Department of Veterans Affairs Manual Prostate Brachytherapy Medical Events

Issue

The Department of Veterans Affairs (DVA) reported a medical event on May 18, 2008, involving a patient undergoing manual brachytherapy treatment for prostate cancer at the Philadelphia Veterans Affairs (VA) Medical Center. The patient received a prostate dose that was less than 80 percent of the prescribed dose. An inspection by DVA's National Health Physics Program led to an expanded review of all the prostate treatments performed. The expanded review identified 97 patient treatments that resulted in medical events out of the 114 total patients treated at this facility. The manual brachytherapy treatment program at the Philadelphia VA Medical Center was suspended in June 2008. Four additional VA medical centers suspended their prostate brachytherapy programs after identifying medical events.

NRC performed a reactive inspection of the Philadelphia VA Medical Center in July 2008 that was expanded into a Special Inspection in September 2008 because of the large number of medical events reported. In October 2008, the NRC issued a formal letter to DVA that documented the commitments made by the DVA 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 erratic seed placement caused a number of patients to have elevated doses to the rectum, bladder, or peri-prostatic tissue. The consultant identified specific patients with rectal bleeding where the increased dose to the patients' colon, which resulted from erratic seed placement, may have been a contributing factor to the condition.

NRC inspectors found a substantial programmatic breakdown in the VA Philadelphia brachytherapy program. The doctors, medical physicists, and radiation safety staff allowed a substandard approach to brachytherapy treatments, which resulted in medical errors; they allowed a patient dose assessment process that lacked rigor and consistency; and did nothing to address the failure to communicate concerns about the quality of procedures, or perform safety checks due to assumptions that someone else was performing them. NRC concluded that the overall program at the VA hospital in Philadelphia lacked focus and commitment to safety. In March 2009 and November 2009, the NRC issued inspection reports that identified a number of 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. A public enforcement conference was held in December 2009 to provide the licensee an opportunity to present NRC with any additional or new information before a final decision was made. In March 2010, NRC proposed a $227,500 fine against the DVA for the 8 identified violations of NRC's regulations.

Status of Issue

The DVA acknowledged the violations and paid the fine. NRC chartered a group to look at the lessons learned from the DVA medical events, NRC's response to the events, and oversight of master materials licenses (MMLs). Information from the medical events and the inspection results were considered in evaluating NRC's proposed rule to revise the written directive and medical event reporting requirements for manual permanent implant brachytherapy.

b-1