St. Francis
Medical Center

2230 Liliha Street • Phone (808) 547-6011
P.O. Box 30100 • Honolulu, Hawaii 96820-0100

January 24, 1997

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

Subject: Response to an Apparent Violation
NRC License No. 53-11966-01
Report No. 030-03557/96-01

Gentlemen:

This letter is submitted in response to your letter forwarding inspection report 030-03557/96-01 and notice of apparent violation.

Apparent Violation

1. Observation and Findings

With our exception, licensed materials stored in the nuclear medicine department at St. Francis Medical Center were observed by the inspector to be secured and locked in the hot lab when the department was not occupied. When not in storage, licensed material was under the surveillance of a nuclear medicine authorized user or a technologist. The exception involved sodium iodide iodine-131 capsules which were stored in a fume hood located in an unsecured room as described below.

During a tour of the facility on November 21, licensee representatives identified a fume hood used to store iodine-131 capsules. According to the radiation safety officer (RSO), the licensee had routinely stored iodine-131 capsules in the fume hood located in a room adjacent to the hot lab following receipt of the capsules from the licensee's vendor. The inspector noted that the fume hood was not secured and the room, where it was located, was also not locked. This room was designated as the "thyroid and osteoporosis" room and was used for some patient procedures and

IE07

radiopharmaceutical administrations. When questioned, the RSO acknowledged that the room was not routinely locked when the department was not occupied or when the technical staff was not in the immediate area.

On November 21, the licensee had six iodine-131 capsules stored in the fume hood. Each capsule originally contained 30 microcuries of iodine I-131. Based on the assay dates, the inspector calculated that on November 21, 1996, the total activity remaining in the six capsules was approximately 19 microcuries. The RSO indicated that maximum quantity of iodine-131 that would have been stored at any given time in the fume hood would have been five capsules containing 30 microcuries each, plus one decayed capsule containing less than one microcurie (the decayed capsule was used to test the effectiveness of the hospital's waste portal monitor). Thus, the maximum quantity of material in the fume hood at any given time would have been approximately 150 microcuries of iodine-131.

Licensee Response

1. Reason for Violation:

10 CFR 20.1801 required that the licensee secure from unauthorized removal or access of licensed materials that are stored in controlled or unrestricted areas. As noted above, on November 21, 1996, the inspector observed that six capsules containing iodine-131 with a total activity of approximately 19 microcuries were stored in a fume hood located in a controlled area and the licensee had not secured the capsules from unauthorized removal or access. This was identified as an apparent violation of 10 CFR 20.1801.

As stated above, on November 21, 1996, I-131 capsules were found in the fume hood with a total activity of 19 microcuries. The I-131 capsules were left in the fume hood after being removed from the hot lab where it is normally stored in order to administer a dose to a thyroid uptake patient. Our normal procedure is to return the I-131 capsules to the hot lab once the dose has been administered but this was not done on the date in question. Contrary to the above statement, I-131 capsules are not routinely stored in the fume hood but are placed in the secured hot lab upon receipt from the radiopharmacy. All technologists were aware of this requirement but the technologist involved was distracted and forgot to return the I-131 capsules to the hot lab.

2. Corrective Actions:

When the inspector pointed out the I-131 capsules in the fume hood, the RSO and chief technologist acknowledged that the I-131 should not be stored in this area and the I-131 capsules were immediately returned to the hot lab. All technologists were reminded that all radioactive materials must be kept within the hot lab. The technologists were again reminded of this regulation at the next department meeting which was held in December 1996.

The radiation safety officer and chief technologist have since checked the fume hood and surrounding area on many occasions since that incident and have found no further violations.

3. Corrective Steps:

All technologists were informed of the findings during the November 20 and 21, 1996 inspection and have been reminded of the proper procedures involving storage of radioactive materials. A sign has been placed on the fume hood stating that no radioactive materials are to be stored in this area. Follow-up inspections have shown complete compliance to this date.

4. We have been in full compliance since the date of the inspection.

Sincerely,

ST. FRANCIS MEDICAL CENTER

Myron L. Tong

Myron L. Tong
Assistant Administrator

cc: Regional Administrator, Region IV
611 Ruan Plaza Drive, Suite 400
Arlington, TX 76011

Regional Administrator, Region IV WCFO
1450 Maria Lane
Walnut Creek, CA 94596