Status of Part 35 Rulemakings

Ed Lohr / Neelam Bhalla
Rulemaking Branch B
DILR/FSME

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


• 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?