Event Detail - Abnormal Occurrence

ITEM #:	090748	**AO #:**	09-03	**AO REPORT:**	NUREG-0090, Vol. 32
TITLE:	Medical Event at the Veterans Affairs San Diego Health Care System in San Diego, California				
NAME:	Veterans Affairs San Diego Health Care System				
DATE:	09/21/2009	**CITY:**	San Diego	**STATE:**	CA

Criteria:

Criterion 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:

The Department of Veterans Affairs (the licensee), National Health Physics Program (NHPP) reported that a medical event occurred at the Veterans Affairs (VA) San Diego Health Care System associated with a therapeutic dosage of iodine-1 31 for the treatment of metastatic thyroid cancer. A patient was prescribed to receive 6.9 GBq (187 mCi) of iodine-131 to the metastatic sites around the body but received 6.1 GBq (166 mCi) to the stomach (wrong treatment site). The patient and the referring physician were informed of this event.

On September 21, 2009, a dosage of 6.9 GBq (187 mCi) of iodine-131 was administered to the patient through an existing feeding tube. Daily radiation measurements indicated small decreases in radiation readings that were consistent with the physical decay of iodine-1 31, but not consistent with the biological elimination of iodine-1 31. On September 25, 2009, the feeding tube was replaced and a subsequent investigation revealed that the majority of the dosage, 6.1 GBq (166 mCi), was administered to the wrong orifice of the feeding tube. As a result, the dosage remained in the balloon of the feeding tube and irradiated the patient's stomach, resulting in an approximate dose of 16 Gy to 19 Gy (1,600 rad to 1,900 rad) to the stomach.

Cause:

Three root causes were identified for this medical event: (1) inadequate training of staff, (2) inadequate procedures, and (3) an inadequate procedure on the verification that administrations involving feeding tubes were being administered in accordance with a written directive.

Licensee Action:

Corrective actions taken by the licensee included (1) immediate suspension of any further gastric tube administrations until the direct cause of the medical event was identified, (2) suspension of one individual's participation in administrations requiring a written directive, (3) informal training of the nuclear medicine technologists by the Radiation Safety Officer, and (4) development of draft written policies and procedures on the administration of iodine-1 31 through a gastric tube.

NRC Action:

The NRC Region III Office conducted a reactive inspection on November 3, 2009, and also contracted a medical consultant to review this event. Based on the results of the inspection, five apparent violations of NRC's regulations were identified. Enforcement action is pending and the medical consultant's review is on-going.

Other Agency Action: