U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03013060/2009001
Docket No.	03013060
License No.	07-17618-01
NMED No.	090597
Licensee:	Nanticoke Memorial Hospital
Address:	801 Middleford Road, Seaford, Delaware 19973
Location Inspected:	Same as above
Inspection Date:	July 21, 2009 and January 6, 2010 (telephone exit)
Additional Information:	July 29, November 2, and December 23, 2009

Inspectors:

/RA/ ***01/06/10***

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EXECUTIVE SUMMARY

Nanticoke Memorial Hospital
NRC Inspection Report No. 03013060/2009001

An announced, special inspection was conducted at Nanticoke Memorial Hospital in Seaford, Delaware to review the circumstances surrounding a medical event that was reported (Event Notification 45206) to the NRC on July 15, 2009. The event notification involved a permanent prostate implant performed on March 5, 2009, using Iodine-125 brachytherapy sources. Immediately following the implant, the urologist performed a cystoscopy and removed 22 of the 61 implanted seeds from the bladder and the patient was advised by the authorized user (AU) that a second implant may be necessary to achieve the prescribed dose. On April 4, 2009, the patient returned to the hospital for a post-implant computed technology (CT) scan. The CT images were reviewed June 17, 2009, when the medical physicist completed the post-implant dosimetry. The AU was informed of the possible medical event on June 26, 2009, when the medical physicist presented the post-implant dosimetry for the AU's final approval. The images demonstrated that 32 seeds were displaced superiorly to the prostate, leaving 7 seeds implanted in the prostate and the post-implant dosimetry calculations indicated the D90 value (minimum dose received by 90% of the prostate volume) was 26.7 Gray (Gy) or approximately 18% of the prescribed dose. In addition, dose to unintended tissue exceeded 50 rem and 50% of the dose expected from the administration defined in the written directive. The licensee reported that the patient was scheduled for additional radiation therapy treatment at another facility.

An NRC medical consultant concluded that "the prostate did not receive the intended therapeutic dose from the brachytherapy procedure, however, since the prostate dose is being boosted to appropriate levels with a second brachytherapy procedure, the tumor control is not expected to be compromised." The medical consultant also stated that "… the extra dose to the seminal vesicles is unlikely to cause medical problems."

Based on the results of this inspection, one apparent violation of NRC regulations was identified. Specifically, following a review of the available post-implant data by the AU and the medical physicist on June 26, 2009, the licensee did not report to the NRC by the next calendar day that a medical event had occurred on March 5, 2009, per the requirements in 10 CFR 35.3045.

REPORT DETAILS

I. Event Details

a. Inspection Scope

The inspectors reviewed the circumstances surrounding a March 5, 2009, prostate implant, which resulted in a medical event (Event Notification 45206) at Nanticoke Memorial Hospital (Seaford, Delaware). The event was reported to the NRC Operations Center on July 15, 2009. The inspectors conducted interviews with the authorized user (AU) radiation oncologist and the medical physicist who were present during the implant operative procedure and reviewed records describing the event and the licensee's planned corrective actions. The inspectors also reviewed the records for all prostate implant cases performed since December 8, 2008, (7 additional patients).

b. Observations and Findings

Prostate Implant Program

The licensee has performed a total of 9 permanent prostate implants since the programs inception in 2008. To determine if a patient is a candidate for brachytherapy, the urologist performs an ultrasound (US) based volumetric study 3 to 5 weeks prior to a brachytherapy implant procedure. If brachytherapy is selected for treatment, the US data is imported into the licensee's treatment planning system and the medical physicist and the AU develop a treatment plan, based on the AU's written directive that designates the intended seed placement within the prostate. The volume data derived from the US images are also used to determine the number and activity of seeds to order from an authorized vendor. On the day of the implant, US imaging is used to visualize the implantation of seeds into the prostate in accordance with the treatment plan. Approximately one month after the implant, the patient returns for a computed tomography (CT) scan to confirm, in part, seed placement. Post-implant dosimetry calculations are performed using the data from these CT images and a D90 value (minimum dose received by 90% of the prostate volume) is calculated.

Event Chronology

2/19/09 A pre-implant US volume study was performed by the urologist (referring physician). Using the images from the US, the AU outlined the target volume and informed the medical physicist of the intended dose of 145 Gy. The medical physicist prepared the treatment plan for the AU's review and approval.

2/26/09 The medical physicist ordered 61 Iodine-125 seeds in 21 preloaded needles from Bard Brachytherapy. 57 seeds in 19 needles per the treatment plan and an additional 2 needles containing 2 seeds each.

3/4/09 The medical physicist verified the seed placement within the needles by comparing the radiograph and the treatment plan.

3/5/09 The patient was taken to the operating room and placed under general anesthesia. A transrectal biplanar US probe was used to verify the position of the prostate. Utilizing a template and the coordinates announced by the medical physicist, the urologist inserted 21 needles row by row. The AU deployed 61 seeds. Following the implant, the urologist performed a cystoscopy and removed 22 seeds and spacers from the bladder, leaving 39 implanted seeds. An x-ray was taken to determine the location of the seeds and showed that the seed pattern may have been inadequate for total coverage, particularly at the apex. Based on the x-ray image and the removal of 22 seeds from the bladder, the physicians noted that the patient may require additional treatment. The AU updated the written directive to reflect the actual number of seeds implanted, the number of seeds returned to storage, the number of needles used in the implant, and the total activity implanted. The AU also noted on the written directive that 22 seeds were removed from the bladder and 2 additional needles (4 seeds total) were used in the implant. The patient was informed by the AU, in the recovery room, that additional treatment to complete the prescription would probably be necessary.

4/4/09 The patient returned for a post-implant CT scan.

6/17/09 Prior to the medical physicist performing the preliminary post-implant dosimetry, the AU completed the contouring of the prostate. The medical physicist conducted the post-implant dosimetry pending review by the AU (who is typically scheduled to be at the facility on different days than the medical physicist). Based on the CT images, it was determined that 7 seeds were implanted in the prostate and 32 seeds were displaced superiorly from the prostate. The D90 value was calculated to be 26.7 Gy (18% of the prescribed dose).

6/26/09 The AU was informed of the possible medical event when the medical physicist presented the post-implant dosimetry for the AU's final review and approval. The AU and medical physicist discussed whether or not this constituted a medical event and whether they should inform the NRC. The AU stated that he did not believe that the seeds that were displaced superiorly to the prostate constituted a medical event.

7/14/09 The medical physicist discussed the facts of the case with his physics supervisor, at his employing organization, and was told to contact the NRC Region I office for assistance on determining whether or not this constituted a medical event.

7/15/09 The licensee's medical physicist contacted the NRC Region I office to discuss the March 5, 2009, medical procedure and was advised to call the NRC Operations Center. On July 15, 2009, the NRC Operations Center was notified (Event Notification 45206) of a possible medical event.

7/29/09 The 15 day report was received by the NRC Region I office.

Notification of the Event

On March 5, 2009, following the implant procedure, the urologist (referring physician) performed a cystoscopy and removed 36% of the total implanted seeds from the bladder. The licensee stated in their letter dated November 2, 2009, that the patient was notified of the medical event, by the radiation oncologist, in the recovery room and that the patient would likely need further radiation therapy to complete the prescribed dose. The licensee notified the NRC Operations Center on July 15, 2009, that a potential medical event had occurred on March 5, 2009. The licensee submitted a 15 day written report, which was received by the NRC on July 29, 2009. The licensee stated in the 15 day report that the possible causes of the event were: (1) seed placement error due to seeds being released at a different depth than the planned needle depth; (2) patient movement; (3) changes in equipment positioning; (4) seed migration after the procedure; or (5) reference depth identified incorrectly on the pre-plan dosimetry. After further investigation, the licensee stated in a letter dated November 2, 2009, that possible patient movement during the procedure contributed to the miscalculation in the depth measurement of the prostate from the skin surface.

Licensee's Corrective and Preventive Actions

During the inspection conducted on July 21, 2009, and in subsequent correspondence dated July 29, November 2, and December 23, 2009 the licensee described the following corrective and preventive actions:

1. The licensee reported that the patient was scheduled for additional radiation treatment at another facility.

2. The licensee stated that a different authorized user will perform prostate implants in the future.

3. The licensee:

    i. revised their policy to define the prostate volume during implantation of seeds using ultrasound which included using the sagittal view option with the trans-rectal US probe to verify the needle depth with relation to the bladder and the base of the prostate during the procedure;

    ii. developed a policy to address unexpected events that take place during prostate implant procedures, including evaluation of whether or not an NRC-defined medical event took place;

    iii. developed a policy to define a timeline between the prostate volume study and evaluation of the post-implant dosimetry; and

    iv. revised their policy for written directives to include the definition of a medical event, the conditions under which a medical event shall be reported to the NRC, and the timeframe for reporting medical events.

4. The licensee provided staff members training on the updated policies and procedures.

c. Conclusions

The licensee performed a prostate implant in which the array of sources were displaced superiorly from the intended position, resulting in a D90 value of 18% of the prescribed dose to the prostate. In addition, unintended tissue received a dose of greater than 50 rem and 50% of the dose expected from the administration defined in the written directive.

The inspectors concluded that:

1. the medical event was likely due to a miscalculation of the prostate depth in relation to the skin surface, due to possible patient movement during the procedure;

2. the event met the criteria of a reportable medical event, per 10 CFR 35.3045. The total dose delivered to the prostate differed by more than 20% from the prescribed dose and the dose to unintended tissue exceeded 50 rem and 50% of the dose expected from the administration defined in the written directive;

3. subsequent to a detailed review of the CT images and post-implant dosimetry, the licensee's AU inaccurately concluded that a medical event had not occurred, even though the data collected and reviewed indicated otherwise. Therefore, the NRC maintains that the licensee should have reported the medical event once it was identified by the licensee's staff on June 26, 2009.

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

5. no additional medical events were identified based on the inspector's audit of all prostate implant cases performed since December 8, 2008. The audit compared the D90 value from the post-implant dosimetry calculations with the prescribed dose; and

6. the licensee implemented corrective actions which addressed the root cause of the event and the apparent violation.

An apparent violation of NRC regulations was identified. Specifically, following a review of the available post-implant data by the AU and the medical physicist on June 26, 2009, the licensee did not report to the NRC by the next calendar day that a medical event had occurred on March 5, 2009, per the requirements in 10 CFR 35.3045.

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. The inspectors interviewed licensee personnel and examined records documenting the brachytherapy program and its implementation since its inception in 2008.

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 radiation from licensed material will be administered as directed by the authorized user.

To meet the objectives of 10 CFR 35.41, the licensee's procedures for brachytherapy included: (i) completion of a written directive; (ii) verification of the patient's identity; (iii) assay of a 10% sample of the seeds; (iv) verification of the treatment plan including radionuclide, prescribed dose, source activity, number of sources, treatment loading sequence, and total dose; (v) documentation of the number of sources and the activity implanted; and (vi) verification of the dose calculations before the total dose has been administered. The inspectors confirmed that the licensee followed these procedures.

c. Conclusions

No violations of NRC requirements or safety concerns 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 29, 2009.

The medical consultant concluded that "the prostate did not receive the intended therapeutic dose from the brachytherapy procedure. However, since the prostate dose is being boosted to appropriate levels with a second brachytherapy procedure, the tumor control is not expected to be compromised." The medical consultant also stated that … the extra dose to the seminal vesicles is unlikely to cause medical problems.

The medical consultant agreed with the licenses's description of the possible causes of the event (i.e. patient movement during the procedure, changes in the equipment positioning, or misidentification of the reference depth on the pre-plan dosimetry). However, the medical consultant did not agree that seed migration may have been the cause of this event.

IV. Exit Meeting

A preliminary exit meeting was conducted on July 21, 2009, to discuss the scope of the inspection and the inspectors' initial observations. On January 6, 2010, a telephonic exit meeting was held to discuss the inspection results with Don Tricarico, Vice President of Clinical Operations, Cancer Care Center and other members of the licensee's staff.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

Manoj Jain, M.D., Authorized User Radiation Oncologist
*+ Matthew Rajotte, Medical Physicist
+ Mary Brown, RN, Oncology Manager
* Mary Beth Waide, Director of Compliance and Risk Management
+ Don Tricarico, Vice President of Clinical Operations, Cancer Care Center
+ Vladimir Ioffe, M.D., Authorized User Radiation Oncologist

* Present at preliminary exit meeting on July 21, 2009
+ Participated in telephonic exit meeting conducted on January 6, 2010