NOTICE OF VIOLATION

Memorial Hospital
South Bend, Indiana

Docket No. 030-17335
License No. 13-18881-01
EA 89-249

During an inspection conducted on September 8, 1989, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1989) the violations are listed below.

A. 10 CFR 20.207(b) requires that licensed materials in an unrestricted area and not in storage be tended under the constant surveillance and immediate control of the licensee.

Contrary to the above, on at least four occasions, during September 7 and 8, 1989, a patient implanted with 10.6 millicuries of iridium-192 entered an unrestricted hallway in the hospital and was not under constant surveillance or immediate control of the licensee.

This is a Severity Level III violation (Supplement IV).

B. 10 CFR 35.33(a) requires that when a misadministration involves a therapy procedure, the licensee notify by telephone the appropriate NRC Regional Office within 24 hours after it discovers the misadministration.

Contrary to the above, the licensee failed to notify the NRC Regional Office by telephone after it discovered a therapy misadministration on September 12, 1989.

This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Memorial Hospital is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator Region III, U.S. Nuclear Regulatory Commission, 799 Roosevelt Road, Glen Ellyn, Illinois, 60137, within 30 days of the date of the letter transmitting this Notice. This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) the reason for the violation if admitted; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance will be achieved. Where good cause is shown, consideration will be given to extending the response time. If an adequate reply is not received within the time specified in this Notice, an order may be issued to show cause why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken.

FOR THE NUCLEAR REGULATORY COMMISSION

Carl J. Paperiello for

A. Bert Davis
Regional Administrator

Dated at Glen Ellyn, Illinois
this 19th day of January, 1990

U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 30-17335/89002(DRSS)

Docket No. 30-17335

License No. 13-18881-01 Category G Priority 3

Licensee: Memorial Hospital
615 North Michigan Street
South Bend, IN 46601

Inspection At: Memorial Hospital, South Bend, Indiana

Inspection Conducted: September 8, 1989

Inspectors: D. R. Gibbons
Radiation Specialist

December 20, 1989
Date

W. T. King
Radiation Specialist

12/20/89
Date

Approved By: D. J. Sreniawski, Chief
Nuclear Materials Safety
Section 1

Dec 20, 1989
Date

Inspection Summary

Inspection on September 8, 1989 (Report No. 30-17335/89002(DRSS))
Areas Inspected: This was an announced special inspection to review the circumstances surrounding a reported loss of an iridium-192 ribbon implant device. The inspection was a response to a telephone call from the licensee informing the Region III Office that an implant device containing three (3) iridium-192 sealed sources could not be located during a survey performed at the end of a patient's prescribed treatment on September 8, 1989. Each source contained 2 millicuries with a total of approximately 6 millicuries in the implant device.
Results: Of the areas inspected, two apparent violations of NRC requirements were identified.

10 CFR 20.207(b): The licensee failed to maintain constant surveillance or immediate control of licensed material (Section 4).

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10 CFR 35.33(a): The licensee failed to notify the Region III Office within 24 hours after the licensee discovered, on September 12, 1989, that a misadministration had occurred that involved a therapy procedure (Section 5).

The implant device was eventually found in a hallway near an elevator on the 10th floor of the Oncology Center.

DETAILS

1. Persons Contacted

*Philip A. Schneider, M.D., Radiation Oncologist
*Alex Hashemi, M.S., Radiation Safety Officer
*Taya Hoskins, RT, Dosimetrist
Beck Strzynski, RN, Risk Manager
Patrick Miller, Director of Radiation Oncology
Jane Meehling, Nurse

*Denotes those present at the exit interview on September 8, 1989.

2. Purpose of Inspection Conducted on September 8, 1989

This was an announced special inspection to review the circumstances surrounding a reported loss of an implant device (a ribbon or tube with iridium-192 sources inside) containing approximately six (6) millicuries of iridium-192. The apparent loss of the device was reported by telephone to the Region III Office at 10:00 a.m. on September 8, 1989. The licensee was advised that two Region III inspectors would be dispatched to the hospital and would assist hospital personnel in an attempt to locate the licensed material.

3. Review of the Incident

The Region III inspectors were informed that an elderly patient was implanted with two ribbon implant devices containing approximately six (6) millicuries in each device. The treatment was to a part of the patient's cheek and was started on September 7, 1989. The patient was very restless during that evening and had walked the halls frequently. She returned to her bed at approximately 11:30 p.m., and the implant devices appeared to be intact at that time. At approximately 12:30 a.m. on September 8, 1989, the patient was checked by one of the attending nurses. The tape covering the implant area appeared to be loose and one of the ribbons was missing; however, the attending nurse was not aware that there were two ribbon implant devices. The remaining ribbon was removed from the patient at 8:00 a.m. on September 8, 1989; at which time the licensee performed an inventory, and noticed a ribbon containing 3 sources was missing. The implant device could not be located during a search of the room or hallway of the hospital and could not be located during a radiation survey of the same area; nor could it be located during a radiation survey of the patient before her release from the hospital.

4. Region III and Licensee Surveys

The Region III inspectors performed radiation surveys of hallways, patient's room on the 10th floor of the hospital, nurses' stations, locker rooms and elevators located on the 10th floor of the hospital

using Ludlum Model 19 Micro-R-Meters. These survey instruments easily detected a similar implant device placed on the floor of a restricted area as a test of the response of the instruments.

Initially, licensee personnel felt that the device may have fallen into the hospital's waste water system. The waste water system was surveyed from the 10th floor to a manhole area outside of the hospital. All of the walkways, paths to the parking lots and the parking lots were surveyed. All of the surveys were unsuccessful in locating the ribbon implant device.

On September 8, 1989, while the inspectors and the the hospital's Radiation Safety Officer (RSO) were performing another final survey of the 10th floor area and the hallway, a member of the nursing staff asked to speak with the RSO. She had worked the previous night, and informed the RSO and inspectors that the patient had been very active that night. The patient had been out of her room a number of times that evening, despite repeated warnings not to leave. The nurse had taken the patient back to her room the last time just prior to shift change (approximately 11:00 p.m.). When the nurse returned to work just before midnight on September 8, 1989, she had just seen what she thought was an iridium-192 implant device lying on the floor near the elevator and placed it on a stand in the hallway. Surveys performed by the inspectors and the RSO confirmed that the ribbon was, indeed, the lost iridium-192 ribbon from the hospital's patient. The ribbon was placed in shielding and stored.

The elapsed time from the nurse placing the ribbon on the stand and reporting it to the survey personnel was about 15 minutes. The exposure to the nurse's hand resulting from picking up the ribbon was estimated at 70 millirem.

The nurse was wearing her whole body badge when she came to work that evening, and during the retrieval of the implant device. She informed the inspectors and the RSO that she had worn her badge home after completing her previous shift. The RSO sent the badge for immediate processing to determine if the nurse might have inadvertently carried the device home on her purse, shoe, or on other parts of her body or apparel. The film badge results were minimal. If the nurse would have carried the source home and was in close proximity to the source for an extended period of time the film badge would have indicated a reading greater than minimal.

The inspectors interviewed others on the nursing staff in an attempt to determine if they may have had contact with the device. None of those interviewed revealed information to help determine the device's location during the 22 hours it was missing.

One apparent violation of NRC requirements was identified.

The loss of immediate control of licensed material in an unrestricted area for approximately 22 hours constitutes an apparent violation of 10 CFR 20.207(b).

5. Licensee's Required Reports

The licensee submitted the required reports in a letter dated September 26, 1989, and received by the Region III Office on September 29, 1989. The report included procedures implemented to prevent recurrence of similar incidents.

The report stated that on September 12, 1989, the licensee determined that a therapy misadministration to a patient had occurred on September 8, 1989. The determination on September 12, 1989 that a misadministration had occurred required a notification by telephone within 24 hours to the Region III Office.

The failure to notify the Region III Office by telephone within 24 hours after determining a therapy misadministration had occurred constitutes an apparent violation of 10 CFR 35.33(a).

One apparent violation of NRC requirements was identified.

6. Evaluation of Exposures

In an effort to determine whether any hospital staff were exposed to the lost ribbon and did not inform the NRC, the inspectors reviewed the licensee's film badge results for employees badged for the month of September 1989, which included nurses attending this patient. The results compared with previous months' reports did not indicate an increase to any personnel during that month. If the sources had adhered to the nurses clothing for an extended period of time while they were wearing film badges, the badge results should have shown an increase.

The licensee's Radiation Safety Officer and the NRC inspector on November 16, 1989 estimated that, in the unlikely event that the ribbon accidentally adhered to a person's skin (arm, wrist etc.), that the 3 seeds (5.28 mCi total) would deliver approximately 50 Rad/hr to an area of the skin about 3 cm long, or a total of approximately 1150 rads absorbed dose from the time the ribbon was determined to be missing (11:30 p.m. September 7, 1989) to the time the ribbon was found (10:30 p.m. September 8, 1989). The exposure to an individual would be much less to a similar area of the foot if the source had adhered to the bottom of a shoe. (The exposure to the hand of the nurse who picked up the ribbon and placed it on the stand was about 70 millirem based on a five second exposure stated in Section 4).

7. Exit Interview

The inspectors reviewed their initial findings with the individuals indicated in Section 1 on September 8, 1989. The inspectors explained that one apparent violation (for failure to maintain surveillance) of NRC requirements was identified, and that further action by the NRC would be deferred until Region III personnel have reviewed the licensee's reports required by 10 CFR 20.402(b). One other apparent violation (for failure to timely report a misadministration) was also discussed with the licensee's Radiation Safety Officer during subsequent telephone calls on September 29 and December 14, 1989.