U.S. NUCLEAR REGULATORY COMMISSION
REGION III

Report No.: 030-02006/96002(DNMS)

License No.: 21-01333-01 Category G1 Priority 1

Licensee: William Beaumont Hospital
3601 West 13 Mile Road
Royal Oak, MI 48073

Inspection Conducted: February 29, 1996 (onsite) with continuing NRC review through December 10, 1996.

Inspector: Thomas Young 12/18/96
Thomas Young Date
Radiation Specialist

Approved by: 12/18/96
Monte Phillips, Chief Date
Nuclear Materials Inspection
Branch 2

Inspection Summary

Inspection on February 29, 1996, with continuing NRC review through December 10, 1996 (Report No. 030-02006/96002(DNMS))

Areas Inspected: This was a special, announced safety inspection to review, (1) the brachytherapy event reported to NRC Region III by telephone on February 27, 1996, and (2) the licensee's implementation of the written Quality Management Program for this specific patient. The event involved an applicator containing iridium-192 seeds that was dislodged from a patient undergoing simultaneous treatment with two low dose rate (LDR) remote afterloading units.

Results: Of the areas inspected, NRC exercised discretion to not cite a violation of 10 CFR 35.32(a)(5) that was identified by the licensee's radiation safety officer (RSO) when the radiation oncology personnel who discovered the dislodged applicator failed to notify the RSO. Please refer to Section 9 of this inspection report. NRC reviewed this event and determined that due to patient intervention the event does not qualify as a misadministration as defined in 10 CFR 35.2.

DETAILS

1. Place of Use

William Beaumont Hospital
3601 West 13 Mile Road
Royal Oak, MI 48073

9 North, Orthopedic Unit, Room No. 9659

2. Persons Contacted

+ Di Yan, Ph.D., Medical Physicist, Radiation Oncology
+ John Wong, Ph.D., Chief of Clinical Physics, Radiation Oncology
+ Peter Chen, M.D., Authorized User, Radiation Oncology
+ Kim Miller, M.D., Resident, Radiation Oncology
+ David Debiose, M.D., Fellow, Radiation Oncology
+ Alvero Martinez, M.D., Medical Director and Chairman, Radiation Oncology
+ Deborah Dunstan, LPN, 9 North, Orthopedic Unit
+ Ann Mortimer, RN, 9 North, Orthopedic Unit
+ Ann Beaver, RN, Supervisor, 9 North, Orthopedic Unit
+ Maureen O'Donnell, RN, Educational Coordinator, 9 North, Orthopedic Unit
+ *Cheryl Culver-Schultz, M.S., Radiation Safety Officer
* Larry Randolph, Associate Hospital Director and Safety Officer
* Jim Safran, Assistant Hospital Director
* Darlene Fink-Bennett, M.D., Assistant Director, Nuclear Medicine, and Chairperson, Radiation Safety Committee
* Marilyn Messina, Associate Hospital Director and Nursing Director
* Carla Cook, M.D., Vice Chief, Radiation Oncology

+ Denotes the individuals interviewed during the inspection.
* Denotes those individuals present during the exit summary conducted on February 29, 1996.

3. Licensed Program

The licensee is authorized for a broad scope medical program. The license specifically authorizes Low Dose Rate (LDR) remote afterloading units and High Dose Rate (HDR) remote afterloading units. The two LDR remote afterloading units are located on 9 North, Orthopedic Unit, and are used for about eight treatments per year. This is a relatively small case load as compared to other radiation oncology treatment modalities.

4. Inspection History

On February 5, 1996, a special inspection was completed to review the brachytherapy event that occurred on January 30, 1996. The event involved iodine-125 seeds that were dislodged from the treatment site. The root cause of the event appeared to be patient intervention.

The most recent routine safety inspection was completed on October 25, 1995. No violations of NRC requirements were identified. The previous routine inspection was completed on July 25, 1994, and two severity level IV violations were identified, both involving iodine-131 therapy.

5. Event Chronology

On Thursday, February 22, 1996, the authorized user prepared the written directive for cervical treatment with 244 iridium-192 seeds with a total activity of 90.92 millicuries (3.367 GBq) for a total dose of 3250 rads (3250 cGy) over a treatment period of 65 hours. The treatment plan was developed and approved by the authorized user. The treatment was initiated at 7:45 p.m. when the iridium-192 seeds were remotely transferred from the two LDR remote afterloading units into the applicator that had been surgically implanted into the patient earlier that day. The applicator consisted of, (1) a vaginal cylinder that was implanted into the patient and that held 26 stainless steel remote afterloading needles, and (2) an external template that was sutured to the patient.

On February 22 and 23, 1996, the treatment continued as planned. The nurses and physicians completed routine checks of the patient every one to two hours. The checks included specific observation of the sutures and the position of the applicator to verify that no displacement of the applicator had occurred. During these checks and during the occasional visits from the immediate family members, the treatment was interrupted and the seeds were retracted into the storage vaults in the two LDR remote afterloading units prior to these individuals entering the patient room.

On Saturday, February 24, 1996, at 7:10 a.m., the nurse attempted to restart the treatment after a visit by a family member. Audible and visible alarms were encountered. The nurse reset the audible alarm, but repeated attempts by the nurse were unsuccessful to reset the visible alarm and the treatment could not be resumed. The nurse notified the RSO and the medical physicist. The medical physicist arrived at 8:10 a.m. and surveyed the room and verified that the iridium-192 seeds were safely shielded in the two LDR remote afterloading units. The medical physicist then discovered a transfer tube connection that was slightly loose. After tightening the connector fitting screw, the medical physicist successfully restarted the treatment at 9:12 a.m. During this episode, the nurse verified that the applicator was properly positioned in the patient.

Later that morning, at 10:36 a.m., the resident physician who was under the supervision of the authorized user physician checked the patient and discovered that the vaginal cylinder was dislodged from the patient. The resident physician noted that the sutures were broken and had allowed displacement of the applicator. The resident physician notified the medical physicist and radiation oncology fellow (also a physician). They also notified the authorized user who immediately came to the hospital. These individuals determined that the event was an interdepartmental variance for further consideration within Radiation Oncology. These individuals were unaware that the licensee's written QMP required them to notify the RSO upon discovery of the event (refer to Section 9 of this inspection report). The authorized user decided to terminate the treatment and revised the written directive accordingly. Later, the authorized user decided to use an HDR remote afterloading unit to treat the patient for the balance of the prescribed dose that was originally intended to be given by the LDR remote afterloading units.

After overnight observation to ensure that the patient was medically stable, the licensee dismissed the patient on Sunday, February 25, 1996.

6. Notifications

On February 24, 1996, the authorized user explained the event to the patient and to the patient's family. The authorized user attempted to contact the referring physician and was unable to speak directly to the referring physician. Later, on February 26, 1996, the authorized user contacted the referring physician to discuss the effect on the patient and the options for continued treatment of the patient.

On February 27, 1996, the RSO learned of the event when the 9 North Nurse Manager requested the RSO to attend a follow up meeting about the event. The RSO notified the NRC Operations Center and NRC Region III Office.

On March 7, 1996, the licensee furnished a written report of the event to the patient.

7. Root Cause and Corrective Actions

The RSO's report dated March 1, 1996, concluded that patient intervention was the root cause of the event. The resident physician who discovered the dislodged applicator interviewed the patient about the broken sutures. The patient indicated that at one time during the previous night the patient shifted superiorly in the bed and heard a "popping" or "snapping" sound that originated from the location of the applicator. Also, the resident physician noted that upon entering the patient room just prior to discovery of the dislodged applicator the patient was in a twisted position in the bed and was trying to reach an object on a bedside table. This type of repetitive motion apparently caused the sutures to rupture and eventually the applicator was dislodged from the patient sometime after 9:12 a.m. on February 24, 1996. On February 29, 1996, the RSO tested the suture material and concluded that it was adequate for continued use in these types of cases.

The RSO's report dated March 1, 1996, indicated that in the future preventive actions would be taken. The licensee will consider fastening the transfer tubes to a surgical abductor pillow used to stabilize the patient's legs, rather than to tape the transfer tubes to the foot board or bed frame. This will allow for stability of the transfer tubes in relation to the patient rather than in relation to the bed. The licensee will revise the instructions to nurses to provide more detailed information about the LDR remote afterloading equipment and specific verification of the sutures and the applicator position. The licensee will ensure that nurses observe the patient via the closed circuit television system. The licensee will encourage nurses to notify the RSO through the licensee's nursing management team. In the future, the licensee will instruct the patient and the patient's family about the procedure. In particular, limitation of patient movement during the overall treatment period will be emphasized. Nurses will also be instructed about the limitations of patient movement to prevent rupture of the sutures and dislodgement of the applicator.

The Region III technical assistance request dated April 17, 1996, recommended that patient intervention appeared to be the root cause of the event. The letter dated November 21, 1996, from NRC's Office of Nuclear Materials Safety and Safeguards concurred that patient intervention appeared to be the root cause of the event. Other relevant information cited included: (1) the licensee's nurses frequently monitored the location of the applicator during routine patient checks during the treatment, and (2) the resident correctly identified the dislodged applicator and temporarily discontinued the treatment until the authorized user decided to terminate the treatment and revised the written directive accordingly.

8. Effect on the Patient

The RSO's report dated March 1, 1996, indicated the maximum skin dose was 22.1 cGy and stated that this is not a medically significant dose when compared to the erythema dose of 500 to 1000 cGy. The licensee expects that no adverse radiobiological effect to the patient will occur from the dislodged applicator that contained iridium-192 seeds. On February 25, 1996, the patient was examined and no skin erythema was evident. On December 10, 1996, the RSO indicated that the patient's condition did not indicate an adverse effect from the event.

The NRC medical consultant's report dated April 23, 1996, indicated concurrence with the licensee. The combined treatments using the LDR remote afterloading units and the HDR remote afterloading unit delivered the prescribed dose in accordance with the written directives prepared by the authorized user. The lack of skin reaction was consistent with the calculated skin dose of 22.1 cGy. Essentially no side effect on the patient occurred and is not likely to occur.

9. Quality Management Program (QMP)

It appears that the objectives stated in 10 CFR 35.32(a)(1) - (4) were met in this case. On February 22, 1996, the authorized user prepared the written directive and approved the treatment plan prior to implantation of the iridium-192 seeds. On

February 24, 1996, the authorized user modified the written directive when the treatment was terminated. However, the RSO identified a violation of 10 CFR 35.32(a)(5) because the Radiation Oncology personnel did not notify the RSO upon discovery of the event as required by the licensee's written QMP dated July 22, 1994.

10 CFR 35.32(a) requires, in part, that the licensee establish and maintain a written QMP to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user. And 10 CFR 35.32(a)(5), requires that the licensee's written QMP include policies and procedures to meet the specific objective that any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken. The licensee's written QMP dated July 22, 1994, states in Section II, Item H.3, that, "Any malfunction of remote afterloading devices that has the potential for causing a misadministration, recordable event, or possible variance shall be reported to the Radiation Safety Officer upon discovery."

On February 24, 1994, the licensee's personnel discovered a malfunction of the LDR remote afterloading devices that had potential for causing a misadministration, recordable event, or variance. These individuals determined that the radiation dose to the patient's legs from the dislodged applicator was within 20% of the radiation dose that the patient's legs would have received during the normal course of treatment if the applicator was not dislodged. Based on this information, these individuals decided to report the event as an interdepartmental variance for further consideration within Radiation Oncology.

On February 26, 1996, the RSO contacted the Radiation Oncology personnel and inquired about the nature of the problem with the LDR remote afterloading unit that occurred on February 24, 1996. However, the Radiation Oncology personnel did not inform the RSO that the treatment was terminated due to the dislodged applicator. The authorized user and medical physicist indicated they were not specifically aware of the general policy statement in the written QMP that required them to notify the RSO of interdepartmental variances involving the remote afterloading units. The RSO actually learned of the dislodged applicator on February 27, 1996, when the Nurse Manager from 9 North, Orthopedic Unit requested the RSO to attend a follow up meeting about the event. As a result of this event, the licensee clarified this matter with all Radiation Oncology and Nursing personnel. The RSO immediately provided verbal instruction to the individuals involved with the event. Later, the RSO held refresher QMP training for all the physicians, medical physicists, and nurses who were involved with the event, as well as other Radiation Oncology staff who were required by the Medical Director to attend the sessions. The QMP refresher training included written examination of the attenders. This action appears to be adequate to prevent recurrence of a failure to report a similar event to the RSO as required by the licensee's written QMP.

Based on the fact that the licensee's RSO identified the violation and the remaining criteria of the NRC Enforcement Policy found in 10 CFR Part 2, Appendix C, Section VII.B.1 appeared to be satisfied, NRC exercised discretion to not cite the violation. No written reply was requested.

10. Other Areas Inspected

The medical physicist completed radiation area surveys on February 22, 1996, when the treatment was initiated and on February 24, 1996, in response to the emergency alarms at 8:10 a.m. and after the applicator was removed from the patient when the treatment was terminated at 11:00 a.m. A fully calibrated and operable survey meter was used. The recorded radiation exposure was less than 1 millirem per hour for each survey.

Radiation exposure to personnel was minimized during this event. The iridium-192 seeds were safely stored in the shielded vaults in the LDR remote afterloading units when individuals were present in the patient room. No unusual radiation exposure levels were encountered by the nurses, medical physicist, physicians, or patient family members.

No violations of NRC requirements were identified.

11. Exit Meeting

On February 29, 1996, an exit meeting was held with the licensee's representatives indicated in Section 2 of this inspection report. The inspector discussed the preliminary findings and the enforcement options. The inspector noted that the inspection would continue until the medical consultant had completed an evaluation of the medical aspects of this event. The licensee indicated that training and review sessions would be held with the nurses and Radiation Oncology personnel, the suture material would be examined for defects and inferiority. The licensee did not indicate that any proprietary information was given to the inspector.

On December 10, 1996, the inspector telephoned the RSO and explained the results of the NRC review that determined that because of patient intervention the event was not categorized as a misadministration. Also, the inspector discussed the violation of 10 CFR 35.32(a)(5) and the licensee's written QMP dated July 22, 1994, Section II, Item H.3 that required the Radiation Oncology personnel to notify the RSO upon discovery of the dislodged LDR remote afterloading applicator that contained licensed material.