ITEM #:	050671	**AO #:**	08-02	**AO REPORT:**	NUREG-0090, Vol. 31
TITLE:	Medical Events at the Department of Veterans Affairs in Philadelphia, Pennsylvania				
NAME:	Department of Veterans Affairs				
DATE:	10/03/2005	**CITY:**	Philadelphia	**STATE:**	PA

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:

The VA Medical Center - Philadelphia reported that 92 medical events involving prostate brachytherapy occurred between February 2002 and May 2008. Each patient was prescribed 160 Gy (16,000 rad) using permanent iodine-125 seeds. The licensee determined that 57 of the 92 patients received less than 80 percent of the prescribed dose to the prostate. Thirty-five patients received excessive doses to other organs. Of these 35 patients, 25 patients received a dose in excess of 100 Gy (10,000 rad) to the rectum due to misplaced iodine-1 25 seeds. Each patient and the referring physicians were notified of these events. The VA Medical Center - Philadelphia is reviewing possible health effects on the patients. The circumstances for each patient are being evaluated to determine if follow-up medical care is needed.

The NRC-contracted medical consultant reviewed a selected number of the cases and agreed with the licensee's dose analysis. However, in one overdose case, the patient experienced rectal bleeding of the colon and laboratory results indicated ulcerative colitis. The NRC-contracted medical consultant and the licensee agreed that the increased dose to the colon could be a contributing factor to the rectal bleeding.

Cause:

The VA Medical Center - Philadelphia identified three root causes as a result of these events in its Report of Administrative Board of Investigation dated September 5, 2008: (1) no corrective action was taken when post-implant dosimetry was performed and low doses were observed, (2) inadequate supervision by the physician/authorized users and (3) posttreatment plans were not performed on patients due to computer interface problems. In addition, two factors contributed to these events: (1) internal procedures were not followed and (2) the succession of minor technical errors that stemmed from a misperception that other team members performed safety checks.

Licensee Action:

Corrective actions taken by the VA Medical Center - Philadelphia included: (1) the prostate brachytherapy program has been suspended until a standardized brachytherapy program is established and implemented; (2) a physician and medical physics consultant, who are experts in performing prostate implants, were hired to evaluate the prostate implant program; and (3) several key staff directly involved in the prostate brachytherapy procedures are no longer employed by the VA Medical Center - Philadelphia.

NRC Action:

The NRC Region III Office conducted a reactive inspection on July 23-25, 2008. Based on the results of this inspection and the high number of medical events identified, NRC conducted a special inspection on September 9-12, 2008. On October 14, 2008, NRC issued a confirmatory action letter (CAL) to the Department of Veterans Affairs (DVA) National Health Physics Program due to the multiple medical events involving permanent prostate brachytherapy treatments. The CAL documents the commitments made by the DVA to identify and address the problems that have led to medical errors and to prevent their recurrence. NRC will verify, through inspections, that the items in the CAL have been successfully completed. Enforcement action is pending.

Other Agency Action: