Reply to a Notice of Violation

May 24, 1994

Regional Administrator
U. S. Nuclear Regulatory Commission
Region IV
611 Ryan Plaza Drive, Suite 400
Arlington, Texas 76011-8064

Docket No.	030-03546
License No.	53-05379-01
Inspection Report No.	030-3546/94-01

Pursuant to the provisions of 10 CFR 2.201, Kaiser Foundation Hospital is submitting this written response to a NOTICE OF VIOLATION dated May 4, 1994.

A. 10 CFR Part 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 shall require the supervised individual to follow the written radiation safety procedures and quality management procedures established by the licensee.

(1) The reason for the violation: The nuclear medicine technologist calculated the volume of phosphorus-32 that contained the prescribed activity based on the radiopharmaceutical label and recorded the volume in the radiopharmaceutical dosage log. He then drew up the initial volume of phosphorus-32 and assayed it in the dose calibrator. When the dose calibrator reading indicated the dosage was not within 10% of the prescribed dosage, he altered the volume and reassayed the dosage. He failed to revise the radiopharmaceutical dosage log record to read the final volume of the phosphorus-32 dosage actually administered to the patient.

(2) The immediate corrective steps taken: Upon discovery of the fact that the nuclear medicine technologist failed to record the actual final volume of each dosage in cases when the initial dosage drawn is adjusted, all nuclear medicine technologists were instructed at the Nuclear Medicine staff meeting on March 17, 1994 of the requirement that the dosage record must reflect the final actual dosage administered to each patient.

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Kaiser Foundation Hospital
3288 Moanalua Road Honolulu HI 96819 (808) 834-5333

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(3) The corrective steps taken to prevent recurrence: All nuclear medicine technologists were retrained in the proper procedure for calculating and recording dosages administered to patients. The training included the procedure for determining the dosage to be drawn of pure beta emitting radionuclides. The Nuclear Medicine Chief Technologist Administrator, authorized physician users, RSO and the consulting auditor will increase their oversight of the nuclear medicine technologists' performance to identify deviations from written radiation safety and quality management procedures.

(4) The date when full compliance was achieved: Full compliance was achieved on March 17, 1994.

B. 10 CFR Part 35.21(a) requires, in part, that a licensee shall appoint a Radiation Safety Officer responsible for implementing the radiation safety program to ensure that the radiation safety activities are being performed in accordance with regulatory and license requirements in the daily operation of the licensee's byproduct material program.

(1) The reason for the violation: The institution's management failed to recognize that the RSO had not implemented the revised procedures which established an inventory record of byproduct material and incorporated the other requirements of 10 CFR Part 20.1001-2401 and to review activities and sign documents generated by the radiation safety program in a timely manner.

(2) The immediate corrective steps taken: Management performed a review of the tasks delegated to the RSO and the expertise and time required to accomplish the tasks. Since the physician designated as the RSO did not feel qualified to perform the radiation safety duties required of the RSO, her resignation was accepted on March 14, 1994. An interim RSO, Philip J. Manly, who is a certified health physicist with the expertise to perform the radiation safety duties, was appointed on March 15, 1994. The appointment of Mr. Manly as permanent RSO was subsequently approved by the Radiation Safety Committee and by the NRC in the materials license Amendment No.45.

(3) The corrective steps taken to prevent recurrence: The consulting contract between the Kaiser Foundation Hospital and the new RSO, Philip J. Manly, CHP, was amended to allow for the amount of time on site identified in the management review that is needed to ensure adequate oversight of the

radiation safety program. Using the review document, management will track the performance of the RSO.

(4) The date when full compliance was achieved: Full compliance was achieved on May 12, 1994.

Submitted by:

Kaiser Foundation Hospital

Dee Jay Mailer

Dee Jay Mailer
Regional Hospital Administrator

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