U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF INSPECTION AND ENFORCEMENT

REGION V

Report No 81-02

License No 53-05379-01 Priority 4 Category G

Licensee: Kaiser Foundation Hospital

1697 Ala Moana Boulevard

Honolulu, Hawaii 96815

Facility Name: (Same as above)

Inspection at Licensee's location

Inspection Conducted: December 11, 1981

Inspectors: R. H. Engelken, Regional Administrator — 1/12/82 Date Signed

R. D. Thomas, Chief — 1/11/82 Date Signed
Materials Radiation Protection Section

Approved by: H. E. Book, Chief — 1/13/82 Date Signed
Radiological Safety Branch

Summary:

Enforcement Conference on December 11, 1981 (Report No. 81-02)

The following matters were discussed:

1. NRC enforcement policies and procedures.
2. Compliance history and items of noncompliance associated with the September 28, 1981 inspection.
3. NRC actions to be taken in the present situation.
4. Possible future actions by the NRC.
5. Other matters of concern to NRC.

This enforcement conference involved a total of one and one half hours on site by two NRC representatives.

RV From 219 (1)

DETAILS

1. Enforcement Conference Participants

C. S. Ashizawa, Administrative Assistant
F. M. Watanabe, Chief Nuclear Medicine Technician
R. H. Ross, Manager, Department of Radiology
M. C. Nahamura, Laboratory Safety Officer and Education Coordinator
J. B. Ramirez, Manager, Department of Laboratories
P. J. Manly, Gamma Corporation-Consultant
R. H. Engelken, Regional Administrator, NRC
R. D. Thomas, Chief, Materials Radiation Protection Section, NRC
G. Yamane, State of Hawaii, Department of Health

2. Enforcement Conference

On December 11, 1981 an enforcement conference was held at Kaiser Foundation Hospital, Honolulu, Hawaii with the individuals listed above participating. The enforcement conference was related to the recent routine safety inspection of the activities authorized by NRC license number 53-05379-01, for the nuclear medicine service. This inspection was conducted on September 28, 1981. The enforcement conference was announced in a letter to the licensee dated November 3, 1981. A copy of that letter is attached.

The Notice of Violation dated November 6, 1981 had been received by the licensee, and a timely response dated November 30, 1981 was received by the NRC Regional Office. A copy of Appendix A to the Notice of Violation is attached.

During the conference, Mr. R. Thomas discussed the individual items of noncompliance and the corresponding licensee's corrective actions. Since the licensee questioned the validity of Items B and E of the Notice of Violation, these items were discussed in greater detail.

Regarding Item B, Mr. Thomas explained that due to the rather unique method by which radiopharmaceuticals are delivered by Pacific Radiopharmacy to Kaiser Hospital, certain conditions of the Department of Transportation regulations and applicable parts of 10 CFR 20 must be considered by the licensee. Pursuant to DOT regulations, the Pacific Radiopharmacy is considered the supplier/shipper of the radioactive materials. As a private carrier the Pacific Radiopharmacy transports the individual packages of radiopharmaceuticals in a metal attache'case which has been approved as a 7A container by DOT standards. Upon arrival at the hospital, a representative of Pacific Radiopharmacy physically transfers a package from the 7A container to the storage location of the licensee. At this time a receipt of transfer shall be initiated

and a radiological survey shall be conducted by the licensee in accordance with 10 CFR 20.205(b)(1), if applicable to the type and quantity of material received. Pursuant to the above requirements and our understanding of the materials transfer procedure, the citation stated in Item B of Appendix A to the Notice of Violation is valid.

Regarding Item E, the licensee stated that 10 CFR 19.12 training had been given to the employee on two separate occasions, once by the immediate supervisor and again by a representative of Gamma Corporation. Mr. R. Thomas stressed the need to maintain records of training pursuant to 10 CFR 19.12. Based upon the licensee's assurance that the training had been given, and the understanding that all future training would be properly recorded, this citation is withdrawn.

The licensee's corrective actions related to the remaining items of noncompliance as stated in Appendix A of the Notice of Violation were acceptable.

The "Management Control System" as stated in the licensee's response dated November 30, 1981 appears to be adequate, if implemented as stated.

At the time of the conference, the enforcement policies and procedures of the NRC, as published in 45 FR 66754, were explained by Mr. R. Engelken, Regional Administrator. Particular emphasis was placed on escalated enforcement actions such as civil penalties, orders to modify, suspend or revoke licenses, and orders to cease and desist. The relative significance of the different severity levels was explained, and it was pointed out that any violations at this licensee would fall into Supplements IV and VII of the Federal Register Notice. A copy of the Federal Register Notice was given to the licensee. The licensee was told that the enforcement action to be taken at this time consisted of the Notice of Violation in conjunction with the enforcement conference which was being held.

Mr. R. Thomas explained that if a violation was not corrected satisfactorily, if it was repeated, or if a similar violation occurred, escalated enforcement action would probably be taken by the NRC. It was also explained that this provision would remain in effect for two years or until the next inspection, which ever was longer. The licensee was also informed that an early reinspection would be conducted by the NRC.

3. NRC Concern

Since the licensee uses a consulting service (Gamma Corporation) for a radiological safety program, Mr. R. Thomas expressed NRC's concern regarding the in-house, day-by-day, radiological safety officer coverage in the hospital. The need for periodic radiological surveys, receipt and transfer records, and personnel monitoring were stressed. The licensee stated that the role of an Assistant Radiological Safety Officer would be assigned to a member of the staff. All activities of the Assistant RSO would be subject to the instructions and audits by the consultant.

4. Conclusions

The licensee's response to the conference was acceptable, and a committment for a stronger management control program was made.

The enforcement conference was adjourned at 11:00 A.M.