UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION V

1450 MARIA LANE
WALNUT CREEK, CALIFORNIA 94596-5368

December 29, 1993

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

The Queen's Medical Center
1301 Punchbowl Street
Honolulu, Hawaii 96813

Attention: Karen Muranaka
Vice President, Organizational Services

SUBJECT: NOTICE OF VIOLATION (NRC INSPECTION REPORT NO. 030-01215/93-01)

This refers to the inspection conducted on September 28 and October 25-27, 1993, of The Queen's Medical Center (Queens), Honolulu, Hawaii. The results of the inspection were documented in NRC Inspection Report No. 030-14522/93-01, dated November 23, 1993. The inspector identified seven apparent violations of NRC requirements and one unresolved item. The apparent violations, their causes, and your corrective actions were discussed with you during an Enforcement Conference on December 2, 1993. Enclosed is Inspection Report 93-02 which summarizes both the Enforcement Conference and the NRC's medical consultant report of the December 2, 1991 event involving the unplanned exposure of a nursing infant.

The violations are described in the enclosed Notice of Violation (Notice). The most significant violation involved your repeated failure to provide training to personnel attending therapy patients as required by 10 CFR 35.310 and 35.410. As noted in the enforcement conference report, your management representatives disagreed that training pursuant to 10 CFR 35.310 and 35.410 was required for non-nursing personnel who attended therapy patients. After careful consideration of your position, the NRC staff asserts that any individual who provides care to a therapy patient (eg., nurse, respiratory therapist, IV therapist, doctor, etc...) must be trained pursuant to 10 CFR 19.12, 35.310, and 35.410. Individuals who frequent a therapy patient room but do not provide patient care (eg., housekeeping or maintenance staff) must be trained pursuant to 10 CFR 19.12.

Regarding the unplanned exposure to the nursing child, the NRC medical consultant who reviewed the December 2, 1991 event concluded that your decision not to obtain either thyroidal or whole-body iodine-131 retention measurements on the infant or any assessment of the infant's thyroid functional status complicated the estimate of the infant's radiation dose. In the absence of in-vivo measurements, the thyroidal dose calculated by the consultant ranged from 16 to 65 rem. In addition, the consultant stated that: (1) the assumptions used by the RSO to estimate the infant's thyroid radiation dose (25 rad) were reasonable, (2) no medical consequences are likely for the infant, (3) a deterministic effect from iodine-131 will not occur from a thyroidal absorbed radiation dose in this range, (4) it is unlikely that the

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infant is at a significant risk for a stochastic effect, (5) the impact of the iodine-131 administration on the health and safety of the infant is negligible, and (6) no long term disability is expected. We encourage you to inform the attending physician of our findings so that he may keep the parents fully informed.

The NRC recognizes that you identified the above unplanned exposure to the infant and the technologist's failure to follow the verbal instructions of the authorized user. However, the violation of 10 CFR 35.25(a)(2) is being cited because: (1) this exposure represents the very failure the regulatory program is designed to prevent, and (2) your corrective actions may not have been fully adequate to prevent a future occurrence.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to take to prevent recurrence. In addition, you are required to provide information which describes how you plan to provide training pursuant to 10 CFR 35.310 and 35.410 to non-nursing personnel who will attend radiopharmaceutical or implant therapy patients. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements. This enforcement action could include a civil penalty, suspension of licensed activities, or an order modifying the license if the failure to provide training to personnel is identified by the NRC during the next inspection.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,

Ross A. Scarano, Director
Division of Radiation Safety and Safeguards

Enclosures:

Notice of Violation
NRC Inspection Report 030-14522/93-02
Queens Report dated December 2, 1993

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bcc w/enclosure:
RV Docket File
Inspection File
GCook
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MBlume
State of Hawaii

This package was discussed with J. Glenn on 12/29/93. He suggested a minor change to violation E which was made by

bcc w/o enclosure:
MSmith
DClevenger

TPrue	Gyuhas	FWenslawski	RCarrano	MBlume
12/28/93	12/28/93	12/28/93	12/28/93	12/28/93
REQUEST COPY YES / NO	REQUEST COPY YES / NO	REQUEST COPY YES / NO	REQUEST COPY YES / NO	REQUEST COPY YES / NO

RHuey	BFaulkenberry
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SEND TO PDR YES / NO

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