



Permanent Implant Brachytherapy Subcommittee Report

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Key Points

- **The Subcommittee**
 - **finds that activity-based metrics for the definition of Medical Events remain preferable to any dose-based metric**
 - **Dose-based metrics are fraught with difficulties**
 - **strongly recommends that NRC seek specific help from stakeholders for development of the definition**

Key Points

- A “medical event” should be of medical significance
- The definition should be sensitive enough to potential harm to a patient
 - Harm due to overdosing of sensitive normal structures and tissues
 - Harm due to under-dosing the cancer and not curing the patient

Key Points

- **Post-implant dosimetry is important and should be performed**
- **The 60-day timeline is controversial**
 - **Patient refusal to return within the defined time-frame should be considered a “patient-related factor” and excluded from classification as Medical Events**

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**

10 CFR 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.**