Event Detail - Abnormal Occurrence

ITEM #:	060659	**AO #:**	07-02	**AO REPORT:**	NUREG-0090, Vol. 30
TITLE:	Medical Event at St. Luke's Hospital of Kansas City, Missouri				
NAME:	St. Luke's Hospital of Kansas City				
DATE:	10/23/2006	**CITY:**	Kansas City	**STATE:**	MO

Criteria:

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report states in part, that a medical event that results in a dose that is equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, or the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site shall be considered for reporting as an AO.

Nature and Probable Consequences:

On October 27, 2006, St. Luke's Hospital of Kansas City (the licensee) notified the NRC of a medical event that occurred during a high dose-rate (HDR) remote afterloader, using a 144 GBq (3.9 Ci) iridium-1 92 source, brachytherapy procedure to treat breast cancer.

The authorized user physician developed a written directive that prescribed 10 fractionated doses, to be administered to the patient's left breast using a balloon catheter technique, with each dose consisting of 3.4 Gy (340 rad), for a total dose of 34 Gy (3,400 rad). The first fractionated dose was administered to the patient on October 23, 2006. On October 26, 2006, after the seventh fraction and prior to administering the eighth fraction to the patient, the chief physicist noted a discrepancy. The investigation into the discrepancy revealed that the catheter length entered into the treatment planning computer was 93.0 cm (36.6 in), rather than 95.0 cm (37.4 in). This error resulted in delivering an unplanned dose of 100 Gy (10,000 rad), 1.0 cm (0.4 in) from the treatment site and proximal from the balloon. The area proximal from the balloon would have received an intended dose of 24.5 Gy (2,450 rad), had the treatment been delivered as prescribed by the authorized user physician. Moreover, because the prescribed dosage was not delivered to the correct location, the patient also received an under dosage to the distal side of the balloon. Specifically, the area intended to be treated received a dose in the range of 7 Gy to 10 Gy (700 rad to 1,000 rad) rather than the prescribed dosage of 34 Gy (3,400 rad). The patient and the referring physician were informed of this event. The authorized user physician did not expect any acute adverse medical effects to the patient as a result of the medical event, but indicated that surgery may be required in the future. The authorized user physician discontinued further treatments and plans to follow-up on the patient clinically.

The NRC-contracted medical consultant expects some necrosis to fatty tissue in the overexposed region of the breast, within 2-4 months.

Cause:

The medical event was caused by the dosimetrist's failure to enter the correct catheter length in preparing the treatment plan parameters for the HDR brachytherapy treatment. In addition, the licensee's written procedures for implementing HDR treatment plans did not require verification of the treatment plan parameters to ensure that they were correct.

Licensee Action:

The licensee initiated several immediate and long-term corrective actions to prevent recurrence. Specifically, those corrective actions included (1) revising the procedures for HDR treatments to include verification of the catheter length and input to the treatment planning computer by both the medical physicist and the authorized user physician, (2) revising the treatment plan record to require that the authorized user physician and the medical physicist document the verification of the catheter length, and (3) conducting in-house training to ensure that staff are aware of the new procedural steps and to ensure that the prescribing authorized user physician and the medical physicist actively participate in the training.

NRC Action:

On March 14, 2007, the NRC issued a Notice of Violation related to this event.

Other Agency Action: