



Part 35 Medical Event Definitions – Permanent Implant Brachytherapy

April 24, 2012

Agenda

- **Opening Comments**
 - **Bill Borchardt, Executive Director for Operations**
 - **Brian McDermott, Director, MSSA/FSME**
- **Presentation**
 - **Ronald Zelac, Ph.D., Senior Health Physicist, MSSA/FSME**

Main Objectives of Recommendations

- **Change treatment site medical event (ME) criterion from dose-based to source-strength-based.**
- **Remove ambiguity from written directive (WD) and ME requirements.**

Reasons for Change

- **Authorized User physicians (AUs) can't control patient-related factors.**
- **Use of available absorbed dose metrics causes much concern.**
- **Current rule is worded toward temporary implants.**

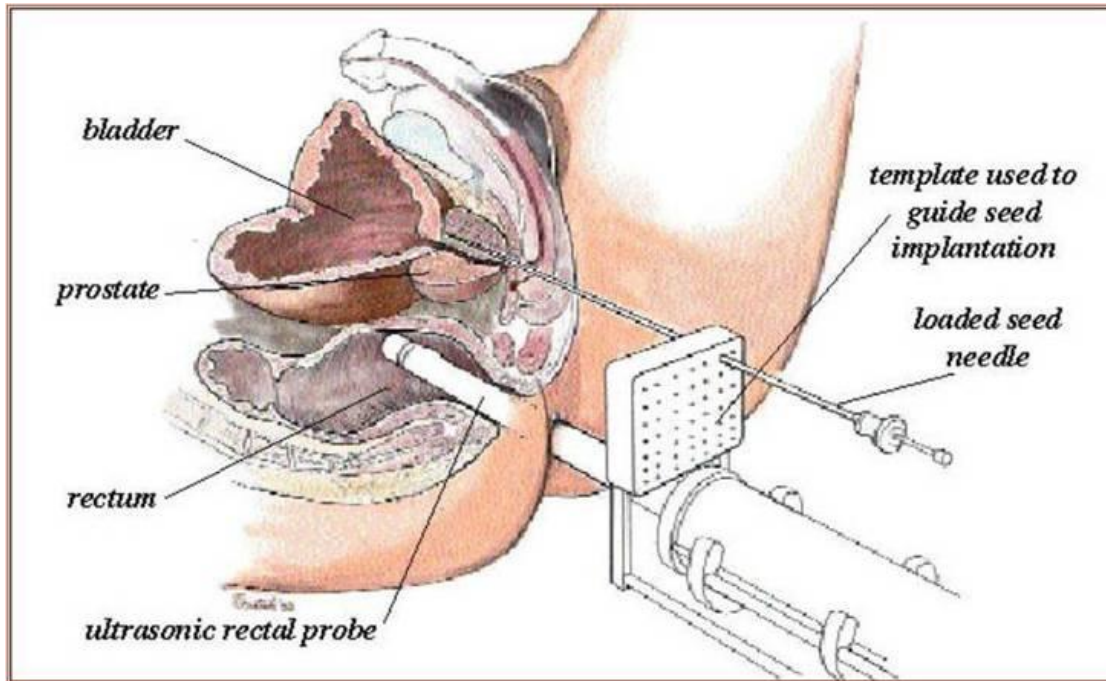
Basis For Current Recommendations

- **ACMUI revised final report.**
- **Stakeholder input from workshops and public meetings.**
- **ASTRO recommendations.**
- **OAS recommendations.**

Recommendations, 10 CFR 35.3045, Reporting MEs

- **Define separate ME criteria for permanent implant brachytherapy utilizing radioactive seeds.**
- **Treatment site ME if 20% or more of implanted seeds are outside the intended implant location.**

Neighboring Structures



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

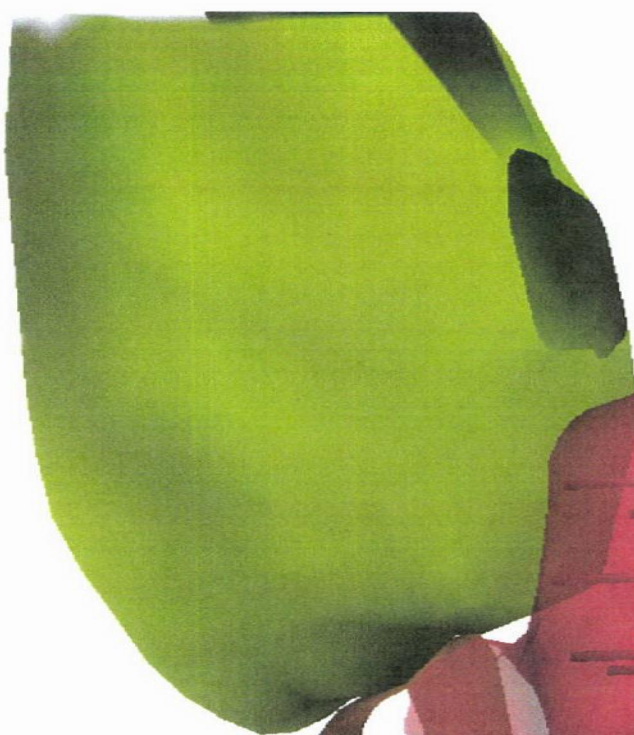
Study: **Post Plan Average Act.**
Variation: **Default**
Images: **57**
Prescription Dose: **160.0 Gy**

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]**

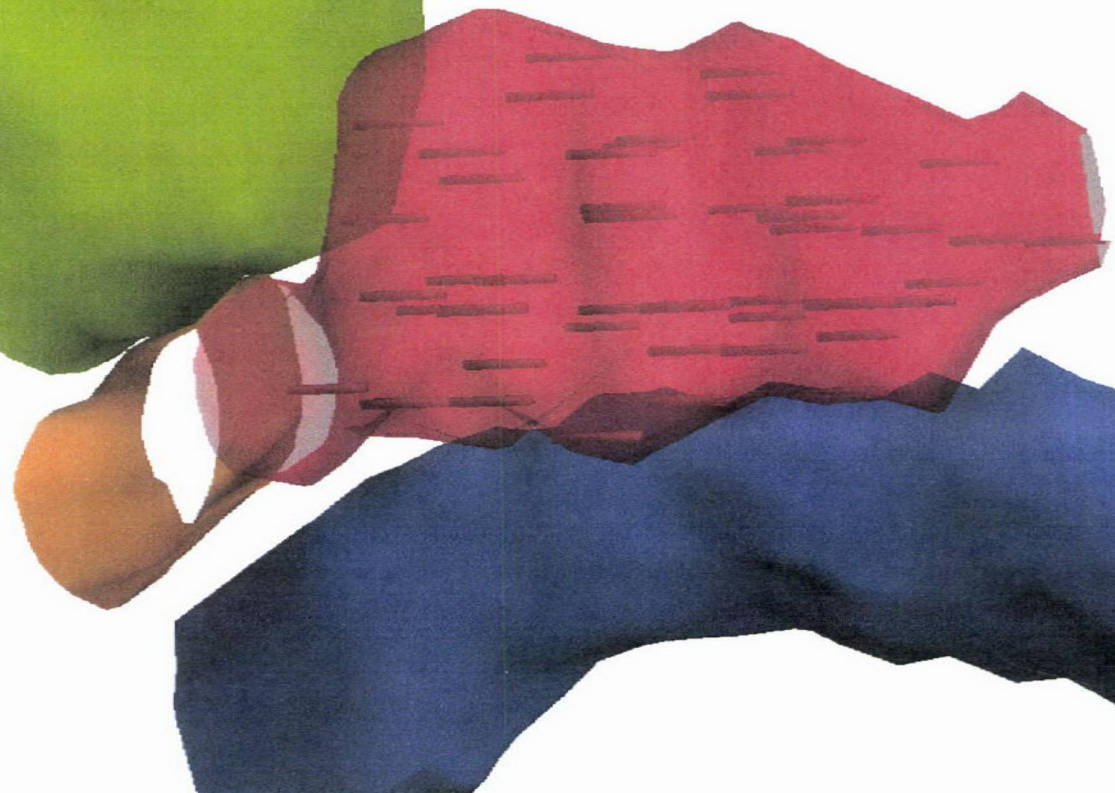
Cincinnati VA

Prescribed dose= 144 Gray

Dose Administered= 148 Gray



← **BLADDER**



← **PROSTATE**



← **RECTUM**

Recommendations, 10 CFR 35.3045 (cont.)

- **For normal tissue in neighboring structures – ME if dose to contiguous ≥ 5 cc exceeds 150% of the absorbed dose prescribed for the treatment site.**

Recommendations, 10 CFR 35.3045 (cont.)

- **For normal tissue structures within treatment site – ME if dose to contiguous ≥ 5 cc exceeds 150% of the expected absorbed dose for that tissue.**

Recommendations, 10 CFR 35.3045 (cont.)

- **ME if treatment is administered:**
 - **using wrong radionuclide;**
 - **using wrong source strength (+/- 20%) as specified in the WD;**
 - **with delivery to the wrong patient;**

Recommendations, 10 CFR 35.3045 (cont.)

- **ME if treatment is administered:**
 - **with implantation directly into the wrong site or body part;**
 - **with delivery using the wrong modality;**
 - **using leaking sources.**

Recommendations, 10 CFR 35.3045 (cont.)

- **All of the proposed ME criteria reflect circumstances in which there is actual or potential harm to patients being treated.**

Recommendations, 10 CFR 35.40, WDs

- **Define separate criteria for permanent implant brachytherapy**
- **Delete “total dose” as an option for completing the WD**
- **Replace “before completion of the procedure”**

Variance of recommendations from ACMUI report

- **No requirement for an AU attestation on source distribution**

Variance from ASTRO recommendations

- **Inclusion of dose-based ME
criteria for normal tissues and
structures**

Variance from OAS recommendations

- **Not having a dose-based ME criterion for the treatment site**
- **Having set dose threshold ME criteria for normal tissues and structures**

Staff position re: its current recommendations

- **Patient interests would be protected.**
- **Physicians would be able to take medically necessary actions.**

Staff position re: its current recommendations (cont.)

- **NRC would be able to continue detecting failures in process, procedures, and training plus misapplications by AUs.**
- **Stakeholder input is reflected in these recommendations.**

Acronyms

- ACMUI – Advisory Committee on the Medical Uses of Isotopes
- ASTRO – American Society for Radiation Oncology
- AU – Authorized User
- cc – cubic centimeter
- FSME – Office of Federal and State Materials and Environmental Management Programs
- ME – Medical Event
- MSSA – Division of Materials Safety and State Agreements
- OAS – Organization of Agreement States
- SRM – Staff Requirements Memorandum
- WD – Written Directive