U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Briefing on Proposed Rule on Part 35 Medical Events Definitions – Permanent Implant Brachytherapy

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Introductory Comments

- A goal: Medical Events should be based on potential clinical significance
- This necessitates a careful balance:
  - Avoiding overly sensitive clinically-insignificant definitions (which might overburden the system)
  - And ensuring that the definition will identify those procedures that are potentially harmful
- This is a difficult task and everyone wants to get it right
- The Subcommittee believes that the re-proposed rule in its present form would not be successful in this very challenging balancing act

Medical Events

- An appropriate definition of a Medical Event is one that reflects the real potential of harm to a patient

- “Harm to a patient” can be from:
  - Overdosing normal tissues
  - Substantially under-dosing the targeted cancer

- Again this requires a very careful balancing act between these two parameters when attempting to come up with acceptable definitions of Medical Events

Inherent Difficulties With an Appropriate Definition for Medical Events for Permanent Implant Brachytherapy

- Brachytherapy is **an art** as well as a science
- No simple definition of Medical Event adequately covers all potential adverse circumstances

Challenges

- In the past ACMUI has not endorsed the concept of an absorbed dose-based criteria
- However, the Subcommittee now acknowledges that there may be rare situations in which activity-based criteria may be inadequate
- On the other hand, all previously proposed dose-based criteria create new difficulties or face new challenges

Challenges (and solutions)

- The difficulty posed by post-implant volume change and absorbed dose calculations
- The dose in the following examples will deviate from the Written Directive yet are NOT considered Medical Events – they are "patient-related factors"
  - If a temporary implant is yanked out by a patient
  - If a seed migrates out of place after being properly positioned
  - Stasis reached during a Y-90 microsphere procedure
- The Subcommittee suggests that alterations in dose due to anatomic prostate volume changes also be considered a "patient-factor" and thus excluded from Medical Event definitions

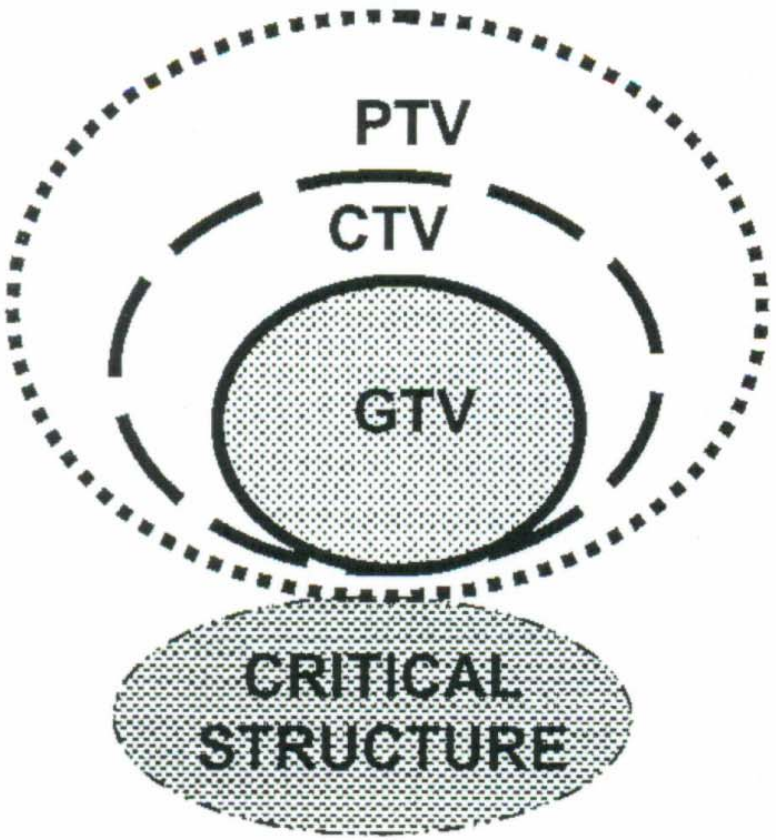
A Proposed Concept

- If using a dose-based criterion, we suggest introducing the concept of normalization to the initial volume *V(init)* on which the authorized user has created the plan
- There can be differences in volumes calculated
- In addition to addressing the concern about anatomic post-implant volume changes that affect dose calculations, V(init) also addresses the problems faced by the above non-anatomic volume differences

A Proposed Concept

- The V(init) concept might be easily implemented
  - Pre-implant prostate volume is known for all implants
  - It does not require additional effort

- To properly address Medical Events in permanent implant brachytherapy we recommend that modern terminology be used rather than “treatment site”



Volume abbreviations:
GTV = gross tumor volume
CTV = clinical target volume
PTV = planning target

Post-implant Dosimetry

- The Subcommittee is divided about the insistence on post-implant dosimetry

Final Thoughts on Dose-based Criteria

- Returning to the original concept of a Medical Event as something that could be of “harm”
  - Perhaps a solution would be to shift the emphasis, focusing more (or equally) on dose to normal tissues
  - This would adequately address the goal of identifying potential harm to a patient
  - Overdoses to normal tissues (i.e. an absorbed dose that exceeds normal tissue tolerances) are potentially harmful
- ACMUI also has a suggestion that would address “harm” due to under-dosing the target and not curing the patient

Conclusions

- The ACMUI Permanent Implant Subcommittee is opposed to certain aspects of the re-proposed rule and urges the Commission NOT to publish it in its present form

- The matter is complicated and will have a huge impact on the regulated community

Conclusions (continued)

- Therefore, it is imperative that the ultimate version be correct (the re-proposed rule fails in too many aspects)

- We recommend that NRC seek stakeholder input during any revision

- If NRC desires a dose-based criterion, the Subcommittee is prepared to offer an understandable, unambiguously measurable and carefully considered solution based on all of the above