Missouri Baptist
MEDICAL CENTER

3015 N. Ballas Road
St. Louis, Missouri 63131

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Report and Notification of a Medical Event NRC Number 53187

Date: February 8, 2018

License Name: Missouri Baptist Medical Center

Prescribing Physician: Pawel T. Dyk

Brief Description:
On January 29, 2018, it was identified that a patient received an incorrect high dose rate (HDR) brachytherapy treatment to the left breast using the SAVI device. This lead to a higher than planned dose to the patient's skin and under-dosing of the target volume. This was the patient's first of ten planned treatments. The mistake was identified after delivery of the first fraction. The treatment delivered did not follow the written directive. The remaining nine treatments were cancelled, and the SAVI catheter removed, as ordered by the attending physician.

Why event occurred:
The error occurred during the treatment planning process. On January 26th the patient underwent CT simulation and three-dimensional treatment planning with SAVI catheter in place. During the treatment planning process, struts 2 and 6 of the SAVI device were misidentified (7 total). As a result, the orientation of the catheter as recognized by the treatment planning software (virtual orientation) did not correspond to the actual orientation of the catheter in the patient's breast (physical orientation). The final treatment plan properly directed the radiation therapy dose AWAY from the skin and towards the target volume, but because the struts were mislabeled, the actual delivered dose was directed TOWARDS the skin and away from the target volume. In consequence, the skin was over-dosed at time of treatment delivery.

The identified Root Cause for the event is the mislabeling of the SAVI catheter struts which define the orientation of the catheter in virtual space during the treatment planning process.

Effect on patient:
Intended maximum dose to skin should not exceed 425cGy in one treatment. Cumulative dose from all ten treatments to the same volume of skin should not exceed 3740cGy.

Skin defined as volume 3mm or less from the surface of the body.

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Dose to 0.03cc volume: 1899cGy
Dose to 0.1cc volume: 1542cGy
Dose to 1cc volume: 850cGy

(Note: 0.03cc and 0.1cc volumes correspond to the summed volumes of two adjacent but separate areas of skin that received the dose.)

Ninety percent of the target received 56 percent of the prescribed dose.

The patient is at increased risk of developing acute and late significant skin toxicity (erythema, desquamation, ulceration, necrosis, scarring, thickening, and retraction of skin, telangiectasia development).

No untoward tissue effects observed to the patient as of 8 days following event. Patient was seen by Dr. Dyk on Jan 30, Feb 2, and Feb 5 for a skin check. Physician will be seeing patient in close follow-up at least once per week for one month, every 2 weeks for an additional month, and then monthly for additional 4 months.

Actions taken to prevent recurrence of similar event:

- HDR Policy was changed to require the second physicist, or physician, to independently check and verify the identification of the catheter struts in the treatment planning system, February 1.
- Designed and added an HDR Plan Review checklist to include a second independent review of the HDR treatment plan, including digitization of the catheter(s)/struts.
- The HDR-Plan review was added to the departmental monthly QMP audit.
- Education to the physicists and radiation oncology physicians occurred on February 2. The documents educated to were the updated HDR policy, the HDR Plan Review check list, the QMP and the QMP audit tool. This education was completed prior to any other HDR treatments.

Certification the patient was notified:
Patient was notified of the event, and possible consequences, on January 29, at 15:00 by Dr. Dyk (same day as the event). Patient expressed understanding. A nurse and department manager were present for the discussion. The discussion of the event with the patient is documented in the Radiation Oncology Follow-up note dated January 29, 2018.

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Notification to referring physician:
Patient's oncology breast surgeon (referring physician) and medical oncologist were notified the same day of the event, January 29. The medical oncologist did see the patient on January 30 in follow-up.

A copy of this annotated report was provided to the referring physician and medical oncologist on Thursday, February 8, 2018.

Thomas J. Moenster
Radiation Safety Officer, Missouri Baptist Medical Center.