U.S. NUCLEAR REGULATORY COMMISSION
REGION I

Report Nos. 030-15085/85-01
030-22055/85-01

Docket Nos. 030-15085
030-22055

License Nos. 37-00865-10
37-00865-11 Priority II III Category G1 G3

Licensee: The Montefiore Hospital Association
of Pennsylvania
3459 Fifth Avenue
Pittsburgh, Pennsylvania 15213

Facility Name: The Montefiore Hospital Association of
Western Pennsylvania

Inspection At: Pittsburgh, Pennsylvania

Inspection Conducted: October 2-3, 1985

Inspectors: _____ 2/21/86
Teresa Hall Darden, Health Physicist date

_____ 2/21/86
Van R. Scovill, Health Physicist date

Approved by: _____ 2/21/86
John D. Kinneman, Chief date
Nuclear Materials Safety Section A

Inspection Summary: Inspection conducted October 2 and 3, 1985 (Combined Report Nos. 030-15085/85-01, 030-22055/85-01)

Areas Inspected: Routine unannounced inspection including review of: organization; licensee internal audits; training; radiation protection procedures; materials receipts and inventory control; material uses; incidents; material storage and security; instrumentation; personnel protection; waste disposal; notifications and reports; and postings.

Results: Five apparent violations were identified: failure to secure licensed material against unauthorized removal (Paragraph 10); failure to provide adequate training in the requirements of the license (Paragraph 5); failure to perform adequate surveys in unrestricted areas (Paragraph 6); failure to do self-monitoring (Paragraph 12A); and failure to calibrate survey meters as required (Paragraph 11).

DETAILS

1. Persons Contacted

*Mr. W. Youngblood, Associate Administrator
*Ms. J. Berger, Associate Administrator
*Dr. R. L. Kalla, Chairman, Radiation Safety Committee
*Ms. M. Eddy, Radiation Safety Officer
*Ms. J. McKenna, Health Physicist
Ms. S. Burns, Chief Nuclear Medicine Technologist
Mr. N. Devich, Nuclear Medicine Technologist
Ms. B. Smith, Nuclear Medicine Technologist

In addition the inspectors interviewed five members of the research staff and one member of the housekeeping staff during the inspection.

*Denotes those present at exit interview.

2. Background

License No. 37-00865-10. This broad scope license authorizes use of radionuclides for medical diagnosis, therapy, and research and development as defined by 10 CRF 30.4(q), including animal studies. The case load averages twelve studies per day in Nuclear Medicine. The Nuclear Medicine Radioimmunoassay (RIA) Department is staffed by six technologists. The Medical Health Physics Department is staffed by five individuals, one of whom is the designated Radiation Safety Officer (RSO), and there are approximately ten active authorized users supervise use of radioactive material in the medical research laboratories.

License No. 37-00865-11: This license authorizes use of cobalt-60 in the therapeutic treatment of humans.

3. Organization

The Radiation Safety Officer is responsible to the Associate Administrator of the Hospital. The RSO provides initial review of users and uses of radioactive materials, controls inventory and conducts regularly scheduled audits of the licensed program.

The Radiation Safety Committee (RSC) is responsible for the review of users and protocols for uses of radioactive materials and gives approval for the users and uses. The RSC includes representatives from the user group, appropriate administrators and safety personnel. The Committee meets at least once in each quarter.

4. Licensee Internal Audits

The licensee has an audit program wherein the Radiation Safety Staff identifies deficiencies and suggests corrective actions. This program is part of the weekly, monthly, and quarterly routine surveys performed by

the Radiation Safety Staff. It is the responsibility of each authorized user to assure that corrective action is initiated. The Radiation Safety Staff assures that the corrective action is implemented and notifies the authorized user when corrective action and procedures are not followed or if the violation recurs. Violations are normally reported to the Department Head. However, this has not always been followed in the Nuclear Medicine Department.

Reports of deficiencies are reviewed at the RSC meetings. The internal audits appear to be effective since identification and correction of deficiencies usually results. However, there apparently has been little attempt to develop alternative corrective actions in cases where deficiencies recur. The inspectors observed through review of survey and audit records, that identified problems seem to recur more frequently in the Nuclear Medicine Department than in other areas, and called this observation to the attention of Nuclear Medicine and Radiation Safety personnel.

The Radiation Safety Officer reviews and reapproves users and uses of radioactive materials every two years or as necessary to review new protocols or new users.

No violations were identified.

5. Training

Review of training records and interviews with personnel verified that annual in-service training is given in hazards associated with the use of radioactive material. An interview with a member of the housekeeping staff verified that he was aware of the procedures associated with handling of waste in areas where radioactive materials are used.

The inspectors observed an administration of 25.3 millicuries of technetium-99m methylenediphosphonate (Tc-99m MDP) for a bone scan in the Nuclear Medicine Department. During the administration of the radiopharmaceutical, the inspectors noted that the dose indicated on the dispensing form was 20 millicuries of Tc-99m MDP and interviewed two Nuclear Medicine technologists. The technologists indicated that the Nuclear Medicine Procedure Manual provided guidance for radiopharmaceutical administration and the allowed radiopharmaceutical dose range for a bone scan was 15-30 millicuries of Tc-99m MDP. Upon reviewing the Manual the inspectors found that, on page 2 of the Manual, a range of 20-25 millicuries is listed for Tc-99m MDP and that under the specific procedure for bone scans, a prescribed dose of 20 millicuries of Tc-99m MDP was listed.

From observations and interviews with the technologists, it was determined that remote handling tools are not routinely utilized in the Nuclear Medicine Department; the licensee's audit program has not identified this as a problem. The inspectors observed that the Nuclear Medicine Hot Laboratory and RIA Laboratory doors are not routinely secured during normal work hours when staff is absent from the area. This is further discussed

in paragraph 10. The inspectors discussed these observations with Nuclear Medicine personnel and the Radiation Safety Staff.

These findings represent an apparent violation of 10 CFR 19.12.

6. Radiation Protection Procedures

A review of patient records, survey records and discussions with the RSO and a Health Physicist confirmed that surveys were performed in unrestricted areas adjacent to rooms where patients treated with radioisotopes are housed. Review of the surveys performed by the Radiation Safety Staff, showed that radiation levels in unrestricted areas did not exceed the limits specified in 10 CFR 20.105(b). However, during the inspection, the inspectors surveyed the unrestricted areas adjacent to a room that had been vacated earlier that day by an iodine-131 therapy patient and found that radiation levels at the wall surface in the adjacent room measured three millirem per hour. At eighteen inches from the wall the radiation levels were 0.5 (mR/hr). The surveys performed by the Radiation Safety Staff were inadequate in that they failed to identify this area during the patient's occupancy of the room.

Failure to make adequate surveys in unrestricted areas is an apparent violation of 10 CFR 20.201(b).

The inspectors observed an iodination procedure during the inspection. The workers followed the appropriate radiation safety protection procedures for iodinations and surveyed the area for contamination prior to and after the completion of, the iodination procedure.

Review of the Radiation Safety Committee Meeting minutes revealed that discussion had taken place concerning emergency procedures for accidental ingestion of I-131 and I-125. It was not evident from the minutes whether this was resolved. The inspectors determined through interviews with the Radiation Safety Officer that there is no standard emergency procedure covering treatment of accidental ingestion of I-131 or I-125 during iodination procedures and during I-131 dose administration. The RSO stated that an emergency procedure would be included in the procedure manual.

7. Materials Receipts and Inventory Control

All radioactive materials requests except those from the Nuclear Medicine Department, are reviewed, ordered and received by the Radiation Safety Office. The licensee's Receiving Department personnel are trained to notify the Radiation Safety Office immediately whenever packages containing radioactive material are received. The Nuclear Medicine Department orders and receives all radioactive material used by that Department.

Records were reviewed for the radioactive material received during 1983, 1984 and 1985 up to the day of inspection by both the Radiation Safety Office and the Nuclear Medicine Department. The records demonstrated that contamination and radiation level surveys were routinely performed on all packages.

An inventory log is maintained by the Radiation Safety Office and it is routinely updated to reflect the current inventory. The current inventory log includes radioactive material that is awaiting disposal.

No violations were identified.

8. Material Uses

The inspectors toured the licensee's facilities and observed the use of materials in Nuclear Medicine, Medical Research, Cobalt-60 Teletherapy, and a pathology laboratory where a 3000-curie gamma cell irradiator is used for blood irradiation. Five research laboratories were visited where authorized uses include hydrogen-3, chromium-51, Iron-59, phosphorus-32, sulfur-35, iodine-125, iodine-131, and carbon-14. The inspectors also toured a laboratory used for iodinations while an iodination procedure was in progress. Amounts of licensed materials possessed were reviewed in specific labs during the tour. Possession limits were not exceeded and materials on hand appeared to agree with the master inventory log.

No violations were identified.

9. Incidents

In the past six years there have been three incidents at the licensee's facility involving the loss or misplacement of radioactive material: The loss of a cesium-137 implant source in 1979; The loss of a cobalt-57 marker in 1983 (cobalt 57 is not licensed by the NRC); and the misplacement of an iodine-125 brachytherapy seed in 1985. The inspectors discussed and reviewed the circumstances associated with these incidents with licensee representatives. Records maintained by the licensee and discussions and interviews with a licensee personnel confirmed the reports submitted to the NRC. The corrective actions taken as a result of each of these incidents were discussed as was preventive action to avoid future incidents. Although use of iodine-125 seeds has not taken place since the most recent incident, procedures are in place to assure that complete surveys will be performed to prevent recurrence.

No violations were identified.

10. Material Storage and Security

Licensed materials are stored in the Nuclear Medicine Hot Laboratory, the RIA Laboratory and the various research laboratories. During the inspection, the inspectors were unchallenged as they entered the Nuclear Medicine Department and proceeded to the unlocked Hot Laboratory and the unlocked RIA Laboratory where millicurie quantities of radioactive materials are stored. The inspectors spent approximately twenty minutes in the area before making contact with a staff member who was returning to the Department. There is an exit at the rear of the Department which opens onto a lower level. Anyone who enters the Department through the front entrance can leave through the rear exit unobserved.

Failure to secure licensed material when not under constant surveillance is an apparent violation of 10 CFR 20.207.

Discussions with Nuclear Medicine personnel revealed that there had been an entry into the Department several months earlier by an individual who apparently entered through the main entrance. This entry resulted in loss of staff personal belongings. As a result of this entry, an alarm system was installed so that workers would be made aware when anyone enters the Department during off hours. However, the alarm is switched off during the normal working hours.

11. Instrumentation

Records were reviewed to verify the frequency and testing procedures of the licensee's instrumentation.

The licensee's procedures submitted with the application dated July 26, 1984 require that survey meters be calibrated biannually (every 6 months). The inspectors found several survey meters in use in the Radiation Safety office which had not been calibrated at the required frequency.

Failure to calibrate survey meters as required is an apparent violation of License Condition 25.

12. Personnel Protection

A. External

The inspectors observed that the licensee provided whole body and TLD finger badges to appropriate personnel working with radioactive materials in the Nuclear Medicine Department , Medical Physics (brachytherapy sources) and in Research.

The licensee has an active ALARA Program and all exposures exceeding Investigation Levels I and II (in accordance with Reg. Guide 10.8, Appendix O) are investigated by the Radiation Safety Officer.

Two Nuclear Medicine technologists were observed doing quality assurance testing using sealed sources without wearing gloves or using remote handling tools. The technologists stated that they did not routinely wear gloves when handling sealed sources, although gloves are used when handling radioactive material in other forms. The inspector surveyed the technologist's hands and found no contamination. One technologist, when questioned about the frequency of self monitoring, stated that she did not recall whether she had monitored herself the previous day because she was in a hurry when she left the Department. Self monitoring records reviewed by the inspector indicated that she had not monitored herself, as required.

Problems concerning self monitoring have previously been identified (e.g., failure to do self monitoring was cited during the 1982 NRC inspection). Review of Radiation Safety audit records indicated that when this problem was identified and discussed with the responsible Nuclear Medicine staff, usually immediate correction occurred. However, by the time of the next audit, the records indicated that the problem had recurred. The Radiation Safety and Nuclear Medicine staffs agreed self monitoring has been sporadic since the previous NRC inspection and that it is a continuing problem. This represents another example of the training deficiency discussed in Paragraph 5.

The findings that individuals do not always wear gloves when handling radioactive materials and do not always self monitor are apparent violations of License Condition 25.

B. Internal

All therapeutic iodine-131 doses and liquid iodine containers are opened under a fume hood. The licensee performs air monitoring in the restricted areas to assure that airborne concentrations of radioactive materials do not exceed regulatory limits. During iodination procedures, the breathing zone of the worker is monitored. Bioassays (thyroid monitoring) are routinely performed on iodination participants within seventy two hours after completion of the procedure. Records indicated that no uptakes had occurred that exceeded the 10 CFR 20.103 limits.

No violations were identified.

13. Waste Disposal

The licensee holds all Nuclear Medicine waste with half lives of less than ten days for decay. After appropriate surveys, disposal is made to normal trash or the material is returned to the nuclear pharmacy in accordance with their contract agreement.

All other waste is collected by the Radiation Safety Office, inventoried and transferred to an authorized commercial disposal company.

No violations were identified.

14. Notifications and Reports

Discussions with Nuclear Medicine Technologists, and review of records in the Radiation Safety Office, indicated that appropriate incident reports were retained as required and proper notification of lost material had been made to the NRC Region I Office.

No violations were identified.

15. Postings

All required notices were posted.

No violations were identified.

16. Exit Interview

The inspectors met with the individuals designated in paragraph 1 at the conclusion of the inspection on October 3, 1985. The inspectors summarized the scope and findings of the inspection. The need for prompt corrective action was emphasized. Special concern about recurrence problems identified through licensee's internal audits 12 was expressed and possible methods of resolution were discussed. Licensee management described a number of actions they plan to correct.

The inspectors reviewed the Commission's enforcement policy. Licensee management and the Radiation Safety Committee Chairman expressed their intention to operate safely and to to bring the program into full compliance.