Event Detail - Abnormal Occurrence

ITEM #:	080132	**AO #:**	08-04	**AO REPORT:**	NUREG-0090, Vol. 31
TITLE:	Medical Event at Reid Hospital and Health Care Services in Richmond, Indiana				
NAME:	Reid Hospital and Health Care Services				
DATE:	02/27/2008	**CITY:**	Richmond	**STATE:**	IN

Criteria:

Criteria III.C.1.b and III.C.2.b(iii), "For Medical Licensees," of Appendix A to this report provide 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:

Reid Hospital and Health Care Services reported that a medical event occurred during a brachytherapy seed implant procedure to treat prostate cancer. The written directive prescribed a total dose of 110 Gy (11,000 rad) to the patient's prostate using 62 iodine-125 seeds as permanent implants. The licensee calculated that the patient received less than 15 Gy (1,500 rad) to the prostate and the region of the patient's perineum, where the seeds were placed, received a dose of 55 Gy (5,500 rad). The patient and the referring physician were informed of this event.

According to the licensee, the base of the prostate was misidentified through ultrasound, causing 37 of the prescribed 62 seeds to be placed approximately 1 cm to 2 cm below the prostate in the perineum. When it was recognized that the seeds were not in the prostate, the procedure was halted. The licensee physicians stated that the patient may develop possible complications, including fibrosis and necrosis of the tissue in the perineum, where the seeds were implanted.

The NRC-contracted medical consultant agreed with the licensee's dose estimate and stated it was unlikely that the patient would experience radiation-induced rectal wall necrosis or soft tissue necrosis below the prostate in the perineum area, but that it was possible to have delayed fibrosis of some areas of the genital tract. The NRC-contracted medical consultant further stated that because no tissue necrosis had occurred one month after the medical event, tissue necrosis was very unlikely to occur.

Cause:

The licensee determined the root cause of the medical event was the misidentification of the base of the prostate. Specifically, the prostate/bladder interface was not identified properly using the ultrasound due to poor image quality. As a result, the needle used to implant the seeds was not located in the prostate during the implantation.

Licensee Action:

The licensee's corrective actions to prevent recurrence included revising its procedure for prostate seed implants to require that the needle location in the prostate be verified by x-ray imaging at the beginning of the procedure, prior to any seeds being implanted, and halting the procedure if the location of the needle in the prostate cannot be verified with certainty.

NRC Action:

On July 11, 2008, NRC issued a Notice of Violation related to this event.

Other Agency Action: