



# **Proposed Expanded 10 CFR Part 35 Rulemaking**

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# 10 CFR Part 35 Rulemaking - Revisions in Proposed Rule

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## ➤ **Introduction of “ARSOs”**

- Expands limited pool of qualified individuals to serve as RSOs
- Same T&E requirements as RSOs

## ➤ **Resolution of Ritenour petition (AAPM) for authorized professionals**

- “...for the modalities that they practiced as of 10/24/05...their previously-acceptable qualifications for authorized status should continue to be adequate and acceptable...and allow them to continue to practice using the same modalities.”
- ACMUI recommends that date of recognition by NRC of certifying board should not impact individuals seeking to be named as authorized professionals

# 10 CFR Part 35 Rulemaking - Revisions in Proposed Rule *cont*

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- **Elimination of preceptor attestation requirement for board-certified individuals**
- **New attestation language for alternative pathways**
  - “...able to independently fulfill radiation safety-related duties....”
- **7-year inspection/servicing requirement for gamma stereotactic radiosurgery units**
  - Replaces 5-year requirement - Inspection/servicing of such units onerous

# 10 CFR Part 35 Rulemaking - Revisions in Proposed Rule *cont*

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- **Requirement for testing of every generator elution for parent breakthrough**
- **Requirement for notification of NRC of generator elutions with out-of-tolerance parent breakthrough**
- **Authorization to use alpha emitters per § 35.300 and § 35.390 (b)(1)(ii)(G)**
  - No additional T&E for current AUs
- **New activity-based definition of ME for permanent implant brachytherapy**
  - Formulated to capture only clinically significant events
  - ACMUI recommends Compatibility Category B, to avoid ASs retaining dose-based ME criteria

# Regulatory Guidance for Proposed Expanded 10 CFR Part 35 Rulemaking

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➤ **Part 1: Draft Supplemental Guidance for NUREG-1556, Volume 9, Revision 2, Consolidated Guidance About Materials Licenses: Program - Specific Guidance About Medical Use Licenses**

➤ **Part 2: Draft Supplemental Guidance for NUREG-1556, Volume 13, Revision 1, Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses**

➤ **Part 3: Questions and Answers**

- *Only sections affected by proposed rule included*
- *Changes red-lined*

*Useful information beyond License preparation*

# **Regulatory Guidance for Proposed Expanded 10 CFR Part 35 Rulemaking *cont***

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- **Preparation of license applications**
- **Documentation (forms) for T&E for AUs, ANPs, AMPs, and ARSOs**
- **Record-keeping requirements**
- **Model procedures**
- **Indexed to applicable sections of CFR**
- **Reliably reflects Proposed Rulemaking**
- **Reviewed by ACMUI and revisions suggested**

# **Abbreviations and Acronyms**

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- **AAPM:** American Association of Physicists in Medicine
- **ACMUI:** Advisory Committee on Medical Uses of Isotopes
- **ANP:** Authorized Nuclear Pharmacist
- **AMP:** Authorized Medical Physicist
- **AS:** Agreement State
- **AU:** Authorized User
- **RSO:** Radiation Safety Officer
- **ARSO:** Associate Radiation Safety Officer
- **CFR:** Code of Federal Regulations
- **ME:** Medical Event
- **NRC:** Nuclear Regulatory Commission
- **Q&A:** Questions and Answers
- **T&E:** Training and Experience