



ACMUI Permanent Implant Brachytherapy Subcommittee Recommendations

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§35.400 (2010)

- **Total = 26 Medical Events (75 patients)**
 - **Permanent prostate brachytherapy:
69 pts**
 - **8 Overdoses**
 - **1 excess dose to normal tissues**
 - **1 incorrect seed activity**
 - **One overdose retracted based on repeat post-implant dosimetry**

§35.400 (2010)

- **Rest were underdoses**
 - **2 underdoses retracted and not deemed to be true Medical Events**
 - **(Prostate swelled and upon re-evaluation, final dose was within 20%)**

§35.400 (2010)

- **A highly unusual retracted Medical Event:**
- **D90 <1% (!)**
- **But NOT regarded an ME since 39/41 seeds within target – all implanted within a few mm of “isoline”**
- **“Could have been placed in better location”**
- **Due to poor image quality**

35.400 Comments

- **Majority based on dose (e.g. D90)**
 - **Would these still be ME's if we used activity or source strength based definitions?**
 - **Many occurred earlier but were reported this year**
 - ***MANY* more next year expected!**

Key Points

- **The Subcommittee**
 - **Believes that activity-based metrics for the definition of Medical Events remain preferable**
 - **Strongly recommends that NRC seek specific help from stakeholders for development of the definition**

Key Points

- **Most members feel that a “Medical Event” should be of medical significance**
- **The definition should be sensitive enough to potential harm to a patient**
- **But also capable of identifying trends and patterns that might eventually lead to patient harm...**

Key Points

- **Post-implant dosimetry is important and should be performed**
- **The proposed 60-day timeline is controversial**
 - “Patient-related factors” should not be Medical Events
 - A slight delay beyond 60d should not be an ME

Key Points

- **The Subcommittee suggests separation into two categories:**
 - **Those which result in significant rearrangement of implant location during completion of the surgical implant procedure**
 - **such as operative lung implants**
 - **and those procedures that do not**
 - **such as prostate implants**

Part §35.3045(a)(3)

- **“A dose ... that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected”**
 - **0.5 Sv is a very small amount compared to therapeutic doses prescribed (amounting typically to 0.35%).**
 - **A 50% overdose could be medically inconsequential if the original expected dose to that normal tissue was very low**
 - **The units used remain inconsistent and confusing. It is suggested that the final rule use appropriate units in a consistent manner.**
 - **It might be preferable to drop this section entirely.**

An Alternative

- For the Target:
- $D_{90} < 70\%$ of the clinical target volume (CTV)

AND

- Less than 5% of sources occupy any octant of the PTV, except by intent
 - (and as specified in the written directive)

For Normal Tissues

•For the bladder and rectum, the D_{5cc} on post-implant dosimetry exceeds 150% of the prescription dose

OR

•For the urethra, the D_{5cc} on post-implant dosimetry exceeds 150% of its value on the planned, approved dose distribution

Features of the Definition

- **This definition *WOULD* catch an event where all the sources are bunched**
- **It would *NOT* signify as a Medical Event an implant with the sources missing an octant, provided the dose coverage is above 70%**

Overall Safety

- **Total permanent prostate brachytherapy:**
- **Total ~20,877 procedures**
- **69 ME's / 20,877 = 0.0033 (0.33%)**

Brachytherapy in the USA is Very Safe but...

2004:

- **192,102 prostate cancer treatments**
- **41,790 permanent prostate implants (22%)**

Brachytherapy in the USA is Very Safe but...

2009:

- **219,760 prostate cancer treatments**
- **17,490 permanent prostate implants (8%)**