Hospital	Event Number: 45721
Rep Org: CHRISTIANA CARE HEALTH SYSTEM Licensee: CHRISTIANA CARE HEALTH SYSTEM Region: 1 City: WILMINGTON State: DE County: License #: 07-1215302 Agreement: N Docket: NRC Notified By: LARRY SIMPSON HQ OPS Officer: DONG HWA PARK	Notification Date: 02/24/2010 Notification Time: 12:56 [ET] Event Date: 02/23/2010 Event Time: 11:00 [EST] Last Update Date: 02/24/2010
Emergency Class: NON EMERGENCY 10 CFR Section: 35.3045(a)(1) - DOSE <> PRESCRIBED DOSAGE	Person (Organization): WAYNE SCHMIDT (R1DO) ANGELA MCINTOSH (FSME)

Event Text

POTENTIAL MEDICAL EVENT FROM DOSAGE DELIVERED TO DIFFERENT LOCATION THAN PRESCRIBED

"[The patient] completed her prescribed 5 day, 10fx [High Dose Rate] HDR Brachytherapy to the left breast on January 22, 2010, utilizing a multi-lumen mammosite catheter device. On Feb 22, 2010, in follow-up, the patient complained about skin reddening on the external breast, outside of the mammosite catheter insertion site. The medical physicist involved in the treatment planning process was notified about the unusual finding, who upon investigating the treatment and the plan used to deliver the radiation treatment, found that an incorrect measurement resulted in placement of the radioactive source 10 cm away from the intended position, thereby delivering the prescribed dose to a portion of the unintended area. 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 could have caused the skin reaction.

"Description of circumstances that led to the event: On Thursday, January 14 at 1130, [the patient] was brought to the HDR suit for CT simulation and the needed measurements. Following the CT scan of the left breast, the physicist went in the room with the source position simulator (a dummy source wire with the exact length of the actual live source cable) to measure the treatment distance for each catheter (distance to the tip of the catheter). A transfer tube was connected to the proximal end of each catheter and dummy cable was fed through the same till it could not go any further. This point is understood as the tip of the closed end catheter. While the dummy cable was being fed, the physicist felt resistance at 115.2 cm, which he recorded as the distance to the tip of the catheter. He then repeated the same measurement for the other three catheters and found that the distance of resistance was the same. All four lumens were measured and the distances were recorded. This multi-lumen mammosite catheter was the first one to be used on a patient and therefore the physicist assumed that this is the correct distance for this device, although other devices similar to this device have different treatment distances. The physicist did not exert extra pressure on the dummy cable fearing the rupture /malfunction of the catheters.

"There were two representatives from the manufacturer present, for proctoring, as this was the first case of the multi-lumen mammosite catheter. The physicist expressed his concern about the unusual treatment distance to one of the representatives, who said that the distance sounded right.

"The measured distances were entered in the plan as the position of the first dwell position of the radiation source for each catheter. The treatment plan was generated and sent to the treatment console for storage and treatment execution that next week. The planning system cannot detect any errors in the treatment distance, as long as the distance is within the length of the closed system.

"The patient returned for her first treatment on the morning of Monday, January 18, and started

with treatments, twice a day for five days. There were no warnings or error messages from the treatment console and the treatments were delivered as planned.

"The radiation oncologist reported that the mammosite multi-lumen catheter had no unusual aspects or appearance at either insertion at surgery or at extraction after the last treatment fraction.

"Discovery of the error: Soon after the physician's follow-up meeting with the patient, Monday, February 22, 2010, the physicist was informed about the unusual skin reaction on the patient, on February 22, 2010. The physicist immediately began investigating the treatment records and the treatment plan. He then tried to measure the treatment distance on a sample mammosite multi-lumen device which the manufacturer had provided, as a test device, with the same source position simulator and encountered a similar resistance at the exact same distance. But when exerted more pressure on the source cable, it advanced further and the distance turned out to be 125.2, which was 10 cm longer than the measurement done on the patient. This observation led him to conclude that the patient did not receive the treatment at the intended area, but at 10 cm proximal to the catheter tip, which included some skin and tissue of the external breast medial to the entry point of the device where the skin reaction is. The physicist recalled similar resistance on the dummy source cable on other occasions, which leads to a possible fault with source position simulator assembly. It was also possible that the lumens were kinked at some point inside, where the housing of the lumens was bent (to facilitate wound dressing), thereby causing resistance for the advancing of the dummy source cable.

"A treatment plan was generated that night representing what happened and the following conclusions were made upon review by physics staff that next morning, February 23, 2010, regarding the treatment of the unintended tissue and skin:

"a. An average dose of 1700 cGy was delivered to approximately 100 cc of the unintended breast tissue.

"b. About 7.5 cc of the skin and underlying tissue received a high maximum dose of 6800 cGy (possibly the area of skin reaction)

"c. 35 cc of the intended breast tissue received an average dose of 340 cGy (10% of the total prescribed dose)

"Recommendations:

"1. The physicist should make a list of treatment distances for all standard applicators including partial breast treatment devices and catheters.

"2. Include a therapist or a nurse in the process of all patient measurements and have them double-check the patient measurements.

"3. Acquire a new source position simulator assembly and a set of transfer tubes.

"4. Make a second measurement of the treatment distance on all patient catheters prior to the first treatment."

A Medical Event may indicate potential problems in a medical facility's use of radioactive materials. It does not necessarily result in harm to the patient.