

Training and Experience Requirements for Administering Radiopharmaceuticals for All Modalities

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Subcommittee Members

- Ronald Ennis, M.D.
- Darlene Metter, M.D. (*Chair*)
- A. Robert Schleipman, Ph.D.
- Michael Sheetz
- Megan Shober, M.S.
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ACMUI Subcommittee Charge

- 2016 Subcommittee on T&E for All Modalities: periodically review the T&E for the medical use of unsealed & sealed byproduct material (10 CFR Part 35 Subpart D-H) and make recommendations for change as needed.



Subcommittee Sub-Charge

- Due to ongoing patient access concerns for unsealed byproduct material requiring a written directive, directed to prioritize review of the T&E requirements for § 35.300 uses
- Consider the development of a limited-scope AU pathway



2017 Commission Staff Directive

- Review 10 CFR 35 Subpart E
- Assess possibility of tailored T&E for different categories of radiopharm
- How to delineate these categories
- Recommend appropriate T&E
- Assess competency: hours vs formal



3/2018 Proposed Reconsideration Alternate AU for 10 CFR 35.390

- 1/2018 FDA approved ^{177}Lu dotatate with a potential for greater use
- Decrease in number of 1st time candidates sitting for the ABNM exam
- No current AU shortage for § 35.300, but raised concerns for a potential future AU shortage



Potential AU Shortage



Current 10 CFR 35.390 AU Pathways

- Nuclear Medicine (NM)
- Diag Radiology, redesigned* (rDR)
- Nuclear Radiology (NR)
- Radiation Oncology (RO)
- ACGME accredited programs

*16 months NR/NM in a 48 month Diagnostic Radiology program



Current 10 CFR 35.390 AU Pathways

- Certified by deemed-status boards:
 - American Board of Nuclear Medicine
 - American Board of Radiology
 - American Board of Osteopathic Radiology

Referred to as the board certification pathway or pathway 1



2018-2019 for 10 CFR 35.390

In-Training

- NM: 79
- NR: 11
- rDR: 56
- RO: 775
- Total: 921

~Graduates/year

- NM: 50
- NR: 11
- rDR: 14
- RO: 194
- Total: 269



AU Shortage?

- 2018-19 AU 35.390 pipeline: 921
- 2019 Graduates: 269
- 2019 ABNM: 3,591 practicing AU

- 2019: **No AU shortage**



Limited-Scope AU



Limited-Scope AU

- Subcommittee **strongly supports maintaining** current AU pathways.
- Due to new multi-use radiopharm & concern for a potential future AU shortage, we recommend reassessment of a limited AU pathway for § 35.300.



Radionuclide Therapy

- Radionuclide(RN) therapy: highest risk & highest impact of all NM procedures.
- To protect public health & safety, AUs must have a basic level of T&E.
- Limited-scope & full AUs **must** have equivalent level of competency.



Limited-Scope AU

- Basic knowledge topics: § 35.390
- Due to complexity & overlap of these topics, any category would include nearly all of § 35.390
- Conclusion: Subcommittee **does not recommend** a limited-scope AU pathway



“AU Partnership”

- Authorized Nuclear Pharmacist (ANP) (prepare & handle RP) + limited-scope AU (administer dose & pt care)
- Well-intended
- Fragmented approach to NM’s highest impact procedures, unintended consequences can make things worse



“AU Partnership”

- Safe & effective RN therapy best administered by a fully-trained AU responsible for the entire RN therapy for patient, personnel & public safety.
- More AUs than ANP & concentrated in same areas. If ANP available, AU is also likely available.



Competency Assessment for a Limited-Scope AU Pathway



Limited-Scope AU

Although the ACMUI Subcommittee does not recommend a limited-scope AU pathway, the following is the Subcommittee's recommendation if such a pathway is pursued -

- Competency assessment **must be required**¹:
 - Not based on hours or preceptor statement
 - Supports broader input from the medical community to create, with final NRC approval

¹ Supported by initial stakeholders, NRC Staff & Subcommittee



Limited-Scope AU

- Competency assessment needs to attest² to the successful acquisition of the knowledge topics in § 35.390 & ability to independently function as an AU for a specific therapy/therapies

² Supported by stakeholders & Subcommittee



Limited-Scope AU

- Subcommittee also explored periodic competency reassessment
 - American Board of Medical Specialties serves the public in quality healthcare
 - Promotes continuing professional certification, recertification & continuing professional certification
 - ABR and ABMM are member boards
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Limited-Scope AU

- Issue of continuous certification stemmed from the concern regarding the infrequency of board recertification exams i.e., 7-10 years
 - Infrequency concept raised with the limited-scope AU pathway
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Limited-Scope AU

- Potential & higher likelihood for infrequent therapies (including rural areas), thus making it difficult for an AU to retain basic competency in therapeutic procedures

Limited-Scope AU

- **Competency reassessment** is also needed to attest to the successful maintenance of the knowledge & skills confirmed by the initial formal competency assessment.

Limited-Scope AU

- Subcommittee **strongly recommends** that the competency reassessment include ongoing longitudinal reassessment with emphasis on radiation safety.



Limited-Scope AU

- The entity to develop these competency tools must ensure that passing these assessments/exams is empirically determined.
 - Angoff Method, a standard in test development, legally defensible & meets Standards for Educational & Psychological Testing



Summary of Subcommittee Recommendations

- The Subcommittee **strongly supports** the current AU pathways for § 35.390 which protects the public health & safety.
- There is no objective data to support an AU shortage.



Summary of Subcommittee Recommendations

- The Subcommittee **does not recommend** a limited-scope AU pathway for unsealed byproduct material for which a written directive is required.



Summary of Subcommittee Recommendations

- The Subcommittee **unanimously agrees** that if the NRC pursues a limited-scope AU pathway, the AU candidate **must** attest to the acquisition of § 35.390 knowledge topics & skills by successfully completing a formal competency assessment with continued formal periodic competency reassessment to maintain his/her limited-scope AU status.



Acronyms

- ABNM – American Board of Nuclear Medicine
- ACGME – Accreditation Council for Graduate Medical Education
- ACMUI – Advisory Committee on the Medical Uses of Isotopes
- ANP – Authorized Nuclear Pharmacist
- AU – Authorized User
- CFR – Code of Federal Regulations



Acronyms

- DR – Diagnostic Radiologist
- FDA – US Food and Drug Administration
- ^{177}Lu – 177 Lutetium
- NM – Nuclear Medicine
- NR – Nuclear Radiology
- NRC – Nuclear Regulatory Commission
- RN – Radionuclide



Acronyms

- RP – Radiopharmaceutical
- RO – Radiation Oncologist
- rDR – Redesigned Diagnostic Radiology Pathway
- T&E – Training and Experience

