Event Detail - Abnormal Occurrence

ITEM #:	070024	**AO #:**	07-03	**AO REPORT:**	NUREG-0090, Vol. 30
TITLE:	Medical Event at Hackley Hospital in Muskegon, Michigan				
NAME:	Hackley Hospital				
DATE:	01/08/2007	**CITY:**	Muskegon	**STATE:**	MI

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 January 8, 2007, Hackley Hospital (the licensee) notified the NRC of a medical event that occurred during a brachytherapy seed implant procedure to treat prostate cancer. The written directive prescribed a total dose of 120 Gy (12,000 rad) to the patient's prostate using 41 iodine-125 seeds as permanent implants. According to the licensee, because the patient moved, only 7 of the prescribed 41 seeds were delivered to the prostate (the intended site), and the other 34 seeds were delivered to an unintended site located approximately 4 cm (1.6 in) inferior to the prostate. As a result, the prostate received a dose of approximately 13 Gy (1,300 rad) rather than the prescribed dose of 120 Gy (12,000 rad) (-90% less than the prescribed dose). In addition, the unintended site received a dose of approximately 110 Gy (11,000 rad) and the patient's skin around the unintended site received a dose of approximately 2.4 Gy (240 rad). The patient and the referring physician were informed of this event. The patient will require further treatment via external beam therapy in order to deliver the appropriate dose to the prostate.

The NRC-contracted medical consultant agreed with the licensee's dose estimate and concluded that the risk for impotence is somewhat increased by the additional radiation dose to the unintended site as a result of the medical event. There may also be some risk of perineal tissue fibrosis and skin irritation, although the risk may not be significant enough to cause clinical concerns.

Cause:

The licensee determined the root cause of the event was a failure to identify the patient's movement before continuing with the procedure. In addition, the NRC inspector determined that the licensee failed to develop adequate written procedures to provide high confidence that each brachytherapy administration was in accordance with the authorized user physician's written directive, as required by 10 CFR 35.41. Specifically, the licensee's procedures did not include appropriate steps or guidance to ensure that radioactive sources were positioned in the patient in accordance with the written directive and treatment plan.

Licensee Action:

The licensee's corrective actions to prevent recurrence included revising its written procedure to ensure that sources are positioned in the patient in accordance with the written directive, and ensuring that the staff implements those revisions.

NRC Action:

On June 20, 2007, the NRC issued a Notice of Violation related to this event.

Other Agency Action: