U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Report No.	030-02464/98-002
Docket No.	030-02464
License No.	29-03038-01
Licensee:	Hospital Center at Orange
Location:	188 S. Essex Avenue Orange, NJ 07051
Inspection Date:	September 16, 1998

Inspector: ORIGINAL SIGNED BY:
Neelam Bhalla — October 15, 1998
Neelam Bhalla — date
Health Physicist

Approved By: ***Original signed by Mohamed M. Shanbaky*** — ***October 15, 1998***
Mohamed M. Shanbaky, Chief — date
Nuclear Materials Safety Branch 1
Division of Nuclear Materials Safety

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EXECUTIVE SUMMARY

Hospital Center at Orange
NRC Inspection Report No. 030-02464/98-002

A special inspection was conducted on September 16, 1998 to review a probable therapeutic misadministration involving a brachytherapy implant that was reported to the NRC by the licensee on September 2, 1998.

A brachytherapy patient was hospitalized for the treatment of uterine cancer. On July 27, 1998 , the patient was implanted with two cesium-137 sources (18.35 milligram radium equivalent, each). The sources were placed in the two ovoids of a gynecologic applicator. A prescribed dose of 2160 rad (cGy) was to be administered to the treatment site over 72 hours period. Approximately two days into the treatment, the patient requested to use the bathroom and the attending nurse indicated that the patient was confined to her bed and was not provided a bedpan. The patient pulled out the applicator 53.5 hours into the treatment, in order to use the bathroom. As a result the patient received only 1616 rads instead of the prescribed 2160 rads. The dose administered was 26 percent less than the prescribed dose.

The implant with the sources in place, was left in the patients room for nearly five hours before it was retrieved and stored away in the Brachy Source Storage Room by the authorized user. Although there was a substantial potential for the staff and members of the public to receive unintended exposure, it appears that no such exposures occurred. However, the patient received unintended exposure to her hands while she carried/held the applicator in her hands when she moved the applicator from the bathroom and packed it with her toothbrush and placed it on the radiator, near her bedside (Section II).

A violation related to failure to immediately notify the facility Radiation Safety Officer (RSO) as required by procedures and license condition was identified (Section III).

The incident may have involved a misadministration to the patient. This possible misadministration is still under NRC review and is considered unresolved at this time (Section II).

REPORT DETAILS

I. Organization and Scope of the Program

a. Inspection Scope: The inspection was a special inspection, limited to a review of a possible misadministration, reported to the NRC by the licensee, on September 2, 1998. The inspection also included a review of all other brachytherapy implants performed since the last NRC inspection conducted in April 1998.

b. Observations and Findings: The inspector noted that the licensee performs 3 to 4 gynecological cesium-137 implants and 6 to 8 iridium-192 breast implants per year. These are temporary implants and the patients are hospitalized for the duration of the implant on the Oncology Floor, located on the seventh floor of the main hospital building.

The Metcalf Center is the hospital's Radiation Oncology Center, located in an annex of the hospital building. The Oncology Center operates a Cobalt-60 treatment unit, under NRC License No. 29-03038-02. Brachytherapy using cesium-137 and iridium-192 sources is performed under NRC License No. 29-03038-01.

c. Conclusions: The reported incident was the only brachytherapy implant patient involving a possible therapeutic misadministration as defined in 10 CFR 35.2.

II. Incident Details

a. Inspection Scope: Through staff interviews and document reviews, the incident details were examined by the inspector.

b. Observations and Findings :

INCIDENT SUMMARY:

A patient was hospitalized for brachytherapy for the treatment of uterine cancer. On July 27, 1998 , at 1:00 PM, the patient was implanted with two cesium-137 sources (18.35 milligram Radium equivalent, each) for a treatment time of 72 hours to administer a prescribed dose of 2160 rads (cGy) to the treatment site. Approximately two days into the treatment, the patient requested to use the bathroom and the attending nurse indicated that the patient was confined to her bed and was not provided a bedpan. The patient pulled out the applicator 53.5 hours into the treatment and received only 1616 rads of the prescribed 2160 rads. The dose administered at that time was approximately 26 percent less than the prescribed dose. The patient pulled out the applicator in order for her to use the bathroom.

The authorized user treated the patient with external cobalt-60 teletherapy to compensate for the missed dose of this application and also for a second implant therapy that was planned for the patient, a week following the first brachytreatment. The patient was also administered 3960 rads by cobalt-60 teletherapy in 36 days prior to the two planned brachytherapy treatments.

The incident was discussed at the licensee's regularly scheduled Radiation Safety Committee (RSC) Meeting on September 2, 1998. The RSC decided that the NRC be notified since a similar incident at another nearby hospital was cited as a misadministration by the NRC. The licensee notified the NRC Operations Center and also Region I via telephone on September 2, 1998. The authorized user informed the patient verbally, and notified the patient's referring physician in writing about the incident.

INCIDENT DETAIL: On July 29, 1998, at approximately 6:30 PM the nurse incharge noted that the patient had pulled out the implant and the implant was located on the patient bathroom sink. The nurse immediately notified the authorized user via telephone, however, she failed to notify the Radiation Safety Officer (RSO) as required by the licensee's procedures. The authorized user instructed the nurse to close the bathroom door and place the portable radiation shield in front of the door, and not allow any one in the room. The nurse was also instructed to watch the patient for any bleeding caused by pulling out the applicator and the foley catheter. The authorized user was at another location in New York, taking care of other patients. At 11:30 PM the authorized user arrived at the hospital and discovered that the applicator was not in the bathroom as noted by the nurse, but was on the radiator located inside the patient's room, in a plastic bag along with the patient's toothbrush. The authorized user transferred the sources from the applicator and secured them in the Brachy Source Storage Room. The patient was rendered medical care and discharged from the hospital next day.

c. Conclusions : Patient intervention may have contributed to a misadministration. It is also concluded that the patient pulled out the applicator in order for her to use the bathroom. The patient was administered 1616 rads, instead of the prescribed dose of 2160 rads. The administered dose was 26 percent less than the prescribed dose and meets the definition of a misadministration as defined in 10 CFR 35.2. Also the radiation dose the patient may have received to her hands and whole body (unintended treatment sites) as a result of her handling and moving the applicator may have contributed to the possible misadministration. This possible misadministration is still under NRC review and is considered unresolved at this time.

III. Training of Workers

a. Inspection Scope The inspector reviewed the licensee's training program and radiation safety instructions provided to all personnel caring for the patient undergoing implant therapy as required by 10 CFR 35.410 and the licensee's procedures.

b. Observations and Findings: The inspector noted that the licensee provides training to nursing staff annually. The nurse who responded to the incident, stated that she was trained in the radiation safety precautions by the consulting physicist, annually. In addition, written instructions are provided to the nursing staff for each patient hospitalized for brachytherapy treatment by the authorized user. The nurse followed the procedures when she observed that the patient had pulled out her implant. In that, she

notified the authorized user immediately and followed the instructions provided by the authorized user. However, she did not notify the RSO as required by the licensee's procedures. The nurse indicated that since all brachytherapy patients are managed by the Radiation Oncologist (A.U.), she notified the authorized user immediately. In addition, the nurse indicated that she was very concerned about the patient's condition (injury due to pulling the implant and foley catheter) and her attention was more on patient care.

The RSO was not notified as required by the procedures. The RSO indicated that had she been informed, she would have responded to the incident by contacting the authorized user and the consulting physicists. There are two physicists, one for Radiation Oncology and another one for Nuclear Medicine. Either physicists would have retrieved and controlled the radioactive material.

License Condition 16 of the NRC License No. 29-03038-01 requires, in part, that the licensee conduct its program in accordance with the statements, representations and procedures contained in the licensee's letter dated August 29, 1991. Item 11 of the letter dated August 29, 1991, requires that for implant therapy the licensee will establish and implement model procedure, Appendix Q to Regulatory Guide 10.8, Revision 2. Appendix Q, Item 3 outlines Nursing Instructions in Exhibit 20. Exhibit 20, requires the nursing staff to call the attending physician and the RSO immediately, if the source appears dislodged. The nurse incharge called the attending physician (authorized user) but failed to call the RSO.

c. Conclusion: Failure to notify the RSO as required by the procedures is a violation of License Condition 16 of NRC License No. 29-03038-01.

IV. UNINTENDED RADIATION EXPOSURE

a. Inspection Scope : Through staff interviews the inspector reviewed unintended radiation exposure that the patient, licensee personnel and members of the public may have received due to this incident.

b. Observations and Findings: As described in Section II, the nurse incharge called the A.U. immediately via telephone when she noted that the patient had pulled out the applicator. The A.U. instructed the nurse to take radiation precautions, including the instruction to not touch the applicator. The nurse stated that she did not handle the loaded applicator as per the instructions of the authorized user. The nurse's whole body dosimetry badge used during the care of this particular patient, read her exposure as "m", indicating that she received less than 10 mrem whole body exposure. The nurse incharge stated that there were three other nursing staff members on that shift that evening and they were all informed of the incident and were instructed not to go into the patient's room. It appears that no other personnel entered patient's room while the applicator was located in the patient's room. The nurse stated that no visitors were permitted in the patient's room during the time the applicator was out. The nurse incharge was the only individual who frequented the patient's room to render care to the patient while the applicator was out.

Although the nurse incharge instructed the patient to not touch the applicator, it appears that the patient handled the loaded applicator at least once more after she pulled it out of her body. It is not known for how long she held the applicator in her hands. The licensee is performing dose assessment to the patient's hands and her whole body from the unintended exposure the patient may have received due to this incident. In a telephone discussion between the inspector and the A.U. on October 15, 1998, the A.U. stated that the patient dose estimate from unintended exposure will be sent to the NRC.

c. Conclusions : Although there was a potential for the staff and members of the public to receive unintended exposure, it appears that under reasonable scenarios, the whole body dose may not significantly exceed the regulatory limit of 100 millirem. However, the patient received unintended exposure to her hands and body while she carried/held the applicator in her hands. Additionally, the patient received unintended whole body exposure since she placed the applicator on the radiator, near her bed.

V. Review of Other Brachy Implant Therapies

a. Inspection Scope: The inspector reviewed all brachytherapy implants that were performed since the last NRC inspection, conducted in April 1998.

b. Observations and Findings: The inspector noted that there were four additional patients that were administered brachy therapy at this hospital since NRC's last inspection conducted in April 1998. All four patients were implanted with iridium-192 for the treatment of breast cancer. The inspector noted that in all four cases the administered dose was in agreement with the dose prescribed on the written directive by the authorized user. In all four cases, the implants remained intact for the duration of the planned treatment times. The iridium sources were removed at the planned time and the patients were released from the hospital after appropriate surveys were performed.

c. Conclusions: No additional misadministrations or incidents were noted for the brachytherapy treatments that were performed since the last NRC inspection conducted in April 1998.

VI. Exit Meeting

Inspection findings were discussed with the licensee representatives, identified in the report.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

*Marjorie D. Blomberg, Senior Vice President, Patient Care Services
Mary Petti, Vice President, Patient Care Services
*J. P. Barba, M.D., Chairman, Metcalf Institute of Radiation Oncology
Mary Natrella, M.D., Director, Nuclear Medicine and Radiation Safety Officer
Rita Babu, Nurse-in-charge, Seventh Floor Nursing Unit
Fridon Kulidzhanov, Medical Physicist
*denotes individuals present at the exit meeting.