



**Status of Part 35 Rulemakings**

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**Part 35 - Medical Event Definitions Proposed Rule**

**Next Part 35 Rulemaking**




**Part 35 - Medical Event Definitions Proposed Rule**

- Adds an ME criterion (reportable under § 35.3045), any administration requiring a written directive (WD) if a WD was not prepared.
- Changes most ME criteria from dose-based to activity-based for permanent implant brachytherapy.
- Clarifies WD requirements for permanent implant brachytherapy.




**Part 35 - Medical Event Definitions Proposed Rule**

- Proposed Rule published in Federal Register Aug 6, 2008 (73 FR 45635).
- Public comment period ends Nov 7, 2008.
- Staff must review and resolve all public comments.



**Part 35 - Medical Event Definitions Proposed Rule**

- Takes up to a year to develop and publish the Final Rule.
- Very dependent on the number of public comments received.
- Staff may have to do additional analysis or research.
- Final Rule should publish in Aug 2009 pending Commission approval.



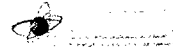
**Why Does It Take This Long?**

- A collaborative, deliberative process.
- Resolution of comments.
- Commission takes very seriously its role in review and approval of regulations.



## Next Part 35 Rulemaking

- Will include numerous amendments identified by the NRC Medical Team.
- The proposed changes have been, or will be reviewed by ACMUI.
- Ritenour Petition should be included.
  - Ritenour Petition requested NRC to amend Training and Experience (T&E) requirements for experienced Authorized Medical Physicists and Radiation Safety Officers.
  - NRC resolution (73 CFR 27775, May 14, 2008) to consider issues in a future rulemaking, pending development of a technical basis.



## Next Part 35 Rulemaking Time Line

- Scheduled to begin Summer 2009.
- Proposed Rule – Tentative Summer 2010
- Final Rule – Tentative Summer 2011



## Status of Part 35 Rulemakings

Questions?