



NRC Medical Rulemaking Workshops

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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?