Stakeholder Workshop Introduction

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Status of the Rule

- Revised Part 35 was published in the Federal Register on April 24, 2002
- Effective date of revised Part 35 is October 24, 2002
- Agreement States have 3 years to implement after October 24, 2002

Licensing Guidance Document Status

- NUREG 1556 Vol. 9
  - Will review latest draft today
  - Final revision by end of September

Specialty Board Issue

- February 2002, ACMUI briefed Commission about concern over specialty boards not meeting requirements in proposed Part 35
- Without specialty board recognition, all new AUs, ANPs AMPs, and RSOs would be required to meet the new T&E requirements
- Result would be a shortage of AUs, ANPs, AMPs, and RSOs
- Commission decided to retain Subpart J for 2 years as another pathway for AU, ANP, AMP, RSO status

Specialty Board Issue continued

- Certification Board of Nuclear Cardiology recognized for users under 35.200 (imaging and localization studies)
- July 2002, ACMUI provided recommendation on resolving specialty board recognition to NRC
- NRC working on issue to determine if rule revision is appropriate

Part 35 Changes

- Structure NRC's regulations to be risk-informed and more performance-based
- Focus regulations on the radiation safety aspects of medical procedures that pose the highest risk
  - Safety procedures and spot checks for therapy devices
- Reduce prescriptiveness of requirements in low risk activities
  - NO radiation safety program procedures submitted by diagnostic use licensees

Part 35 Changes continued

- Allows the licensee flexibility in deciding how to implement a radiation protection program
  - Radiation Safety Committee prescriptiveness deleted
  - Program changes allowed without NRC review
- Use of Sealed Source and Device Registry
- Use of nationally recognized standards and protocols

Part 35 Changes continued

- Update requirements for existing treatment modalities, codifies license conditions
- Deletion of Quality Management Program
- “Misadministration” is redefined as “medical event”
  - Dose thresholds for each type of event

Written Directive

- Written directive required before administrations of:
  - I-131 NaI >30 uCi
  - Any therapeutic dosage of unsealed byproduct material
  - Any therapeutic dose of radiation from byproduct material

Structure of New Rule

Types of Use

- 35.100 Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required
  - Not much change

Structure of New Rule

Types of Use

- 35.200 Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required
  - Written directive is threshold (not diagnostic)
  - I-131 > 30 uCi moved to 35.300 (requires a written directive, even if used for diagnostic purposes)

Structure of New Rule

Types of Use

- 35.300 Use of unsealed byproduct material for which a written directive is required
  - Therapy dosages
  - Unsealed I-131 >30 uCi for all uses

Structure of New Rule

Types of Use

- 35.400 Use of sources for manual brachytherapy
  - Limited to manual brachtherapy
  - Remote brachytherapy moved to 35.600
  - Definition: Manually placed topically on or inserted either into body cavities that are in close proximity to a treatment site or directly into the tissue volume

Structure of New Rule

Types of Use

- 35.500 Use of sealed sources for diagnosis
  - No written directive required
  - Any sealed source in SS&D approved for diagnostic use

Structure of New Rule

Types of Use

- 35.600 Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit
  - Written directive required
  - Was teletherapy only

Structure of New Rule

Types of Use

- 35.1000 Other medical uses of byproduct material or radiation from byproduct material
  - For any type of use not falling into another subpart
  - Provides requirements for licensee wanting to use a new modality

Structure of New Rule

Organizational Changes

- Training and experience (T&E) requirements found in 2 separate areas:
  - New T&E requirements located in each type of use subsection
  - Subpart J still in 35.900s
- Can use either part to meet new user status until October 24, 2004

Structure of New Rule

Organizational Changes

- Record keeping requirements detailed in Subpart L - 35.2000s
- Requirements also referenced in appropriate sections

Structure of New Rule

Organizational Changes

- Reporting requirements now in one area Subpart M

Slide Presentation

- Slides are busy - meant for reference
- Not all inclusive
- Color Coding
  - White - unchanged
  - Yellow- new
  - Brown - deleted