U.S. NUCLEAR REGULATORY COMMISSION
REGION I

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License Nos. 37-00432-02
37-00432-03
SNM-1412 Priority: III Category: G

Licensee: Abington Memorial Hospital

1200 Old York Road

Abington, Pennsylvania

Facility Name: Abington Memorial Hospital

Inspection At: Abington, Pennsylvania

Inspection Conducted: December 20, 1985

Inspector: John T. Jensen
John T. Jensen, Health Physicist — date: 1/28/86

Approved by: John E. Glenn
John E. Glenn, Ph.D., Chief
Nuclear Materials Safety Section B — date: 1/28/86

Inspection Summary: Inspection conducted on December 20, 1985 (Report Number 85-01).

Areas Inspected: Scope of operations, organization, training, use of materials, storage of licensed material, receipt and transfer of licensed material, personnel protection (internal and external), effluent controls, notifications and reports, posting, teletherapy calibrations and surveys.

Results: Twelve apparent violations were identified: 1) failure of the Radiation Safety Committee to meet once in each quarter; 2) failure to perform daily constancy checks and plot on a graph the measured activity of the reference standard; 3) failure to perform molybdenum-99 contamination tests on elutions from generators; 4) possession of material by the in-vitro studies laboratory in excess of 10 CFR 31.11 limits; 5) failure to secure licensed material; 6) failure to perform surveys of radiation levels of incoming packages; 7) failure to calibrate a survey meter for a period exceeding one year; 8) failure to maintain radiation levels in unrestricted areas below 10 CFR 20.105(b) limits; 9) failure to maintain records of exposure on Form NRC-5 or equivalent; 10) failure to perform daily area surveys; 11) failure to post emergency procedures at the teletherapy console; 12) failure to use a dosimetry system calibrated by an accredited laboratory for the annual calibration of the teletherapy unit.

DETAILS

1. Persons Contacted

*Dr. Tulsky, Chairman-Radiation Safety Committee (RSC)
*Dr. Griffith, Member - RSC, Authorized User
*Dr. Lapioca, Member - RSC, Authorized User
*Richard L. Jones, Jr., Senior Vice President
*Victoria Castro, Radiation Safety Officer
*Raminik Patel, Physicist
Al Zettlemoyer, Chief - Nuclear Medicine Technologist (NMT)
Myra Dent, NMT
Irving Schreibman, Laboratory Supervisor

The inspectors also interviewed members of the nursing staff, other nuclear medicine technologists and laboratory personnel.

*Individuals present at exit interview.

2. Licensee Action on Previous Inspection Findings

(Closed) Inspection 83-01 Failure to perform a follow-up examination every six months of a patient implanted with a pacemaker containing radioactive material. The inspectors examined a log containing the dates of the follow-up examination of all patients implanted with nuclear pacemakers and found that all patients had received follow-up examinations at six month intervals and that pacemakers had been returned to the hospital after patient deaths.

3. Scope of Operations

The licensee is authorized for human uses of licensed material for diagnostic and therapeutic procedures, as well as nuclear pacemaker implantation.

4. Organization

The license has two medical physicists, one of whom is named as the Radiation Safety Officer (RSO). The second medical physicist has some responsibility for radiation safety in the Nuclear Medicine Department. The RSO has overall responsibility for radiation safety in the Nuclear Medicine Department and the Brachytherapy and Teletherapy programs. The RSO and the other medical physicist report to the Radiation Safety Committee (RSC), which has the authority to implement procedures and practices concerning radiation safety. The RSC consists of staff physicians, a hospital administrator, a staff nurse, the RSO and the medical physicist.

The inspectors reviewed minutes of the RSC meetings and determined that the RSC has met twice in 1983, twice in 1984 and once in 1985. License Condition 19 requires that the RSC meet at least quarterly.

The finding that the RSC has not met quarterly is an apparent violation of License Condition 19.

5. Training

The RSO performs orientation and in-service training of the nuclear medicine staff, nursing staff, teletherapy staff and ancillary staff.

No violations were identified.

6. Use of Materials

The inspectors reviewed dose calibrator records and procedures. The inspectors observed that, according to the licensee's log of the daily dose calibrator constancy checks, on June 11, 1985 an activity of 43.6 microcuries was obtained when a cesium-137 reference standard of approximately 88 microcuries was placed in the licensee's dose calibrator and read on the cesium-137 setting. This represents a deviation of approximately 50% from the expected value. Similar deviations from expected values were obtained when the standard was checked on all commonly used settings. In addition, according to the log, on May 15, 1985 an activity of 70.1 microcuries was obtained for this reference standard, a deviation of approximately 20%. The medical physicist stated that he felt that the dose calibrator potentiometer was malfunctioning and that the dose calibrator was eventually sent to the manufacturer for repair at the end of November 1985.

Since June 1985, the licensee had not plotted either the measured activity or the calculated, decay corrected activity of the reference standard used in the daily constancy check on a graph, nor had the licensee calculated the deviation of the measured activity from the decay corrected activity. License Condition 19 requires that, as part of the daily constancy check, the value of the measured activity of the reference standard used in the daily constancy check be plotted on a graph along with the decay corrected activity.

The inspectors discovered from records and interviews with licensee personnel that daily constancy checks had not been performed from October 5, 1984 through April 5, 1985 or from May 17 through June 10, June 14 through July 8, July 12 through August 1, and August 8 through October 29, 1985 on the licensee's own dose calibrator. In addition, the licensee had not performed a daily constancy check on a dose calibrator loaned to them by the manufacturer since December 2, 1985 its first day of use by the licensee. Radiopharmaceutical doses had been assayed daily on both dose calibrators during these periods. License Condition 19 requires that a daily constancy check of the dose calibrator be performed by the licensee.

The finding that the licensee did not perform daily constancy checks and that the licensee did not plot the measured activity of the reference standard used in the daily constancy check is an apparent violation of License Condition 19.

The inspectors noted from the licensee's records that, for the period December 5 through December 12, 1985, tests for molybdenum-99 contamination in elutions of technetium-99m from molybdenum-99/technetium-99m generators were not performed. 10 CFR 35.14(b)(4)(ii) requires that, before administration to patients, each elution of technetium-99m from a generator be tested to determine the total molybdenum-99 activity or concentration.

The finding that the licensee failed to perform the required molybdenum-99 contamination test from December 5 to December 12, 1985 is an apparent violation of 10 CFR 35.14(b).

The inspectors toured the in-vitro studies laboratory and were informed by the laboratory supervisor that the current inventory of the laboratory was approximately 357 microcuries of iodine-125. The inspectors were informed that solid waste is disposed of through a commercial disposal company and that liquid waste is released to the sanitary sewerage system. The laboratory supervisor estimated that releases to the sewerage system averaged 10 microcuries per day and stated that no records of the releases were kept. The inspectors discovered low level contamination in the sink designated for liquid disposal. 10 CFR 31.11(c)(1) limits possession to 200 microcuries of iodine-125, at any one time, under the general license.

The finding that the in-vitro laboratory possessed more than 200 microcuries of iodine-125 at one time is an apparent violation of 10 CFR 31.11.

7. Storage of Licensed Material

The inspectors observed that licensed material is stored in a laboratory in the Nuclear Medicine Department, in the in-vitro studies laboratory, in the teletherapy room and in a basement storage room (brachytherapy sources, reference standards and decay-in-storage material.) The inspectors were informed that it is a practice of the Nuclear Medicine Department to deposit molybdenum-99/technetium-99m generators containing hundreds of millicuries of licensed material in the hallway outside of the department's office on Monday evenings for pick-up by the deliverer of the new generator (placed in the same location) early on Tuesday mornings. The area is not capable of being secured. In addition, the inspectors observed that the door to the Nuclear Medicine Department's laboratory remained open during the day and that the inspectors were able (at approximately 1:00 p.m.) to move freely in and out of the laboratory for approximately 5 minutes without seeing a technologist or other licensee personnel. The inspectors also observed a non-licensed (accelerator

produced) krypton-85 generator that remained on a cart in an active hallway throughout the day. 10 CFR 20.207 requires that licensed materials stored in an unrestricted area be secured from unauthorized removal.

The finding that a molybdenum-99/technetium-99m generator containing hundreds of millicuries of licensed material was routinely stored in an unrestricted area and not secured from unauthorized removal is an apparent violation of 10 CFR 20.207.

8. Receipt and Transfer of Licensed Material

The inspectors reviewed records of surveys of incoming packages, waste material prior to disposal into ordinary trash and waste disposed by commercial means. The inspectors observed that surveys of radiation levels of incoming packages had not been performed prior to June 19, 1985 and that all surveys that had been performed were noted as zero mR/hr. The inspectors inquired of a survey of an incoming molybdenum-99/technetium-99m that was labelled with a DOT Radioactive Yellow III label. A technologist stated that incoming packages of generators were not usually surveyed since the generators were immediately removed from the package and placed behind shielding. License Condition 19 requires that surveys be made of radiation levels at the surface of incoming packages.

The finding that surveys had not been made of the radiation levels at the surface of packages of incoming generators is an apparent violation of License Condition 19.

The inspectors were informed that a survey of an incoming package of iodine-131 performed on December 20, 1985 was performed with a survey meter, CDV-700, Serial Number 12087 last calibrated on June 12, 1984. License Condition 19 requires that survey meters be calibrated annually.

The finding that a survey meter calibrated on June 12, 1984 was used to survey an incoming package of licensed material on December 20, 1985, a period in excess of the required annual calibration, is an apparent violation of License Condition 19.

9. Personnel Protection

A. External Radiation Exposure

The inspectors reviewed records of surveys associated with the housing of patients receiving therapeutic doses of radiopharmaceuticals or brachytherapy implants. On November 13, 1984, Rm. #3W27 was surveyed by the licensee to determine radiation levels emanating from a patient implanted with a cesium-137 brachytherapy source. The licensee's survey indicated a reading of 7 millirems per hour on the surface of a wall in the adjacent room. A conservative estimate of

the dose rate at one foot from the walls surface indicates a dose rate of approximately 3 millirems per hour. 10 CFR 20.105(b) prohibits a licensee from creating through possession or use of licensed material, in an unrestricted area, radiation levels that could result in an individual receiving in excess of 2 millirems in any one hour.

The finding that a dose rate of 3 millirems per hour existed in a patient's room, an unrestricted area adjacent to a brachytherapy patient's room, is an apparent violation of 10 CFR 20.105(b).

The inspectors reviewed dosimetry records for members of the nursing staff responsible for caring for patients who either receive therapeutic doses of radiopharmaceuticals or brachytherapy implants. Film badges are provided to these nurses and changed each month. However, rather than assign the same badge number to each nurse each month, the badges are assigned randomly. The inspectors reviewed a log book maintained by the licensee that indicated, by badge number, the nurse to whom the badge was assigned and the period that the badge was worn. Monthly dosimetry reports provided by the film badge processor show the monthly and quarterly exposure to each badge, by badge number, but do not identify the individual(s) to whom the badge was assigned. The hospital did not accumulate the monthly exposure data by named individual to determine the quarterly exposure to each nurse. 10 CFR 20.401(a) requires that records maintained pursuant to 10 CFR 20.202(a)(1) be kept on the equivalent of a Form NRC-5, including the social security number, birth date and quaterly accumulated exposure.

The finding that a NRC Form-5 or its equivalent had not been maintained by the licensee for records of exposure of individuals caring for patients treated with licensed material is an apparent violation of 10 CFR 20.401(a).

B. Internal Radiation Exposure

The inspectors reviewed records of daily surveys of the laboratory and camera rooms. The records indicate that these surveys had been performed approximately 5 times since the previous NRC inspection on March 15, 1983, although laboratory and camera rooms (injection areas) are used daily. The inspectors were informed by a technologist that daily surveys were not routinely performed due to heavy patient load.

License Condition 19 requires that daily surveys of camera rooms and the laboratory be performed and recorded on the appropriate log sheet.

The finding that daily surveys of the laboratory and camera rooms were not performed is an apparent violation of License Condition 19.

10. Effluent Controls

The inspectors were informed that no Xenon-133 (gas) studies are performed and that no radioactive waste is released to the sanitary sewerage system by the Nuclear Medicine Department.

No apparent violations were identified.

11. Notifications and Reports

Licensee representatives informed the inspectors that no incidents requiring notification or reports to the Commission had occurred since the last inspection.

No apparent violations were identified.

12. Posting

The inspectors determined that all required notices were posted and up to date.

No apparent violations were identified.

13. License No. 37-00432-03

A. Radiation Protection Procedures

Interviews with the technologists and the RSO confirmed that emergency procedures had been implemented and that instruction had been given. However, on December 20, 1985, the emergency procedures were not posted at the teletherapy machine control. The procedures were posted during the inspection.

The failure to post emergency procedures is an apparent violation of Condition 16 of License No. 37-00432-03.

A radiation room monitor had been installed and was operational. Licensee representatives stated the monitor was checked daily.

The required five year maintenance of the teletherapy unit was last performed in 1982 and covered all the required items.

B. Facilities

The teletherapy unit was installed as described in the license application. The inspectors verified that the interlock system was working and was checked daily. The entrance door was properly posted as "Caution - High Radiation Area." The licensee has a patient viewing system to observe patients during treatment and properly calibrated survey meters were available.

No apparent violations were identified.

C. Personnel Protection - External Exposure

Personnel were assigned film badges and were observed wearing the assigned dosimetry. Teletherapy head surveys for radiation levels were conducted following the last source change. Measurements by the inspectors confirmed no levels at 1 meter exceeded 10 mR/hr and that the average exposure levels were less than 1.5 mR/hr.

Measurements by the inspectors of radiation levels in an unrestricted areas during patient treatment indicated no levels in excess of 0.2 mR/hr. Stops have been installed to prevent the teletherapy head from being oriented more than 25° off the center of the beam stopper. The inspectors verified that the stop switches were installed and operational.

No apparent violations were observed.

D. Leak Tests

Leak tests of the cobalt-60 source had been made by the RSO at six month intervals. Reports were maintained in microcuries and indicated no leakage had occurred.

No apparent violations were identified.

E. Teletherapy Calibration

Annual calibrations had been performed as required. The licensee has available two dosimetry systems. A Capintec PR-06C ionization chamber had been calibrated by an accredited Regional Calibration Laboratory within two years of the last annual calibration. A PTW Farmer Chamber with a Victoreen electrometer had been calibrated by direct intercomparison against the other chamber by the licensee. However, the licensee used the intercomparison dosimetry system for performance of the annual calibration.

The failure to use a dosimetry system calibrated by an accredited laboratory for performance of the annual calibration is an apparent violation of 10 CFR 35.23.

Spot checks were performed monthly as required. Spot checks are performed by the RSO who meets the requirements for a qualified expert.

14. Exit Interview

The inspectors discussed the results of the inspection with the individuals identified in Section 1. The inspectors stressed that the apparent violations discovered during the inspection indicate the need for a better understanding of the basis of some of the procedures referenced in the license and for an internal audit program to assure compliance with license requirements. The enforcement options available to the NRC were reviewed.