APPENDIX A

NOTICE OF VIOLATION

The Queen's Medical Center
1301 Punchbowl Street
Honolulu, Hawaii 96813

License No. 53-16533-02

As a result of the inspection conducted October 1, 1981, and in accordance with the Interim Enforcement Policy, 45 FR 66754 (October 7, 1980), the following violations were identified:

A. 10 CFR 35.14(e)(1)(i) requires that any licensee who possesses sealed sources as calibration or reference sources pursuant to paragraph (d) of this section shall cause each sealed source containing byproduct material, other than hydrogen-3, with a half life greater than thirty days in any form other than gas to be leak tested at intervals not to exceed six months.

Contrary to the above requirement leak tests have not been conducted on the 215 microcurie cesium-137, Serial No. 3560880A-37, 272 microcurie barium-133, Serial No. 3580780A-39, and the 308 microcurie cobalt-57, Serial No. 3510980A-08 dose calibrator calibration sources during the period of December 2, 1980 to October 1, 1981.

B. 10 CFR 35.14(b)(5)(i) requires that for Group VI, any licensee who possesses and uses sources or devices containing byproduct material shall cause each source or device containing more than 100 microcuries of byproduct material with a half life greater than thirty days, except iridium-192 seeds encased in nylon ribbon, to be leak tested at intervals not to exceed six months.

Contrary to the above requirement, at the time of the inspection, leak tests on 10 cesium-137 sources, Serial No. 67-803, totaling 39 millicuries, were due for leak testing on May 26, 1980, but were not leak tested until June 25, 1981. Also, leak tests on five cesium-137 sources totaling 51.7 millicuries, Serial No. 67-804 were due for leak testing on March 10, 1980, but were not leak tested until June 25, 1981.

The above items A. and B. constitute a Severity Level IV Violation (Supplement VII)

C. 10 CFR 35.14(f)(2) requires that any licensee holding specific licenses pursuant to 10 CFR 35.14 shall conduct quarterly physical inventories to account for all calibration or reference sources not exceeding three millicuries, received and possessed.

Contrary to the above requirement, physical inventories have not been conducted of the 215 microcurie cesium-137, Serial No.

3560880A-37, 272 microcurie barium-133, Serial No. 3580780A-39, and the 308 microcurie cobalt-57, Serial No. 3510980A-08 dose calibrator calibration sources during the period of December 2, 1980 to October 1, 1981.

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

D. 10 CFR 19.11(a) requires that each licensee shall post current copies of the following documents: (1) the regulations in this part and in part 20 of this chapter; (2) the license, license conditions, or documents incorporated into a license by reference, and amendments thereto; (3) the operating procedures applicable to the licensed activities. 10 CFR 19.11(b) states that if posting of a document specified in paragraph (a)(1), (2) or (3) of this section is not practicable, the licensee may post a notice which describes the document and states where it may be examined.

Contrary to the above requirements, at the time of the inspection, the above documents were not posted in the Cardiovascular Laboratory where licensed materials is stored, nor was there a notice which describes the documents and states where they may be examined.

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

E. 10 CFR 19.11(c), (d) requires that Form NRC-3 "Notice to Employees", shall be posted by each licensee in sufficient number of places to permit individuals engaged in the licensed activities to observe them on the way to and from any particular licensed activity location.

Contrary to the above requirement, at the time of the inspection, a Form NRC-3 was not posted in the Cardiovascular Laboratory where licensed material is stored, nor at locations to permit persons to observe them on the way to and from the laboratory.

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

F. 10 CFR 30.51(a) states that each person who receives byproduct material pursuant to a license issued pursuant to the regulations in this part and parts 31-35 shall keep records showing the receipt, transfer, and disposal of such byproduct material. 10 CFR 30.51(c)(1) requires such records to be maintained as long as the licensee retains possession of the byproduct material and for two years following transfer.

Contrary to the above requirement, at the time of the inspection, records of receipt from the University of Hawaii of microcurie amounts of licensed tritiated materials used in the radiochemistry laboratory have not been maintained.

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

G. License Condition 17 requires that the licensee shall possess and use licensed material in accordance with statements, representations, and procedures contained in letter dated August 29, 1975 signed by

Eugene M. Edynak, M.D., originally submitted with reference to Byproduct Materials License No. 53-16533-01, application dated July 31, 1978, and letters dated November 22, 1978, February 13, 1979, February 21, 1979, May 31, 1979 and April 14, 1980.

(1) Item 10 of the application dated July 31, 1978 gives the methods for calibration of the dose calibrator. Tests for instrument linearity and accuracy are to be done at installation, and at quarterly and annual intervals respectively. Constancy tests are to be made on a daily basis or before each use of the instrument.

(a) Contrary to the above requirement, quarterly linearity tests of the dose calibrator had only been conducted on December 31, 1980 and on August 3, 1981.

(b) Contrary to the above requirement, during the interval from January 4, 1980 to September 8, 1981, 17 daily constancy checks had not been conducted.

The above items constitute a Severity Level IV Violation (Supplement VII).

(2) Pages 1 and 2 of item 12 of the application dated July 31, 1978 state that all personnel who work with or in the vicinity of radioactive materials will receive training as per the items specified in 10 CFR 19.12 before beginning work and annually thereafter.

Contrary to this requirement, at the time of the inspection, a technician did not receive the two one-hour training sessions prior to working in the nuclear medicine department.

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

Pursuant to the provisions of 10 CFR 2.201, The Queen's Medical Center is 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.

The responses directed by this notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

dated NOV 4 1981

J. Frank Pang, Radiation Specialist
Radiological Safety Branch