U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

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NMED No.	080801
Licensee:	Department of the Army Walter Reed Army Medical Center
Location:	6900 Georgia Avenue, NW Washington, D.C. 20307-5001
Inspection Dates:	December 19, 2008; Exit Meeting March 20, 2009
Date Followup Information Received:	February 8 and 11, 2009

Inspectors:

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EXECUTIVE SUMMARY

Department of the Army
Walter Reed Army Medical Center
NRC Inspection Report No. 03001317/2008001

An announced, special inspection was performed to follow up on the licensee's notification, on November 19, 2008, that three manual brachytherapy ribbons containing a total of 29.2 millicuries (mCi) of irdium-192 were missing for approximately 5.5 hours on November 14, 2008. The licensee also reported that the sources were inadvertently placed in the regular trash and that minimal exposure to non-radiation workers and no exposure to members of the general public was expected.

On December 19, 2008, NRC staff conducted an inspection at the licensee's facility. The Radiation Safety Officer (RSO) and his staff stated that their investigation indicated that an untrained medical student entered a brachytherapy patient's room on November 14, 2008, and changed the patient's bandages. The medical student did not identify that three ribbons were attached to the bandages he removed, and improperly discarded the bandages into the regular trash in the patient's room. Subsequent to the bandage change, housekeeping staff improperly entered the patient's room and removed the trash. The licensee identified the seed loss two to two and one-half hours after the medical student had discarded them, and began a search for the seeds. Approximately three hours later, the three ribbons were found in a trash compactor located on the loading dock. The RSO was unavailable at the time of the event and the radiation safety staff responding to the event did not report the event immediately, based on their understanding that the sources had been found. The RSO reported the event to the NRC upon his return to the facility on November 19, 2008.

Within the scope of this inspection, three apparent violations of NRC regulations were identified: (i) failure to control access to 3 ribbons containing iridium-192 seeds as required by 10 CFR 20.1802 that resulted in the ribbons being placed into an uncontrolled trash container; (ii) failure to report the missing ribbons immediately as required by 10 CFR 20.2201; and (iii) failure to train a medical student on the safe handling of manual brachytherapy sources as required by 10 CFR 35.410.

REPORT DETAILS

I. Event Description

a. Inspection Scope

This inspection was limited to a review of the circumstances surrounding the loss of control of licensed material that occurred on November 14, 2008, and was reported to the NRC on November 19, 2008. The inspection consisted of observations by the inspectors, interviews with licensee personnel, and examination of records describing the event and followup actions.

b. Observations and Findings

Event Details

On November 10, 2008, a patient was admitted for a manual brachytherapy treatment. The treatment consisted of implanting eight nylon ribbons, each containing seven 1.39 mCi iridium-192 seeds (for a total of 77.8 mCi), into the patient's shoulder. The treatment was to administer 4500 rads (cGy) to the target tissue over 90 hours. On November 14, 2008, at 9:00 am, when the sources were scheduled to be removed, it was discovered that three ribbons containing 29.2 millicuries of iridium-192 were missing. The licensee conducted an investigation and determined that a medical student changed the bandage on the patient's shoulder sometime between 6:30 am and 7:00 am and improperly discarded the bandage with three of the iridium-192 ribbons attached into the regular trash within the patient's room. Subsequently, housekeeping staff improperly entered the radiologically controlled patient's room, removed the trash, and eventually placed the trash into a compactor on the loading dock at approximately 9:00 am. After identifying that the sources were missing, the radiation safety staff surveyed all hospital areas, and discovered the three ribbons in the trash compactor at 12:10 pm. The sources were leak tested, with no detectable leakage noted.

Notification of the Event

The RSO was unavailable at the time of the event, and a Senior Health Physicist improperly determined that immediate notification to the NRC was not required, based on his understanding that the sources had been found. Upon the RSO's return on November 19, 2008, the required NRC telephone notification was made in accordance with 10 CFR 20.2201(a)(1). The licensee confirmed that a medical event did not occur since the patient received 4444 rads of the prescribed dose of 4500 rads (a difference of 1.2%). The licensee also estimated a maximum dose of 18 millirem to the housekeeping staff, 32 milllirem to the medical student, and determined that no other exposure to a member of the general public was expected to have occurred.

NRC On-Site Inspection

On December 19, 2008, NRC staff performed an on-site inspection to review the details of the reported loss of control of licensed material. The inspectors interviewed all licensee staff involved in this event and toured all areas where the radioactive seeds

were used and inadvertently stored during this event, which included the patient's room, a temporary waste storage room, and a waste compactor located on the loading dock. During the tour, the inspectors gathered information to confirm the licensee's calculated maximum exposure to their employees and to a member of the public.

The inspectors reviewed the licensee's investigative results. This included that the housekeeping staff, who are trained to stay out of a patient's room when a patient is undergoing radiation therapy, entered the patient's room and removed the trash, which resulted in loss of control of the licensed material in violation of 10 CFR 20.1802. To compound this error, the licensee noted that a sign with old procedures had been improperly posted on the patient's door indicating that housekeeping staff may enter the room and remove trash. Finally, the licensee noted that while the licensee had provided training to nursing staff to control access to the patient's room to those trained on safety precautions pursuant to 10 CFR 35.410; during this implant, the nursing staff did not observe the medical student or housekeeping staff entering the patient's room.

In addition to verifying the licensee's investigative results, the inspectors identified that the medical student who removed the patient's bandages had not received training in accordance with 10 CFR 35.410 and, therefore, was unaware of the safe handling and shielding requirements for manual brachytherapy sources (e.g., survey the bandages to check for loose radioactive sources prior to disposal). This resulted in the medical student inadvertently discarding the sources into the regular trash without conducting a proper survey. With regards to the failure to report the event immediately in accordance with 10 CFR 20.2201, the inspectors interviewed the radiation safety staff and noted that although the Senior Health Physicist had received training on the reporting requirements in 10 CFR 20.2201, this training was not entirely effective, since he misinterpreted the requirements to refer only to radioactive material that could not be found.

Licensee's Corrective and Preventive Actions

The licensee discovered the loss of the radioactive sources and recovered them in a relatively short period of time with minimal radiological consequences. The licensee immediately retrained the medical staff on entry requirements, safe handling requirements, and shielding requirements for active brachytherapy patient rooms. The licensee also instituted a new requirement for a member of the radiation safety staff to be present to survey bandages/ dressings and any trash prior to removal from a controlled brachytherapy room. Additionally, brachytherapy room door signs were promptly updated to clearly state that housekeeping is prohibited from entering active brachytherapy patient rooms, and the housekeeping staff was subsequently retrained on these revised hospital operating procedures. Finally, the licensee immediately retrained the radiation safety staff on reporting requirements to ensure there is no future misinterpretation of what constitutes a loss of radioactive material control.

c. Conclusions

The inspectors concluded that the loss of control of licensed material for approximately 5.5 hours was caused by several factors and resulted in two apparent violations. In addition, the failure to report the temporary loss of the radioactive material resulted in an additional apparent violation. These included:

1) Failure to train a medical student on the safe handling of manual brachytherapy sources as required by 10 CFR 35.410. As detailed in 10 CFR 35.410, this training should have included the safe handling and shielding instructions of the brachytherapy sources. In general, safe handling instructions include a requirement to survey any items involving the implant, either visually or with a radiation detection instrument, to ensure that no loose seeds are inadvertently removed. The licensee's failure to provide this training to all personnel caring for the brachytherapy patient, including the medical student, resulted in the inadvertent disposal of radioactive seeds into the normal trash within the patient's room.

2) Failure to control and maintain constant surveillance of 3 ribbons containing iridium-192 seeds as required by 10 CFR 20.1802 that resulted in the ribbons being placed into an uncontrolled trash container. Several years prior to this event, the licensee's procedures allowed housekeeping staff to enter brachytherapy patients' rooms to remove non-radioactive trash. The licensee revised their procedures to strictly prohibit this entry to further control accountability of brachytherapy sources during implants. While it was noted that the licensee had provided this training periodically to housekeeping staff on the new procedures, it was also noted that a sign that reflected old procedures was inadvertently posted on the patient's door during this implant. This resulted in a misunderstanding by the housekeeping staff who entered the patient's room and removed the trash, in which the medical student had placed the bandages containing the radioactive seeds. The trash was later placed in a waste compactor located in an uncontrolled area; a violation of 10 CFR 20.1802.

3) Failure to report the missing ribbons immediately as required by 10 CFR 20.2201. As described above, the RSO was unavailable during this event and the Senior Health Physicist responding to the event mistakenly interpreted the regulations in 10 CFR 20.2201 to apply to sources that remained lost. Even though the individual had received training on reporting events, the inspectors concluded that the training was not entirely effective, since he failed to report the loss.

The licensee's corrective actions as described above, were reviewed by the inspectors and found to adequately address the causes of the event.

II. Exit Meeting

A preliminary exit meeting was conducted on December 19, 2008, to discuss the scope of the inspection and the inspector's initial observations. On March 20, 2009, at the conclusion of the inspection, an exit meeting was held by telephone to discuss the inspector's final observations.

PARTIAL LIST OF PERSONS CONTACTED

Licensee
*+Col. Mark Melanson, Ph.D., RSO
+Van Coots, M.D., Hospital Commander
+Col. Felicia Pehrson, Chief Medical Officer and RSC Chair
*+David Burton, Health Physicist
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Deedee Smart, M.D., Department of Radiology
Wilfred Sewchand, M.D.
Dustin Boyer, M.D.
Robin Smith, Nursing Manager, 6th Floor
Florence Johnson, Housekeeping Work Leader, 6th Floor

* Present at preliminary exit meeting conducted on December 19, 2008
+ Participated in telephonic exit meeting conducted on March 20, 2009