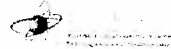


**DEPARTMENT OF VETERANS AFFAIRS
MEDICAL CENTER – PHILADELPHIA
MULTIPLE MEDICAL EVENTS INVOLVING
PROSTATE BRACHY THERAPY TREATMENTS**

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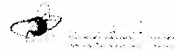
Background

- Department of Veterans Affairs (DVA) holds a master materials license (MML)
- An MML is a materials license issued to a Federal organization, authorizing the use of material at multiple sites.
- The DVA National Radiation Safety Committee (NRSC) has responsibility for providing oversight of the DVA's implementation of its MML .



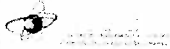
Background

- The NRSC has delegated the authority to manage the DVA radiation safety program to its National Health Physics Program (NHPP).
- The NHPP is responsible for issuing permits, conducting inspections and event follow-up, investigating incidents, allegations, and enforcement.
- The Veterans Affairs Medical Center, Philadelphia (PVAMC) is a permittee issued under the DVA MML.



Background

- 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.



Sequence of Events

- February 2002, PVAMC initiated its prostate brachytherapy program and implanted its first patient.
- 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 that because the written directive was revised, no medical event occurred.



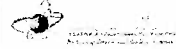
Sequence of Events

- October 2005, during a seed prostate implant, many seeds (45 out of 90) were again mistakenly implanted into the patient's bladder and subsequently recovered. NHPP determined that because the written directive was revised, no medical event occurred.
- May 2008, the NHPP notified the NRC of a possible medical event involving a patient that received a dose to the prostate that was less than 80 percent of the prescribed dose.



Sequence of Events

- May 2008, the NHPP initiated an onsite reactive inspection at the PVAMC in response to the reported medical event.
- June 2008, the PVAMC prostate brachytherapy program suspended.
- The PVAMC commissioned an external review of the entire prostate brachytherapy program.



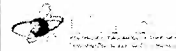
Sequence of Events

- July 2008, the PVAMC appointed an Administrative Board of Investigation (ABI) to review the facts and circumstances surrounding the medical events.
- As of October 2, 2008, the licensee identified and reported to the NRC a total of 92 medical events.



Medical Event Criteria

- Phase I: \pm 20% of prescribed dose
- Phase II:
 - Rectum – dose to 1.33cc volume exceeds 150% of pre-treatment plan dose
 - External Tissue – 5 or more seeds located beyond 1cm exterior, and inferior, to the surface of prostate
 - Bladder – 3 or more seeds located in bladder wall



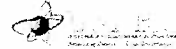
Basis for Medical Event Criteria

- 1) Rectum -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.
- 2) Tissue External to Prostate - A perimeter of 1cm 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 1cm cloud around the prostate was counted as exterior to the prostate and evaluated for dose contribution to the perineum, rectum and bladder.



Basis for Medical Event Criteria

- 3) Tissue Inferior to Prostate - A determination was made that 10 percent (5) of the minimum number (53) of seeds implanted in the Phase II patients located more than 1 cm exterior to and inferior to the surface of the prostate was the criteria for a possible medical event.
- 4) Bladder - 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 criterion was well below the bladder tolerance dose.



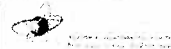
92 Total Medical Events

- 57 Medical Events due to a dose less than 80% of the prescribed dose (underdose)
- 35 Medical Events due to a dose to the skin or an organ or tissue other than the treatment site that exceeds 0.5 Sv (50 rem) (over doses to rectum, bladder wall or surrounding tissue)



Causes of Medical Events

- 1) Incorrect Placement of Seeds
- 2) Inadequate Procedures
- 3) Poor Management Oversight of Contractors
- 4) Inadequate Training of Licensee staff



Causes of Medical Events

- 5) Poor Management Oversight of Brachytherapy Program
- 6) No Peer Review
- 7) Observed Poor Placement of Seeds and No Correction Actions Taken
- 8) Lack of Safety Culture



Corrective Actions Taken

The licensee instituted the following corrective actions:

- 1) Suspended the prostate brachytherapy program on June 11, 2008, and ordered an external review of the prostate brachytherapy program by a Administrative Board of Investigation;



Corrective Actions Taken

- 2) Amended the PVAMC Sealed Source Radiotherapy policy to include:
 - a. A comparison and evaluation of both treatment plans and associated calculations with the written directive;
 - b. Direction to allow prostate implant treatments to proceed only when the treatment planning computer is able to produce pre or post-treatment plans; and
 - c. Instruction to the Radiation Safety Officer (RSO) and quality management staff to immediately report all deviations that exceed ten percent of the prescribed dose or dose fraction.



Corrective Actions Taken

- 3) 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;
- 4) Instituted a medical center peer-review system for radiation oncology services and post-treatment evaluations.
- 5) Revised the contract for radiation oncology services to realign services under the PVAMC RSO;



Corrective Actions Taken

- 6) Instituted an internal quality assurance program to ensure communications between radiation oncology team members regarding safety and treatment concerns; and
- 7) Modified the PVAMC written procedures to incorporate a dual verification system and to clarify responsibilities.

