

COMMISSION BRIEFING SLIDES/EXHIBITS

MEETING WITH ACMUI & NRC STAFF

MARCH 2, 2004



Commission Briefing

March 2, 2004

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Division of Industrial and Medical
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
Safeguards

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

Ralph P. Lieto

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