



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

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Division of Nuclear Materials Safety  
NRC Region III  
Organization of Agreement States Annual Meeting  
August 24, 2010

## 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

# 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

## 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

## 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

## 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

## 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.

# DVA 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

## 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)

# Causes of Medical Events

- Incorrect Placement of Seeds
- Inadequate Procedures
- Poor Management Oversight of Contractors
- Inadequate Training of Licensee Staff

## Causes of Medical Events

- Poor Management Oversight of Brachytherapy Program
- No Peer Review
- Observed Poor Placement of Seeds and No Corrective Actions Taken
- Lack of Safety Culture

## 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.

## **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

## **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

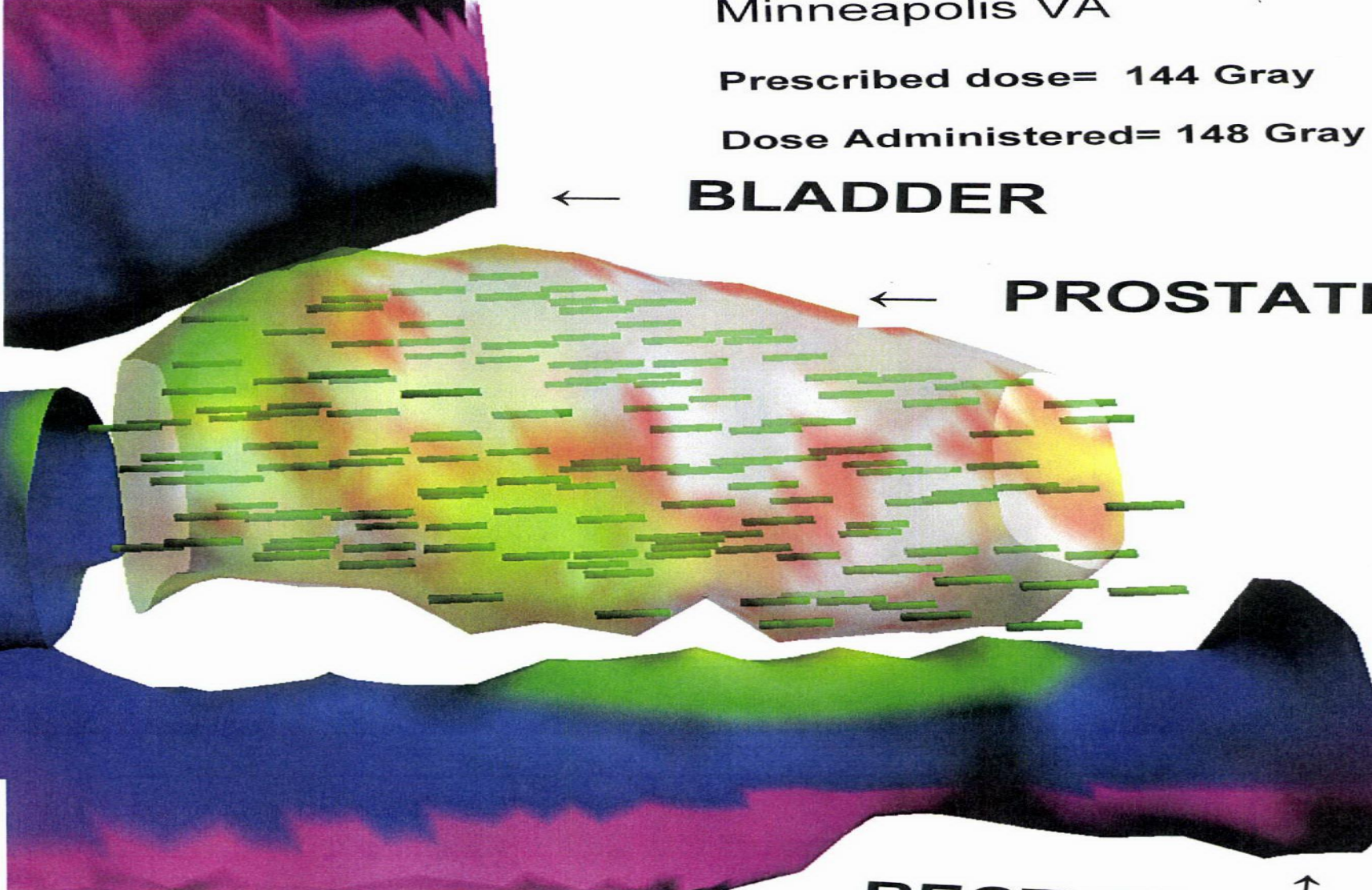
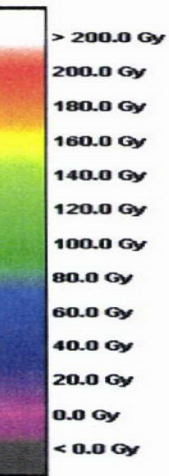
## **NRC Response To Events**

- 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 issued May 2010
- Conducted a Pre-Decisional Enforcement Conference with the DVA in June 2010

## **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

Procedure Date: 7/2/2008	Study: <b>POST PLAN</b> Variation: <b>Default</b> Images: <b>37</b>	Source: <b>I-125 (IAI-125A) [NIST 00]</b> Comment: Sources: <b>152</b> Anisotropy: <b>Function (Line Model)</b> Source Activity: <b>0.394 U [ 0.310 mCi ]</b> Total Activity: <b>59.888 U [ 47.156 mCi ]</b>
Prescription Dose: <b>144.0 Gy</b>		



Minneapolis VA

Prescribed dose= 144 Gray

Dose Administered= 148 Gray

← **BLADDER**

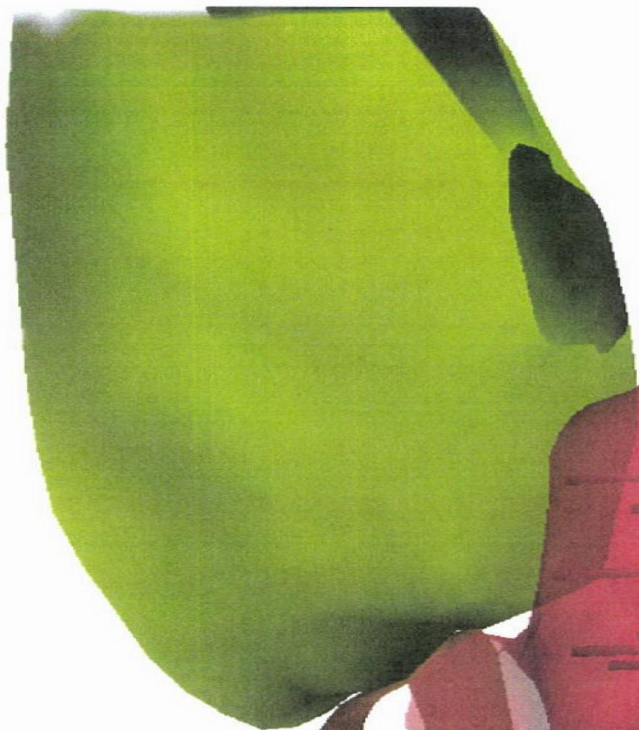
← **PROSTATE**

**RECTUM** ↑

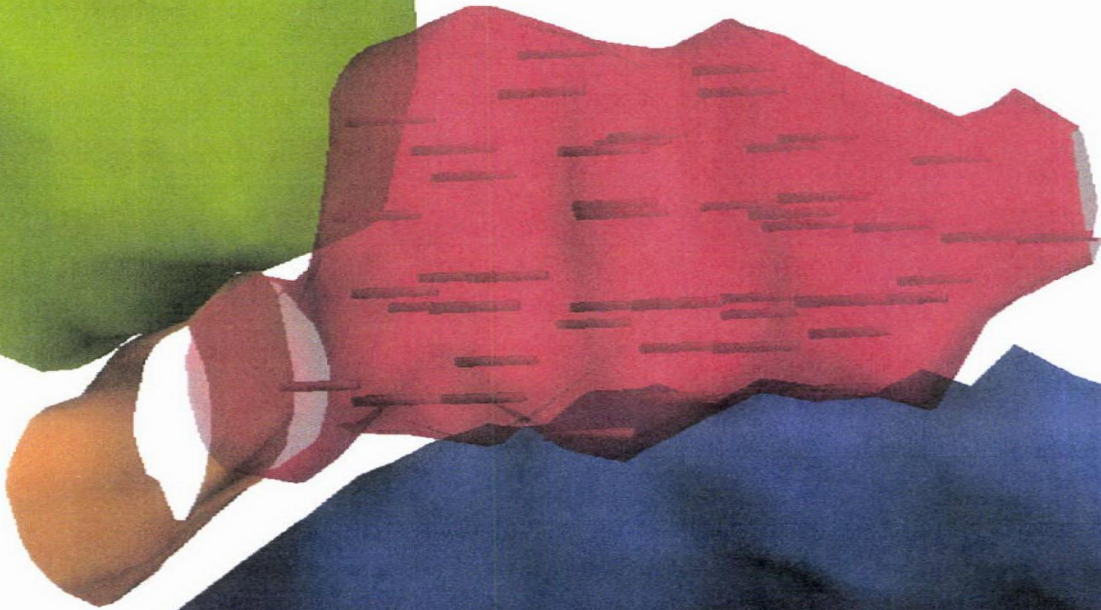
Name: /  
PID: /  
Dept. ID: /  
Procedure Date: **6/5/2008**

Study: **Post Plan Average Act.**  
Variation: **Default**  
Images: **57**  
Prescription Dose: **160.0 Gy**

Source: **I-125 (6711) [NIST 99]**  
Comment:  
Sources: **46**  
Anisotropy: **Factors (Point Model)**  
Source Activity: **0.660 U [ 0.520 mCi ]**  
Total Activity: **30.360 U [ 23.906 mCi ]**



**BLADDER**



**PROSTATE**



**RECTUM**

Cincinnati VA

Prescribed dose= 144 Gray

Dose Administered= 148 Gray

# VariSeed: 3D View Report [Page 1]

VariSeed 7.0 (Build 1955) · Philadelphia VA Medical Center · · · 9/9/2008 4:47:17 PM

Study: followupEval\_061108  
Variation: Default  
# Scans: 29

Isotope: I-125 (2301) [NIST 00]  
# Seeds: 54  
Prescription Dose: 160.000  
Anisotropic Correction: 0.982

U/mCi: 1.270  
U/Seed: 0.483  
mCi/Seed: 0.38

Philadelphia VA

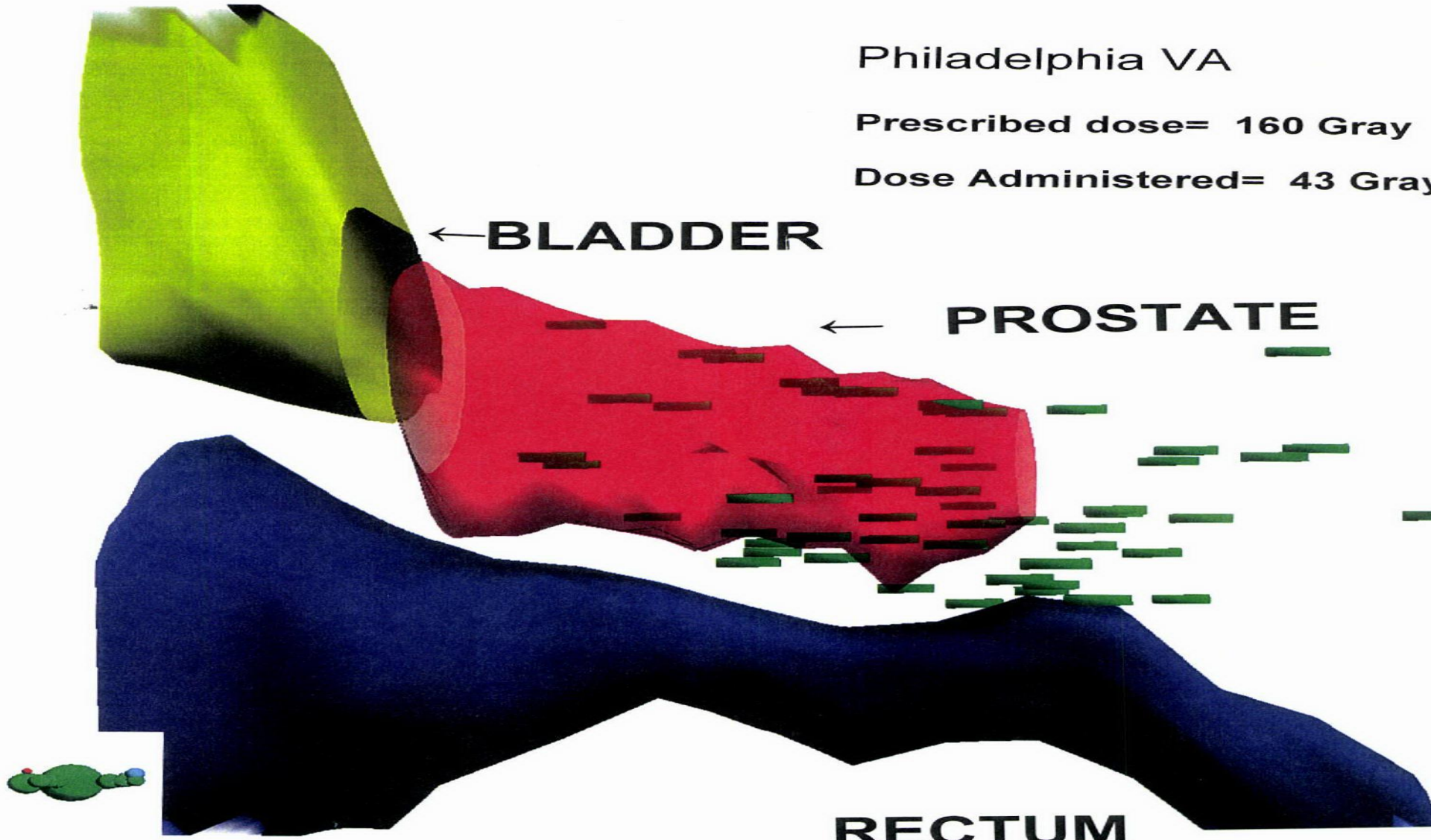
Prescribed dose= 160 Gray

Dose Administered= 43 Gray

← **BLADDER**

← **PROSTATE**

**RECTUM**



# VariSeed: 3D View Report [Page 1]

VariSeed 7.0 (Build 1955) · Philadelphia VA Medical Center · · 9/9/2008 4:54:55 PM

Study: followupEval\_062408  
Variation: Default  
# Scans: 54

Isotope: I-125 (2301) [NIST 00]  
# Seeds: 58  
Prescription Dose: 160.000  
Anisotropic Correction: Fac

U/mCi: 1.270  
U/Seed: 0.483  
mCi/Seed: 0.380

Philadelphia VA

Prescribed dose= 160 Gray

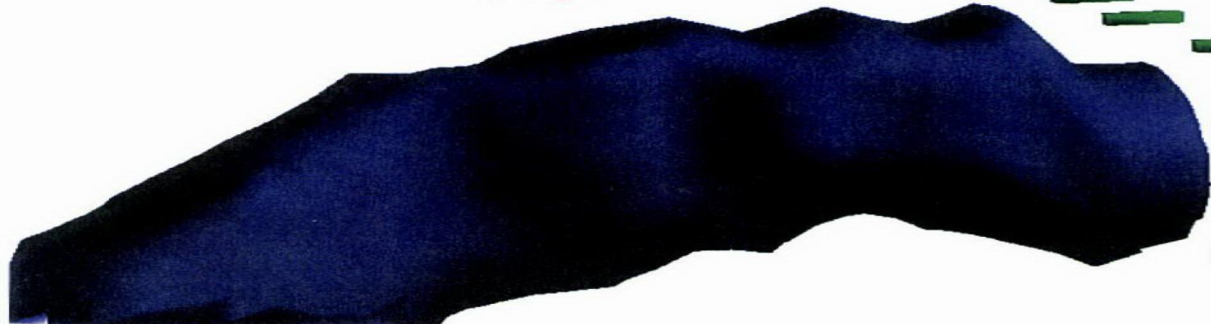
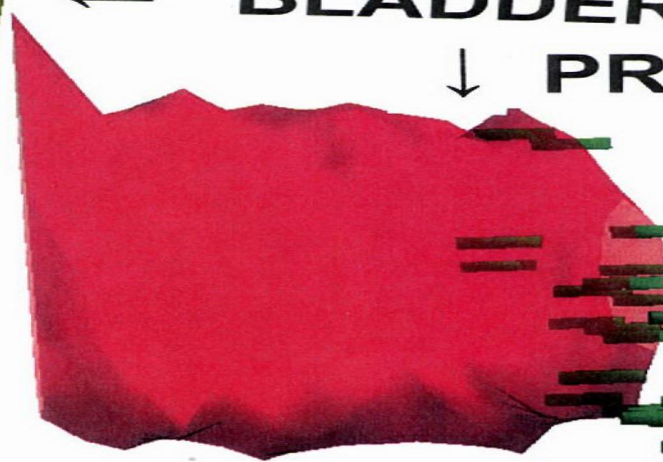
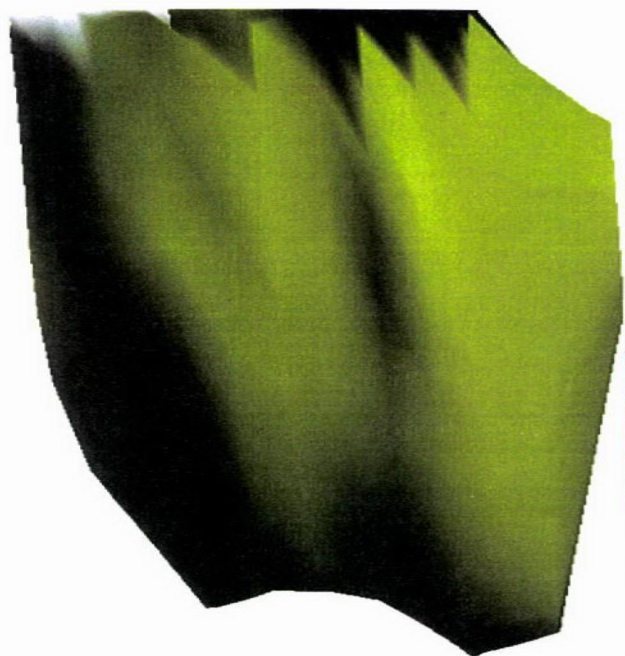
Dose Administered= 24 Gra



**BLADDER**



**PROSTATE**



**RECTU**



# Questions ?