2009

VA Philadelphia Medical Event Abstract

The purpose of this presentation is to share inspection and regulatory insights associated with the multiple medical events that occurred at the Veterans Affairs (VA) Medical Center in Philadelphia, Pennsylvania.

On May 18, 2008, the U.S. Nuclear Regulatory Commission (NRC) received notification that a patient undergoing manual brachytherapy treatment for prostate cancer at the Philadelphia VA Medical Center received a dose more than 20 percent lower than the prescribed dose. An inspection by the Department of Veterans Affairs, National Health Physics Program led to an expanded review of more prostate treatments and resulted in identifying more reportable medical events. The manual brachytherapy treatment program at the Philadelphia VA Medical Center was suspended in June 2008. Four additional VA medical centers in the United States suspended their prostate brachytherapy programs after identifying medical events. Eventually the Philadelphia VA Medical Center reviewed all 116 prostrate cancer treatments performed since the beginning of its prostate cancer brachytherapy treatment program in February 2002 and reported 98 medical events to NRC. These medical events included treatments resulting in under-doses delivered to the treatment site (the prostate) that differed by more than 20 percent of the prescribed dose (63 events) and over doses to other sites (rectum, bladder and peri-prostatic tissue) that exceeded the medical event criteria of expected dose to that site by 50 rem and 50 percent of the prescribed dose (35 events). Although only counted once as a medical event, some treatments resulted in both low doses to the prostrate and high doses to the wrong treatment site. While medical events do not necessarily result in harm to the patient, some of the patients were reported to have radiation complications such as rectal radiation burns. NRC performed a reactive inspection of the Philadelphia VA Medical Center in July 2008. Based on the preliminary findings and the continued number of medical events reported, the NRC launched a Special Inspection at the hospital in September 2008. In October 2008, the NRC issued a formal letter to the Department of Veterans Affairs that documented the commitments made by the Department of Veterans Affairs to identify and address the problems that led to these medical errors at VA hospitals and to prevent their recurrence. An NRC medical consultant reviewed a selected number of medical events to determine if any health consequences to the patients would be expected. The medical consultant concluded that the seed placement in the cases reviewed was erratic and not consistent with current medical standards. In March 2009, the NRC issued an inspection report that identified several regulatory violations and several concerns that were contributing factors to the medical events which involved inadequate management oversight of the prostate brachytherapy program, including contractor oversight, and lack of a safety culture. Additionally, in June and July 2009, there were congressional hearings into the prostate brachytherapy program at the Department of Veterans Affairs.

B-11