U. S. NUCLEAR REGULATORY COMMISSION
REGION I

Report No. 030-01808/87-001

Docket No. 030-01808

License No. 20-00289-07 Priority II Category G1

Licensee: New England Deaconess Hospital
185 Pilgrim Road
Boston, Massachusetts 02215

Facility Name: New England Deaconess Hospital and Strichman Medical Equipment, Inc.

Inspection At: Boston and Medfield, Massachusetts

Inspection Conducted: October 22, 23 and 26, 1987

Inspectors: _____ 3/24/88
Terence F. Friedman, Ph.D., C.H.P. date signed

_____ March 11, 1988
C. Thor Oberg, Health Physicist date signed

Approved by: _____ 3/24/88
John R. White, Chief date signed
NMSSC, NMSB, DRSS

Inspection Summary: Special unannounced safety inspection (Report No. 030-01808/87-001) of the circumstances surrounding apparent unauthorized transfers of byproduct material including identification of the unauthorized transfer, hospital regulations, packaging, corrective action, and use of licensed material by the non-licensee.

Results: Three violations were identified; failure to verify a transferee's authorization to receive licensed material - Section 3.0; failure to obtain authorization from the Radiation Safety Committee (RSC) to transfer licensed material - Section 4.0; and failure to properly package licensed material for transport - Section 5.0.

DETAILS

1.0 Persons Contacted

*Phillip Cobb, Radiation Safety Officer
**Joyce Tower, Vice President, Operations
**Robert D. Pence, Director, Division of Research
Melvin Clouse, M.D., Director, Radiology Department
John Chaffey, M.D., Chairman, Radiation Safety Committee
Louis Emond, Chief Technologist, Nuclear Medicine Department
Terry Carroll, Technologist, Nuclear Medicine Department
***Thomas C. Hill, M.D., Section Head, Nuclear Medicine Department

+Pearl T. Dennehey, Assistant Treasurer
+Mark D. Doherty, Manager of Manufacturing
+Dale Martin, Supervisor Manufacturing

*Present at both entrance and exit interviews.
**Present at exit interview.
***Contacted by telephone
+Strichman Medical Equipment, Inc. representatives

2.0 Purpose of Inspection

This special inspection was performed to review the circumstances surrounding the apparent unauthorized transfer of licensed material by the licensee to persons not licensed or authorized by the U.S. NRC to receive, possess, use, or transfer byproduct material.

3.0 Identification of the Unauthorized Transfers

Licensee representatives informed NRC Region I, by telephone, of the following occurrence on October 9, 1987. A written followup report was submitted by the licensee in this regard on October 21, 1987.

On October 5, 1987, an employee from the Radiation Safety Office of the licensee, the New England Deaconess Hospital (NEDH), observed an individual (a former employee of the NEDH) place a container with radioactive material label tape affixed to it into the trunk of an automobile.

Upon investigation of this observation, the Radiation Safety Office personnel learned that 20 millicuries of technitium-99m (Tc-99m) pertechnetate was in the container and had been obtained from the NEDH Nuclear Medicine Department of Radiology. The material was being transferred to the Strichman Medical Equipment Inc. (Strichman), Tech Center, 93 West Street, Medfield, Massachusetts 02052, by their employee Mark D. Doherty, Manager of Manufacturing.

The NEDH Radiation Safety Officer (RSO) contacted Strichman by telephone and learned that since September 10, 1987, a total of nine transfers of Tc-99m pertechnetate had been made from NEDH to Strichman. Strichman informed the NEDH RSO that they had a registration certificate from the Commonwealth of Massachusetts (MA) for this material and that they were told by the state's representative that this was all they needed to use the Tc-99m for industrial purposes. The RSO verified that Strichman did not have an NRC license.

The RSO contacted the NEDH Nuclear Medicine Department and verified the transfers of licensed material (Tc-99m pertechnetate) made to Strichman. The NEDH Nuclear Medicine Technologists indicated that they were aware of the transfers and had maintained records of them. They indicated that they had been told by Dr. Hill that Strichman was authorized to have the licensed material. Based on this information, the NEDH RSO took immediate action to stop any further transfers of radioactive material to Strichman.

The inspector determined from the foregoing information that the licensee was in violation with Section 30.41(c) of 10 CFR Part 30. This regulation requires each licensee, prior to transferring licensed material, to verify that the recipient's license authorizes the receipt in quantity and kind, of the material being transferred.

This is an apparent violation of 10 CFR 30.41(c).

4.0 Hospital Regulations

The transfers made to Strichman by the NEDH was done so in apparent violation of hospital regulations.

The NEDH Radiation Safety Manual is incorporated into the NEDH license by reference to a letter dated September 4, 1986, in License Condition No. 21. In this manual, Subheading 3.3 Hospital Regulations states: "No person may use within, bring into or remove from the hospital any radiation source without authorization from the RSC."

The nine transfers of licensed material from the NEDH to Strichman in which Tc-99m was removed from the hospital were done so without the knowledge or authorization of the RSC.

This is an apparent violation of License Condition No. 21.

5.0 Packaging

Through discussions with personnel in the NEDH Radiation Safety Office, the NRC inspectors learned that the transfer of radioactive material observed on October 5, 1987, appeared not to be properly packaged. NEDH personnel indicated that the material was contained in what looked like a shielded tube in which xenon-133 is usually packaged (a cylinder about 1.5 inches in diameter by about 10 inches long covered with red plastic). The licensed material, Tc-99m, packaged in this tube was deposited within the trunk of an automobile with no apparent additional containment or without being tied down. The container appeared to be sealed with yellow, radioactive label tape. No other labeling was observed to be on the external surface of the tube. In addition, no shipping papers appeared to be in the possession of the individual making the shipment.

During discussions with Nuclear Medicine Department personnel, the inspectors were informed that there was some concern over the packaging of the Tc-99m for the transfers to Strichman but they did not follow-up on this concern.

Section 71.5 of 10 CFR Part 71, requires each licensee who transports licensed material or who delivers licensed material for transport, to comply with the applicable requirements of the regulations appropriate to the mode of transport of the DOT in 49 CFR Parts, 170 through 189. The transfer of Tc-99m to Strichman by NEDH was an apparent violation of the requirements of 49 CFR 172 and 49 CFR 173 with regard to specifications pertaining to marking and labeling of radioactive materials, standards for packaging, and documentation of such shipments.

This is an apparent violation of 10 CFR 71.5.

6.0 Corrective Action

The inspectors learned that the unauthorized transfers of Tc-99m were stopped by the RSO on October 5, 1987, until appropriate procedures and authorizations could be established. The nuclear medicine technologists were instructed not to transfer licensed material to anyone without prior permission from the RSO.

The incident and the information available were reported to the Chairman of the Radiation Safety Committee and to the Director of the Division of Research.

The licensee's RSO reviewed the incident with the NEDH and Strichman personnel involved. The RSO learned that a Commonwealth of Massachusetts representative from the Department of Labor and Industries (DOLI), Division of Occupational Hygiene, had informed Strichman that a registration certificate, Registration of Ionizing Radiation Sources, was all that was required to possess sealed and unsealed sources of radiation for industrial use.

The NEDH Radiation Safety Committee addressed the unauthorized transfer incident at their meeting held on October 9, 1987. The committee delegated the RSO to notify the NRC of the occurrence. Region I staff personnel were notified of the apparent unauthorized transfer on that day. The licensee documented further corrective actions in a letter to Mr. Thomas Martin, USNRC Region I, dated October 26, 1987.

7.0 Use of Licensed Material by the Non-Licensee

On October 23, 1987, an NRC inspector met with Strichman personnel at their facility in Medfield, Massachusetts. The inspector obtained the following information from Strichman through discussions with personnel, a tour of the facility, and a review of records maintained.

Strichman used the Tc-99m for quality control testing of a new brain imaging device. Arrangements had been made with Dr. Hill, Section Head, Nuclear Medicine Department, NEDH, for the hospital's Nuclear Medicine Department to provide the licensed material (Tc-99m pertechnetate) to Strichman personnel when requested.

The NEDH is collaborating with Strichman in the development of the new brain imaging device that is patented by Harvard University. During February 1987, Strichman obtained a license to manufacture and sell the imaging device under the Harvard University patent. In view of these factors, it seemed quite appropriate to both NEDH and Strichman personnel that licensed material used for QC testing of the imaging device be supplied by the NEDH, since: (1) Mr. Doherty of Strichman Medical Equipment, Inc., was known professionally and personably to Dr. Hill and others at the hospital; (2) Mr. Doherty was known to be familiar with, and possess expertise in handling radioisotopes; and (3) Dr. Hill of NEDH had been informed that Strichman had a registration certificate from the Commonwealth of Massachusetts to use Tc-99m for industrial purposes. Consequently, as part of the collaborative effort, personnel at NEDH provided Strichman with radioactive Tc-99m to test and calibrate the device.

When Tc-99m was required for testing, Mr. Doherty of Strichman went to the NEDH Nuclear Medicine Department and asked for the material. Staff personnel at the NEDH knew Mr. Doherty and had been told that Strichman was authorized to have the Tc-99m pertechnetate. The NEDH Technologists drew the requested dose of Tc-99m into a syringe and deposited it in a shielded container.

The inspector was informed by Strichman personnel that the shielded Tc-99m was placed in an "ammunition box" in the trunk of Mr. Doherty's personal automobile. The Neutron Products Corporation "ammunition box" was purchased from Photon Diagnostics Corporation where it had been used for transporting radioactive material.

The shipping container and contents were taken to the Strichman facility. Strichman personnel maintained records of each receipt of material, records of the utilization of each dose of Tc-99m, and the actual label used on each transfer container.

Strichman Medical Equipment, Inc., constructed a small hot-lab in which they have been using the radioactive materials at their facility. The Tc-99m pertechnetate was injected into a "flood" source container or a "phantom" which was then used in testing the imaging devices. The equipment used in the hot-lab and for testing the devices was also purchased from Photon Diagnostics Corporation. The hot-lab and the equipment were observed by the inspector during tours of the facility.

The Strichman facility also has a lead lined storage box to shield and contain the flood and phantom sources. One of the sources in this storage box was a cobalt-57 phantom (NEN No. NES 9021 September 20, 1984, nominal activity 4.8 millicuries, Lot No. 90210984E). The inspector observed that Strichman personnel use a Ludlum Model 3 survey instrument with a "pancake" type of detector that is operational and functional. This instrument has not been calibrated in about 1½ years but measurements made with it were in acceptable agreement with those made by the NRC inspector using an NRC instrument (NRC No. 9654 Ludlum Model 18 Analyzer calibrated May 26, 1987). Strichman has initiated a personnel dosimetry film badge program with R.S. Landauer Jr., and Co., on September 20, 1987.

On September 9, 1987, Strichman contacted the Commonwealth of Massachusetts, Department of Labor (DOL), regarding requirements for the use of radioactive material, specifically Tc-99m and Co-57 sealed and unsealed sources. Strichman was told that a registration certificate from the Massachusetts DOL was all that was needed to possess and use the listed sources for industrial applications. No other licensing was necessary. Strichman received a registration certificate on September 10, 1987, via personal delivery by an inspector from the Massachusetts DOL.

On October 5, 1987, at about 10:00 a.m., after talking to the NEDH RSO, Strichman personnel again contacted the Commonwealth of Massachusetts, DOL, and asked specifically if they needed an NRC license. They were again informed that as long as they didn't have a Mo-99/Tc-99m generator on site, they did not need an NRC license to use Tc-99m pertechnetate for industrial purposes. However, at about 3:00 p.m. that same day, DOL personnel called Strichman by telephone and informed them that they now believed that an NRC license was needed.

Consequently, since the date of this inspection, Strichman Medical Equipment, Inc., has submitted an application for an NRC license for the receipt, possession and use of liquid Tc-99m to be used in flood sources for testing and energy alignment of the new brain imaging device.

8.0 Exit Interview

On October 22, 1987, an exit interview was held by the Region I inspectors with those individuals identified in Section 1.0 of this report.

The inspectors discussed the findings of the inspection as discussed in this report. The licensee confirmed their understanding of the apparent violations identified and their commitment to establish implement and maintain the necessary corrective actions.