U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03001303/2010001
Docket No.	03001303
License No.	07-12153-02
Licensee:	Christiana Care Health Services
Location:	Newark, Delaware
Inspection Dates:	March 1 and 3, 2010; April 1, 2010; July 12 2010 (exit meeting)
Dates of Follow-up Information:	March 10, April 1, May 19, May 20, June 1, July 1, and July 12, 2010

Inspectors: _/RA by Penny Lanzisera For/_____ __7/13/10_____
Lester Tripp date
Health Physicist
Medical Branch
Division of Nuclear Materials Safety

__/RA/_____ _____7/13/10_____
Penny Lanzisera date
Senior Health Physicist
Medical Branch
Division of Nuclear Materials Safety

Approved By: ___/RA/_____ _____7/13/10_____
Marc S. Ferdas, Chief date
Medical Branch
Division of Nuclear Materials Safety

Document Name: C:\FileNET\ML101950062.doc

EXECUTIVE SUMMARY

Christiana Care Health Services
NRC Inspection Report No. 03001303/2010001

An announced, reactive inspection was conducted on March 1 and 3, and April 1, 2010 at Christiana Care Health Services (Christiana) in Newark, Delaware to review the circumstances surrounding a medical event (NRC Event Notification 45721) that was reported on February 24, 2010. An in-office review to evaluate the event, the NRC's Medical Consultant's report, and Christiana's corrective actions continued through July 12. The medical event was identified by Christiana during medical follow-up of a patient who received ten high dose-rate remote after-loading device (HDR) treatments between January 18 and 22, 2010. The Authorized User (AU) intended to deliver a total prescribed dose of 3400 centigray (cGy) over a five day period to the patient's left breast using a Mammosite multi-lumen catheter. On Feb 22, 2010, in follow-up with the patient's surgeon, the patient complained about skin reddening and tenderness on the external left breast, distal to the Mammosite catheter insertion site.

Christiana performed an evaluation of the treatment and determined that an incorrect measurement made during patient simulation resulted in placement of the radioactive source 10 centimeters (100 mm) proximal to the intended position, thereby delivering the prescribed dose to a portion of unintended skin area and underlying breast tissue. Based on their evaluation, Christiana concluded that: (i) an average dose of 1700 cGy was delivered to approximately 100 cubic centimeters (cc) of unintended breast tissue; (ii) 7.5 cc of skin and underlying tissue received a dose of 6800 cGy; and (iii) 35 cc of intended breast tissue received an average dose of 340 cGy (10% of the total prescribed dose). Christiana's root cause analysis concluded that the "absence of an established quality assurance process for checking the measuring device (source position simulator) led to the unknown malfunctioning of the measurement tool; this increased the likelihood of inaccurate measurements which resulted in the patient receiving the radiation dose to the unintended area." The inspectors also identified an additional contributing factor related to Christiana personnel not fully resolving questions that arose regarding treatment parameters during patient simulation.

The medical event was evaluated by an NRC medical consultant. In the medical consultant's report dated May 19, 2010, the consultant noted that the patient experienced acute/sub-acute radiodermatitis and could experience fat necrosis, a "clinically insignificant complication." The consultant also concluded that the dose delivered to a portion of the unintended area may not heal from the acute radiodermatitis and there is a significant risk that local tumor recurrence could occur if additional intervention is not performed, due to the inadequate treatment of the intended breast tissue.

Based on the results of this inspection, one apparent violation of NRC requirements was identified. 10 CFR 35.41(a)(2) requires that for any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. Christiana did not develop and maintain written procedures to provide high confidence that each administration was in accordance with the written directive. Specifically, Christiana's written procedures for HDR treatments did not: (i) require a quality assurance process to test and evaluate proper functioning of all measurement tools used to determine treatment parameters (e.g., the source positioning simulator tool); and (ii) did not specify how hospital personnel should respond when unknown and questionable treatment distances were encountered during HDR simulation measurements. These procedural inadequacies resulted in a medical event, because Christiana did not identify that the measurement tool was functioning improperly and did not identify that an incorrect measurement distance was accepted for a patient treatment conducted between January 18 and January 22, 2010.

REPORT DETAILS

I. Event Description

a. Inspection Scope

An announced, reactive inspection was conducted on March 1, March 3, and April 1, 2010 at Christiana Care Health Services (Christiana) in Newark, Delaware to review the circumstances surrounding a medical event (NRC Event Notification 45721) that was reported on February 24, 2010. An in-office review to evaluate the event, the NRC's Medical Consultant's report, and Christiana's corrective actions continued through July 12, 2010. The medical event was identified by Christiana during medical follow-up of a patient who received ten high dose-rate (HDR) remote after-loading device treatments between January 18 and 22, 2010. The inspectors conducted interviews with the HDR manufacturer's service engineer and Christiana personnel (including the authorized user (AU) and authorized medical physicist (AMP) involved in the event). The inspectors toured the facility and observed re-enactments of the event performed by Christiana personnel and the manufacturer's service engineer. The inspectors also reviewed documents and procedures related to HDR use and the HDR source position simulator (SPS) measurement tool.

b. Observations and Findings

High Dose Rate Remote Afterloader Program

License No. 07-12153-02 authorizes Christiana Health Service to provide HDR services using a Nucletron Corporation HDR remote after-loader unit at its facility in Newark Delaware. The licensee began its HDR Program in 2003. Christiana treats approximately 10 patients per month. Christiana has several AUs and AMPs approved to use the HDR, however, in general, two AUs and two AMPs conduct HDR treatments. The majority of the HDR treatments are breast treatments which utilized Mammosite single lumen catheters and Savi multilumen catheters. A Mammosite multi-lumen catheter was used for the first time during the treatment involved in the reported medical event. Christiana indicated that they have no future plans to use the Mammosite multi-lumen catheter.

Event Chronology

In December 2009, the vendor provided training to Christiana personnel on the use of the Mammosite multi-lumen catheter. The AMP stated that during the training he had measured a catheter distance of 1252 mm. AUs did not participate in the vendor training.

On January 14, 2010, the patient was brought to the HDR suite for CT simulation and SPS measurements for the Mammosite multi-lumen catheter that had been implanted in the patient. Following the CT scan of the left breast, the AMP performed measurements using the SPS measurement tool. The SPS contains a dummy source wire that

simulates the exact length of the actual live source wire in the HDR unit. While the dummy cable was being fed, the AMP felt resistance at 1152 millimeters (mm), which he recorded as the distance to the tip of the catheter lumen. He then repeated the same measurement for the other three catheter lumens and found that the distance of resistances were all at 1152 mm. The SPS was used to measure the treatment distance to the tip of each lumen of the catheter. To perform this measurement, an HDR source transfer tube was connected to the distal end of each catheter and the dummy source wire was fed through the SPS until it could go no further with constant and moderate pressure, indicating the tip of the catheter has been reached

During interviews with the inspectors, the AMP indicated that he expressed concerns about the treatment distances he had measured to representatives from the manufacturer of the Mammosite multi-lumen catheter, who were present to proctor the case because it was the first application of this type of catheter at Christiana. In addition, the AMP stated that he did not have his original training measurements available for comparison. The Christiana AMP stated that the manufacture representative told him that his measured distance appeared appropriate and he therefore assumed he was correct and proceeded without further verification, and entered the measured values into the treatment planning computer. The AMP did not discuss his concerns about the treatment distance with the AU or any other Christiana personnel. The treatment plan was generated and following approval by the AU, was sent to the treatment console for treatment execution.

The patient returned for their first treatment on January 18, 2010. The patient was scheduled to be treated twice a day for five days. The patient finished their final treatment on January 22, 2010. It was noted by the AMP that there were no warnings or error messages from the treatment console and the treatments were delivered as planned.

On February 22, 2010, during a follow-up examination with the breast surgeon, the patient complained about skin reddening on the external breast, distal to the Mammosite catheter insertion site. The AMP involved in the treatment planning process was notified. The AMP performed an evaluation of the treatment, and subsequently identified that an incorrect measurement caused the placement of the radioactive source 10 cm (100 mm) proximal to the intended position.

Between February 23 and 24, 2010, Christiana personnel performed a dosimetric assessment based on the incorrect treatment distance and concluded that: (i) an average dose of 1700 cGy was delivered to approximately 100 cc of unintended breast tissue; (ii) 7.5 cc of unintended skin and underlying tissue received a dose of 6800 cGy (possibly the area of skin reaction); and (iii) 35 cc of intended breast tissue received an average dose of 340 cGy (10% of the total prescribed dose). Based on this review, Christiana contacted the NRC Headquarters Operations Center on February 24, 2010, to report that a medical event had occurred.

On February 25, 2010, the patient received clinical follow-up and the AU noted cellulitis at the incision site. The AU noted that the patient had been prescribed antibiotics and a topical steroid by the patient's surgeon. The AU prescribed a topical burn ointment to

speed skin recovery. The AU notified the referring physician, the patient, and the patient's spouse of the event.

On-Site Inspection

On March 1, 2010, an on-site inspection was initiated by the NRC. During the inspection, the AMP demonstrated the use of the SPS with three different catheter types connected to a transfer tube. The inspectors noted that the SPS dummy source wire indicated resistance at 1152 mm in all three catheter types even though the expected measurement for each different catheter type was 1202 mm, 1252 mm, and 1302 mm, respectively. The inspectors also noted that the SPS appeared to be damaged. The AMP indicated that he had dropped the device sometime between December 2009 and January 2010 and that the device's calibration was not checked after the device was dropped. The inspectors noted that the correct measurements for the commonly used Mammosite single-lumen catheter and Savi multi-lumen catheter were well known by Christiana personnel and confirmed that this was the first use of the Mammosite multi-lumen catheter. Christiana personnel indicated that no additional inaccurate measurements had been identified for patient treatments. Christiana personnel also stated that a new SPS had been ordered.

The on-site inspection was continued on March 3, 2010, after Christiana received a new SPS and new source transfer tube. The inspectors observed the comparison made between the newly delivered SPS/new source transfer tube and the old SPS/old source transfer tube in use at the time of the medical event. The new SPS connected to the new transfer tube functioned well. The comparisons were made with both the multi-lumen Mammosite and Savi catheters, with no concerns noted. Additionally, the inspectors noted that the manufacturer's service report dated March 31, 2010, stated that the SPS should be inspected more frequently for proper functioning. At the time of the medical event, Christiana did not have a quality assurance procedure to assure the proper functioning of the SPS.

On April 1, 2010, an on-site follow-up visit was conducted with Christiana personnel and the manufacturer's service engineer to observe the manufacturer's evaluation of the old SPS. The service engineer examined the SPS dummy source wire and noted that there was a kink located "at the point when the cable diameter changes." The service engineer concluded that "the kink would catch on the connector at 1152 mm." The connector refers to the stainless steel part at the end of the SPS used to connect the SPS to the source transfer tube.

Notification of Event

Christiana reported the medical event to the NRC Headquarters Operations Center on February 24, 2010 (NRC Event Notification 45721). The AU notified the patient on February 25, 2010 following clinical follow-up with the patient. Christiana submitted a 15-day written report to the NRC on March 10, 2010.

Licensee's Corrective and Preventive Actions

Christiana conducted a root cause analysis of the event and concluded that the "absence of an established quality assurance process for checking the measuring device (source position simulator) led to the unknown malfunctioning of the measurement tool; this increased the likelihood of inaccurate measurements which resulted in the patient receiving the radiation dose to the unintended area."

During the on-site inspection, in subsequent correspondence from Christiana on March 10, May 20, and July 1, 2010, and in telephone conversations and electronic mail submittals dated April 1, June 1, and July 12, 2010, Christiana described the following corrective and preventive actions:

1. Christiana evaluated the effect on the patient and noted cellulitis at the incision site, which was being treated with antibiotics and a topical burn ointment. Christiana also concluded that the treatment site received approximately ten percent of the intended dose and Christiana continues to monitor the patient through follow-up visits to assess future treatment options.

2. The SPS/source transfer tube involved in the medical event and all Mammosite multi-lumen catheters were immediately removed from use.

3. A replacement SPS/source transfer tube was acquired and placed into service after it was confirmed to be functioning properly by Christiana personnel.

4. A table of Reference Source to Catheter Tip Distances was created, posted at the HDR control console, and implemented for all standard applicators.

5. The Quality Management Procedure for HDR Brachytherapy was revised to include:

    a. A double-check requirement for all patient measurements.
    b. A monthly quality assurance requirement to confirm that the SPS is functioning properly.
    c. A time-out process to ensure that all members of the treatment team agree on the specifics of the treatment, as detailed in Section II of this report.

6. All personnel involved in the HDR program were trained on use of the reference distance table; double-check requirements; monthly quality assurance revisions, and time-out process. Christiana also confirmed during the inspection that this training would be repeated periodically.

7. Christiana implemented a "New Product" committee that will review all new product plans for implementation, education, training and vendor support.

c. Conclusions

The inspectors determined the following:

1. Christiana administered a course of HDR treatment for carcinoma of the breast with an incorrectly calculated treatment distance. This resulted in a suboptimal delivery of dose to the treatment site and inadvertent delivery of dose to unintended tissue.

2. The treatment planning computer is unable to detect errors in the treatment distance, as long as the distance is within the length of the treatment delivery catheter used. Therefore, the measurement of the treatment distance is critical to determining the treatment position within the treatment catheter.

3. An inaccurate measurement was collected during source position simulation measurements with the SPS measurement tool, because a kink in the catheter caught on the connector to the source transfer tube. The inaccurate measurement was accepted by Christiana personnel and resulted in a treatment distance offset of 10 cm.

4. A new multi-lumen catheter was used for this treatment, and the measurement distance determined during initial vendor training was not referenced prior to acceptance of the inaccurate measurement. Additionally, Christiana personnel, involved in the simulation measurements, questioned the distance value measured; however, no further verification with other Christiana personnel or against initial measurements was performed.

5. The measurement tool was not included in Christiana's quality assurance program to ensure that the tool was operational. Additionally, the measurement tool appeared to have been damaged, most likely when the AMP dropped the SPS. Christiana did not evaluate the impact of the damage after it occurred or return the SPS to the manufacturer for evaluation; as was recommended by the manufacturer.

6. The event met the requirements of a reportable medical event per 10 CFR 35.3045 since the dose to unintended tissue exceeded 50 rem and 50% of the dose expected from the administration defined in the written directive and treatment plan; and the total dose delivered to the intended site differed by more than 20% of the prescribed dose.

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

8. In addition to the quality assurance testing issue identified in Christiana's root cause analysis, the inspectors concluded that the event was also attributed to a lack of procedural guidance to fully resolve questions prior to treatment.

9. The corrective actions taken by Christiana appear to be adequate to prevent inaccurate distances from being obtained and used in the treatment planning process.

No violations of NRC reporting requirements were identified. See Section II for details concerning Christiana's written directive procedures.

II. Written Directive Procedures

a. Inspection Scope

The inspectors reviewed Christiana's procedures for administrations requiring a written directive to assess compliance with 10 CFR 35.41. The review focused on the implementation and adequacy of Christiana's HDR treatment procedures. The inspectors interviewed Christiana personnel and reviewed records documenting the program and its implementation during the January 2010 treatment 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 licensed material or radiation from licensed material will be administered as directed by the AU as documented in the written directive.

The inspectors noted that Christiana's quality management procedures for HDR dated July 28, 2003 (ML032170155) required: (i) a written order for HDR treatments that is verified prior to treatment to include verification of the treatment site, the radioisotope (Ir-192), and the dose to be delivered; (ii) verification of patient identity; and (iii) training of all personnel involved in treatments which will include emergency training, encouragement to ask questions prior to continuing a procedure when there is doubt, medical events, and radiation safety.

The inspectors confirmed that the written directive components were verified by personnel prior to treatment. The inspectors also confirmed that training had been provided on the procedures to personnel involved in the medical event. However, the inspectors noted that the procedures did not specifically address how hospital personnel should respond when unexpected issues arise before or during patient treatment that might impact the delivery of patient treatment. As noted during the inspection, Christiana personnel questioned the treatment distance when using a new multi-lumen catheter, but did not verify the measurement with other Christiana staff involved in the patient treatment and did not inter-compare the distance with measurements made with the new catheter during vendor training. In addition, Christiana's procedures did not include quality assurance testing on all measurement tools used to determine treatment parameters (e.g., the SPS measurement tool) which resulted in Christiana not identifying that the SPS was functioning improperly.

On July 1, 2010, Christiana submitted revised procedures that included: (i) verification that the SPS is functional and the dummy source wire is not kinked prior to each treatment; (ii) independent verification of the each distance measured with the SPS, with the exception of the reference distance of 1500 mm; (iii) monthly quality assurance

testing of the SPS; and (iv) a time-out process to verbally confirm the correct patient, positioning, procedure, treatment site, applicator/catheter, and source transfer tubes immediately prior to patient treatment. The time-out process also included a condition that any concern expressed by any member of the treatment team could not be dismissed until resolved with 100 percent agreement among team members.

c. Conclusions

Based on the results of this inspection, one apparent violation of NRC requirements was identified. 10 CFR 35.41(a)(2) requires that for any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. Christiana did not develop and maintain written procedures to provide high confidence that each administration was in accordance with the written directive. Specifically, Christiana's written procedures for HDR treatments did not: (i) require a quality assurance process to test and evaluate proper functioning of all measurement tools used to determine treatment parameters (e.g., the source positioning simulator tool); and (ii) did not specify how hospital personnel should respond when unknown and questionable treatment distances were encountered during HDR simulation measurements. These procedural inadequacies resulted in a medical event, because Christiana did not identify that the measurement tool was functioning improperly and did not identify that an incorrect measurement distance was accepted for a patient treatment conducted between January 18 and January 22, 2010. As discussed in Section I, the licensee implemented reasonable corrective actions to address this concern.

III. Medical Consultants Report

The medical event was evaluated by an NRC medical consultant. In the medical consultant's report dated May 19, 2010, the consultant stated that the patient had experienced acute/sub-acute radiodermatitis. The medical consultant also stated that the patient could experience fat necrosis, but that fat necrosis is a "…typically self-limited and clinically insignificant complication." The consultant concluded that "…the average dose of 1700 cGy that was administered to approximately 100 cc of unintended left breast tissue is probably unlikely to result in any significant or unusual adverse effect." He also noted that approximately 7.5 cc of skin received a maximum dose of 6800 cGy and indicated there was a possibility of that volume of skin would not heal due to acute radiodermatitis and could ulcerate. The medical consultant also concluded that "…there is a significant risk that local tumor recurrence can occur if additional intervention is not performed." This information was discussed with Christiana personnel on July 12, 2010, and they indicated general agreement with the medical consultant's findings. A Christiana AU also confirmed that the patient is continuing to review treatment options with the possibility of resuming chemotherapy to address the risk of tumor recurrence and the addition of drug therapy to promote healing of the unintended skin tissue treated.

IV. Exit Meeting

A preliminary exit meeting was conducted on March 1, 2010, to discuss the scope of the inspection and the inspectors' initial observations. On July 12, 2010, an exit meeting was held by telephone with Dr. Patrick Grusenmeyer, Senior Vice President, and other members of Christiana's staff, to discuss the results of the inspection and the medical consultant's conclusions.

PARTIAL LIST OF PERSONS CONTACTED

Licensee
*+Larry Simpson, Chief, Medical Physics
*Dayee Jacob, Authorized Medical Physicist
+Joseph Solge, Radiation Safety Officer
*Carol Sirkoski, Risk Management
+Michael Sorenson, M.D, Authorized User
*Cynthia D. Griffin, Patient Safety and Accreditation
*+Patrick Grusenmeyer, Senior Vice President
+William Holden, Director, Radiation Oncology

*Present at preliminary exit on March 1, 2010
+Particpated in telephonic exit meeting on July 12, 2010