§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 a 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%)