U.S. NUCLEAR REGULATORY COMMISSION
REGION I

Report Nos. 030-02988/85-01
030-18925/85-01

Docket Nos. 030-02988
030-18925

License Nos. 37-01553-01
37-01553-04 Priority III Category G

Licensee: The Germantown Hospital and Medical Center
One Penn Boulevard
Philadelphia, Pennsylvania

Inspection Conducted: June 26 and 28, 1985

Inspector: Francis Costello 7/5/85
J. Piccone, Ph.D., Health Physicist date

Approved by: Francis Costello 7/5/85
F. Costello, Chief, Nuclear Materials date
Safety Section A

Inspection Summary: A special announced inspection of the circumstances surrounding the reported shipment of radioactive waste with contamination in excess of allowable limits and of the routine radiation safety program on June 26 and 28, 1985. (Combined NRC Region I Inspection Report Nos. 30-02988/85-01 and 30-19825/85-01)

Areas Inspected: Organization and scope of licensed activities; notification of incident; interviews; training and qualification of personnel; exposure control; receipt and transfer procedures; radiation safety records; and independent calculations.

Results: Seven apparent violations were identified: Surface contamination levels on a radioactive materials shipment in excess of regulatory limits (Paragraph 4); failure to perform appropriate tests on radioactive packages to ensure that the external radiation and contamination levels are within allowable limits (Paragraph 7); failure to provide adequate surveys of the radiation exposure to the extremities of individuals (Paragraph 6); failure to calibrate the dose calibrator in accordance with license procedures (Paragraph 8); failure to open packages containing radioactive materials in accordance with license procedures (Paragraph 7); failure to provide adequate training (Paragraph 5); failure to maintain records of surveys (Paragraph 8);

Details

1. Persons Contacted

*Mr. Frank T. Alcaraz, Vice President
*Dr. Frances Esposito, Radiologist, RSO
Ms. Roberta Dubin, Nuclear Medicine Technologist
Ms. Elizabeth Johnson, Nuclear Medicine Technologist
Ms. Eleanor Brennan, Radiation Therapy Technologist
Ms. Linda Smith, Radiation Therapy Technologist

*Present at exit interview.

2. Organization and Scope of Licensed Activities

The Germantown Hospital and Medical Center is authorized to possess and use licensed material for the purposes of medical diagnosis and therapy. Nuclear Medicine and Radiation Therapy are sections of the Radiology Department. There are 7 authorized users, 2 nuclear medicine technologists and 2 radiation therapy technologists.

The hospital has approximately 300 beds and handles approximately 70 therapy patients and 55 nuclear medicine patients per week. Ms. Roberta Dubin is the Chief Nuclear Medicine Technologist and reports to Dr. F. Esposito. Dr. Esposito is also the Radiation Safety Officer.

3. Notification of Incident

On June 18, 1985, Region I received a telephone report from the Office of Regulatory Affairs of Nuclear Pharmacy Incorporated (NPI) that a driver from their Philadelphia pharmacy had become externally contaminated with Tc-99m on June 14, 1985 by handling a returned waste shipment from The Germantown Hospital and Medical Center (TGHMC). A copy of the June 19, 1985, letter to TGHMC from Nuclear Pharmacy Incorporated detailing the incident was received by Region I on June 25, 1985 (Attachment 1).

No violations were identified.

4. Interviews

On June 26 and 28, 1985, a Region I inspector interviewed the personnel involved in the incident, including, among others, the Radiation Safety Officer, the Nuclear Medicine Technologist (NMT) and the driver who picked up the radioactive waste shipment. A description of the incident gleaned from the interviews is summarized below.

The hospital receives radioactive materials from NPI, for the most part in the form of multi-dose vials and bulk Tc-99m. These materials are ordered on a daily basis by the two Nuclear Medicine Technologists and delivered two or three times a day by NPI. The first delivery arrives at approximately 7:00 a.m. and is secured in a locked examination room until surveyed and opened by the Nuclear Medicine Technologists at approximately 8:00 a.m. The radioactive materials are packaged in ammunition boxes. Radioactive waste is returned to Nuclear Pharmacy Incorporated in these same boxes. On June 14, 1985, a NMT surveyed an incoming package and, finding no evidence of contamination, proceeded to utilize the materials. She placed the ammunition box on the work area next to the L-shield and prepared a stock solution of Tc-99m MDP for bone imaging containing approximately 40 millicuries of Tc-99m. An absorbent pad covered the work area. A patient's dose was withdrawn from this stock vial behind the L-shield and, while removing the syringe and attached needle from the vial, some liquid squirted out of the syringe. The technologist continued with her work, closed the ammunition box, and put it on the floor for pick-up by the NPI driver. The technologist was wearing gloves during these activities. She stated that she did not monitor her gloves for contamination prior to disposing of them in the radioactive waste container.

The NMT then measured the dose in the dose calibrator, found it to be 20 millicuries, and assumed the activity lost while withdrawing the syringe was contained on the absorbent pad behind the L-shield and was of very low activity. No other doses were withdrawn from the vial and the activity remaining in the vial was not measured. The technologist stated that she surveyed her hands and clothing before leaving the hot lab and found no contamination.

At approximately 10:00 a.m. on June 14, 1985, a Nuclear Pharmacy Incorporated driver made a second delivery of the day to the hospital and picked up the return waste shipments. At no time were the ammunition boxes being returned to the NPI surveyed for external radiation and contamination levels.

In accordance with 10 CFR 71.5(a), licensees who transfer radioactive material to a carrier for transport must comply with the applicable requirements of the regulations of the Department of Transportation. 49 CFR 173.393(n)(9) requires that, prior to each shipment of any package, the shipper ensure, by examination or appropriate test, that the external radiation and contamination levels are within allowable limits. A licensee representative stated that surveys and wipe tests have never been performed on the outgoing boxes of radioactive waste in the approximately five years the waste has been shipped to NPI.

The failure to perform appropriate tests to ensure that the external radiation and contamination levels are within allowable limits is an apparent violation of 10 CFR 71.5(a).

Shortly after the NPI driver left, a nuclear medicine technology student found contamination (1200-5000 cpm) on the hot lab work area and on two locations on the floor during routine wipe tests. The background count rate forthe detector used was approximately 700 cpm. This finding was reported to the NMT who cleaned and surveyed the room several hours later. Surveys after cleanup indicated no measurable contamination. The hospital was not aware of the contaminated box until the following week when an NPI representative mentioned it while receiving an order from the hospital. TGHMC was not aware of the level of contamination until the NRC inspection.

The contaminated box was discovered by NPI during routine monitoring of the driver's hands. A measurement of a wipe of the box indicated greater than 500,000 cpm. The driver's hand's measured 0.5 mR/hr after washing and his clothing (pants and tie) measured 25 mR/hr. The clothing was removed and held for decay. No other boxes handled by the driver were found by NPI to be contaminated. Surveys of the automobile used by the NPI employee indicated low levels of removable contamination (100 - 200 cpm above background).

The shipping of radioactive waste with removable contamination in excess of allowable limits on June 14, 1985, constitutes an apparent violation of 10 CFR 71.5(a).

Calculations made by the inspector regarding the incident are contained in Paragraph 9.

5. Training and Qualification of Personnel

Through discussions with the RSO and Nuclear Medicine Technologists, the inspector determined that the licensee had not provided the technologists with instructions in their responsibilities for prompt reporting of unsafe or potentially unsafe conditions, employee protection and in the DOT regulations for the transfer of radioactive materials. The RSO and technologists were not aware that the proper transfer procedure for transfering radioactive materials was documented in their procedure manual.

The failure to provide the required training to individuals working in a restricted area constitutes an apparent violation of 10 CFR 19.12.

6. Exposure Control

The inspector reviewed the licensee's records of whole body and extremity dosimetry for the first five months of 1985. Whole body and extremity doses were within the limits specified by 10 CFR 20. However, the RSO stated that she had identified a failure on the part of the NMTs to routinely wear TLD finger dosimeters. The RSO stated that she had emphasized the necessity of wearing the dosimeters to the technologists. However, she stated that no evaluation of the extremity dose had been made for the period when finger dosimetry was not worn.

The failure to provide an evaluation of the radiation dose to the hands and fingers of personnel who prepare and inject patient doses is an apparent violation of 10 CFR 20.201(b).

7. Receipt and Transfer Procedures

The licensee's "Procedures for Safely Opening Packages Containing Radioactive Material" are the procedures in Appendix F of Regulatory Guide 10.8. These procedures require wipe test results to be expressed in units of disintegrations per minute (dpm). As of June 26, 1985, this determination was not being made and the Chief NMT was not aware of the procedure for converting cpm to dpm and had not determined the counting efficiency of their detector.

The failure to properly assess results of package wipe tests constitutes an apparent violation of Condition 17 of License No. 37-01553-01.

8. Radiation Safety Records

The licensee's dose calibrator procedures require the determination of dose calibrator linearity at quarterly intervals and require that the net activity measured be plotted versus the predicted activity.

As of June 26, 1985, the results of linearity tests were not plotted and evaluated as required nor determined at the required frequency. The dose calibrator linearity had been determined in May 1983, January 1984, November 1984, and April 1985.

The failure to calibrate the dose calibrator according to license procedures is an apparent violation of Condition 17 of License No. 37-01553-01.

The inspector reviewed the procedure for monitoring patients who have received I-131 therapy for carcinoma and the monitoring of the room before release of the room for unrestricted use. As of June 26, 1985 records of surveys made prior to the release of the patients' rooms were not recorded.

The failure to maintain records of the room surveys before release for unrestricted use is an apparent violation of 10 CFR 20.401(b).

The inspector also reviewed procedures and representative records regarding the daily and weekly surveys and wipe tests in the Nuclear Medicine Department, disposal of radioactive waste and bioassays.

9. Independent Calculations

The inspector performed calculations to estimate of the activity found on the contaminated ammunition box.

The removable activity determined from the wipe test of the box is as follows:

a. The efficiency of the counting equipment for Tc-99m is assumed to be approximately 8.98% (based on NPI records).

b. NPI measured 500,000 cpm on the wipe, which covered approximately 300 cm. sq.

c. Based on these values, the measured contamination level is 1.86×10^6 dpm per 100 cm. sq.

This value is 84 times the 10 CFR 71.87 allowable limit of 0.01 μCi per 100 cm. sq. of removable contamination on packages.

10. Teletherapy Program

The inspector reviewed the requirements of License No. 37-01553-04 for cobalt-60 teletherapy. This included an examination of emergency procedures, monthly spot check measurements, annual calibration reports, leak tests of the therapy source, source "on-off" indicators at the control panel and at the door, interlock operation of the entrance door, personnel exposure records, and training.

No violations were identified.

11. Exit Interview

The inspector met with the licensee representatives denoted in paragraph 1 at the conclusion of the inspection. Dr. Piccone briefly explained the NRC Enforcement Policy.