



NRC Medical Rulemaking Workshops

Michael Fuller
Team Leader
Medical Radiation Safety Team
US NRC



Purpose

To Provide an Overview of the Key Messages NRC Staff Received During the Medical Rulemaking Public Workshops Held in New York and Houston in June and August 2011

Outline

- Key Messages
 - Medical Event Definitions Associated with Permanent Implant Brachytherapy
 - Amending Attestation Requirements and Extending Grandfathering to Certain Certified Individuals
 - Naming Assistant/ Associate RSOs on Licenses



Outline

- Additional Requirements for Mo-99/Tc-99m Generators
- Next Steps

Background

- Commission Directed NRC Staff To:
 - Work Closely with the ACMUI and the Medical Community to Develop Event Definitions That Would:
 - Protect the interests of patients
 - Allow physicians the flexibility to take actions that they deem medically necessary
 - Preserve the NRC's ability to detect misapplications of radioactive material and failures in process, procedure and training



Background

- ACMUI Meeting in Rockville, April 2011
- First Workshop in New York, June 2011
- Second Workshop in Houston, August 2011

Background

- Two Separate Panels of Experts
 - Medical Event Definition Panel Included ACMUI, Agreement States, ASTRO, AAPM, NRC Staff, VA (licensee), Patient's Rights Advocate
 - Attestation Panel Included ACMUI, Agreement States, AAPM, ACR, NRC Staff

Key Messages

- Medical Event Definition
 - Among the States - Fairly Consistent Regulations, but Wide Variance in the Interpretation and Implementation of the Regulations
 - ME Definition for Permanent Implant Brachytherapy Needs to be Revised, and Should be Based Upon Total Source Strength (activity) not Absorbed Dose

Key Messages

- If ME Definition is Based Upon Total Source Strength, a Tolerance of \pm 20% is reasonable
- The Term “Medical Event” Should Be Reserved for Those Instances Where There is Real Harm to the Patient or a Potential for Same (clinically significant)

Key Messages

- Licensee Staff Should be Trained in the Policies and Procedures for Identifying MEs
- Patient's Rights Should be Protected
- AUs should be required to Attest in Writing, That the Distribution of Seeds, Within the Target Was Implanted As Intended
- Post-Implant Imaging Should be Required

Key Messages

- Attestation
 - The Requirement for Attestation for Board Certified AUs, AMPs, RSOs, and ANP Should be Removed
 - Board Certification Coupled with the “Recentness of Training” Requirement Should be Sufficient for the Regulator’s Needs

Key Messages

- There Should be No Requirement for Attesting to Someone's Competency, but Rather Preceptors Should be Attesting to Someone's Training and Experience Necessary to Carry Out One's Responsibilities Independently

Key Messages

- Assistant /Associate RSO
 - NRC Should Allow for the Naming of Associate/Assistant RSOs on an NRC Medical-use License
 - There Should be No Arbitrary Limit Placed on the Number That Can be So Named

Key Messages

- New Testing Requirements for Mo-99/Tc-99m Generators
 - There Should be a New Requirement for Testing Each Mo-99/Tc-99m Generator Elution (not just the first elution)
 - There Should Not be a Requirement for NRC Licensees to Report Failures to NRC



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WHAT'S NEXT?



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QUESTIONS?