Event Detail - Abnormal Occurrence

ITEM #:	080707	**AO #:**	09-01	**AO REPORT:**	NUREG-0090, Vol. 32
TITLE:	Medical Event at Saint Mary's Medical Center in Huntington, West Virginia				
NAME:	Saint Mary's Medical Center				
DATE:	10/15/2008	**CITY:**	Huntington	**STATE:**	WV

Criteria:

Criterion III.C.1.b and III.C.2.a, "For Medical Licensees," of Appendix A to this report provides, 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 either a dose or dosage that is at least 50 percent greater than that prescribed, shall be considered for reporting as an AO.

Nature and Probable Consequences:

Saint Mary's Medical Center (the licensee) reported that a medical event occurred associated with the administration of a 5.55 GBq (150 mCi) iodine-131 capsule for thyroid cancer. A patient was prescribed to receive 10.12 Gy (1,012 rad) to the esophagus but received 18 Gy (1,800 rad) to the esophagus. The patient and the referring physician were informed of this event.

During the administration, the patient attempted to swallow the capsule, but it became lodged in an obstruction in the upper portion of the esophagus. Licensee staff provided the patient with soda and applesauce to help dissolve the capsule, and after 2.5 hours the capsule passed the obstruction. Since the capsule was lodged in the patient's upper portion of the esophagus for longer than expected, an estimated dose of 18 Gy (1,800 rad) was received to a small area of esophageal tissue. If the capsule had not become lodged in the upper portion of the patient's esophagus, the esophagus would have received the intended dose of 10.12 Gy (1,012 rad) instead of 18 Gy (1,800 rad). The dose to the esophagus exceeded the intended dose by 78 percent.

On October 22, 2008, the event was discussed with the patient during a follow-up visit with the prescribing physician. The prescribing physician indicated that potential health effects from this administration could include esophagitis and radiation fibrosis.

Cause:

The cause of the medical event was human error in failing to recognize that the esophageal obstruction might interfere with the patient's ability to swallow the iodine-131 capsule.

Licensee Action:

The licensee modified its procedure to include a pre-therapy esophageal dilation for patients known to have difficulty swallowing. In addition, patients known to have this difficulty may be administered liquid iodine-131 for treatment.

NRC Action:

NRC contracted a medical consultant to review this event, its effect on the patient, and the licensee's corrective actions taken to prevent recurrence of similar events. The medical consultant concluded that no significant adverse health effect to the patient is expected. The NRC concluded an inspection on February 6, 2009, and one non-cited violation was issued to the licensee on February 10, 2009.

Other Agency Action: