U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03002474/2009002
Docket No.	03002474
License No.	29-03845-01
NMED No.	090662
Licensee:	The Valley Hospital
Address:	223 North Van Dien Avenue Ridgewood, New Jersey 07450
Location Inspected:	The Luckow Pavilion, 1 Valley Health Plaza Paramus, New Jersey
Inspection Dates:	August 13, 2009 and October 29, 2009 (telephone exit)
Additional Information:	August 21, September 3, October 9, and October 21, 2009

Inspectors:

Original Signed by: P. Lanzisera for/ ***11/19/09***

Lester Tripp — date
Health Physicist

Original Signed by: ***11/19/09***

Penny Lanzisera — date
Senior Health Physicist

Approved By:

Original Signed by: ***11/19/09***

Marc Ferdas, Chief — date
Medical Branch
Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

The Valley Hospital (Valley Hospital)
NRC Inspection Report No. 03002474/2009002

An announced, special inspection was conducted at the Valley Hospital's Luckow Pavillion in Paramus, New Jersey to review the circumstances surrounding a medical event (NRC Event Notification 45250) that was reported to the NRC on August 11, 2009. The medical event involved a permanent prostate implant performed on July 29, 2009, using cesium-131 brachytherapy sources. On August 11, 2009, the patient had a CT scan with intravenous contrast and the images demonstrated that the seeds were implanted into soft tissue 4 to 5 centimeters inferior to the prostate. Post-implant dosimetry calculations performed using the CT data indicated that none of the prostate received the prescribed dose of 6500 centigray. The D90 value (minimum dose received by 90% of the prostate volume) was 300 centigray or approximately 5% of the prescribed dose. Based on this assessment, the licensee reported a medical event. The patient was immediately advised by the physician and elected to receive follow-up linear accelerator treatment (tomotherapy). The licensee subsequently calculated that an unintended volume of 30.1 ml of soft tissue received 100% of the prescribed prostate dose of 6500 centigray.

An NRC medical consultant concluded that "since the prostate dose is being boosted to appropriate level with tomotherapy, the eventual tumor control is not expected to be compromised." The medical consultant also stated that, due to irradiation of unintended tissue, the "higher dose to the penile bulb compared to a properly administered implant …can increase the risk of soft tissue fibrosis or increase the risk of impotency compared to a properly administered implant."

Based on the results of this inspection, no violations of NRC requirements were identified.

REPORT DETAILS

I. Event Details

a. **Inspection Scope**

This inspection was limited to review of the circumstances surrounding the prostate implant medical event (NRC Event Notification 45250) that occurred on July 29, 2009 at Valley Hospital's Luckow Pavillion in Paramus, New Jersey. The inspection consisted of observations by the inspectors, interviews with the authorized user (AU) radiation oncologist and medical physicists who were present during the implant operative procedure, and a review of records describing the event and follow-up actions planned by the licensee. The inspectors also reviewed a sampling of prostate implant records from additional patients.

b. **Observations and Findings**

Prostate Implant Program

The licensee began its manual brachytherapy prostate implant program in 1987. The licensee performs approximately 60 to 70 permanent prostate implants per year. Cesium-131 has been used for the last 2 to 5 years. At the time of this inspection, the licensee had performed 35 prostate implants in 2009. To determine if a patient is a candidate for brachytherapy, the urologist performs a CT based volumetric study 3 to 5 weeks prior to a brachytherapy implant procedure. If brachytherapy is selected for treatment, the CT based volumetric study data is imported into the licensee's treatment planning system (ADAC Pinnacle), and the medical physicist and the AU develop a predetermined computerized treatment plan (pre-plan) for the implant procedure that designates the intended seed placement within the prostate. The volume data derived from the CT images are also used to determine the number and activity of seeds to order from an authorized vendor. On the day of the implant, ultrasound imaging is used to visualize the implantation of seeds into the prostate in accordance with the pre-plan. These real-time images may also be used to modify the pre-plan during the operative procedure. Any discrepancies in the images are reviewed by both the AU and the urologist prior to the implant. In accordance with the licensee's implant procedures, approximately one week after the implant, the patient returns for a CT scan to confirm, in part, seed placement. Post-implant dosimetry calculations are performed by the medical physicist using the data from these CT images and a D90 value (minimum dose received by 90% of the prostate volume) is calculated. The licensee's AU reviews the dosimetry information using an acceptance criterion of a D90 greater than 80%.

Event Chronology

June 11 — The referring urologist performed the CT based volumetric study, marked the outline of the prostate, and saved the images to a disk which was sent to the AU.

June 12 — Using the volumetric study, the medical physicist completed the pre-plan with an intended dose of 6500 centigray, which was checked and approved by the AU. The medical physicist then placed the order for cesium-131 sources.

July 29 — The medical physicist compared the activity of sources received with the pre-plan and confirmed that it matched the intended activity. The patient

was taken to the operating room. The urologist and AU inserted the ultrasound probe and attempted to identify the prostate tissue. The patient's unusual anatomy and obesity made identification of the prostate difficult. The urologist and AU removed the ultrasound probe two times and re-inserted it attempting to appropriately visualize the prostate. The urologist and AU agreed on the positioning during the third attempt. The urologist inserted the 12 needles used in the implant and the urologist and AU verified the placement of the needles. The AU implanted the seeds with a Mick applicator using the treatment pre-plan as a guide to the placement of the seeds. 46 cesium-131 seeds were implanted.

August 6 The patient returned for a post-implant CT scan, which was performed without intravenous contrast. The scan suggested that the array of sources may have been improperly placed inferior to the intended position; however the image quality was insufficient to provide definitive information.

August 7 The AU notified the referring physician that a possible medical event had occurred. The patient was scheduled for a CT scan with contrast to provide a definitive evaluation of source placement.

The licensee notified the NRC Headquarters Operation Center that a possible medical event had occurred (NRC Event Notification 45250) and that the patient was scheduled for a follow-up CT scan to verify.

August 11 The patient returned for his post-implant CT scan with intravenous contrast. Evaluation of the scan confirmed that the array of sources was displaced 4-5 centimeters inferior to the intended position. Post-implant dosimetry calculations provided by the licensee showed that none of the prostate received the prescribed dose of 6500 centigray and the D90 value (minimum dose received by 90% of the prostate volume) was 300 centigray, or about 5% of the prescribed dose. Upon review of this information, licensee personnel identified that a medical event had occurred.

The AU immediately informed the referring physician, and met with the patient to discuss the results of the implant. The AU informed the patient that a medical event had occurred, and discussed treatment options with him.

The licensee's medical physicist called the NRC Headquarters Operations Center to update NRC Event Notification 45250 and confirm that a medical event had occurred.

August 13 The licensee performed an evaluation of dose to unintended tissue for the patient involved in the medical event. This evaluation showed that an unintended volume of 30.1 ml of soft tissue received 100% of the prescribed prostate dose of 6500 cGy.

Notification of the Event

The licensee made a preliminary telephone report to the NRC Headquarters Operations Center on August 7, 2009, when they suspected that the sources may have been improperly positioned. On August 11, 2009, the licensee confirmed that a medical event had occurred and notified the NRC. The AU notified the patient and the urologist

(referring physician) of the medical event on August 11, 2009. The licensee also submitted a 15-day written report, which was received in Region I on August 21, 2009.

Licensee's Corrective and Preventive Actions

During the inspection conducted on August 13, 2009, and in subsequent correspondence and a telephone conversation with the licensee on August 21, September 3, October 9, and October 21, 2009, the licensee described the following corrective and preventive actions.

1. The licensee provided additional radiation treatment to the patient using a linear accelerator (tomotherapy) to ensure that the prostate received an adequate therapeutic dose.

2. The licensee conducted an audit of all prostate implant cases performed in 2009 to compare the D90 value from the post-implant dosimetry calculations with the prescribed dose. This audit identified no other cases in which the D90 value was less than 80% of the prescribed dose. The licensee identified 4 cases with the D90 value greater than 120% and performed an additional assessment (on October 9, 2009) of the prescribed dose to the treatment volume. The licensee ultimately determined that 93.3% - 97.7% of seeds were placed within the treatment volume as intended and that none of the cases met the medical event reporting criteria.

3. A root cause analysis of the medical event was conducted and indicated that a possible contributing factor was failure to accurately identify the prostate due to unusual anatomy and the obesity of the patient.

4 The licensee updated their prostate implant procedures to include the following:

   i. Fluoroscopic imaging will be used if the prostate gland and surrounding associated anatomy is not readily identifiable.

   ii. An attempt will be made to consult with another urologist and/or radiation oncologist experienced with prostate implants if fluoroscopy fails to clearly identify the prostate gland and surrounding anatomy.

   iii. The prostate implant treatment will be cancelled if the prostate gland and surrounding anatomy cannot be visualized adequately.

c. **Conclusions**

The inspectors determined that:

- the licensee performed a prostate implant in which the array of sources was displaced inferiorly from the intended position, resulting in a D90 (minimum dose received by 90% of the prostate volume) of 5% of the prescribed dose to the prostate, and delivery of 100% of the prescribed dose to an unintended tissue volume of 30.1 ml. The patient's unusual anatomy and obesity made it difficult for the AU and urologist to accurately identify the position of the prostate using ultrasound imaging;

- the reported event met the criteria of a reportable medical event per 10 CFR 35.3045, "Report and Notification of a Medical Event," since the dose to unintended tissue exceeded 50 rem and 50% of the dose expected from the administration

defined in the written directive and the total dose delivered to the prostate differed by more than 20% from the prescribed dose;

- the licensee's notification to the NRC, referring physician, and patient, and submission of a 15-day report were in compliance with the requirements of 10 CFR 35.3045;

- the root cause of the event was failure to accurately identify the position of the prostate due to the patient's unusual anatomy and obesity;

- when questions arose regarding localization of the prostate, the urologist and AU implemented their procedures associated with written directives to resolve any questions by any of the implant members by repeatedly re-imaging the prostate and reaching agreement on the final positioning;

- no additional medical events were identified following the inspectors' detailed review of several prostate brachytherapy implants performed in 2009 and detailed analysis of the licensee's documentation of delivered dose for all implants performed in 2009;

- the licensee's proposed updates to their prostate implant procedures appear adequate to address any future difficulty in accurate intraoperative identification of the prostate using ultrasound imaging.

No violations of NRC requirements were identified.

II. Written Directive Procedures

a. Inspection Scope

The inspectors reviewed the licensee's procedures for administrations requiring a written directive to assess compliance with 10 CFR 35.41, "Procedures for Administrations Requiring a Written Directive." The review focused on the implementation and adequacy of the licensee's prostate implant program procedures. The inspectors interviewed licensee personnel and examined records documenting the program and its implementation during the July 29, 2009 implant which resulted in a medical event.

b. Observations and Findings

10 CFR 35.41 requires, in part, that the licensee develop, implement, and maintain written procedures to provide high confidence that license material or radiation from licensed material will be administered in accordance with the written directive.

The inspectors noted that the licensee's written procedures for brachytherapy require: (i) complete written directives; (ii) verification of patient identity; (iii) verification of the treatment plan including number of sources, source activity, and treatment loading sequence; (iv) resolving any questions by team members during the implant; (v) documenting number of sources and activity implanted; and (vi) verification of dose calculations before the total dose has been administered. The inspectors confirmed that the licensee followed these procedures; and in this event when questions arose regarding visualization of the treatment site, the licensee's brachytheapy team addressed the questions prior to initiating the implant.

c. Conclusions

The inspectors concluded that the licensee consistently implemented written procedures to provide high confidence that each administration was in accordance with the written directive. On July 29, 2009, when questions arose regarding visualization of the patient's treatment site, team members addressed the questions prior to initiating the implant. The inspectors concluded that although the patient's abnormal anatomy caused the licensee to mis-identify soft tissue inferior to the prostate as prostate tissue, the licensee acted appropriately under the circumstances and in compliance with 10 CFR 35.41.

No violations of NRC requirements were identified.

III. Medical Consultant's Report

The NRC contracted a medical consultant to review this event, its effect on the patient, and the licensee's corrective actions taken to prevent recurrence of similar events. The medical consultant's report was received on September 3, 2009. The NRC's medical consultant concluded that "since the prostate dose is being boosted to appropriate level with tomotherapy, the eventual tumor control is not expected to be compromised." The medical consultant further stated that, due to irradiation of unintended tissue, the "higher dose to the penile bulb compared to a properly administered implant …can increase the risk of soft tissue fibrosis or increase the risk of impotency compared to a properly administered implant." The medical consultant agreed with the licensee's corrective and preventive actions.

IV. Exit Meeting

A preliminary exit meeting was conducted on August 13, 2009 to discuss the scope of the inspection and the inspectors' initial observations. On October 29, 2009, an exit meeting was held by telephone with Ms. Nancy Librera, Assistant Vice President for Oncology, and other members of her staff, to discuss the results of this inspection.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

+Nancy Librera, Assistant Vice President for Oncology
+*Michael Wesson, M.D., Authorized User Radiation Oncologist
+*Chad DeYoung, M.D., Authorized User Radiation Oncologist
Chih-Ming Lo, Medical Physicist
+*Ki-Cheun Chak, Ph.D., Medical Physicist
*Kim Marie Robles, Director, QA/QI and Regulatory Compliance
*Linda Malkin, Director of Risk Management
*Patricia Caputo, Director, Radiation Oncology
Philip Sorabella, M.D., Authorized User Radiologist and Radiation Safety Officer

* Present at preliminary exit meeting on August 13, 2009
+ Participated in telephonic exit meeting conducted on October 29, 2009