APPENDIX A

NOTICE OF VIOLATION

Brigham and Women's Hospital
Boston, Massachusetts 02115

Docket No. 030-12239
License No. 20-17131-01

As a result of the inspection conducted on August 20-21, 1985, and in accordance with the NRC Enforcement Policy (10 CFR 2, Appendix C), the following violations were identified:

A. 10 CFR 20.207(a) requires that licensed materials stored in an unrestricted area be secured against unauthorized removal from the place of storage. 10 CFR 20.207(b) requires that materials not in storage be under constant surveillance and immediate control of the licensee. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.

Contrary to the above, on August 20, 1985, five receptacles of radioactive waste containing hydrogen-3, carbon-14, calcium-45 and phosphorus-32 (according to a content list and radioactive materials sign on the containers) were found in an unrestricted hallway that was neither under constant surveillance nor immediate control. Additionally, the door to the thyroid uptake lab where leaded storage vials containing iodine-123 were left on a benchtop was found unlocked and the radioactive materials were not under constant surveillance nor immediate control.

This is a Severity Level IV violation (Supplement IV).

B. 10 CFR 35.14(b)(4)(ii) requires that technetium-99m separated from molybdenum-99 by elution from a molybdenum-99/technetium-99m generator be tested to determine either the total molybdenum-99 activity or the concentration of molybdenum-99 prior to administration to patients.

Contrary to the above, as of August 21, 1985, technetium-99m eluted from a generator was not adequately tested for total molybdenum 99 activity or concentration in that the calculation of the total molybdenum-99 activity was performed incorrectly. Specifically, a technologist in Nuclear Medicine stated he did not use the manufacturer's correction factor to determine total molybdenum-99 activity or concentration on those days since August 16, 1983, that he eluted the generator for on-call and weekend emergency scans.

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

C. 10 CFR 19.12 requires that all individuals working in or frequenting any portion of a restricted area be instructed in the applicable provisions of

the Commissions's regulations and licenses. 10 CFR 35.14(b)(4)(ii) requires that tests to detect and quantify molybdenum-99 contamination be performed by personnel specifically trained to perform the test.

Contrary to the above, on August 20-21, 1985, a security guard was unaware that radioactive packages occasionally left at the information desk were not to be transported to the Radiopharmacy by security personnel. Additionally, a nuclear medicine technologist who performed tests to quantify molybdenum-99 in technetium-99m eluates from a generator used for on-call and weekend emergency scans had not been specifically trained in the dose calibrator manufacturer's instructions, in that he was unaware of the requirement to multiply the measured value for molybdenum-99 by a factor of 3.5 to obtain the total molybdenum-99 content in the technetium-99 eluate.

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

D. Condition 27 of License No. 20-17131-01 requires that licensed material be possessed and used in accordance with the statements, representations and procedures contained in application dated November 30, 1981, and letter dated June 16, 1933.

1. Block 10 of this license application requires that dose calibrators be calibrated in accordance with procedures contained in Appendix D, Section 2, of Regulatory Guide 10.8.

   a. Item C.4. of Appendix D. Section 2 requires that for each source the net activity versus the day of the year be plotted on semilog graph paper. Items C.4 and C.8 require that the measured net activity of the sources be compared to the predicted activity of the sources to assure that the measured activity is within ±5 percent of the predicted activity.

      Contrary to the above, as of August 20-21, 1985, the measured cesium-137 net activity and the measured cobalt-57 net activity had not been plotted on semilog graph paper to assure that the measured activity was within ± 5 percent of predicted activity since July 25, 1985, for the cesium-137 source and since August 4, 1985, for the cobalt-57 source in the Radiopharmacy. Additionally, in Nuclear Medicine the net activity measured for the cobalt-57 source used for daily constancy testing had not been plotted on semilog graph paper nor compared to the predicted activity of this source to assure the measured activity was within ± 5 percent of the predicted activity since the previous inspection.

   b. Item C.7 of Appendix D, Section 2, requires that dose calibrators be checked daily with a long-lived standard radionuclide at all commonly used radionuclide settings.

Contrary to the above, as of August 21, 1985, a cesium-137 source (a long-lived standard) was not used to check the dose calibrator in Nuclear Medicine on either the cesium-137 setting or all other commonly used radionuclide settings.

These are Severity Level IV violations. (Supplement VI)

2. Item 12 of this letter requires that detailed audits, to include radiation surveys, contamination surveys, inventories, review of records and procedures and verification of user training, be conducted twice annually for all users, and quarterly for the Thyroid Unit, Nuclear Medicine, Radiopharmacy and Radiation Therapy.

   Contrary to the above, as of August 20-21, 1985, the quarterly audits performed for Nuclear Medicine and the Radiopharmacy were inadequate in that they did not either identify violations of NRC regulations or license conditions found in a previous inspection in a similar department; verify that a nuclear medicine technologist had been trained in the manufacturer's written procedures for molybdenum-99 assay on the dose calibrator; identify that records for safe opening procedures on radioactive materials packages did not document the results of exposure level measurements performed as required as part of the procedures; or assure that package seals for packages shipped via common carrier did not deviate from the licensee's stated corrective action.

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

3. Block 14 of this license application requires that packages containing radioactive material be opened in accordance with the procedures in Appendix F of Regulatory Guide 10.8.

   Items 2.c. and 2.d. of Appendix F require that records be maintained of measurements of exposure rates made at 3 feet from the package surfaces and at the package surface.

   Contrary to the above, as of August 20-21, 1985, the measured three foot and surface exposure rates were not recorded as part of the procedures for safely opening packages of radioactive materials.

   This is a Severity Level V violation. (Supplement VI)

4. Items 10. and 11.b. of this letter require surveys to be documented and that surveys be performed in the Radiopharmacy daily.

   Contrary to the above, as of August 20, 1985, daily surveys performed in the Radiopharmacy on August 15, and August 19, 1985, were not recorded.

   This is a Severity Level V violation. (Supplement VI)

Pursuant to the provisions of 10 CFR 2.201, Brigham and Women's Hospital is hereby required to submit to this office within thirty days of the date of the letter which transmitted 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 violations; and (3) the date when full compliance will be achieved. Where good cause is shown, consideration will be given to extending this response time.