U.S. NUCLEAR REGULATORY COMMISSION
REGION I

Report No. 030-02435/88-001

Docket No. 030-02435

License No. 29-01423-01 Priority ? Category G

Licensee: United Hospitals of Newark
Presbyterian Hospital Unit
15 South Ninth Street
Newark, New Jersey 07107

Facility Name: United Hospitals of Newark

Inspection At: Newark, New Jersey

Inspection Conducted: May 25, 1988

Inspector: Teresa Hall Darden 10/27/88
Teresa Hall Darden, Health Physicist date signed

Approved by: John E. Glenn 10/27/88
John E. Glenn, Ph.D., Chief date signed
Nuclear Materials Safety Section A

Inspection Summary: Routine, unannounced inspection of radiation safety program on May 25, 1988. Inspection Report No. 030-02435/88-001

Areas Inspected: Organization and Scope of Activities; Audits; Radiation Safety Committee; Dose Calibrator Testing; Security; Personnel Protection; Surveys; Waste Disposal.

Results: Eight apparent violations of NRC requirements were identified: failure to hold quarterly Radiation Safety Committee meetings (paragraph 4); failure to record accurate information for dose calibrator checks, failure to perform dose calibrator checks on a daily basis, and failure to evaluate dose calibrator measurements to determine instrument precision (paragraph 5); failure to wear lab coats and disposable gloves when handling radioactive material (paragraph 7); failure to maintain survey records (paragraph 8); failure to maintain waste for 10 half lives prior to disposal (paragraph 9); failure to have Nursing Representation at Radiation Safety Committee Meetings (paragraph 4).

DETAILS

1. Persons Contacted

*M. Sommer, Vice President of Professional Services
*A. Cuzzola, Assistant Administrator for Professional Services
A. Brenner, M.D., Nuclear Medicine Physician
G. Wallace, Nuclear Medicine Technologist
*R. Pillai, Nuclear Medicine Administrator
B. Kodery, Physicist
D. Marsden, Ph.D., Nuclear Medicine Consultant

*Present at exit interview.

2. Organization and Scope of Licensed Activities

United Hospitals of Newark holds a specific license which authorizes use of licensed material for nuclear medicine studies and brachytherapy. Presently, there are two staff technologists. Normally, five staff technologists perform approximately 100 studies a week. During 1987, approximately 18 brachytherapy implants were done.

3. Audits

Monthly audits and quarterly ALARA (as low as reasonably achievable) reviews are conducted by an outside consultant. The audit and ALARA reports were reviewed during the inspection. The Nuclear Medicine Physician stated that deficiencies are identified and discussed with the Nuclear Medicine Administrator (NMA). The reports are given to the NMA and she is expected to follow thru with corrective action. As described in paragraph 5, the response to these audits appeared to be cosmetic only, without management oversight to assure effective corrective action.

4. Radiation Safety Committee

The Radiation Safety Committee (RSC) is required to meet at least once in each quarter to review and evaluate radiation safety issues. From a review of the RSC meeting minutes, the inspector observed that Nursing is frequently not represented at the meetings as required by Part 35. Nuclear Medicine has the largest number of representatives as well as the most consistent representation. In addition, during the fourth quarter of 1986, no RSC meeting was held. The purpose and responsibilities of the Radiation Safety Committee were discussed with management during the Exit Interview. Also discussed was the importance of having Nursing and all other required representatives attend the RSC meetings. The licensee's management representative agreed that aggressive implementation of this requirement is necessary.

Failure of the RSC to meet during the fourth quarter of 1986 is an apparent violation of Condition 19 of License No. 29-01423-01.

Failure to have the Department of Nursing represented at Radiation Safety Committee meetings is an apparent violation of (superceeded) 35.11.

5. Dose Calibrator Testing

The inspector reviewed procedures and records for testing the operation of the dose calibrator. At the request of the inspector, the nuclear medicine technician repeated the daily constancy test with a long-lived cobalt-57 source. The cobalt-57 source was measured to be 78 microcuries (μCi) by the dose calibrator. The reading recorded earlier that morning for the same source was 98 μCi, a difference of 21%. The technologist repeated the test and again measured 78 microcuries. Review of dose calibrator records of daily constancy tests revealed that recorded measurements for the cobalt-57 reference source indicated no apparent decay since March 1, 1988. The normal decay for cobalt 57 is approximately 1.5 percent a day. When questioned, the technologist could not account for the difference in the measurements, but suggested that maybe a power surge was responsible. The inspector concluded that either the test was performed inadequately or that the data was recorded inaccurately or that the data was recorded without the test being performed.

Failure to record accurate results of daily constancy tests is an apparent violation of the requirements in 10 CFR 30.9(a).

A graph maintained to compare the predicted and actual decay activities of the reference source was posted. This record is required to demonstrate that differences between the predicted and measured activities do not exceed plus or minus 5%. However, the technologist could not explain why the measurements plotted were not the same as those recorded for the daily constancy tests. If the actual recorded values had been plotted, some measurements would have been outside the ± 5% range indicated on the graph.

Failure to correctly plot the reference source decay to determine instrument precision is an apparent violation of Condition 19 of License No. 29-01423-01.

Review of the quarterly audit reports performed by the consultant physicist showed that, on several occasions since 1985, he noted that daily constancy checks of the dose calibrator were not performed. The dates noted in his reports were July 14 to August 7, 1985, February 2 to February 13, 1987, and July 30 to August 20, 1987. However, records made available to the inspector to be reviewed during the inspection were complete, even for the periods cited as missing in the consultant's reports. In this regard, the inspector noted that a page was cut out of the Daily Constancy Record Book and the next page was filled in with data for the time period January 28, 1987 thru February 26, 1987, which encompassed the February 2-13, 1987 period for which the consultant physicist noted missing data.

When questioned, the Nuclear Medicine Administrator stated that she could not account for either the discrepancies between the recorded results and the actual results of the reference sources measured during the inspection, or for the recorded daily constancy tests results that were formerly identified as missing by the consultant but were made available for review during the inspection.

Failure to perform constancy tests daily is an apparent violation of Condition 19 of License No. 29-01423-01.

6. Security of Materials

The configuration of the Nuclear Medicine Department is such that the hot lab can be left unattended and open once the department is unlocked for the day. The greatest potential for inadequate security exists during early morning hours when technical and secretarial staff are small. Although a security violation was not observed during the inspection, the potential for such and possible preventive and corrective measures were discussed with management.

7. Personnel Protection and Dosimetry

Inspector observation of the morning instrument quality control procedures revealed that the nuclear medicine technologist did not wear gloves or a lab coat while handling radioactive material for these tests. However, she donned a lab coat and gloves when she injected patients. The license requires that, for safe handling of radioactive materials, radiation workers wear lab coats and gloves while handling radioactive material.

Failure to wear a lab coat and disposable gloves while handling radioactive material is an apparent violation of Condition 19 of License No. 29-01423-01.

Based on observation people were using dosimetry as required. Review of dosimetry records revealed no exposure in excess of regulatory limits.

8. Surveys

Daily and weekly surveys are performed to measure contamination and radiation levels in the Nuclear Medicine Department. Records of these surveys were reviewed during the inspection. Area surveys to measure radiation levels in the unrestricted areas surrounding patient rooms are required when iodine-131 therapeutic doses greater than 30 millicuries are administered to in-house patients. It could not be resolved through discussions with the Nuclear Medicine Physician and the Nuclear Medicine Administrator whether these surveys were always done. Records of area surveys were not maintained for all iodine-131 therapies performed during 1986, 1987 and 1988 to date. The Nuclear Medicine Physician said that he had been unaware that surveys had to be documented and records retained.

Failure to maintain records of area surveys of radiation levels in unrestricted areas surrounding iodine-131 therapy patient rooms is an apparent violation of 10 CFR 20.401.

9. Waste Disposal

The Nuclear Medicine Administrator stated that short lived isotope waste is normally held for decay a minimum of ten half-lives, surveyed and then disposed to the normal trash. Iridium-192 seeds in ribbons are returned to the distributor. Review of waste disposal records by the inspector indicated that waste from patients who received iodine-131 therapeutic doses is sometimes disposed of to normal trash prior to decay for ten half-lives. When the Nuclear Medicine Administrator was asked about the disagreement between her statement and the records, she said that sometimes the therapeutic waste is disposed of prior to the ten half life decay requirement.

Failure to hold short lived radioactive waste for the required ten half-life decay interval is an apparent violation of Condition 17 of License No. 29-01423-01.

10. Exit Interview

The inspector met with the individuals denoted in paragraph 1 at the conclusion of the inspection. The purpose, scope and inspection findings were summarized. The inspector expressed concern about the lack of management control of the licensed program and the discrepancy between the records of measurements and actual observations of dose calibrator testing. Licensee Management expressed a desire to effect the necessary changes to bring and maintain the program in accordance with regulatory requirements.

SYNOPSIS

This investigation was initiated upon written request, dated July 11, 1988, from the Regional Administrator (RA), Nuclear Regulatory Commission (NRC), Region I, King of Prussia, Pennsylvania. The Office of Investigations (OI) was asked to determine if records made by United Hospitals of Newark (UHN), Newark, New Jersey, were falsified; and, if so, the circumstances surrounding the falsification and the identity of persons involved in or aware of such falsification within the UHN organization.

The RA advised, in the July 11 request, that on May 25, 1988, a routine inspection was conducted at UHN. During the inspection, the Inspector requested a Nuclear Medicine Technologist (Tech) to repeat the daily constancy test (DCT) with the long-lived Cobalt-57 source. The reading showed a 26% difference on two tests that were performed than the reading recorded earlier that morning. When the Inspector reviewed the dose calibrator records of the DCTs, the Cobalt-57 records showed no decay of the reference source since March 1, 1988.

The RA further advised that a review of the quarterly audit reports performed by the Consultant Physicist showed that on at least three occasions since 1985, it was noted that daily constancy checks of the dose calibrator were not being performed.

The Tech admitted that she did not perform the DCTs on several occasions. However, she denied intentionally violating NRC regulations but said that due to insufficient time, prior to patient treatment, she did not perform the DCTs.

The Nuclear Medicine Administrator, the Director of Nuclear Medicine, and the Consultant Physicist all denied any knowledge of falsification of the DCT or any other records.

It is concluded that due to careless disregard for NRC regulations, the Tech falsified the Cobalt-57 DCT records.