MULTIPLE MEDICAL EVENTS INVOLVING PROSTATE BRACHYTHERAPY TREATMENTS AT DEPARTMENT OF VETERANS AFFAIRS MEDICAL CENTER - PHILADELPHIA

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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
- DVA National Radiation Safety Committee (NRSC) has responsibility for providing oversight of the DVA's implementation of its MML

2

Background

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

3

Background

- PVAMC retained the services of consulting radiation oncology physicians and medical physics from Hospitals of the University of Pennsylvania for pre-treatment planning, implant preparations, implant treatments, post treatment planning, etc.
- 114 patients treated from February 2002 thru May 2008

4

Sequence of Events

- February 2002: PVAMC initiated prostate brachytherapy program and implanted first patient
- May 2008: NRC notified of a medical event where dose to the prostate was less than 80% of the prescribed dose

5

Sequence of Events

- May 2008: the NHPP conducted inspection at the PVAMC in response to the reported medical event
- June 2008: the PVAMC prostate brachytherapy program suspended
- PVAMC commissioned an external review of the prostate brachytherapy program

6

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Sequence of Events

- July 2008: the NRC began independent Special Inspection
- October 2008: NRC issued Confirmatory Action Letter
- As of December 2009, the licensee identified and reported to the NRC a total of **97** medical events.

7

DVA Medical Event Criteria

➢ Phase I:	± 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

8

97 Medical Events Reported to NRC

- Medical Events due to a dose less than 80% of the prescribed dose (underdose)
- 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)

9

Causes of Medical Events

➢ Incorrect Placement of Seeds

➢ Inadequate Procedures

➢ Poor Management Oversight of Contractors

➢ Inadequate Training of Licensee Staff

10

Causes of Medical Events

➢ Poor Management Oversight of Brachytherapy Program

➢ No Peer Review

➢ Observed Poor Placement of Seeds and No Correction Actions Taken

➢ Lack of Safety Culture

11

PVAMC Patient Care Actions

- Performed verification CT scans on patients that received prostate implants
- Re-evaluated the dose delivered to the treatment area
- Re-implanted seeds at a different DVA location for at least four individuals
- Removed one individual from performing brachytherapy treatments at PVAMC.

12

NRC Response to Events

- Conducted inspections at PVAMC in July and September 2008; June, August, and October 2009
- Issued a Confirmatory Action Letter to the DVA in October 2008
- Issued two inspection reports in March and November 2009
- Issued Demand for Information to a physician authorized user in May 2009

13

NRC Response To Events

- Conducted a Pre-Decisional Enforcement Conference with the DVA in December 2009
- Substantial civil penalty issued to DVA for violations identified at PVAMC ($227,500) in March 2010

14

NRC Response To Events

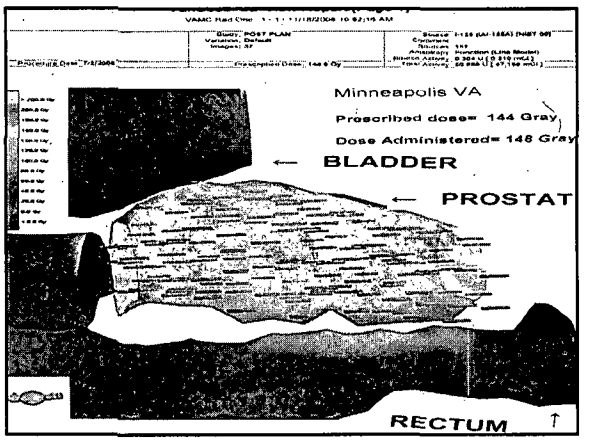
- Conducted inspections at other DVA facilities performing prostate implants
- Conducted inspections at NHPP
- Results of inspections at other DVA facilities performing prostate implants and at NHPP will be issued in one report due late May 2010

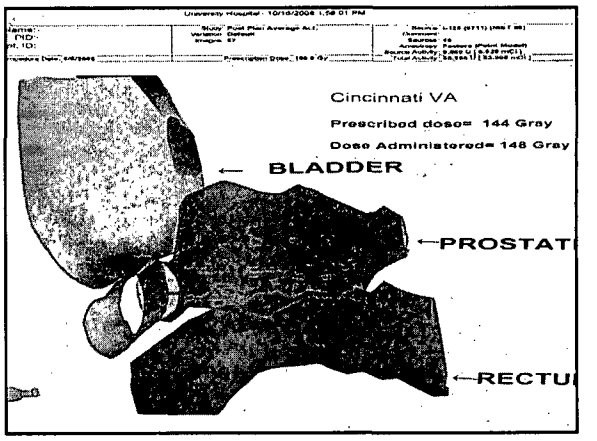
15

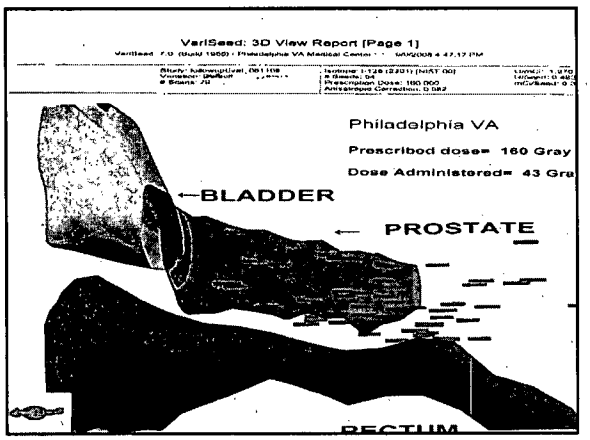
NRC Actions Going Forward

- Enhanced oversight of the DVA
  - Global actions instituted by DVA
  - NRC actions to assess performance improvements
- Assess NRC's policies, procedures, and practices related to prostate brachytherapy to identify program enhancements

18



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Dose Administered= 43 Gra
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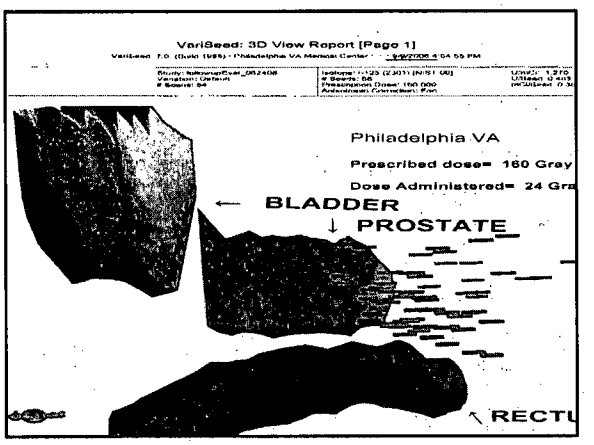
← PROSTATE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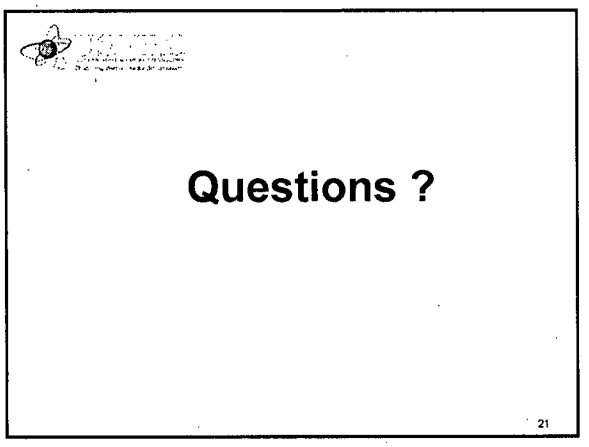
Questions ?
21