



10 CFR Part 35 Medical Event Reporting Rule and Implementation Plan

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A Brief History

- July 25, 2008: SRM-SECY-08-0080
- May 18, 2010: SECY-10-0062
- July 8, 2010: Commission Meeting
- August 10, 2010: SRM-SECY-10-0062

SRM-SECY 10-0062

- Commission Disapproved Re-proposed Rule and Directed Staff to:
 - Work Closely with ACMUI and Broader Medical and Stakeholder Community to Develop Medical Event Definitions
 - Hold a Series of Stakeholder Workshops to Discuss Issues Associated with the Medical Event Definition
 - Develop Integrated Plan Denoting Schedule and Agreement State Participation

Integrated Plan

- NRC Has Three Options for Rulemaking:
 - Continue with 10 CFR Part 35 (expanded) Rulemaking Then Begin a New Permanent Implant Brachytherapy Medical Event Rulemaking
 - Begin a New Permanent Implant Brachytherapy Medical Event Rulemaking Then Begin the 10 CFR Part 35 (expanded) Rulemaking
 - Combine the 10 CFR Part 35 (expanded) Rulemaking with a New Permanent Implant Brachytherapy Medical Event Rulemaking

Integrated Plan

- Current Rules Will Be in Effect for At Least Three Years
 - Currently Drafting Enhanced Permanent Implant Brachytherapy and Medical Event Reporting Inspection and Licensing Guidance for Current Rules
 - Will Soon Be Sharing Enhanced Guidance with ACMUI and OAS for Feasibility Review
 - Will Use Draft Guidance as a Starting Point for Series of Public Workshops
 - If Enhanced Guidance is Found to be Effective, a Combined Rulemaking May Be Feasible (with some limited changes to rules for Medical Event reporting)

Schedule

- Winter/Spring 2011 - Develop Enhanced Guidance for Permanent Implant Brachytherapy and Medical Event Reporting, with Agreement State Participation
- May Devote Spring 2011 ACMUI Meeting to 10 CFR Part 35 Rulemaking Issues
- Spring/Summer 2011 - Hold Two or Three Public Workshops
 - Scope of Workshops May Be Expanded to Include Discussion of All of the More Controversial 10 CFR Part 35 Rulemaking Topics if a Combined Rule is Undertaken

Schedule Continued

- Current Schedule for 10 CFR Part 35 Rulemaking :
 - Proposed Rule March 2012
 - Final Rule September 2013
- If Rulemaking is Expanded:
 - Workshops - Spring/Summer 2011
 - Consolidate - Comments Summer 2011
 - Start Proposed Rule – Fall 2011

Schedule Continued

- If Rulemaking is Expanded (continued):
 - Complete Proposed Rule – Winter 2012/2013
 - Publish Proposed Rule – Spring 2013
 - Conduct Three Public Meetings for Comment on Proposed Rule – Spring 2013
 - Final Rule to Commission Fall 2014



Questions?

Acronyms

ACMUI – Advisory Committee on the
Medical Uses of Isotopes

CFR – Code of Federal Regulations

NRC – Nuclear Regulatory Commission

OAS – Organization of Agreement States

SRM – Staff Requirements Memorandum