U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Briefing on Medical Issues

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Part 35 Rulemaking Issues

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AGENDA

- Recent Part 35 revisions
- Current Rulemaking
- High Visibility Issues
- Impacts on Current Schedule

Part 35 Revisions

- Revised in its entirety in 2002
- Training and Experience regulations in 2005
- 8 additional Part 35 amendments

Current Rulemaking

- Items identified through implementation of Part 35, ACMUI recommendations, and a petition for rulemaking
- A total of 28 specific items/issues in the expanded Part 35 rulemaking

High Visibility Issues in Proposed Rulemaking

- Amend preceptor attestations
- Ritenour Petition (AAPM) regarding T&E requirements
- Frequency of Molybdenum-99m testing
- Naming Assistant RSOs on a medical use license

Preceptor Attestation Revision

- Proposed by the ACMUI
- Not required for board-certified individuals prior to 2005
- In SRM-SECY-08-0179, the Commission approved the staff recommendations

Preceptor Attestation Revision

- Eliminate for all board-certified individuals
- Revise the wording on “achievement of competency”
- Allow Residency program Directors to provide attestations

Ritenour Petition (PRM-35-20)

- Petitioner requested amendment of T&E requirements for experienced AMPs and RSOs
- NRC resolved the petition in May 2008 and concluded that 2005 revision may have adversely affected some board-certified professionals, including AUs

Ritenour Petition (cont'd)

- NRC staff asked all certifying boards to survey their Diplomates who are or may be affected by the 2005 T&E revision
- Responses indicated that about 10,000 individuals may be affected

Frequency of Mo-99 Testing

- Current: Mo-99 breakthrough testing on 1st elution of Molybdenum-99/Technetium-99m generators
- Proposed: Mo-99 testing of each eluate; reporting requirement if the regulatory limit is exceeded

Assistant RSOs on the License

- Current policy: Part 35 does not allow more than one permanent RSO on the license
- Regulations require licensees to appoint an RSO, who agrees in writing to implement the Radiation Safety program

Assistant RSOs (cont'd)

- ACMUI (June 2007 meeting) expressed concern about naming only one person as the RSO
- ACMUI believed that it was contributing to a shortage of RSOs

Assistant RSOs (cont'd)

- ACMUI believes that naming more than one individual would
  - increase the RSO pool
  - duly recognize the qualified individuals
  - allow the licensee to quickly appoint an RSO if the named RSO leaves

Impacts on Schedule

- Current
  - -Proposed Rule: March 2012
  - -Final Rule: September 2013
- Incorporation of ACMUI Procedure and expanded comment periods
- Development of an Integrated Plan including consideration of high priority medical-related tasks

Release of Patients and the Nuclear Materials Events Database

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Patient Release Background

- May 1997 - NRC revised 10 CFR 35.75 to base each release on dose
- September 2005 – NRC received Petition for Rulemaking to return 10 CFR 35.75 to previous activity-based release criteria

Patient Release Background (cont'd)

- May 2008 – NRC denied Petition – current rule adequate to protect public health and safety
- October 2009 and January 2010 – Congressman Markey sent letters on this issue to NRC

Patient Release Requirements (excluding nursing patients)

Patients can be released if:

- Dose to any other individual from exposure to the patient is not likely to exceed 5 mSv (500 mrem)
- The patient or parent or guardian is provided written instructions, including recommendations for maintaining doses ALARA, if total dose to other individuals is likely to exceed 1 mSv (100 mrem)

Patient Release Requirements (excluding nursing patients) (cont'd)

Patients can be released if:

- The licensee maintains a record of the basis for authorizing the release

Patient Release Criteria for Nursing Patients

If TEDE to a nursing infant or child could exceed 1 mSv (100 mrem), the instructions must also include:

- Guidance on the interruption of breast-feeding; and
- Consequences, if any, of failure to follow the guidance

National and International Guidance

- NCRP Report No. 155, “Management of Radionuclide Therapy Patients” (2006)
- IAEA Safety Report Series # 63 “Release of Patients After Radionuclide Therapy” (2010)

National and International Guidance (cont'd)

- ICRP Publication 94, "Release of Patients after Therapy with unsealed Radionuclides" (2005)

NRC Requirements

- NRC's Current Regulations:
  - Provide No Distinction Between Exposure Limits for Family Members, General Public, and Children
  - Are Silent on the Issue of per Episode vs. per Annum

Table 1: ICRP (2005), NCRP (2006) AND IAEA (2010) RECOMMENDED DOSE LIMITS

Dose Limits	***IAEA & ICRP (2010)***	***NCRP (2006)***	***NRC***
Pregnant Women & Children	**1 mSv/year**	**1 mSv/year**	***5 mSv**
Immediate Family	**5 mSv/episode**	**5 mSv/year**	***5 mSv ** **
Public	**1 mSv/year**	**1 mSv/year**	***5 mSv**

* ALARA instructions required if dose estimate > 1 mSv.

** NRC regulations make no differentiation between members of the public and the immediate family.

Current NRC Guidance

- Regulatory Issue Summaries
  - Dose Limit for Patient Release Under 10 CFR 35.75 (3/08)
  - Precautions to Protect Children Who May Come In Contact with Patients Released After Therapeutic Administration of Iodine -131 (5/08)
- NUREG-1556, Vol. 9, App. U.

Path Forward

- ACMUI Patient Release Subcommittee Evaluated Adequacy of Existing Regulations and Guidance & Recommended:
  - NRC Dose Limit be on a per Episode Basis
  - 10 CFR 35.75 Not be Changed

Path Forward (cont'd)

- Staff Will Evaluate All ACMUI Recommendations
- Staff Is Developing a RIS for the Release of Iodine-131 Therapy Patients to Locations Other Than Private Residences

Nuclear Materials Events Database

Why Does NRC Use NMED ?

- To Identify:
  - Deficiencies in Safe Use of Materials; Precursors in Higher Risk Problems; Generic Issues and Concerns; AO's
- Responds to:
  - 1993 Govt. Performance Results Act
  - 1993 GAO Report Recommendations

What Is NMED ?

- Database Collects Event Info Involving AEA Materials
  - Medical Events that are Required to be Reported are Captured in NMED
  - Licensees are Identified in NMED
- Web-based Database at INL (http://nmed.inl.gov/)
- Powerful Search Engine

NMED Item Number: 100XXX

Narrative: Last Updated: 10/XX/20XX

ABC Hospital reported that a gamma knife (Leksell model Perfexion, serial #MV010) gave a fatal error and terminated treatment to a patient on 9/XX/20XX. The gamma knife contained 511.49 TBq (13,824 Ci) of Co-60 sources (model 43047). The error appeared to be a failed computer disc drive. The gamma knife safety system functioned as designed, moving the patient out of the unit and closing the shielding doors. The patient was safely removed from the treatment room. The patient was prescribed a dose of 1,400 cGy (rad) to the brain, but only received 71.5 cGy (rad). The patient was informed of the error on the same day. A service representative was contacted and repairs are in progress. ABC Hospital intends to give the remaining prescribed dose to the patient once the unit is repaired.

Event Date:	Discovery Date:	Report Date:
09/27/2010	09/27/2010	09/28/2010

Acronyms

- AAPM - American Association of Physicists in Medicine
- ACMUI – Advisory Committee on Medical Uses of Isotopes
- AEA- Atomic Energy Act
- ALARA- As Low As Reasonably Achievable

Acronyms (cont'd)

- AMP – authorized medical physicist
- AO- Abnormal Occurrence
- AS – Agreement States
- AU – authorized user
- CFR- Code of Federal Regulations

Acronyms (cont'd)

- GAO- U.S. Government Accountability Office
- IAEA- International Atomic Energy Agency
- ICRP- International Commission on Radiological Protection
- INL- Idaho National Laboratory

Acronyms (cont'd)

- NCRP- National Council on Radiation Protection and Measurements
- RIS- Regulatory Issues Summary
- RSO – Radiation Safety Officer
- SECY- Office of the Secretary

Acronyms (cont'd)

- SRM- Staff Requirements Memorandum
- T&E – Training and Experience
- TEDE- Total Effective Dose Equivalence