APPENDIX A

NOTICE OF VIOLATION

St. Francis Hospital and
Medical Center
Hartford, Connecticut
License Nos. 06-00854-03
06-00854-08

Docket No. 30-1246
30-112

Based on the results of an NRC inspection conducted on March 26 and 27, 1980, it appears that certain of your activities were not conducted in full compliance with NRC regulations and the conditions of your license as indicated below:

A. Condition 17 of License 06-00854-03 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in an application dated April 22, 1977 and letters dated October 11, 1977 and February 14, 1978.

1. Item 4 of your letter dated February 14, 1978 requires that all individual doses be assayed just prior to patient administration.

   Contrary to this requirement, as of March 26, 1980, you failed to assay Iodine-131 capsules prior to patient administration.

2. Item 4 of your letter dated October 11, 1977 requires that activity linearity tests be performed on your dose calibrator annually.

   Contrary to this requirement, as of March 26, 1980, you failed to perform the activity linearity test at the required frequency.

3. Item 10 of your letter dated October 11, 1977 requires that syringe shields be routinely used when handling radioisotopes.

   Contrary to this requirement, on March 26, 1980, you failed to use syringe shields during preparation of radiopharmaceuticals.

4. Item 11.1 of your letter dated October 11, 1977 requires that gloves be worn when working with radioisotopes.

   Contrary to this requirement, as of March 26, 1980, you routinely failed to wear gloves during the injection of radiopharmaceuticals.

5. Item 11.2 of your letter dated October 11, 1977 requires that in areas where radioisotopes are used there be no eating, drinking, smoking or application of cosmetics.

   Contrary to this requirement, on the March 26, 1980, you had a filled coffee pot located within your imaging room where radioisotopes are used.

6. Item 11.21 of your letter dated October 11, 1977 requires that a suitable radiation monitor be used to check for contamination on hands and clothing after handling open sources of radioactive material.

   Contrary to this requirement, on March 26, 1980, personnel failed to monitor themselves for possible contamination after handling unsealed sources of radioactive materials. Specifically, one of your technicians had measurable contamination on his hands and had not performed the required monitoring check.

7. Item 12 of your application dated April 22, 1977 requires that TLD finger monitors be furnished to persons who routinely handle millicurie amounts of radioactive materials. Item 14 of your application further states that these finger monitors will be worn.

   Contrary to this requirement, on March 26 and 27, 1980, at least two of your nuclear medicine technicians did not wear their TLD finger monitors while handling millicurie amounts of radioactive material.

8. Item 8 of your letter dated October 11, 1977 requires, in part, that you monitor incoming packages for radiation and removable radioactivity.

   Contrary to this requirement, as of March 26, 1980 you failed to monitor incoming packages for radiation and removable radioactivity.

These items are infractions.

B. 10 CFR 20.201(b) requires that you make such surveys as may be necessary for you to comply with all sections of Part 20. As defined in 10 CFR 20.201(a), "Survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal or presence of radioactive materials or other sources of radiation under a specific set of conditions.

   1. Contrary to this requirement, you failed to make such surveys as were necessary to assure compliance with 10 CFR 20.301, a regulation that describes authorized means of disposing of licensed material contained in waste. Specifically, on March 26, 1980, you failed to

make such surveys of waste material stored in your imaging rooms prior to discharge to the normal trash as was necessary to assure that licensed material was not disposed in a manner not authorized by 10 CFR 20.301. (License No. 06-00854-03)

2. Contrary to this requirement, you failed to make such surveys as were necessary to determine that individuals who handled significant quantities of iodine-131 were not exposed to airborne concentrations exceeding the limits specified in 10 CFR 20.103, "Exposure of individuals to concentrations of radioactive materials in restricted areas." Specifically, no surveys (evaluations, including air monitoring and thyroid monitoring where applicable) were made during the preparation of patient doses for treatment of hyperthryoidism using bulk solutions of sodium iodide labeled with iodine-131. (License No. 06-00854-03)

These are infractions.

C. 10 CFR 20.105(b) requires that radiation levels in unrestricted areas be limited so that if an individual were continuously present in the area, he could not receive a dose in excess of 2 millirems in any hour or 100 millirems in any seven consecutive days.

Contrary to this requirement, on March 26, 1980 radiation levels existed along the wall of laundry chute room adjacent to your nuclear medicine hot laboratory of such a magnitude that if an individual had been continuously present in the area, he could have received a dose in excess of 100 millirems in any seven consecutive days. (License No. 06-00854-03)

This is an infraction.

D. 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 must 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 this requirement, on March 26, 1980, licensed materials were stored in your unlocked hot laboratory which was neither under constant surveillance nor under your immediate control. (License No. 06-00854-03)

This is an infraction.

E. 10 CFR 35.22 requires that you perform specified spot-check measurements of your teletherapy unit at intervals not to exceed one month.

Contrary to this requirement as of March 26, 1980, you failed to perform two of the specified checks. Specifically, you failed to perform timer accuracy checks and you last performed a check for congruence between the radiation field and the field indicated by the light beam localizing device in June 1979. (License No. 06-00854-08)

This is an infraction.

F. 10 CFR 35.23(a) requires that full calibration measurements of your teletherapy unit be performed using a dosimetry system that has been calibrated by the National Bureau of Standards or by a Regional Calibration Laboratory accredited by the American Association of Physicists in Medicine within the previous 2 years.

Contrary to this requirement, as of March 26, 1980, you last calibrated your ion chambers in 1975, a period greater than 2 years. It was noted that you did check the ion chambers by direct intercomparison with a system that was correctly calibrated within the past two years. (License No. 06-00854-08)

This is an infraction.

G. License Condition 14 of License 06-00854-08 requires that your teletherapy source be tested for leakage at intervals not to exceed six months.

Contrary to this requirement, as of March 26, 1980, you last performed a leak test of your teletherapy source on June 26, 1979, a period greater than six months.

This is an infraction.

H. 10 CFR 20.401(b) requires that you maintain records of each survey made under the provisions of 10 CFR 20.201(b).

Contrary to this requirement, as of the date of the inspection, March 26, 1980, you failed to maintain records of your surveys of radioactive material after it had decayed to background levels before its release to the normal trash. (License No. 06-00854-03)

This is a deficiency.