U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

EA No.	EA-09-212
Inspection No.	03002443/2009001
Docket No.	03002443
License No.	29-01862-02
Licensee:	Virtua Health System-West Jersey Hospital
Address:	101 Carnie Boulevard, Voorhees, New Jersey
Other Locations Inspected:	106 Carnie Blvd., Suite A, Voorhees, New Jersey, and 906 Brick Road, Marlton, New Jersey
Routine Inspection Date:	May 15, 2009
Special Inspection Dates:	March 20, May 18-19, and August 5, 2009
Date Followup Information Received:	March 25, April 3, 20, May 15, 18, and August 5, 2009

Inspectors: ____/RA/_____ ____9/1/09____
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Health Physicist

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Medical Branch
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EXECUTIVE SUMMARY

Virtua Health System-West Jersey Hospital
NRC Inspection Report No. 03002443/2009001

An announced, special inspection was conducted on March 20, 2009 at Virtua Health System – West New Jersey Hospital (Virtua). The special inspection reviewed the circumstances surrounding a medical event that was identified by Virtua during post-implant dosimetry calculations conducted on March 19, 2009, and reported to the NRC on the same day (see Sections II and III). The medical event involved a permanent prostate implant performed on January 19, 2009, using 93 Iodine-125 (I-125) brachytherapy sources (seeds). The accuracy of prostate visualization was in question prior to the implantation of the seeds. A post-implant CT scan showed that all of the I-125 seeds were implanted outside of the intended target. This constitutes a medical event. In-office review of the licensee's evaluation of the event and corrective actions continued on May 18-19, 2009. During the review, the inspectors identified two additional possible medical events and requested further licensee evaluation. On August 5, 2009, the licensee completed their evaluation and determined that the cases did not meet the criteria for reportable medical events. Region I concurred with the evaluation and notified the licensee on August 27, 2009.

The event was evaluated by an NRC medical consultant. The consultant concluded that the prostate did not receive sufficient dose to effectively treat the patient's cancer. The prostate received approximately 10 Gray (Gy) instead of the planned 145 Gy. The consultant agreed with the licensee's conclusion that the probability of other long-lasting negative health effects to the patient is low.

Within the scope of this special inspection, one violation of NRC regulations was identified. The licensee's written procedures failed to provide high confidence that each administration is in accordance with the written directive, as required by 10 CFR 35.41(a)(2). Specifically, the licensee's procedures for permanent prostate implants did not include actions to provide high confidence of the position of the prostate prior to seed implantation.

In addition, a routine inspection was conducted on May 15, 2009. No violations were identified during the routine inspection.

REPORT DETAILS

I. Organization and Scope of the Program

a. Inspection Scope

The scope of the licensee's activities were reviewed during both the special inspection conducted on March 20, May 18-19, and August 5, 2009 and during the routine inspection conducted on May 15, 2009. The special inspection was limited to a review of the circumstances surrounding the reported permanent prostate implant medical event that occurred on January 19, 2009 and consisted of a review of the patient records and interviews with staff, including the authorized medical physicist (AMP) and the authorized user (AU) (see Sections II and III). The routine inspection consisted of tours of the facilities, observations of day-to-day operations, a review of records, and interviews with staff members.

b. Observations and Findings from the Routine Inspection

The licensee has three hospital campuses located in Voorhees, Berlin, and Marlton, New Jersey. The inspectors toured the facilities located in Marlton and Voorhees, New Jersey. The Voorhees campus provides both diagnostic and therapeutic nuclear medicine. The facility has three cameras and one treadmill. There are three full time technologists and one student. The inspectors observed the technologists prepare and administer unit doses of Technetium-99m to patients. The inspectors determined from interviews with the staff that approximately 15 diagnostic studies are performed daily. The majority of the studies performed are cardiac stress tests. Technetium-99m (unit doses and bulk) are assayed in a dose calibrator prior to administration. The inspectors reviewed the written directives and determined that Iodine-131 is used for whole body scans and hyperthyroid treatments. Approximately 32 Iodine-131 therapy cases were performed in 2008. The inspectors noted that phosphorus-32 is used a few times a year.

The Marlton campus nuclear medicine department has three cameras and one treadmill. The nuclear medicine staff consist of three technologists and one student. The inspectors observed one technologist perform a mock demonstration of receipt of packages and contamination surveys. The inspectors interviewed the technologists to gain knowledge of the scope of the nuclear medicine program. The inspectors determined that approximately eight to ten diagnostics studies are performed per day. The majority of the studies performed are cardiac stress-tests, HIDA's, and lung scans. The inspectors noted that no therapies involving Iodine-131 are performed at this location.

The inspectors also reviewed the following records while onsite: dosimetry reports, calibration record, incident reports, program audits, and radiation safety committee meeting minutes. The inspectors noted that the licensee is licensed for Bexxar and SIR-Spheres; however the licensee has not performed any procedures involving these materials.

c. Conclusions

The inspectors concluded that the licensee's current program was organized and operating within the bounds of the limited medical license. No violations or safety concerns were identified during the safety inspection.

II. Medical Event

a. Inspection Scope

The special inspection conducted on March 20, May 18-19, and August 5, 2009, was limited to a review of the circumstances surrounding the reported permanent prostate implant medical event that occurred on January 19, 2009. The inspection consisted of a review of the patient records and interviews with staff, including the AMP and the AU.

b. Observations and Findings from the Special Inspection

The inspectors interviewed the AMP and determined that prostate implants are performed at the Marlton location only. The inspectors noted that approximately two or three prostate implants, using either I-125 or Paladium-103 seeds, are performed each month. The licensee's implant process begins with the urologist performing the ultrasound volumetric analysis several weeks prior to the implant procedure followed by development of a treatment plan, which is then approved by the AU. The seeds are ordered through a commercial vendor 2-3 days prior to the implant procedure, and upon arrival are stored in the hot lab. The AMP transports the seeds from the hot lab to the operating room on the day of the prostate implant procedure. During the implant procedure, ultrasound is used to image the patient's anatomy while pre-sterilized needles are inserted into the patient. Typically, the patient is released from the hospital shortly after the procedure and returns approximately one month later for a post-implant CT scan. The AU reviews the post-implant CT scan after which the AMP performs the dosimetry calculations based on the post-implant CT scan images.

Event Chronology

September 8 In preparation for a low-dose permanent prostate brachytherapy procedure, a male patient underwent ultrasonic volume analysis with no concerns noted by the urologist. The ultrasound images were provided to the radiation oncologist AU.

October 6 A pre-operative treatment plan was created by the AMP and approved by the AU.

October 23 The implant was scheduled. Due to a recurring bladder infection, the patient was rescheduled for January 19, 2009. The urologist and AU decided to use the September 8, 2008, ultrasonic volume analysis and October 6, 2008, treatment plan for the January 19, 2009, treatment. The plan called for the implantation of 93, I-125 seeds via 32 needles.

January 19 The patient reported to the hospital and was cleared for surgery. The patient was anesthetized. The AMP, who is also the RSO, normally transports the hot needles pre-loaded with the I-125 seeds to the operating room; however, due to a scheduling change, he did not report directly to the operating room. After making several phone calls and pages to contact the AMP, the AU and the urologist decided it was medically necessary to move forward with the procedure since the patient was already under anesthesia. The AU left the operating room to retrieve the pre-loaded needles from the hot lab and the urologist began prepping the patient by placing the ultrasound probe and confirming the position of the prostate gland. The AU returned to the operating room and began to prepare the pre-loaded needles for implant. The AU did not witness the positioning of the prostate gland on ultrasound by the urologist. The AU also did not observe the urologist adjust the needle template to match the pre-plan ultrasound images.

The urologist began to insert the cold needles that would be used for insertion of the pre-loaded hot needles. By the time the AMP arrived, three cold needles had already been inserted into the patient by the urologist. Two more cold needles were inserted to complete the row, and the ultrasound display was switched to visualize the base of the prostate gland, which is used as the reference point for the retraction distance of each needle. At this point, the AMP placed a digital marker at the location of the prostatic base as identified by the urologist. The AMP questioned the position of the base of the prostate gland identified by the urologist and stated that he could not visualize it; however, he placed the marker as directed by the urologist. According to the licensee's written report, the AU may have also questioned the exact location of the prostatic base at this time. The pre-loaded hot needles were all advanced to what was believed to be the planned location and the seeds were discharged by the AU.

February 20 Due to a miscommunication between the patient and the licensee, the patient went to a private radiology office for a follow-up CT scan instead of to the hospital (licensee). The scan was read by a diagnostic radiologist from the private radiology office. The radiologist identified mispositioning of the sources and stated that "the seeds are not within the prostate gland." The licensee's urologist was notified immediately. The licensee's urologist did not recognize the need to inform anyone else, since the patient was scheduled for follow-up imaging by the AU within a couple of days.

February 23 The patient returned to the licensee's facility for a post-implant CT scan. The AU reviewed the CT scan on that same day and identified mispositioning of the sources, but believed that some of the sources were implanted into the prostate. He concluded that "some additional external radiation beam treatment would likely be necessary" and notified the patient to this effect. He did not conclude that the implant was fully displaced from the intended position. Discussions with the AU confirmed

that he assessed the significance of the implant error clinically and did not focus on whether a reportable medical event occurred.

March 19 The AMP performed the post-implant dosimetry calculations based on the post-implant CT scan. He determined that no I-125 sealed sources were in the prostate and the implant was fully displaced from the intended position. As a result, none of the prostate received the target dose of 145 Gy. The AMP recognized that a reportable medical event had occurred and immediately made the report to the NRC Operations Center.

March 20 In response to a request from the NRC, the licensee began an audit of recent prostate implant cases to determine whether the event was an isolated occurrence.

April 23 In response to a request from the NRC, the licensee re-reviewed two cases conducted in April and October 2008 in which estimated doses varied by more than 20 percent from that prescribed.

August 5 The licensee concluded that in using "the activity based definition of a medical event," neither case met the criteria to be reported as medical events and the NRC inspectors reviewed and concurred with the licensee's assessment.

Notification of the Event

Although the event occurred January 19, 2009, the licensee did not identify that a reportable event had occurred until March 19, 2009. The NRC Operations Center was notified by the licensee on the same day of the identification. The RSO/AMP who identified the medical event notified the AU and licensee senior management. The AU notified the urologist and the patient. The licensee also submitted a 15-day written report, which was received in Region I on April 3, 2009.

Corrective Actions

The licensee updated their existing manual brachytherapy policies and procedures. The licensee has implemented the following corrective actions:

1) All members of the implant team (AU, AMP, and urologist) shall be present before the patient is brought to the operating room and placed under anesthesia.

2) The AMP will be included in the pre-implantation ultrasound.

3) The Policy and Procedure for positioning and visualizing the target anatomy was updated to include the following changes:
   - AU shall consult with the urologist before needle insertion.
   - Both physicians must agree on the positioning and the visualizing of the target anatomy.
   - Any objection by an implant team member is cause for review.

- The implant must be stopped if there are any image questions.

4) Post-operation CT Scan abnormalities or misplacement of seeds shall be immediately reported to the RSO.

5) All members of the implant team have reviewed NRC and State radioisotope regulations which included a review of the definition of a medical event and the reporting requirements.

c. Conclusions

Through interviews of the staff members, reviewing the additional information submitted by the licensee, and reviewing of the consultant's report, the inspectors concluded the following:

1. The licensee performed a prostate implant that resulted in the prostate receiving only 10 Gy instead of the planned 145 Gy. One hundred percent of the seeds were implanted outside of the prostate.

2. The AU did not consider nor understand the NRC's reporting requirements and thus failed to consider that the mispositioned implant shown on the February 23rd CT images constituted a reportable medical event.

3. The root cause of the event was due to failure of the implant team to adequately visualize and identify the target organ prior to placement of the implant needles, causing the radioactive sources to be implanted outside of the target volume. This was an isolated event.

4. The licensee's corrective actions address the cause of the medical event and appear to be adequate to prevent recurrence.

III. Medical Consultant's Report

The NRC contracted a medical consultant to review this event and its effect on the patient. The medical consultant's report was received on April 20, 2009. The consultant concluded that, other than the patient's prostate cancer, the probability of long-lasting negative health effects is low. The licensee planned additional treatment for the patient's prostate cancer.

IV. Exit Meetings

Preliminary exit meetings were conducted on March 20, 2009, to discuss the purpose of the special inspection, the inspectors' initial observations, and additional information needed; and on May 19, 2009 to discuss the results of the routine inspection, the medical consultant's report, the corrective actions implemented by the licensee, and the apparent violation of 10 CFR 35.41(a). The final exit meeting was conducted on August 26, 2009.

PARTIAL LIST OF PERSONS CONTACTED

Licensee
*#+Debra Grigiani, Nuclear Medicine Manager
Ruth Dougherty, Risk Manager
*#+Daniel Januseski, RSO/AMP
* +Barry Graf, Vice President of Operations

NRC
*+Michelle Simmons, Health Physicist
*#Sandra Gabriel, Ph.D., Senior Health Physicist
+Pamela Henderson, Chief Health Physicist

Medical Consultant

Subir Nag, M.D.

* Attended the preliminary exit meeting for the special inspection on March 20, 2009
# Participated (by telephone) in exit meeting for the routine inspection on May 19, 2009
+ Attended the final exit meeting on August 26, 2009