THE QUEEN'S MEDICAL CENTER

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Docket No. 030-14522
License No. 53-16533-02

August 2, 2012

Regional Administrator, Region IV
1600 East Lamar Blvd
Arlington, TX 76011-4511

SUBJECT: REPLY TO A NOTICE OF VIOLATION

The attached statement is submitted in reply to the Notice of Violation pursuant to NRC Inspection Report No. 030-14522/2011-001.

For additional information, please contact Brian Oyadomari, Radiation Safety Officer, at (808) 691-4884.

Sincerely,

Darlena Chadwick
Vice President of Patient Care

NRC Inspection Report No. 030-14522/2011-001

Violation 1 Failure to develop, implement and maintain written procedures for the safe handling and disposal of unused therapeutic doses. Specifically, from August 30, 2004, through September 13, 2011, the licensee's program failed to address the storage, segregation, or disposal of canceled or unused therapeutic doses to prevent inadvertent use of the radiopharmaceutical.

(1) The reason for the violation:

a. All radiopharmaceutical doses, including therapeutic doses, are stored in the hot lab according to license conditions. However, the storage boxes used to separately hold diagnostic doses, therapeutic doses, and QC sources within the hot lab fume hood were not distinctly identified during the specified period of violation and the storage boxes were close together. This practice was considered sufficient because each therapeutic dose received by the licensee was labeled with the isotope, procedure, and patient name on the lead-shielded container. In addition, the syringe containing the therapeutic unit dose was labeled with the isotope and patient name. This practice of clearly identifying each therapeutic dose in addition to established operating procedures for verification of patient identity and prescribed dose was considered to be sufficient to ensure patient safety and prevent a misadministration.

b. In the event that a therapeutic dose is not used due to cancellation of the procedure, such doses are not immediately disposed of to permit the authorized user additional time to check if there is another suitable patient that could be treated with the dose prior to expiration. However, written operating procedures regarding the storage and handling of unused or unopened doses for future use until their expiration had not been established during the specified period of violation. There were written operating procedures ("Daily Checklist for Hot Lab Responsibilities" and "Daily Checklist for On Call Technologist") in place, which addressed only the disposal of unused or unopened doses upon their expiration, that were considered to be sufficient to ensure patient safety.

(2) The corrective steps that have been taken and the results achieved:

a. The RSO understands the NRC position regarding this practice. Separate storage boxes located within the hot lab fume hood were placed further apart and distinctly labeled to improve the segregation of diagnostic doses, QC sources, and therapeutic doses.

b. The RSO understands the NRC position regarding this practice. To address the proper storage and handling of unused or unopened doses until their expiration, a written operating procedure ("Unused Radioactive Doses and Ordering Doses") was established. In addition, a written log for unused high-risk doses was established for tracking these doses until expiration. Technologists are required to initial the log every day to verify completion of the tracking of these doses.

Violation 1 (continued)

(3) The corrective steps that will be taken to avoid further violations:

No additional corrective steps other than those specified above shall be taken.

(4) The date when full compliance will be achieved:

Corrective actions were deemed sufficient to address the causes of the incident during a NRC inspection conducted 2/28/2012.

NRC Inspection Report No. 030-14522/2011-001

Violation 2 Failure to adhere to written procedures for the disposal of expired doses. Specifically, from August 3, through September 13, 2011, the licensee failed to dispose a therapeutic dose of strontium-89, after it expired on August 2, 2011.

(1) The reason for the violation:

After receiving the Sr-89 therapeutic dose, the procedure was cancelled. The licensee kept the unused therapeutic dose in the hot lab fume hood pending another patient that could be treated with the dose prior to expiration. Although there were existing standard operating procedures regarding the disposal of an unopened expired dose, there was insufficient follow-up and communication within the nuclear medicine department regarding the status of the planned usage of the unused dose and then the plan to dispose of it, which resulted in staff passing on the responsibility for the expired dose to someone else.

(2) The corrective steps that have been taken and the results achieved:

A written log for unused or unopened doses was established for tracking the status of these doses until expiration. Technologists are required to initial the log every day to verify completion of the tracking of these doses. In addition, a daily Hot Lab checklist for technologists was implemented to reinforce established operating procedures.

(3) The corrective steps that will be taken to avoid further violations:

No additional corrective steps other than those specified above shall be taken.

(4) The date when full compliance will be achieved:

Corrective actions were deemed sufficient to address the causes of the incident during a NRC inspection conducted 2/28/2012.

NRC Inspection Report No. 030-14522/2011-001

Violation 3 Failure to verify the patient's name and identification number and the prescribed radionuclide, chemical form, and dosage prior to administration. Specifically, on September 13, 2011, a certified nuclear medicine technologist administered a 1.47 mCi dose of Sr-89 when the prescribed dose was for 6.0 mCi of In-111, and did not check the patient's name and identification number and the prescribed radionuclide, chemical form and dosage before administering the dose.

(1) The reason for the violation:

The patient had traveled from a neighboring island to the QMC Nuclear Medicine department for an Octreotide procedure. This imaging procedure using In-111 cannot be performed until 24 hours post injection and the technologist was more focused on hurrying the dose administration to minimize inconvenience and permit more time for the patient to explore the local venues instead of ensuring procedural requirements.

(2) The corrective steps that have been taken and the results achieved:

Established an operating procedure for a double-validation step in the electronic record system for all nuclear medicine procedures (except Xe-133 and blood volume exams) that requires a second technologist to validate the correct dose has been prepared for the specified examination prior to administration. Electronic records of the double-validation will be maintained.

Revised the "Radiopharmaceutical Use Authorization" written procedure to require all nuclear medicine technologists to input all doses into the electronic record system prior to radiopharmaceutical administration. This provides visual cues for the correct radiopharmaceutical for each procedure and will automatically flag doses that have not been checked in and dose assays that are not within the prescribed dose range.

Posted the document titled "Dose Range for Administration of Radiopharmaceuticals" on the hot lab wall next to the dose calibrator in order to be readily visible as a cue to the technologist during dose assays. This document specifies the normal dose range and radiopharmaceutical for each nuclear medicine procedure.

Provided the technologist involved in the medical event with remedial training and competency validation for all high-risk procedures. Implemented core competency validation for high-risk procedures in the annual performance evaluation for all nuclear medicine technologists.

The RSO reviewed the "Rules for Safe Use of Radiopharmaceuticals" and related procedures with all nuclear medicine technologists as part of in-service training.

Violation 3 (continued)

(3) The corrective steps that will be taken to avoid further violations:

No additional corrective steps other than those specified above shall be taken.

(4) The date when full compliance will be achieved:

Corrective actions were deemed sufficient to address the causes of the incident during a NRC inspection conducted 2/28/2012.