

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

Report No. 82-02

License No. 53-09585-01 Priority IV Category G

Licensee: Winfred Y.. Lee, M.D.
Internist Clinic, Inc.
1441 Kapiolani Boulevard
Honolulu, Hawaii 96814

Facility Name: Same as above

Conference Location: 1441 Kapiolani Boulevard, Room 1111

Conference conducted: August 5, 1982

Participants: *B. H. Faulkenberry* 8/27/82
B. H. Faulkenberry, Deputy Regional Date Signed
Administrator

H. E. Book 8/27/82
H. E. Book, Chief, Radiological Safety Date Signed
Branch

Approved by: *R. D. Thomas* 8/27/82
R. D. Thomas, Chief, Materials Radiation Date Signed
Protection Section

Approved by: *H. E. Book* 8/27/82
H. E. Book, Chief, Radiological Safety Date Signed
Branch

Summary:

An Enforcement Conference was held on August 5, 1982. The following matters were discussed:

1. NRC Enforcement Policy and Procedures
2. Noncompliances observed during last inspection made on July 2, 1982, at this facility.
3. Enforcement history at this facility.
4. NRC actions to be taken in the present situation.
5. Possible future actions by NRC.

The Enforcement Conference involved a total of 3 manhours on site, utilizing two NRC representatives.

DETAILS

1. Enforcement Conference Participants

Winfred Y. Lee, M.D., Licensee
B. H. Faulkenberry, Deputy Regional Administrator, NRC
H. E. Book, Chief, Radiological Safety Branch, NRC
T. M. Anamizu, State of Hawaii, Department of Health

2. Enforcement Conference

On August 5, 1982 an enforcement conference was held in the offices of Dr. Winfred Y. Lee, with the individuals listed above participating. The enforcement conference was related to a routine safety inspection of activities authorized by NRC license number 53-09585-01. That inspection was conducted on July 2, 1982. The enforcement conference was announced in a letter to the licensee dated July 27, 1982. A copy of that letter is attached to this report.

The current General Policy and Procedures for NRC Enforcement Actions as published in Appendix C of 10 CFR Part 2 were explained by Mr. Faulkenberry. Dr. Lee said he had a copy and was generally familiar with the contents. Another copy was given to Dr. Lee for his use and retention. Mr. Faulkenberry explained the significance of an enforcement conference and described when such a conference was held. He also described under what conditions civil penalties and other escalated enforcement actions were utilized. Mr. Faulkenberry made certain that Dr. Lee understood that an enforcement conference concerning his licensed activities was in progress.

The violations observed during the most recent inspection were discussed by Mr. Book. Dr. Lee had already received the Notice of Violation dated July 21, 1982. Appendix A of that Notice of Violation is attached to this report and was used in the discussions with Dr. Lee. Each violation was individually discussed. In general, Dr. Lee said the reason for the noncompliance was poor communication. He said he thought the technologists were aware of requirements and internal audit findings, and were taking appropriate action, when actually that was not the case. He said, as a result, as part of his corrective action, he had made a direct delegation to his Chief Technologist, to act as day-to-day Radiation Safety Officer. Dr. Lee felt that by so doing, he placed the Chief Technologist in direct communication with his radiation safety consultant, and avoided any future misunderstandings.

The above response applied principally to the violations related to radiation surveys and the one related to linearity tests on the dose calibrator. Dr. Lee also said they were establishing a chart "tickle"

system to remind them when such actions (calibrations, surveys, checks, etc.) should be taken. Dr. Lee also pointed out that corrective action had been taken on those two violations some time ago and that he had been in compliance since March, 1982.

Dr. Lee said the training of the new technologist had been an inadvertent omission on his part and that arrangements had been made for that individual to receive appropriate training.

Regarding Item B, Dr. Lee said he believed it was in error, since no I-131 was disposed to the sewer at this location. He said all I-131 was received in capsule form and if not administered to a patient, it was returned to the supplier, a local radiopharmacy. Dr. Lee was told that this item would be rechecked with the inspector. Later, in the Region V offices, the NRC inspector said the violation was based on statements by the technologists working in the lab. He said it had been discussed with Dr. Lee at the exit interview, and no objection was raised at that time.

The enforcement history was reviewed with Dr. Lee, and a summary of noncompliance was given to him. A copy of that summary is attached to this report. Dr. Lee was told that we were particularly concerned with the repetitive violations (Items A.1 and B), and those which went uncorrected after they were observed during internal audits by his own radiological consultant (Items A.1 and A.2). Dr. Lee was also reminded that a similar enforcement conference had been held with St. Francis Hospital, Honolulu, where he is the physician in charge of the program.

Dr. Lee was cautioned concerning his management responsibilities with respect to the NRC licensed program. It was explained to him that he was management, he was the licensee, and he was responsible for the safety of the program. He was told that he could delegate duties to other persons, but in the final analysis, he was the responsible person and if violations occur, enforcement action would be taken against him and not his employees or his safety consultants.

Dr. Lee was told that no escalated enforcement action was planned at this time, but that we expected a written response to our Notice of Violation dated July 21, 1982. He was also told that if the violations were not corrected satisfactorily, if they were repeated, or if similar violations occurred, escalated enforcement action would probably be taken by the NRC. It was explained that this provision would remain in effect for two years or until the next inspection, whichever was longer. The licensee was also informed that an early reinspection would be conducted by the NRC.

Dr. Lee said he was a busy Internist, trying to supply good medical care at an affordable cost. He said sometimes he had other things on his mind and inadvertently was in noncompliance. He said corrective

action had been taken, and that he had every desire and intent to operate in compliance with NRC requirements. Dr. Lee also complained about unannounced inspections, and their intrusion on his busy schedule. We apologized for the intrusions, but explained that one of the NRC policies was to conduct unannounced inspections, because we believe it gives us a truer picture of licensed operations.

3. Conclusions

The licensee's response to the enforcement conference was acceptable. The NRC will receive a written response to the Notice of Violation. No escalated enforcement action is contemplated at this time. An early reinspection will be scheduled.