perform ambient exposure rate surveys as directed in ATT 10.12 Area Surveys. If necessary, decontaminate or secure the area for decay.

REVISED: MARCH 2005

13. Confine radiopharmaceutical solutions in shielded containers that are clearly labeled and/or color coded. The following information should either be recorded in a log book or in the Nuclear Medicine Manager computer program.
    a. Radiopharmaceutical name
    b. Radionuclide
    c. Date of receipt or preparation
    d. Total activity
    e. Specific concentration in mCi/ml at a specified time
    f. Total volume prepared and remaining volume
    g. Measured activity at each patient dosage
    h. Any other appropriate information

14. Assay each patient dosage in the dose calibrator before administering it. Do not use a dose if it is more than 10 percent off from the prescribed dose, except for prescriptions of less than 30 microcuries. Check the patient's name and identification number or birth date and the prescribed radionuclide, chemical form, and dosage before administering. For pediatric patients, (less than 18 years old), two technologists will verify the dosage before administering.

15. Always keep flood sources, waste and other radioactive material.

16. All Iodine-131 therapeutic oral solutions should be vented in an exhaust hood or in a room under negative pressure from an exhaust vent before being administered to a patient.
17. The airflow rate of the exhaust hoods and vents will be measured every six months with a rotating vane anermometer. The minimum air flow rate maintained in the exhaust hoods and vents will be 100 linear feet per minute.

18. Radioactivity in the effluent to unrestricted areas will not exceed concentrations specified in Appendix B, Table II of Part 20, 10 CFR.

Pediatric Weight Documentation Form

Patient's Name: _____

Patient D.O.B.: _____

Injection Technologist: _____

Radiopharmacy Technologist: _____

Converting pounds (lbs) to Kilograms (kg):

Pounds divided by 2.2 equals kilograms
Lbs / 2.2 = kg

_____ lbs / 2.2 = _____ kg

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Effective April 2005

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