U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Reported Prostate Brachytherapy Medical Events at the Department of Veterans Affairs (DVA) Medical Center
Philadelphia, Pennsylvania

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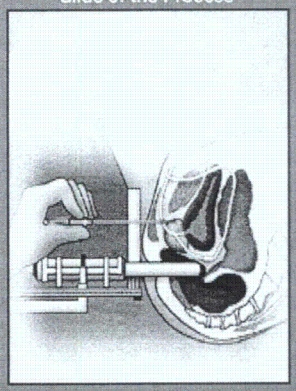
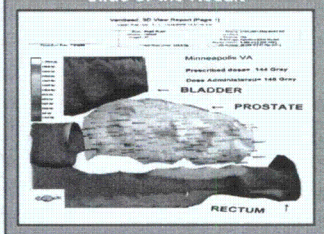
Manual Brachytherapy Procedures:
The manual implantation of I-125 seeds into the prostate using a grid template attached to a trans-rectal ultrasound imaging probe to provide either 145 or 160 Gray to the treatment site.

Slide of the Process



Slide of the Result



Sequence of Events at the Philadelphia VA Medical Center [1]

- Since February 2002 when the prostate brachytherapy program started a total of 114 patients were treated.
- **Originally Identified events:**
  - February 2003, during a seed prostate implant, many seeds (40 out of 74) were mistakenly implanted into the patient's bladder and subsequently recovered. NRC determined the regulations permitted the revision of the written directive for manual brachytherapy procedures and no medical event occurred because the written directive was revised to indicate only the 34 seeds were to be implanted.
  - October 2005, again many seeds (45 out of 90) were mistakenly implanted into the patient's bladder and subsequently recovered. The National Health Physics Program (based on NRC's earlier determination) determined that because the written directive was revised, no medical event occurred.
  - May 2008. The National Health Physics Program notified the NRC of a possible medical event involving incorrect seed activity causing a patient to receive a dose to the prostate that was less than 80 percent of the prescribed dose.
- The National Health Physics Program initiated an onsite reactive inspection at the Philadelphia VA Medical Center in response to the reported medical event and discovered an ever increasing number of medical events.
- **Results:**
  - As of October 19, 2009, the licensee identified and reported to the NRC a total of 97 medical events.

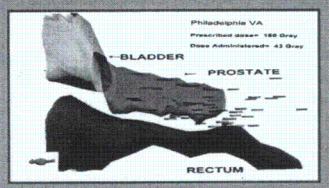
[1] One of 113 hospitals run by the US Department of Veterans Affairs to treat veterans

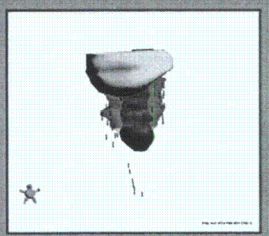
NRC Manual Brachytherapy Medical Event Criteria
(In 10 Code of Federal Regulations 35.3045, "Report and notification of a medical event")

97 Reported Medical Events (114 total prostrate brachytherapy patients)	
NRC Manual Brachytherapy Medical Event Reporting Requirement	**Number of reported medical events and DVA method of evaluating if the administration met NRC's requirement for a reportable medical event**
Treatment Site 35.3045(1)(a) A licensee shall report any event, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material results in— (1) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and (i) The total dose delivered differs from the prescribed dose by 20 percent or more;	**76 Medical Events** The dose calculated to 90 percent of the designated treatment site (i.e., the prostate) is less than or greater than 20% of prescribed dose (80% >D90> 120%)
Other than the treatment site 35.3045(1)(a)(3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).	**21 Medical Events** Rectum – dose to 1.33cc volume exceeds 150% of pre-treatment plan dose (The D1.33 dose to 1.33 cc) was selected because it is the volume the VariSeed® treatment planning program used to identify high dose volume during the pre-treatment planning.) External Tissue – 5 or more seeds located beyond 1cm exterior, and inferior, to the surface of prostate (A perimeter of 1 cm was selected because it fully encompassed seeds positioned parallel and perpendicular to the external prostate surface. It was determined that any prostate brachytherapy seed protruding beyond the 1 cm cloud around the prostate was counted as exterior to the prostate and evaluated for dose contribution to the perineum, rectum and bladder.) Bladder – 3 or more seeds located in bladder wall. The criteria of 3 or more seeds located in the bladder wall was selected based on the review of a patient's post-treatment plan which identified that 2 seeds in the bladder contributed to less than 60 Gy (equivalent to 60 Sv) to the bladder wall. The dose to the bladder wall with the seeds in the wall was compared to the dose to the bladder wall with the seeds removed. This criteria was well below the bladder tolerance dose.

Note: If the administration met several medical event criteria it was still considered as a single reportable medical event.

Causes of Medical Events	Licensee Corrective Actions Taken
Incorrect Placement of Seeds	Suspended the prostate brachytherapy program on June 11, 2008 and ordered an external review of the prostate brachytherapy program by an Administrative Board of Investigation Performed verification CT scans on all 114 patients that received prostate implants between CY 2002 and May 2008; Re-evaluated the dose delivered to the treatment area for all 114 patients Re-implanted brachytherapy seeds at a different VA location for at least four individuals Removed at least one individual from performing brachytherapy treatments at the VA.
Inadequate Procedures	Modified the PVAMC written procedures to incorporate a dual verification system and to clarify responsibilities. Require a comparison and evaluation of both treatment plans and associated calculations with the written directive. Instituted a directive to allow prostate implant treatments to proceed only when the treatment planning computer is able to produce pre or post- treatment plans Instituted an internal QA program to ensure communications between radiation oncology team members regarding safety and treatment concerns
Poor Management Oversight of Contractors	Revised the contract for radiation oncology services to realign services under the Philadelphia VA Medical Center Radiation Safety Officer
Inadequate Training of Licensee staff	Provided radiation safety training to radiation oncology staff, nuclear medicine staff, new employees, trainees and contractors regarding NRC regulations for written directives and medical events, including training on PVAMC's open door policy for reporting concerns and suspected violations
Poor Management Oversight of Brachytherapy Program	
No Peer Review	Instituted a medical center peer-review system for radiation oncology services and post-treatment evaluations
Observed Poor Placement of Seeds and No Correction Actions Taken	Instruction to the Radiation Safety Officer, and quality management staff to immediately report all deviations that exceed ten percent of the prescribed dose or dose fraction
Lack of Safety Culture	





Department of Veterans Affairs (DVA) master materials license

- A Master Material License is a NRC materials license issued to a Federal organization that authorizes the use of material at multiple sites and gives the licensee authority to issue licenses (permits), perform inspections (which includes event follow-up, investigating incidents, allegations), and issue enforcement actions in accordance with NRC regulations policies and procedures.
- The DVA National Radiation Safety Committee has responsibility for providing oversight of the DVA's implementation of its Master Material License .
- The National Radiation Safety Committee delegated the authority to manage the DVA radiation safety program to its National Health Physics Program .
- The National Health Physics Program is responsible for issuing permits, conducting inspections and event follow-up, investigating incidents, allegations, and enforcement.
- The Veterans Affairs Medical Center, Philadelphia VA Medical Center is a permittee under the DVA's Master Material License.
- The PVAMC retained the services of consulting radiation oncology physicians and medical physics for pre-treatment planning, implant preparations, implant treatments, post treatment planning, etc.