

# Permanent Implant Brachytherapy Medical Event Definition

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#### References

- All publically available at <u>www.nrc.gov</u>
- Click, in order, "NRC Library," "Document Collections," "Commission."
- Then, either "Commission Papers" or "Staff Requirements Memoranda."
- Documents are listed by number (and title); first part of number is year.



# Background

 SECY-05-0234, "Adequacy of Medical Event Definitions in 10 CFR 35.3045, and Communicating Associated Risks to the Public"



 Staff Requirements, SRM-SECY-05-0234, "Adequacy of Medical Event Definitions in 10 CFR 35.3045, and Communicating Associated Risks to the Public."



 SECY-08-0080, "Proposed Rule: Medical Use of Byproduct Material — Amendments/Medical Event Definitions (RIN 3150- AI26)."



 Staff Requirements, SRM-SECY-08-0080, "Proposed Rule: Medical use of Byproduct Material -Amendments/Medical Event Definitions (RIN 3150-AI26)."



 SECY-10-0062, "Reproposed Rule: Medical Use of Byproduct Material – Amendments/Medical Event Definitions (RIN 3150- AI26)."



 Staff Requirements, SRM-SECY-10-0062, "Reproposed Rule: Medical Use of Byproduct Material -Amendments/Medical Event Definitions (RIN 3150- AI26)."



### Discussion – the Challenge

 How do we appropriately balance between the general medical community's desire to define an ME in terms of clinical significance with NRC's need to have mistakes in the process reported, even if there is no actual negative consequence to the patient?



#### Acronyms

- ME: Medical Events
- SECY: Office of the Secretary
- SRM: Staff Requirements Memorandum



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