NOTICE OF VIOLATION

The Queen's Medical Center
Honolulu, Hawaii

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

During an NRC inspection conducted on September 28 and October 25-27, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violations are listed below:

A. 10 CFR 35.310 and 35.410 require in part that licensees provide radiation safety instruction to all personnel caring for patients receiving radiopharmaceutical therapy or undergoing implant therapy.

Contrary to the above, between December 10, 1991, and October 25, 1993, licensee personnel (nurses, IV therapists, respiratory therapists, chemotherapists, pharmacists, social workers, and physicians) cared for patients receiving radiopharmaceutical or implant therapy, but the licensee had not provided the required radiation safety instruction. Specifically, the licensee did not provide instruction to approximately 58 individuals who provided such care.

This is a Severity Level IV repeat violation, third occurrence. (Supplement VI). (93-01-01)

B. 10 CFR 35.25(a)(2) requires in part that a licensee that permits the use of byproduct material by an individual under the supervision of an authorized user require the supervised individual to follow the instructions of the supervising authorized user.

As of October 25, 1993, the licensee had instructed nuclear medicine technologists to stop any diagnostic or therapeutic nuclear medicine procedure and notify an authorized user when a patient indicated that she is either pregnant or breast feeding.

Contrary to the above, on December 2, 1991, a nuclear medicine technologist, an individual under the supervision of the licensee's authorized user, did not stop a diagnostic nuclear medicine procedure using iodine-131 or notify the authorized user after a patient indicated on the screening form that she was breast feeding.

This is a Severity Level IV violation (Supplement VI). (93-01-02)

C. 10 CFR 35.50(b)(3) requires in part that a licensee test each dose calibrator for linearity over the range of its use between the highest dosage that will be administered to a patient and 10 microcuries.

Contrary to the above, between October 5, 1992 and October 7, 1993, the licensee administered dosages to patients that were greater than the highest dosage measured during dose calibrator linearity tests on approximately sixteen occasions.

This is Severity Level IV violation (Supplement VI). (93-01-03)

D. License Condition 20 requires in part that the licensee possess and use licensed material in accordance with the statements, representations, and procedures contained in the application dated August 25, 1989.

Item 10.4.3 of the licensee's application dated August 25, 1989, requires that individuals monitor their hands for contamination in a low background area after each procedure or before leaving the area.

Contrary to the above, between March 30 and October 25, 1993, the licensee failed to monitor for the presence of contamination on personnel who had performed procedures in Nuclear Medicine. Specifically, the Victoreen Model 808E radiation area monitor used to perform personal contamination monitoring by nuclear medicine personnel was not capable of detecting levels of technetium-99m below 75 microcuries (1.7E8 disintegrations per minute).

This is Severity Level IV violation (Supplement VI). (93-01-04)

E. 10 CFR 35.92(a) permits the licensee to dispose of byproduct material with a physical half-life of less than 65 days in ordinary trash, provided in part that the licensee first holds such byproduct material for decay a minimum of ten half-lives.

Contrary to the above, on November 16 and 25, 1992, the licensee disposed of radioactive iodine-125 waste Item Numbers 496, 501, and 504 in ordinary trash without first holding this material for decay a minimum of ten half-lives. Licensee surveys of the material indicated that no radioactivity above background was released.

This is a Severity Level IV violation (Supplement VI). (93-01-05)

F. 10 CFR 35.92(b) requires that a licensee retain for three years a record of each disposal of byproduct material permitted under 10 CFR 35.92(a), and that the record include, in part, the radionuclides disposed.

Contrary to the above, between July 24, 1992, and October 1, 1993, approximately 35 records of radioactive waste disposal permitted under 10 CFR 35.92(a) did not include the radionuclides disposed.

This is a Severity Level V violation (Supplement VI). (93-01-06)

Pursuant to the provisions of 10 CFR 2.201, The Queen's Medical Center, is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington D.C. 20555, with a copy to the Regional Administrator, Region V, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation (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. If an adequate reply is not received within the time

specified in this Notice, the Commission may issue an Order or a Demand for Information as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Where good cause is shown, consideration may be given to extending the response time.

Dated at Walnut Creek, California
this 29th day of December 1993