



**Part 35 Medical Events Definitions –
Permanent Implant Brachytherapy
Advisory Committee on the Medical Uses
of Isotopes Recommendations**

James S. Welsh, M.S., M.D., FACRO
Advisory Committee on the Medical Uses of Isotopes
Radiation Oncologist

April 24, 2012

Need for New Definition of Medical Event?

- **Edema or atrophy alter prostate shape or volume and affect dose calculations possibly leading to cases being inappropriately labeled as ME's**
- **3 retracted MEs in FY2011**

2012 ACMUI Recommendations Source-Strength Based Criteria

- **Greater than 20% of the sources fall outside of the treatment site**

2012 ACMUI Recommendations

Dose-Based Criterion

- For normal-tissue structures
 - For *neighboring* structures the dose to at least 5 contiguous cm³ exceeds 150% of the dose prescribed to the treatment site
 - OR
 - For *intra-target* structures, the dose to at least 5 contiguous cm³ exceeds 150% of that structure's expected dose based on the approved pre-implant, dose distribution

2012 ACMUI Recommendations Other Existing Criteria

Or if a treatment is executed

- **Using the wrong radionuclide**
- **Using the wrong activity or source strength (>20% different from the WD)**
- **Delivered to the wrong patient**
- **Delivered directly to the wrong site or body part**
- **Delivered using the wrong modality**
- **Using leaking sources**

2012 ACMUI Recommendations Written Directive Completion

- **At completion of procedure**
- **Document unusual aspects**

2012 ACMUI Recommendations

Written Directive Completion:

AU Attestation

- **AU should provide a statement in the WD attesting that the permanently implanted sources have been placed in accordance with the plan**

ACMUI Dissenting Opinion

- **Ambiguity of the term, treatment site, may prove impractical**
- **Dissociation of definition with potential harm to patient**
- **Lack of distribution criterion**
- **Attestation may cause regulatory ambiguity**

2012 ACMUI Recommendations

Treatment Site

- **Recommendation to NRC – Definition for treatment site in 10 CFR 35.2 should include the modern concepts of GTV, CTV and PTV**
 - **Non-specific, could be GTV, CTV or PTV**
 - **AU can create written directive to volume of choice**

2012 ACMUI Recommendations Bunching

- **AU Attestation on WD**
- **ACMUI Dissenting Opinion – Octants**
- **Post-implant imaging**

Summary

- **Need for new ME definition**
- **2012 ACMUI Recommendations**
 - **Source-strength based criteria for treatment site**
 - **Dose based criterion for neighboring and intra-target structures**
 - **Other existing criteria**
 - **No change to definition of treatment site**
 - **Completion of written directive**
 - **AU attestation**
 - **Post-implant imaging and dosimetry**

Definitions/Abbreviations

- **ACMUI – Advisory Committee on the Medical Uses of Isotopes**
- **AU - Authorized User**
- **CFR – Code of Federal Regulations**
- **CTV - Clinical target volume, where microscopic extension of disease might exist**
- **D₉₀ - Dose that covers 90% of CTV**
- **GTV - Gross tumor volume, the visible or palpable target**
- **ME - Medical Event**
- **PTV - Planning target volume, which includes factors such as set-up variability and patient movement in external beam radiotherapy and normal internal organ motion in brachytherapy and which is where the sources are to be within**
- **WD - Written Directive**