U.S. NUCLEAR REGULATORY COMMISSION
REGION I

Report No. 030-03207/87-001

Docket No. 030-03207

License No. 37-13919-01 Priority 3 Category G

Licensee: Chestnut Hill Hospital
8835 Germantown Avenue
Philadelphia, PA 19118

Facility Name: Chestnut Hill Hospital

Inspection At: Philadelphia, PA

Inspection Conducted: September 10, 1987

Inspectors: _____ 4/4/88
C. Thor Oberg, Health Physicist date signed

Approved by: _____ 4/4/88
John R. White, Chief date signed
Nuclear Materials Safety Section C
Division of Radiation Safety and Safeguards

Inspection Summary: Unannounced safety inspection on September 10, 1987, (Report No. 030-03207/87-001) of: Corrective Action taken on previously identified violations; organization; licensee audits; training; radiation protection procedures; use and storage of materials; facilities; instruments; receipt and transfer of materials; personnel protection - external and internal; effluent controls and waste disposal; notifications and reports; posting of notices; confirmatory measurements; and incidents and events.

Results: Of the areas inspected, five violations were identified; dose calibrator accuracy for tests records were not maintained, 10 CFR 35.50(e) - Section 8; ordering of specially used radioactive materials was not by written request, License Condition No. 17 - Section 8; records of waste disposal were not maintained, 10 CFR 35.92(b) - Section 13; air sampling was not performed, 10 CFR 20.201(b) - Section 17; and survey records were not maintained, 10 CFR 20.401(b) - Section 17.

DETAILS

1.0 Persons Contacted

*C. Lawrence Woodruff, M.D., Radiation Safety Officer
**Richard G. Williams, Vice President for Professional Services
Ross L. Applebaum, Staff Senior Nuclear Medicine Technologist
Anita Kokinda, Chief Nuclear Medicine Technologist
Benjamin M. Galkin, CRP, Consultant (contact by telephone)

*Attended both entrance and exit interviews
**Attended exit interview only

2.0 Scope of Activities and Purpose of Inspection

2.1 Scope of Activities

License No. 37-13919-01 authorizes the licensee to receive, acquire, possess, and transfer designated byproduct material for diagnostic and therapeutic medical purposes. This license is subject to all applicable rules, regulations, and orders of the NRC and the license conditions specified.

2.2 Purpose of Inspection

The purpose of this special inspection is to verify that the licensee is performing in accordance with applicable regulatory requirements and license conditions, is maintaining adequate management control over licensed activities, and that the health and safety of workers and the public is not compromised by continued operations.

3.0 Corrective Action Taken on Previously Identified Violations

This inspection examined the corrective action taken and planned as described in the licensee's letters dated November 27, 1985, and January 20, 1986 regarding apparent violations identified during the previous inspection on September 10, 1985, (Inspection Report No. 85-001). The violations were described in the Notice of Violation enclosed as Appendix A to our letter dated October 31, 1985. Based on a review of the actions taken by the licensee, the violations appear to have been corrected and are considered to be closed as described in the following paragraphs.

3.1 (Closed): Violation (030-03207/85-01, Section 2.) Failure of the Radiation Safety Committee (RSC) to meet quarterly. A review of the RSC meeting minutes verified that the RSC meetings were held as specified.

3.2 (Closed): Violation (030-03207/85-01, Sections 5. and 6.) Failure to calibrate the dose calibrator in accordance with procedures specified. A review of the licensee's records and RSC meeting minutes showed that the dose calibrator calibration checks had been performed as specified.

3.3 (Closed): Violation (030-03207/85-01, Section 10.) Failure to correctly evaluate wipe tests. Wipe surveys are properly assayed to detect 200 dpm/100 cm^2.

3.4 (Closed): Violation (030-03207/85-01, Section 11.) Failure to measure exhaust system air flow rates annually. Established procedures for the use of radioactive gases such as xenon-133 are being followed.

4.0 Organization

The structure of the radiation control organization for this license is as delineated in the license application dated April 28, 1986. The Medical Isotopes Committee/Radiation Safety Committee (RSC), meets on a quarterly frequency and minutes of the meeting are maintained. A review of the minutes verified that meeting had been held as specified.

This is an institutional nuclear medicine licensed program authorizing the use of diagnostic and therapeutic radiopharmaceuticals, in-vitro studies, radioactive aerosols and gases, and sealed sources for diagnostic purposes. The patient load for this license is about 200 per month.

No violations were identified.

5.0 Licensee Audits

On at least quarterly intervals, the licensee's consultant reviews the program for conformance with the ALARA requirements. The Radiation Safety Officer (RSO) provides the day-to-day overview of the licensed program. Appropriate records are maintained and are reviewed during the Medical Isotopes Committee meetings.

No violations were identified.

6.0 Training

Training and annual retraining is provided as outlined in the license application dated April 28, 1986, and in accordance with 19.12 of 10 CFR Part 19.

No violations were identified.

7.0 Radiation Protection Procedures

Radiation protection procedures are available and implemented as required. These procedures include a guide for the care of patients receiving radioactive materials. General rules for the safe use of radioactive materials and emergency procedures are posted. Based on responses to questions asked by the inspector, personnel appear to understand these procedures.

No violations were identified.

8.0 Use and Storage of Materials

The licensed program appeared to be in compliance with the kind, quantity and utilization of licensed material authorized. A system for ordering and receiving routinely used licensed material from a nuclear pharmacy has been established and implemented in accordance with Item 13 of the application dated April 28, 1986, incorporated by reference in License Conditions No. 17.

The procedure for procurement of specially used radioactive material, (i.e., therapeutic uses) requires a written request from the authorized user performing the procedure. During this inspection, the inspector was informed by the RSO and Chief Technologist that these materials were ordered verbally, and that written requests from authorized user have not been used. This is a violation of License Condition No. 17.

Special tests such as leak tests and dose calibrator checks and tests have been performed as required. The dose calibrator annual accuracy tests were performed during 1986 as verified by a statement in the minutes of the December 1986 RSC meeting. However, the record of the accuracy test for 1986 had not been maintained. The record had been misplaced and could not be located. This is a violation of 10 CFR 35.50(e), which requires that such records be maintained for 2 years.

Posting and labeling of the licensee's controlled areas and facilities appeared to be in accordance with requirements. The licensee's security procedures for preventing unauthorized entry into controlled areas or unauthorized removal of materials from controlled and storage areas, appeared to be adequate for the program.

9.0 Facilities

The licensee's facilities appeared to conform with descriptions in the application dated April 28, 1986.

No violations were identified.

10.0 Instruments

The licensee's survey meters and instruments appeared to be adequate for the licensed program. The instruments and meters were operational and functional and had been calibrated in accordance with requirements.

No violations were identified.

11.0 Receipt and Transfer of Materials

The licensee has implemented written procedures for receiving, surveying and opening packages. Records of these receipt and surveys are maintained. Material transfers, i.e., return of devices to the contract nuclear pharmacy, are made in accordance with regulatory requirements.

No violations were identified.

12.0 Personnel Protection - External and Internal

12.1 External

Based upon a review of personnel exposure records for the years 1985, 1986 and 1987 to date, annual exposure levels are well within the Level I limits established for ALARA purposes. The highest annual exposure levels recorded were 150 mrem whole body and 1,970 mrem for extremities. Form NRC-5 exposure records are maintained and available for employee review.

Surveys for fixed radiation levels in controlled areas are performed and records of these surveys are maintained. The radiation levels measured were within regulatory limits for these areas.

No violations were identified.

12.2 Internal

Based on the quantity and form of licensed material used, airborne concentrations appeared to be adequately controlled in restricted areas. Blood flow and pulmonary function studies using gaseous xenon-133 are performed about weekly. Established procedures for the use of xenon-133 appeared to be followed as specified. Iodine-131 in capsule form is used in diagnostic and therapeutic procedures. Bioassays are not required on a routine basis.

Wipe sample surveys are conducted weekly and are properly assayed to determine levels of removable contamination.

No violations were identified.

13.0 Effluent Controls and Waste Disposal

Gaseous xenon-133 is effectively controlled using a Medi-Physics Ventilation Study System. The gas is retained in a shielded rebreathing bag and subsequently exhausted through a charcoal trap to the atmosphere above the hospital roof via a continuously operating, stack exhaust system.

Radioactive waste is returned to the contracted nuclear pharmacy supplier in accordance with requirements, or held for decay and ultimate disposal in normal trash as specified in 10 CFR 35.92. In accordance with requirements, the licensee holds waste for decay, performs surveys, and disposes of the material when decayed to background radiation levels. However, the licensee has not maintained a record of each disposal as required. This is a violation of 10 CFR 35.92(b).

14.0 Notifications and Reports

Exposure reports are made available for review by individual workers. Termination reports of personal exposures are furnished upon request.

No thefts or loss of licensed material have been identified.

Notification of misadministrations is reported as required by 10 CFR 35.33. All misadministrations are documented and the reports are retained by the licensee. A diagnostic misadministration report of an incident that occurred on July 31, 1987, was reviewed by the inspector. The report appeared to be adequate and notification to the NRC was not required.

No violations were identified.

15.0 Posting of Notices

Documents, including the license, procedures and copies of Parts 19 and 20 of 10 CFR, were posted as required by Section 19.11(a) of 10 CFR Part 19. The NRC-3 was also posted as required by Section 19.11(c) of this same part of the regulations.

No violations were identified.

16.0 Confirmatory Measurements

During this inspection, survey measurements were made by the inspector with NRC Instrument No. 9654 that was due to be calibrated on November 26, 1987. Within the waste storage area, high readings of about 1.5 mR/hr were obtained from linens used for an incontinent patient. Outside of the storage area, levels measured were equivalent to background (0.01 to 0.03 mR/hr). The highest radiation level measurement made in the Nuclear Medicine Hot Lab was about 1.5 mR/hr over the shielded area. The general radiation level in the hot lab was about 0.05 mR/hr. These radiation level measurements were not significantly different from those made by the licensee.

No violations were identified.

17.0 Incidents and Events

The following event was reviewed: On Sunday, March 29, 1987, an outpatient from a nursing home was treated with 14 millicuries of iodine-131 that was administered orally. An hour or so later, while awaiting transportation back to the nursing home, the patient asked the Nuclear Medicine technologist if he could use a urinal. He was taken into an x-ray room for privacy and helped off the litter, or stretcher, to use a disposable plastic urinal.

After the patient voided, the technologist placed the plastic urinal on the floor while she assisted the patient back onto the litter. The patient started to fall and other technologists also came to his aid. In the process the plastic urinal was kicked and the urine spilled. The Nuclear Medicine technologist was aware that the patient had been administered radioiodine. She advised the others to don gloves and start to clean up the spill. The Chief Technologist, who was also aware that the patient had been administered iodine-131, was notified.

The Chief Technologist immediately implemented radiological controls. He terminated the cleanup work, had the technologists leave the room and closed the doors, and requested the assistance of the RSO and the facility's health physics consultant.

Within two hours the health physics consultant was on-site and performed area and personnel monitoring, and verified the radiological status of the affected room. The RSO and the Chief Technologist completed the clean up and decontamination of the area.

According to a summary report of the hospital's consultant, dated March 30, 1987, probably less than a few millicuries of activity was estimated to have spilled. The technologists' lab coats were splattered with a few drops of radioactive urine and their shoes were slightly contaminated. One individual's hand was also slightly contaminated. Small amounts of residual contamination were on the floor, the litter mattress and sheets. The levels of contamination were less than 1 mR/hr at about 3 inches. The area of the spill on the floor was covered with several sheets of stainless steel to reduce the radiation level to about background. The contaminated clothing and bedding were put into the waste storage area for decay. The RSO prescribed doses of Lugol's solution for those who participated in the clean up. Thyroid checks performed 18 hours later showed no I-131 uptake for those individuals. All individuals were monitored and decontaminated as necessary. No significant personnel exposure was expected as a result of this event.

From the inspector's review of this event, the licensee's remedial actions were proper and correct. Personnel and area decontamination and controls, including shielding of the immediate spill area with metal sheets were sufficient to eliminate the possibility of further personnel external exposure. However, while personnel monitoring did not reveal any significant exposure due to this event, air sampling in accordance with 10 CFR 20.201(b) was not performed to assure compliance with the requirements of 10 CFR 20.106.

Further, the inspector noted that the licensee did not maintain any radiological documentation of the event, except as provided in the consultants summary report. While some evidence indicates that proper surveys were performed (with the exception of surveys of possible airborne radioactivity), independent evaluation by the inspector was not possible due to lack of documentation.

The failure to perform surveys to evaluate possible concentrations of airborne radioactivity is an apparent violation of 10 CFR 20.201(b); and the failure to maintain records of the results of surveys that were performed in accordance with 10 CFR 20.201(b) is an apparent violation of 10 CFR 20.401(b).

18.0 Exit Interview

On September 10, 1987, an exit interview was held by the inspector with those individuals identified in Section 1.0 of this report. The scope and findings of the inspection were discussed and the apparent violations were identified.