



# Part 35 Reproposed Rule on Medical Event Definitions

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# Agenda

- History
- Stakeholder Involvement
- Development of Rule
- Conclusion

# History

- 1973 - Proposed Misadministration Rule
- 1980 - Final Misadministration Rule
- 1987-2002 - Three Major Revisions of Part 35

# Stakeholder Involvement

- ACMUI
- Medical community
- Other stakeholders

# Medical Event Summary

| Year    | Total ME Reports <sup>1</sup> | # 35.400 Prostate Reports <sup>1</sup> | # of Prostate Patients |
|---------|-------------------------------|--|------------------------|
| 2004    | 35                            | 5                                      | 5                      |
| 2005    | 41                            | 5                                      | 5                      |
| 2006    | 33                            | 5                                      | 5                      |
| 2007    | 40                            | 8                                      | 25                     |
| 2008    | 31                            | 9 <sup>2</sup>                         | 115                    |
| 2009    | 46                            | 15 <sup>2</sup>                        | 23                     |
| Average | 38                            | 8                                      |                        |

<sup>1</sup>Approximately 150,000 therapeutic procedures are performed each year, of which less than 50,000 are permanent implant brachytherapy procedures.

<sup>2</sup>8 DVA Permittees reported during one or both years (121 patients - 97 from 1 facility).

# Purpose of Rule

- To prevent recurrence;
- To identify potential generic problems; and
- To allow timely decisions on health care

# Development of Rule

- 2004 ACMUI Commission Meeting
  - Are we communicating the right risk information?
- SECY-05-0234
  - Recommendation based on input from ACMUI

# Development of Rule (cont'd)

- SECY-08-0080
  - Proposed rule changes most ME criteria from dose- to activity- based
- SECY-10-0062
  - Adds some new-activity-based criteria
  - Retains dose-based criteria

# Conclusion

- Medical event reporting required since 1980
- Protect patient safety without intruding on the practice of medicine
- Stakeholder involvement throughout rule development

# Acronyms

- ACMUI - Advisory Committee on Medical Uses of Isotopes
- DVA - Department of Veterans Affairs
- ME - Medical Event
- SECY - Office of the Secretary