Saint Francis Hospital and Medical Center
114 Woodland Street
Hartford, Connecticut 06105

OFFICE OF THE EXECUTIVE DIRECTOR

TELEPHONE
548-4805
(AREA CODE 203)

June 30, 1980

Mr. Boyce Grier, Director
United States Nuclear
Regulatory Commission
Region I
631 Park Avenue
King of Prussia, PA 19406

Dear Mr. Grier:

Saint Francis Hospital and Medical Center has received your letter regarding Inspection Numbers 30-1246/80-1, 30-112/80-01 and 70-2390/80-01 on June 13, 1980. I have reviewed the items of non-compliance as delineated in your letter with the appropriate individuals and steps have been taken to insure that compliance will be achieved.

The responses to each of the items are provided below. Steps have also been taken to improve the effectiveness of our management control to maintain compliance with the approved license program according to the Nuclear Regulatory Commission requirements. It is our sincere wish to comply fully with obligations specified in our current license.

Please contact Mr. Mark L. Penkhus, Assistant Director, if you have any further questions or concerns regarding the responses submitted or the proposed audit.

Sincerely,

Sister Francis Marie

Sister Francis Marie
Executive Director

SFM/sm

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.

   Response - Iodine-131 capsules will be assayed prior to administration and recorded. Full compliance by July 1, 1980.

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.

   Response - The activity linearity test will be performed annually. Full compliance by July 1, 1980.

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.

   Response - Per the October 11, 1977 letter we will reinforce the policy of routinely using shielded syringes except where their use would not be in the patient's best interest. This will include utilization of syringe shields during preparation of radiopharmaceuticals. Full compliance by July 1, 1980.

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.

   Response - Gloves will be work when injecting radiopharmaceuticals with the exception where it compromises the palpation of patient veins. Full compliance by July 1, 1980.

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

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

Response - Coffee pot will be relocated and removed from the area where radioisotopes are used. Full compliance immediately.

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.

   Response - Personnel will be required to monitor hands and clothing after handling open sources of radioactive materials. Compliance effective immediately. Any measurable contamination will be logged and reported to the Radiation Safety Officer.

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.

   Response - TLD finger monitors will be worn at all times. Effective immediately.

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.

   Response - Incoming packages for radiation and removable radioactivity will be monitored and recorded. Any measurable contamination will be reported to the Radiation Safety Officer. Full compliance by July 1, 1980.

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).

Response - A separate waste container will be provided for disposal for contaminated waste. This recepticle will be monitored prior to disposal and recorded. Full compliance by July 1, 1980.

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 hyperthyroidism using bulk solutions of sodium iodide labeled with iodine-131. (License No. 06-00854-03).

   Response - Routinely technologists involved with the preparation and administration of patient doses for treatment of hyperthyroidism using bulk solutions of sodium iodide labeled with iodine-131 are monitored weekly and records of each are maintained. Full compliance effective immediately.

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 continously 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).

   Response - The area in question has been properly shielded. Effective immediately.

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 licenses 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).

Response - Hot Lab is now locked at all times.

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).

Response - Radiation Physicist routinely checks timer against a stop watch. In addition the timer correction checks are made monthly. Although the congruence between the radiation field and the field indicated by light beam localizing device were not checked directly the optical range finder was checked against a mechanical aligning device which indicated congruency. The Radiation Physicist is now checking congruence directly once a month. Records are maintained. Compliance effective immediately.

F. 10 CRF 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).

Response - The Radiation Physicist borrowed a National Bureau of Standards calibrated ion chamber to check ion chambers by direct intercomparison.

The Radiation Physicist calibrated the teletherapy unit with a National Bureau of Standards calibrated ion chamber. Compliance effective April, 1980.

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.

Leak tests will be performed every six months as required by the Radiation Safety Officer. Compliance effective April, 1980.

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).

Response - Records will be maintained of all surveys taken of radioactive materials after it has decayed to background level before its release. (See B 1).

The items of non-compliance were reviweed by the Isotope Committee and a plan of correction was defined included in the responses given above. A meeting was held between the Radiation Safety Officer and Technologists to review the items of non-compliance following the inspection. An additional meeting will be held to reivew the full license requirements to avoid further items of non-compliance.

An effective monitoring program will be carried out by the Radiation Safety Officer and recorded in compliance with Nuclear Regulatory Commission regulations quarterly. In addition a management audit will be performed by the Assistant Director or his designee semi-annually. This audit will incorporate the survey suggested in Appendix E Radiation Protection Officer Inspection, Page E1, Principles and Practices for keeping Occupational Radiation Exposures at Medical Institutions as Low as Reasonably Achievable. NUREG 0267 (Attached).

Audit program will be conducted and full compliance will be in effect by September, 1980.