U.S. NUCLEAR REGULATORY COMMISSION
REGION I

Report No. 030-01244/89-002

Docket No. 030-01244

License No. 06-00819-03 Priority I Category G Program Code 2110

Licensee: Yale-New Haven Hospital
20 York Street
New Haven, Connecticut 06504

Facility Name: Yale-New Haven Hospital

Inspection Conducted: March 21, 1989

Inspectors: JoAnn V. Stambaugh, Health Physicist — 6/7/89 date

John M. Pelchat, Health Physicist — 6/7/89 date

Approved by: Mohamed M. Shanbaky, Chief — 6/7/89 date
Nuclear Materials Safety Section A

Inspection Summary: Special, unannounced Inspection Conducted March 21, 1989 (Inspection Report No. 030-01244/89-002).

Areas Inspected: Review of the circumstances surrounding the loss and subsequent retrieval of a discarded 27.53 millicurie (mCi) cesium-137 source, including: organization and scope of licensed activities, notification of the event, review of the brachytherapy procedure, review of the source event, personnel and storage area monitoring, licensee action on previous violation, and corrective actions.

Results: Within the scope of this inspection, four apparent violations were identified: failure to inventory brachytherapy sources upon returning them to storage (Section 4); failure to survey brachytherapy waste in order to detect the presence of radioactive material (Section 4); failure to prevent unauthorized disposal of radioactive material (Section 5); failure to limit radiation levels in unrestricted areas (Section 4 and Section 7).

## DETAILS

1. Persons Contacted

*Norman G. Roth, Assistant Vice President
*Robert Schulz, Ph.D., Chief, Radiation Physics
*Michael J. Bohan, Radiation Safety Officer and Health Physicist
Carol Kramer, M.D., Radiation Oncology Resident
Sharon Trumpore, Medical Dosimetrist

*Present at the March 21, 1989 exit conference.

2. Organization and Scope of Licensed Activities

Yale-New Haven Hospital is authorized by NRC License No. 06-00819-03 to possess and use licensed material for purposes of medical research, diagnosis and therapy. The hospital's radiation oncology department has a large brachytherapy program which performs approximately 80 gynecological (GYN) implants per year. A variety of methods for GYN implantation are performed at Yale-New Haven Hospital including the Simon System which utilizes Heyman capsules.

3. Notification of the Licensee Event

On March 10, 1989 at 4:30 p.m., NRC Region I received a telephone call from Yale-New Haven Hospital's Radiation Safety Officer (RSO). The RSO stated that a 25 millicurie (mCi) cesium-137 (Cs-137) brachytherapy source was retrieved from trash that was rejected by the RESCO Company, a trash-to-energy plant located in Bridgeport, Connecticut on March 9, 1989 because of measurable radiation levels. The RSO stated he went to the site, surveyed the trash dumpster and measured radiation levels of up to 12 milliroentgen per hr (mR/hr). He immediately returned to the hospital to inventory all radioactive material but no loss was identified. On March 10, 1989, after the trash dumpster was returned to the hospital, a decision was made to retrieve the radioactive material from the dumpster. A Cs-137 brachytherapy source in a Heyman applicator was found.

The State of Connecticut was notified by Mr. James Dourghty of the RESCO Company on Thursday, March 9, 1989 at 9:15 a.m.. Mr. Shepard K. Linscott, Radiation Control Physicist from the State of Connecticut, was on site during the efforts to recover the source from the trash.

No apparent notification violations were identified.

4. Review of the Brachytherapy Procedure

On Friday, March 3, 1989, a gynecological brachytherapy afterloading intracavitary placement was performed in the operating room. The Simon System of implanting the uterus was used. This system utilizes Heyman applicators/capsules which contain Cesium-137. The Heyman capsules are miniaturized tube sources doubly encapsulated in stainless steel. The Cs-137 source is brazed onto a thin metal rod assembly. The entire mechanism is called a source assembly. This source assembly is placed into an applicator and secured in position for the course of a patient's treatment. The Heyman sources were calibrated in April, 1988 and received by Yale-New Haven on May 16, 1988. Each source has an actual length of 19.6 mm and an active length of 12 mm. The activity of each source is 27.53 mCi, (10.94 mg. radium equivalent).

The radiation oncologist and gynecological oncologist placed four 3M disposable nylon Heyman applicators and packing material into a patient's cervix. After the operating room procedure, the patient was loaded with non-radioactive or dummy source assemblies. Orthogonal x-ray films were then taken for treatment planning. The dosimetrist calculated the treatment dose using a computerized system, determining length of time the radioactive material was to remain in the patient for the source activity used in order to fulfill the physician's treatment prescription. The patient was returned to her private room where the dummy sources were replaced with four 27.53 mCi Cs-137 source assemblies.

On Sunday, March 5, 1989, the GYN Oncology Resident removed the four Cs-137 source assemblies from the patient's applicators, and placed each in a lead shielded transport cart. He then removed the packing material and placed the sponges into the normal trash. The nylon Heyman applicators were removed and also placed into the shielded transport cart. The resident transported the shielded cart to the restricted area storage room where it remained until Monday morning. The nursing staff performed a patient and room survey immediately after source removal and found that all sources had been removed.

On Monday, March 6, 1989 at 11:00 a.m., the dosimetrist removed the Cs-137 source assemblies from the lead transport shield. The source assemblies are 308 mm. in length with the Cs-137 source at the proximal end. The dosimetrist placed these assemblies into an ultrasonic cleaner, which is an approved disinfection method. The source assemblies were then placed into the storage container. The distal end of the assemblies, which consist of a leveled handle with a screw-lock mechanism for securing into the Heyman capsule, protrudes far enough out of the lead storage container to ensure ease in handling. The dosimetrist, in returning these sources to storage, failed to check the source tip on each assembly. Inventory was obtained by counting the distal portions of each assembly, not the actual sources. Condition 27 of radioactive material license No. 06-00819-03 requires that licensed radioactive material be possessed and used in accordance with the procedures, representations, and statements contained in the application dated December 13, 1984 and in the letters submitted in support of that

application. Item 20(e) of the application dated December 13, 1984 states that the dosimetrist keeps accounting records for all therapeutic use of sealed sources and after each procedure the dosimetrist is to account for each of the sources before returning them to storage. Failure to inventory each sealed source before returning them to storage is an apparent violation of License Condition 27.

The dosimetrist continued the clean-up routine and disposed of all non-reusable items such as the Heyman applicators. No surveys were performed on these items nor were surveys performed on the trash receptacle. 10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with all sections of Part 20 including Section 20.301 concerning disposal of licensed materials. On March 6, 1989, surveys were not performed on the brachytherapy applicators nor the waste receptacle which contained implant disposable items. Failure to perform surveys according to 10 CFR 20.201(b) is an apparent violation.

No other violations were identified.

5. Review of the Lost Source Event

On Sunday, March 5, 1989, a 27.53 mCi Cs-137 source became detached from a Heyman source assembly during an implant removal from a patient. The source remained in the brachytherapy applicator. The applicator, which was also removed from the patient at the same time as the sources, was placed with the radioactive material in a lead transport shield. The source remained in the transport cart until Monday, March 6, 1989. The applicator was then placed in the normal trash in the restricted area storage room, often referred to as the radium room. The trash receptacle in the radium room was not set out for disposal until Wednesday, March 8, 1989. On Wednesday, the receptacle was placed in a low occupancy corridor. Housekeeping personnel emptied the trash container into a trash chute in an adjacent room. The trash chute lead directly to a dumpster. The dumpster was then picked up Thursday, March 9, 1989 at 6:30 a.m. by the Latella Carting Company. The hauler proceeded to take the dumpster to the RESCO Company, a trash-to-energy plant in Bridgeport, Connecticut. At 7:40 a.m., the dumpster was positioned for unloading when a radiation alarm sounded. The radiation detection device was installed by RESCO to prevent radioactive material from getting into the trash burner. The dumpster was then monitored by RESCO personnel using an Eberline E-520 survey instrument verifying the presence of radioactivity. The dumpster was returned to the hauler's office. The Latella Company tracked the dumpster to Yale-New Haven Hospital. The engineering department at Yale-New Haven was notified of the trash radioactivity. The engineering department notified the hospital's RSO of the event. The RSO responded to the incident, arriving at the hauler's office with a Ludlum 3 pancake probe survey instrument. The trash dumpster was surveyed and radiation levels up to 12 mR/hr on contact with the dumpster were measured. This resulted in a general area dose rate in excess of 2 mRem/hr. 10 CFR 20.105(b) requires, in part, that no licensee shall possess, use or transfer licensed material in such a manner as to create in any Unrestricted Area a radiation level in excess

of 2 mRem in any one hour. The inspector stated that exceeding the regulatory dose limit at the hauler's office and the steam plant (Unrestricted Areas) was an apparent violation of 10 CFR 20.105(b). The RSO returned to Yale-New Haven Hospital where he conducted an inventory of all radioactive material. No lost sources or generators were identified.

The trash hauler returned the dumpster to Yale-New Haven Hospital. The RSO again surveyed the dumpster and posted a caution radiation area sign on the dumpster, where the highest reading were measured.

Another sign was posted, stating "keep 10 feet back from this point". The RSO instructed all persons in the immediate area, such as: shipping and receiving, security and environmental staff, to stay at least 20 feet from the dumpster and to ensure the dumpster not be removed. In addition, the RSO contacted the chief of radiation physics, and the engineering department notified risk management and public relations. All were briefed on the immediate situation and the future evaluation process that was to occur.

The RSO notified Mr. Ken Price from Yale University's Radiation Safety Office and borrowed a multi-channel analyzer (MCA) in order to identify the source in the dumpster. While waiting for the University staff to arrive with the MCA, the RSO conducted several measurements on the dumpster through ½ inch and 1 inch sheets of lead in an effort to determine the half-value layer thickness of the radiation from the source. The results were inconclusive. The MCA was then used to further evaluate the source. The instrument was set up fifteen feet from the dumpster and a two source calibration was performed using a cesium-137 and a barium-133 source. A gamma spectrum was run to identify the source. The MCA, Canberra Model 35 with a 3 x 3 sodium iodide well crystal, measured a gamma peak at about 720-740 KeV. A review of the gamma spectrum tables led the RSO and Mr. Price to believe the source in the dumpster was a molybdenum-99/technetium-99m (Mo-99/Tc-99m) generator. At approximately 4:30 p.m. on Thursday, March 9, 1989, the RSO, satisfied with the MCA results, instructed security to lock the gate to the yard which housed the dumpster.

On Friday March 10, 1989, prior to 9:00 a.m., a second source inventory had been conducted and again appeared to account for all sources. Additional measurements were taken of the dumpster and the findings showed no change in the radiation readings, indicating the source in question had not decayed and could not be a Mo-99/Tc-99m generator. At this point, the state investigator urged the licensee to resolve the problem by locating the source in the dumpster. At 12:45 p.m., a meeting was conducted with the maintenance and engineering managers and the RSO. It was decided that the dumpster would be unloaded into a second dumpster. The maintenance and engineering departments supplied the manpower. The RSO trained the workers and supplied them with dosimetry. The RSO also handled the monitoring function. The source was located on the left side of the dumpster in a plastic bag. The RSO removed the plastic bag from the dumpster and found that a disposable nylon Heyman applicator was the source of the radiation readings. Further examination of the applicator revealed a 27.53 mCi Cs-137 source inside the nylon tube. Apparently, a Heyman afterloading source,

which is brazed to an assembly, became fractured at the braze point, leaving the source in the disposable applicator. The source was placed into a shielded transportation cart and escorted back to the radium room. Release surveys were conducted on both dumpsters including wipe sample surveys to rule out radioactive contamination. All surveys were negative for contamination. The radiation postings were removed, returning the area to its normal function.

10 CFR 20.301 requires that no licensee dispose of licensed material except by certain specified procedures. The failure to prevent the unauthorized disposal of a 27.53 mCi Cs-137 source is an apparent violation of 10 CFR 20.301.

The RSO performed a leak test on the found Cs-137 source. The leak test result was less than 0.005 microcurie (μCi) of detectable activity. The manufacturer, the 3M Company, was notified by telephone on March 15, 1989 of the braze failure. Mr. Lee Marks, a manufacturer representative, noted that this was an unusual occurrence which had never been brought to their attention before. The RSO was instructed to return the source and assembly to 3M for an evaluation of the braze failure and possible repair or replacement.

No other violations were identified.

6. Personnel and Storage Area Monitoring

The radium room is located in the short procedure Operating Room (OR) unit of the hospital. All personnel working in the radium room, where the Cs-137 source was in the waste receptacle unshielded from Monday, March 6, 1989 through Wednesday, March 8, 1989, were wearing whole body dosimetry. The trash receptacle was located at the doorway of the radium room. This enabled personnel to maintain a minimum distance of three feet when working inside the room. Four radiation oncology personnel visited the radium room when the Cs-137 source was in the trash receptacle.

The following table summarizes personnel occupancy times during the period in which the unshielded source was in the radium room:

| Personnel | Date | Approximate Time in Radium Room |
|---|---|---|
| 1. Dosimetrist | March 6, 1989 | 60 minutes |
| | March 8, 1989 | 180 minutes |
| 2. RSO | March 6, 1989 | 15 minutes |
| | March 8, 1989 | 15 minutes |
| 3. Radiation Oncologist | March 8, 1989 | 15 minutes |
| 4. Radiation Oncology Resident | March 8, 1989 | 15 minutes |

The radium room is monitored monthly with an area badge. The adjacent room which is an operating room is also monitored monthly. The RSO determined a maximum exposure estimate of 40 mRem for four hours at one meter from the unshielded Cs-137 source. Due to these findings, the RSO did not feel it was necessary to send personnel and area film badge dosimetry for immediate evaluation. The routine monthly dosimetry reading interval was maintained.

There is a small, low traffic corridor leading to the radium room. A janitorial supply closet is the only other room occupying the corridor. The janitorial closet is used by environmental personnel who work in the short procedure unit. Housekeeping uses the closet to pick up and drop off OR cleaning supplies and trash. The radium room trash receptacle was placed into this corridor at the end of the day on Wednesday, March 8, 1989. Housekeeping personnel emptied the receptacle by entering the janitorial closet and placing the plastic trash bag into a trash chute. Minimal time was spent on this effort and the RSO estimated no significant radiation exposure resulted.

All personnel working on the source retrieval effort were instructed on radiation safety and were badged with whole body dosimetry (See Section 5).

No apparent violations were identified.

7. Licensee Action on Previous Violations

(Open) Inspection No. 88-01: Failure to limit radiation levels in Unrestricted Areas so that an individual who was continuously present in the area could not receive a dose in excess of 2 mRem in any one hour and 100 mRem in any seven consecutive days. Yale-New Haven installed shadow shields in six patient rooms in the brachytherapy patient area. These shields were positioned to protect the area of highest occupancy in adjacent rooms.

On March 21, 1989, a brachytherapy patient treatment was being performed. The inspector surveyed an unoccupied adjacent room with a Ludlum Model 3 G/M survey instrument (NRC #007765 calibrated February 24, 1989) and found radiation levels in a visitor chair to be greater than 2 mR/hr. This room was not posted as a restricted area. The RSO stated that a license amendment requesting authorization under 10 CFR 20.105(a) to allow radiation levels in excess of 2 mR/hr as long as any individual would not be likely to receive a dose in excess of 500 mR in any calendar year was planned to be submitted to the NRC. The inspector indicated that Yale-New Haven Hospital must have the license amendment approval by the NRC prior to exceeding the dose rate limit of 2 mR/hr in any Unrestricted Area. This finding was a repeat violation of 10 CFR 20.105(b) which was identified during a previous routine inspection dated September 20, 1988.

8. Corrective Action

The RSO and management discussed five corrective action measures to prevent future loss of radioactive material with the NRC inspector during the inspection on March 21, 1989. The actions proposed include the following:

- The RSO was to conduct a re-training program for all staff dosimetrists on all brachytherapy source and assembly configurations.

- The RSO stated he was going to request medical staff approval to limit personnel authorized to remove sealed radioactive sources from an implant patient to Radiation Oncologists and Radiation Oncology Residents.

- The RSO stated he would establish a procedure for removing sealed radioactive sources from a patient. All physicians involved in the brachytherapy program would be trained to implement such procedures.

- The RSO suggested placing a Rad-Alert radiation monitor with a light indicator above the waste receptacle in the radium room. An audible alarm will not be used since it may present interference with general operating room equipment. All radiation workers frequenting the radium room would be sensitized to the Rad-Alert light indicator.

- The chief of radiation physics stated he would suggest to the manufacturer, 3M, a possible change in source appearance, specifically, designing a color coding system so that sources can be distinguished from assemblies.

9. Exit Interview

The inspectors met with the licensee representatives denoted in Section 1 at the conclusion of the inspection. The scope and findings including apparent violations were summarized. The inspectors reviewed NRC enforcement policy and procedures with the licensee's representatives.