THE QUEEN'S MEDICAL CENTER

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Docket No. 030-14522
License No. 53-16533-02
EA No. 93-291

January 25, 1994

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D.C. 20555

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. 030-01215/93-01.

For additional information, please call Scott Dube, Radiation Safety Officer, at (808) 547-4884.

Sincerely,

Karen K. Muraraka

Karen Muraraka
Vice President, Organizational Services

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Violation A Failure to Provide Training to Personnel Attending Therapy Patients

(1) The reason for the violation:

USNRC Region V asserts that any individual who provides care to a therapy patient must be trained pursuant to 10 CFR 19.12, 35.310, and 35.410. It is agreed that were a number of nurses attending to therapy patients who have no record of training. The majority of these training deficient nurses have been "floats", "flyers", and call-in staff. These individuals are not permanently assigned to the two therapy units, and are therefore difficult to schedule for training.

There were also a number of ancillary staff, primarily IV therapists and respiratory therapists, who did not receive training pursuant to 10 CFR 35.310 and 35.410. The reason for this deficiency is that the RSO did not believe 35.310 and 35.410 applied to these ancillary staff. (see QMC Response presented at the December 2, 1993 Enforcement Conference) This had never been an issue during previous inspections. Consequently, the RSO did not attempt to provide such training.

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

The supervisory staff of the two nursing units caring for therapy patients were reminded immediately after the October 27, 1993 Exit Conference that they were responsible to:

a. Enforce the rule that no floats, flyers, or call-in nurses will care for brachytherapy patients.

b. Enforce the rule that untrained nurses will first read and sign the Self Learning Module before caring for brachytherapy patients.

At that time, the training of ancillary staff was considered an unresolved issue. No immediate corrective action plan was implemented, pending the final outcome of the inspection.

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

Donna Christle (Management Representative) and Scott Dube (RSO) met with the Duane Walker (Vice-President, Patient Services) on December 15, 1993. Mr. Walker was informed of the escalated enforcement which will result from any future training non-compliance. It was agreed that the full support of management was required to correct the non-compliance.

Subsequently, Scott Dube (RSO) and Brent Murphy (Assistant RSO) met with Beth Freitas (T7E) and Toni Harada (T9E) on January 14, 1993 to decide how to best improve compliance. The following corrective action plan shall be implemented:

Nurses:

a. Provide a current list of trained nurse to each unit caring for therapy patients. Post this list at the scheduling desk where nurses are assigned to specific patients. Only traine nurses will be assigned to brachytherapy patients. The list will be updated with each change of status.

a. Include brachytherapy radiation safety in the orientation "skills checklist" for new nurses assigned to units which care for therapy patients. The RSO will be notified when new staff is hired so that an inservice can be provided.

Non-nurse care givers:

a. This group is defined as IV therapists, respiratory therapists, phlebotomists, and physicians who provide hands-on care to the therapy patient.

b. A self learning module will be developed at posted at the door for each therapy procedure. The non-nurse care giver will be required to review the module and sign the training record before entering the therapy room.

Ancillary staff:

a. Include 19.12 type radiation safety training in the new employee orientation for all new employees.

b. Continue to provide 19.12 type training at the annual Safety Fair.

Signage:

a. Post a sign at the patient's door, such as:
"DO NOT ENTER WITHOUT PERMISSION FROM NURSE"

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

Full compliance will be achieved as of March 1, 1994.

Violation B Failure of a Technologist to Follow Instructions of the Authorized User

(1) The reason for the violation:

The nuclear medicine technologists have been instructed to screen female patients who may be pregnant or breast feeding. The technologists are to stop the procedure and notify the authorized user if a patient indicates she is pregnant or breast feeding. On one occasion, a patient indicated she was breastfeeding, yet the technologist administered the low activity dose of iodine-131 anyway without notifying the authorized user. The diligence of that nuclear medicine technologist may have been compromised because the low activity (15 uCi) would not present a substantial hazard to the fetus of a pregnant patient or the infant of a nursing mother.

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

The nuclear medicine staff reviewed this event soon after it occurred in December 1991. At that time, the importance of diligent screening was emphasized and appreciated by all. There have been no repeat incidents since then.

The RSO reminded the staff by memo on November 19, 1993 to always be diligent in the screening procedure.

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

The screening procedure has been documented and reviewed by each of the technologists. The procedure is now incorporated into the clinical procedure manual.

The clinical procedure manual will be reviewed by all new technologists and will be reviewed at the annual radiation safety inservice.

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

Full compliance was achieved as of December 1991.

Violation C Failure to Test Dose Calibrator for Linearity over Full Range

(1) The reason for the violation:

The linearity test was once performed using a single source which decayed for several days. The entire range was presented on one page, and was easy to review. Since 1990, the test has been performed using a Lineator tool. This requires using two separate sources (high and low strength) to cover the full range. The two tests are reported on separate pages.

During the 12/91 inspection, Frank Pang identified two occasions when the linearity test did not measure down to 10 uCi. At the exit conference, he stated this was one of the four potential violations. Since that time, the RSO has been diligent to audit the quarterly linearity tests to make sure the range goes down to 10 uCi. Unfortunately, the RSO was not as careful to check the high end, which is reported on a separate page.

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

The RSO reviewed the range requirement with the nuclear medicine supervisor. The high range was tested on 10/28/93 and found to meet the linearity specifications.

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

The nuclear medicine supervisor was later notified by memo to be diligent in the linearity testing to cover the full range of 200 mCi to 10 uCi.

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

Full compliance was achieved as of 10/28/93.

Violation D Failure to Monitor Hands

(1) The reason for the violation:

The QMC license application dated 8/25/89 states the nuclear medicine technologists will monitor their hands for radioactivity after each procedure or before leaving the area. The instrument shall be a crystal probe or gamma camera. In the past, the technologists have always used one of the gamma cameras to monitor their hands.

On 3/30/93, the renovated Hot Lab was commissioned. A new instrument in the Hot Lab was the Victoreen 808E Area Monitor. This GM detector came with a manufacturer's calibration report. The performance specifications indicated a minimum sensitivity of 0.1 mrem per hour. At the time, the RSO believed this to be suitable for hand monitoring.

Also, the RSO believed there would be an advantage if the technologists used the 808E to monitor their hands because of the proximity to the fume hood. In that way, the staff would identify hand contamination in the Hot Lab, and prevent contaminating the door handles and other surfaces in the department.

Therefore, the RSO instructed the nuclear medicine technologists to use the 808E to monitor their hands rather than use one of the gamma camera.

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

The nuclear medicine supervisor was notified by memo on November 19, 1993 to instruct the staff to resume using one of the gamma cameras to monitor their hands until further notice. This change in procedure was immediately adopted by the nuclear medicine staff.

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

The nuclear medicine technologists will be reminded during the initial inservice and annual refresher inservice to use one of the gamma camera to monitor their hands.

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

Full compliance was achieved as of November 20, 1993.

Violation E Failure to Hold Radioactive Waste for Ten Half-Lives

(1) The reason for the violation:

Radioactive waste from nuclear medicine procedures must be held for ten half-lives before disposal as non-radioactive trash. (This does not apply to isotopes with a $T_{1/2}$ > 64 days.) Historically, the waste has been segregated into two groups: short-lived (exclusively Tc-99m) and long-lived (all others, including I-131, Ga-67, Ti-201, I-131, P-32, I-125, etc.).

The bulk of the long-lived waste includes I-131 and Tl-201. These and most other isotopes can all be disposed after three months. However, there is occasionally a minute amount of I-125 which must be held for 600 days. This I-125 waste is generated by plasma volume studies and Neoprobe procedures.

On several occasions, a container of mixed long-lived waste was disposed after 90 days, which is the typical decay period. The technologist failed to recognize there was a minute amount of I-125 present in the container, which should have been held for 600 days.

The waste disposal system worked well for the majority of the containers. It is understandable that failure would occur for those infrequent containers which included I-125 waste. Nonetheless, the RSO and technologists should have been diligent over time in identifying those exceptions.

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

The nuclear medicine supervisor was notified by memo on November 19, 1993 to hold all waste for ten half-lives.

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

A new procedure has been adopted whereby the waste will be segregated into three different containers:

Short-lived:	$T_{1/2}$ < 24 hours	(Tc-99m exclusively)
Mid-lived:	1 day < $T_{1/2}$ < 10 days	(I-131, Tl-201, etc.)
Long-lived:	10 days < $T_{1/2}$ < 65 days	(P-32, Sr-89, I-125)

This procedure has been documented for inclusion in the procedure manual.

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

Full compliance was achieved as of November 20, 1993.

Violation F Failure to Record Identity of Radionuclides Disposed

(1) The reason for the violation:

Radioactive waste is generated in the course of the nuclear medicine procedures. Vials, syringes, swabs, gloves, and other items are routinely and unavoidably contaminated. Such waste is deposited in appropriately labeled containers throughout the department. When a container is full, it is sealed and put into the Waste Room for decay-in-storage.

In order to ensure the waste is held for a minimum of ten half-lives, it is necessary to maintain records which identify all the isotopes collected in each container. Historically, these records were maintained manually.

In May 1992, the Nuclear Medicine Department began using the computerized Nuclear Medicine Information System (NMIS) for such recordkeeping. The NMIS did not provide a convenient method to identify the different isotopes which may be in each general collection container. Therefore, the contents were simply identified as "TRASH". It was assumed that the longest-lived isotope included in the container was I-131, unless otherwise noted.

The conversion of recordkeeping from the manual system to the NMIS introduced a non-compliance with regards to the recordkeeping requirements. This was not identified by the RSO.

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

The nuclear medicine supervisor was notified by memo on November 19, 1993 to identify all isotopes in each container.

The supervisor has established a procedure using NMIS whereby all isotopes are identified for each container. Generic identification shall no longer be used.

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

The RSO now understands the full requirement to document all radionuclides held for decay-in-storage. Future quarterly audits will include review of each disposal record for completeness.

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

Full compliance was achieved as of November 20, 1993.