



# **Update, Proposed Regulatory Changes– Permanent Implant Brachytherapy**

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**ACMUI Meeting**  
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# **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.**

# **Basis For Current Recommendations**

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

# **Status of Recommendations**

- **SECY-12-0053,**  
**“Recommendations on Regulatory Changes for Permanent Implant Brachytherapy Programs” (4/5/12)**
- **SRM-SECY-12-0053,**  
**“Staff Requirements...” (8/13/12)**

# **Recommendations, 10 CFR 35.3045, Reporting MEs**

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

# **Recommendations, 10 CFR 35.3045 (cont.)**

- **For normal tissue in neighboring structures – ME if dose to contiguous  $\geq 5$  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  $\geq 5$  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”**

# **Staff position re: these current recommendations**

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

## **Staff position re: these 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
- ME – Medical Event
- OAS – Organization of Agreement States
- WD – Written Directive