HELEN F. GRAHAM CANCER CENTER

CHRISTIANA CARE ◎ HEALTH SYSTEM

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One of only 14 cancer centers in the nation selected for the National Cancer Institute Community Cancer Centers Program.

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August 3, 2010

Marc Ferdas,
Chief, Medical Branch
Division of Nuclear Materials Safety
Region I
475 Allendale Road
King of Prussia, Pennsylvania 19406

Dear Dr. Ferdas:

This letter is a follow up to the exit teleconference held July 12, 2010 regarding the event at Christiana Care on January 22, 2010.

Brief Summary of Event & Outcome:
A 66 year old female with a diagnosis of stage one left breast cancer had a left breast lumpectomy and sentinel node biopsy. The sentinel nodes were unremarkable for malignancy. The patient elected to receive a prescription of High Dose Rate (HDR) Brachytherapy. On January 22, 2010, the patient completed (HDR) Brachytherapy to the left breast utilizing a multi lumen MammoSite catheter. Two weeks post-treatment, the patient complained of skin reaction on the left breast near the MammoSite catheter incision. A Medical Physicist reviewed the treatment and the plan used to deliver the radiation treatment and found that an incorrect measurement resulted in placement of the radioactive source ten centimeters away from the intended position, thereby delivering the prescribed dose to a portion of the unintended area. The majority of the dose was delivered in air, but a significantly high dose was delivered to a small volume of the skin distal to the connector end of the catheter which caused the skin reaction. This was the first time that this particular make and model multi-lumen catheter was used in this organization. Vendor representatives present on site during the day were asked about the measurements and they thought the measurements were correct.

Christiana Care has taken the following corrective and preventive actions:

1. Christiana Care 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 Care concluded that the treatment site received approximately ten percent of the intended dose. Christiana Care 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 Care 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 daily and 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

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 Care also confirmed during the inspection that this training would be repeated annually. New hires or reassigned staff shall receive their training before conducting clinical HDR procedures.

7. Christiana Care Department of Radiation Oncology implemented a "New Product" committee that will review all new product plans for implementation, education, training and vendor support. This process has concluded, for example, that Christiana Care will not use the Hologics' Mammosite ML, multilumen catheter for hypofractionated breast HDR treatments, but will continue to use the Savi multilumen catheter.

These actions are embodied in the attached major revision of our "HDR Quality Management Program" document.

Thank you and your team (Penny Lanzisera and Lester Tripp) for participating in sessions to review and evaluate this event.

If we can provide any further information, do not hesitate to contact me.

Best Regards,

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