APPENDIX A

NOTICE OF VIOLATION

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

License No. 53-09585-01

As a result of the inspection conducted July 2, 1982, and in accordance with the NRC Enforcement Policy, (10 CFR Part 2, Appendix C), 47 FR 9987 (March 9, 1982), the following violations were identified:

A. License Condition 14. states that the licensee shall possess and use licensed material in accordance with statements, representations, and procedures contained in application received June 20, 1978.

1. Item 17, Page 1 of the attachment to the application, states that all laboratory areas where radioactive materials are used in quantities larger than 100 microcuries will be surveyed weekly.

   Contrary to the above requirement, weekly radiation surveys had not been performed in Suite 1111, an office and examination room where therapeutic doses up to 10 millicuries of iodine-131 had been administered to patients between the period of November 1979 and February 1982.

   The above matter was identified during an internal radiological consultant audit of the Nuclear Medicine radiation safety program and reported to the licensee in a letter dated February 25, 1981. However, no corrective action was taken by the licensee until March 10, 1982, when a radiation survey was performed in response to a second internal radiological consultant audit made on February 24, 1982, which again identified this failure to conduct weekly radiation surveys.

   This is a Severity Level IV Violation (Supplement VI).

2. Item 10, Page 1 of the attachment to the application, states that the dose calibrator will be checked for linearity prior to initial use and quarterly thereafter.

   Contrary to the above requirement, tests to determine instrument linearity had not been performed on the dose calibrator (Serial Number 6133) during the period of use from November 21, 1979 to February 1982.

   The above matter was identified during an internal radiological consultant audit of the Nuclear Medicine radiation safety program which was reported to the licensee in a letter dated February 25, 1981. However, no corrective action was taken by

the licensee until March 11, 1982, when a linearity test was conducted in response to a second internal radiological consultant audit made on February 24, 1982, which again identified the failure to conduct linearity checks.

This is a Severity Level IV Violation (Supplement VI).

3. Item 12, Page 1 of the attachment to the application, states that all radioisotope laboratory personnel will be given a one hour lecture and additional radiation safety training before being permitted work in the controlled areas.

Contrary to the above requirement, at the time of the inspection, the inspector identified a technologist working in the radioisotope laboratory who had not received appropriate training in radiation safety pursuant to employment on April 1, 1982.

This is a Severity Level IV Violation (Supplement VI).

B. 10 CFR 30.51(a) requires each licensee to maintain records showing the disposal of byproduct material. Also, 10 CFR 20.401(c)(3) requires that records of disposals made pursuant to 10 CFR 20.303 to the sanitary sewer be maintained.

Contrary to these requirements, at the time of the inspection, there were no records maintained by the radioisotope laboratory of iodine-131 disposed to the sanitary sewer between July 20, 1978, and the date of inspection, July 2, 1982.

This is a Severity Level V Violation (Supplement IV).

Pursuant to the provisions of 10 CFR 2.201, you are hereby required to submit to this office within thirty days of the date of this Notice, a written statement or explanation in reply, including: (1) the corrective steps which have been taken and the results achieved; (2) corrective steps which will be taken to avoid further items of noncompliance; and (3) the date when full compliance will be achieved. Consideration may be given to extending your response time for good cause shown.

dated July 21, 1982

for B. A. Ruddlesden
R. D. Thomas, Chief, Materials
Radiation Protection Section

WINFRED LEE, M.D.

COMPLIANCE HISTORY

January 16, 1967	No noncompliance
November 5, 1969	No noncompliance
February 23, 1976	(1) 10 CFR 20.401 (b) - Records of radiation surveys not maintained for surveys of decayed I-131 capsules discarded to sanitary sewer system and for surveys on empty I-131 therapeutic dose vials discarded to common trash.
	(2) 10 CFR 20.401 (b) - Records of disposals were not maintained for monthly disposals of I-125 to the sanitary sewer system.
	(3) 10 CFR 19.11 (a) - Failure to post Parts 19 and 20 of the regulations, and a copy of the license.
December 12, 1978	(1) 10 CFR 20.201 (b) - Surveys were not performed on empty I-131 therapeutic dose cups discarded to ordinary trash.
	(2) LC 14 - Patient doses were not assayed in dose calibrator prior to administration (no calibrator was available for use).
	(3) LC 14 - Failure to perform daily and weekly radiation surveys.
September 30, 1981 (St. Francis Hospital)	(1) 10 CFR 20.207 - Licensed material was not secured from unauthorized removal from nuclear medicine and RIA laboratories (doors were open and room unattended).
	(2) LC 19 - Dose calibrator constancy checks were not conducted on daily basis.
	(3) LC 19 - Annual review of radiation safety program was not conducted by Medical Isotopes Committee for 1979 and 1980.
	(4) LC 19 - Records of daily surveys by Nuclear Medicine not maintained.

CONTINUED

September 30, 1981
(St. Francis Hospital)

(5) LC 19 - Packages of radioactive material, including amounts greater than 100 millicuries of Tc-99m, had never been surveyed.

(6) LC 19 - Daily surveys of elution, preparation, and injection areas, had not been performed for certain periods in 1981.

(7) LC 19 - Monthly surveys were not performed in the surgical laboratory during April and June, 1981.

(8) 10 CFR 20.401 (b) - Records were not maintained for liquid waste disposal by RIA laboratory between January and April, 1980.