U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-02283/90-001(DRSS)

Docket No. 030-02283

License No. 24-00794-03

Licensee: St. John's Mercy Medical Center
615 S. Ballas Road
St. Louis, MO 63141

Inspection Conducted: January 23 and 26, 1990

Purpose of Inspection: Special safety inspection to review the circumstances surrounding the reported loss of a nominal 2 millicurie brachytherapy source.

Inspector: James R. Mullauer, M.H.S.
Radiation Specialist, Nuclear
Materials Safety Section 2
Date: 2/6/90

Reviewed By: R. J. Caniano, Chief
Nuclear Materials Safety
Section 2
Date: 2/6/90

Approved By: R. J. Caniano for B. S. Mallett, Ph.D., Chief
Nuclear Materials Safety
Branch
Date: 2/6/90

Inspection Summary

Inspection on January 23 and 26, 1990 (Report No. 030-02283/90-001(DRSS))
Areas Inspected: Special safety inspection which included a review of quarterly brachytherapy source inventory, source accountability during and after use, brachytherapy source leak tests, survey instrument calibration records and a review of the circumstances surrounding the events which led to the reported loss of a cesium-137 brachytherapy needle.
Results: Of the areas inspected, three apparent violations were identified as follows: (1) License Condition No. 18 - failure to log out and log in brachytherapy sources used for instrument calibration (Section 5); (2) 10 CFR 20.207(b) - failure to maintain constant surveillance and immediate control of a brachytherapy source while in an unrestricted area and not in storage (Section 5); (3) 10 CFR 30.41(a) - failure to transfer licensed material as authorized by 10 CFR Part 30 (Section 5).

DETAILS

1. Persons Contacted

Sister Mary Angelique Foto, RSM, Vice President
*Don G. Spalding, M. D., Chairman of Radiology
*George D. Oliver, Ph.D., Radiation Safety Officer
Sam Hancock, Ph.D., Physicist
Gloria Yowell, Radiology Administrator
Judy Ruback, Supervisor, Radiation Therapy
Ken Andrews, Health Physics Technologist

*Denotes those present during the exit interview conducted on January 26, 1990.

2. Previous Inspection

License No. 24-00794-03 was last inspected on September 27 and 28, 1989. During the course of that inspection, six (6) violations were identified. The violations pertained to the licensee's failure to (1) leak test brachytherapy sealed sources every six months; (2) check airflow in fume hoods quarterly; (3) wear an extremity monitor and disposable gloves while handling radioactive material; (4) survey the RIA laboratory monthly; (5) use licensed material as authorized; (6) make a record of licensed material disposal in the sanitary sewer.

In addition to the violations, an area of concern was addressed in the transmittal letter to the licensee concerning an apparent lack of management attention to the Nuclear Pacemaker License. On November 29, 1989, the licensee provided an interim response to the violations; however, requested an extension to respond to the NRC's concern over the apparent lack of management control over the licensed program. That response is expected to be provided to the Region-III office no later than March 1, 1990.

3. Organization

Tim Farrell is the Administrator and CEO; Sister Mary Angelique Foto, RSM is the Vice President; John Lindeman, M.D. is the Chairman of the Radiation Safety Committee; Don G. Spalding, M.D. is the Chairman of Radiology; George Oliver, Ph.D., is the Radiation Safety Officer; Judy Ruback, is the supervisor of radiation therapy; and Sam Hancock, Ph.D., is the medical physicist.

4. December 29, 1989, Notification

On December 29, 1989, the licensee notified Region-III of the loss of a nominal 2 millicurie (0.8 milligram radium equivalent or mg.Ra.eq.) cesium-137 brachytherapy source (one of eight such needles possessed by the licensee) which had been used for instrument calibration. The source was discovered missing at approximately 4:30 p.m. on December 28, 1989,

during a routine quarterly inventory. The licensee also reported that the source was used exclusively for instrument calibration and there was no patient involvement. Radiation levels from the source were calculated to be 0.66 milliroentgen per hour at a distance of one meter and 6.6 roentgen per hour at the source surface. As such, the source could represent a safety hazard if it was held in proximity to a person for a long period of time. The licensee also reported that the source was probably lost either on October 13, 1989, or October 23, 1989, when one of the licensee's eight 0.8 mg.Ra.eq. implant sources was used for instrument calibration.

At the time of the reporting, the licensee had already begun conducting extensive radiation surveys of hospital facilities with a sodium-iodide detector. These surveys included housekeeping areas such as closets, vacuum cleaners, hallways, source storage rooms, laundromat and instrument calibration areas. The licensee was also interviewing hospital personnel who may have come in contact with the source. A notice was posted informing hospital personnel of the missing source. The licensee's initial impression was that the source was inadvertently placed in the normal trash sometime following the October 13, 1989, or October 23, 1989, use and subsequently sent to a landfill for disposal.

On January 26, 1990, the licensee's 30 day report required by 10 CFR 20.402(b) was received in the Region III office.

5. Review of Reported Loss

The Radiation Safety Officer (RSO), Medical Physicist (MP) and Physics Technician (PT) were interviewed during the inspection concerning the events related to the reported loss of the brachytherapy needle.

According to the RSO, who is authorized to do instrument calibrations at St. John's Mercy Medical Center, high, medium and low activity cesium-137 brachytherapy sources are used for instrument calibration depending on the type of instrument being calibrated. A September 26, 1989, inventory showed that all cesium-137 brachytherapy sources were present in the source storage safe located in the radiation therapy department. Therefore, the loss occurred sometime after September 26, 1989. The cesium-137 storage safe has six separate drawers in which implant sources are stored. Implant sources of equal activity are stored together in the same drawer. The licensee possessed eight 0.8 mg.Ra.eq. cesium-137 needles which were stored in the lower right hand corner of the safe or drawer number six. A review of the licensee's source log out, log in book showed that the licensee did not record removal or return of sources from the safe when the sources were used for instrument calibrations. (Recent calibrations were conducted on October 3, 13, and 23, 1989, and December 6, 1989.) License Condition No. 18 which references letter dated March 13, 1986, (with attachments) states in attached Item No. 10.11 under Implant Source Use Records that Appendix M.4 to Regulatory Guide 10.8, Revision 2 would be followed. Appendix M.4 requires that each time a source is removed from the safe, a record will be made of the number and activity of sources removed, the room number of use or patient's name, and the time and date

they were removed from storage and initial the record. Appendix M.4 further requires that each time a source is returned to storage, they are to be immediately counted to ensure that every source removed has been returned. A record is to be made of the number and activity of sources returned, the room number of use or patient's name, and the time and date they were returned to storage and initial the record. The licensee's apparent failure to count and make the required records as described above when sources were used for instrument calibrations on October 3, 13 and 23, 1989, and December 6, 1989, is an apparent violation of License Condition No. 18. Sources used for patient therapy treatments are recorded in the source accountability book as required. Between the September 26, 1989, quarterly inventory, and the date of the reported loss, December 29, 1989, cesium-137 implant sources were used for patient therapy on four separate occasions; however, the 0.8 mg.Ra.eq. sources were not used during these treatments. According to the RSO, if a certain source strength is not used, there would be no need to enter that source drawer.

Survey instrument calibration records, indicated that on October 3, 1989, and October 13, 1989, a 0.8 mg.Ra.eq. source was used. According to the RSO, if the source was missing on either of these dates, it most likely would have been noticed immediately; therefore, the licensee believes all sources were accountable at least up to October 13, 1989. Another survey instrument calibration record dated October 23, 1989, shows that a 19.0 mg.Ra.eq. source was used for the calibration; however, the RSO stated that a 0.8 mg.Ra.eq. source could have been removed from the safe and not used for the calibration. The RSO cannot recall how many sources were removed from the safe on October 23, 1989. Implant sources were also used on December 6, 1989, for instrument calibration; however, the health physics technician performing that calibration stated that 0.8 mg.Ra.eq. sources were not used or even removed from the storage safe.

According to the RSO, survey instruments are calibrated in the licensee's linear accelerator room when the room is not being used for patient treatment. This room is located in the radiation therapy department. The RSO stated that he was probably rushed either on October 13, 1989, or October 23, 1989 when he was calibrating instruments which resulted in the implant source to probably drop on the floor. The RSO added that the source was probably swept up in a vacuum cleaner used by housekeeping on the evening of either October 13 or 23, 1989, thus the source was not in the immediate control of the licensee. 10 CFR 20.207(b) requires that licensed materials in an unrestricted area and not in storage shall be tended under the constant surveillance and immediate control of the licensee. The licensee's apparent failure to maintain constant surveillance and immediate control of the implant source is an apparent violation of 10 CFR 20.207(b).

The source to date has not been located. The licensee has concluded that the source was probably disposed of in the local landfill. 10 CFR 30.41(a) states that no licensee shall transfer byproduct material except as

authorized pursuant to Part 30. The apparent disposition of a brachytherapy source in the local landfill is an apparent violation of 10 CFR 30.41(a).

Although the licensee believes that the source was lost on either October 13, or 23, 1989, it appears that the source was actually last accounted for on September 26, 1989, during the quarterly inventory; therefore, the loss could have occurred anytime between the September 26, 1989, and the December 28, 1989, inventory.

Three apparent violations of NRC requirements were identified.

6. Corrective Actions

The licensee initiated corrective action to preclude recurrence of similar events. For example, implant sources are now logged out and logged in when these sources are used for instrument calibration as evidenced by the January 10, 1990, survey meter calibration. The log shows for the January 10th calibration that the date and time out, purpose of source removal, room of use, each source strength, total activity, date and time returned and the initials of the individual performing the brachytherapy storage room survey are recorded. In addition, the licensee has ordered a cesium-137 survey meter instrument calibrator so that brachytherapy sources will not be needed for such calibrations in the future.

7. Exit Meeting on January 26, 1990

At the conclusion of the special inspection on January 26, 1990, the inspector met with those individuals noted in Section 1 of this report. The information learned during the inspection was reviewed, the apparent violations and the enforcement options available to the NRC. The licensee was informed that pending review of the circumstances surrounding the reported loss of byproduct material, the licensee would be informed of any decision made by Region III management and resulting proposed enforcement action. Although the licensee did not indicate that any information learned during this inspection was proprietary, the licensee did voice an interest in not alerting the news media of the lost source.