



# Commission Briefing

## March 2, 2004

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**Nuclear Safety**  
**Office of Nuclear Material Safety and Safeguards**

# Staff Presentation

- Licensing and inspection experience under new Part 35, a regional perspective
- Status report on NRC method of dose reconstruction on a member of the public from a medical exposure

# ACMUI Presentation

- Revision on Proposed Part 35 Training and Experience Rulemaking
- ACMUI's efforts on reviewing NRC method of dose reconstruction



# NRC Regional Experience with New Part 35 (effective October 24, 2002)

**Pamela J. Henderson**  
**Chief, Nuclear Materials Safety**  
**Branch 1, NRC Region I**

# Change

- New Part 35 is a significant change in NRC's approach to regulation of medical uses of byproduct material.

# What We See in the Field:

- Licensees are still adjusting to the idea that we no longer require submittal of detailed procedures and commitments for limited diagnostic programs.
- Licensees frequently have questions concerning interpretation of the regulations and the expectations of the NRC.

# What We See in the Field:

- One of the most significant licensing challenges is to encourage licensees to use NUREG-1556, Volume 9, “Program Specific Guidance About Medical Use Licenses.”

# What we see in the field:

- Inspectors are finding most licensees express a preference for the earlier, more prescriptive approach of Part 35.
  - RSC meetings are still held quarterly
  - Daily surveys are still being done in diagnostic use areas
  - Dose calibrators are still being used to measure unit dosages prior to administration
  - Dose Calibrator linearity, geometry and accuracy are being done at the same frequency and following the same procedures that were provided in Regulatory Guide 10.8, Revision 2



# Licensing Challenges

- Licensees continue to submit items that are no longer required
  - quality management programs
  - detailed procedures for diagnostic uses

# Licensing Challenges

- Improved licensee understanding of the details that need to be submitted for 35.600 technologies (HDR and Gamma Knife) for safety procedures and spot checks
- Improved licensee understanding of 35.1000 (emergent technologies) procedures

# Updating Licenses

- The Regions are updating medical licenses as licensees come in for amendments and not waiting until renewal of the license. Updates include:
  - user authorizations
  - removal of old license conditions now covered by the regulations
  - addition of new license conditions to permit flexibility

# Inspections

- Inspectors agree that new Part 35 focuses inspections on more safety significant areas of medical programs.

# Inspection Challenges

- Ensuring that inspectors:
  - do a performance-based inspection
  - do not do a “record-keeping” inspection (look at a representative sample of records)

**Labor rates for inspection and management accompaniments confirm inspectors are implementing this new approach.**

# Inspection Challenges

- For most licensees, the first inspection under new Part 35 includes education about the details of the new regulation, and guidance about program changes that may be needed.

# Staff Actions to Address Challenges

- Continuing dialogue with licensee community
- Close coordination of Regions and Headquarters on Part 35 issues (Part 35 Working Group)
- NRC Public Website – Guidance



# St Joseph Mercy Hospital Exposure Case

Thomas H. Essig  
Office of Nuclear Material Safety and  
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# Actions to Date

- Region III conducted a special inspection in October 2002. The inspection report documents the details of the case and the dose assessment.
- Enforcement action was taken on the basis of the inspection findings.

# Actions to Date

- In December 2003, SNM challenged the dose assessment in the inspection report as excessively conservative.
- NMSS staff performed evaluations of the Region III dose assessment as well as of the critique submitted to the NRC by SNM.

# Actions to Date

- The Commission directed the staff to solicit an independent review by ACMUI.
- ACMUI is preparing its report to be submitted to NMSS.

# Actions to Close this Case

- NMSS will evaluate ACMUI's report when submitted.
- Using the Region III assessment, its own evaluations, and the ACMUI report, NMSS staff will form conclusions regarding the merits of the SNM critique.

# Actions to Close this Case

- A report will be prepared detailing the staff's findings and conclusions for the Chairman's signature.



# PROPOSED RULEMAKING ON PART 35 REVISION

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ACMUI, Nuclear Medicine Physicist

March 2, 2004

# Proposed Rulemaking On Part 35 Revision

## Training & Experience

- Board Certification
- Preceptor Statement
  - Attest vs. Certify
- Transitional Issues
- Comment period ended 2/23/04

# Board Certification

- Recognition
  - Important especially for AMP, RSO
- §35.50(d)(2)(i) excludes non-AMP
- Process for Board Listing
  - Written notice
  - Workshop with Stakeholders



# Preceptor Statement

- ACMUI provided basis for NRC action to decouple preceptor statement from board certification
- New requirement for both board certified & alternate pathway
- **Def** [§35.2]: an individual who provides or directs the training and experience required for an individual to become an AU, an AMP, an ANP, or a RSO

# Preceptor Statement

- Must be flexible, practical, minimize implementation burden and allow:
  - 1) preceptor who is not providing the training and experience
  - 2) allow multiple preceptor statements
- Modify?: “an individual who provides or directs training and experience...”

# Preceptor Statement

## Implementation Concerns/Issues:

- Who may be preceptor
- Grandfathering
- Unwilling/Unavailable
- Standard language practical for all

# Preceptor Statement

Implementation Concerns/Issues:

- Multiple statements for AU or AMP named as RSO
- Resolution in rules or guidance space

# Transition Issues

- Individuals currently in training programs
- AMP Grandfathering
- Authorized users of I-131 for diagnostic purposes meeting T&E for written directive use
- Concerns raised from Public Comment period or during implementation may benefit from ACMUI review