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

# Comments on Training and Experience Requirements for All Modalities

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# ACMUI Subcommittee on T & E

Established in 2016

Charge

- Periodically review T&E requirements currently in effect for all modalities
- Make recommendations for changes as needed

# ACMUI Subcommittee on T & E

Review T&E requirements currently in effect for uses of

- Unsealed byproduct materials (10 CFR 35.100, 35.200, 35.300, & 35.1000)
- Sealed byproduct materials (10 CFR 35.400, 35.500, 35.600, & 35.1000)

# Review Template

Comprehensive review template developed to ensure

- Standardized review process
- Meaningful comparisons of reviews over time
- Decisions about changes in T&E requirements based on data

# Subcommittee Review Plan

Begin with 10 CFR  35.100, followed by 35.200, 35.300, etc.

However, because of ongoing patient access concerns subcommittee directed to prioritize review of T & E requirements for use of unsealed byproduct material for which a written directive is required (10CFR 35.390)

# Significant Developments

January 26, 2018: FDA approved $^{177}$Lu dotatate for treatment of somatostatin receptor-positive GEP-NET's, including foregut, midgut and hindgut

- Broad indication
- 2$^{nd}$ most common GI tumor

Potentially high demand for $^{177}$Lu-dotatate

# Significant Developments

Waning number of nuclear medicine physicians in the US.

– Fewer than 50 first time candidates sat for 2016 ABNM CE (80-100 candidates in previous years)

– ACGME database

2007-2008: 61 Nuclear Medicine Residency Programs with 157 residents

2017-2018: 41 Nuclear Medicine Residency Programs with 75 residents

# Significant Developments

Number of Nuclear Radiologists appears to be trending downward.

ABR Nuclear Radiology CAQ examination candidates

| | |
|---|---|
| 2008: 3 | 2013: 13 |
| 2009: 2 | 2014: 11 |
| 2010: 5 | 2015: 10 |
| 2011: 7 | 2016: 2 |
| 2012: 7 | 2017: 5 |

# Emerging Concerns

Previous discussions/presentations focused on sufficient versus insufficient number of AU's at the present time for administration of an infrequently used therapeutic radiopharmaceutical (Zevalin®).

FDA approval of new CFR Part 35.390 drug, $^{177}$Lu-dotatate, with potential for high volume suggests reevaluation is in order.

# Emerging Concerns

In considering development of alternate pathway

– Future needs should be addressed

– No data to suggest surplus of AUs

– Could a decrease in number of AUs & an increase in procedures affect patient access as new agents in this class of radiopharmaceuticals become available?

# Conclusion

Time to reconsider developing an alternate AU pathway for10 CFR 35.390

# Acronyms

- ACGME – Accreditation Council for Graduate Medical Education
- ACMUI – Advisory Committee on the Medical Uses of Isotopes
- ABNM – American Board of Nuclear Medicine
- ABR – American Board of Radiology
- AU – Authorized User
- CE – Certification Examination
- CAQ – Certificate of Added Qualifications
- FDA – Food & Drug Administration
- GEP-NETS – Gastroenteropancreatic neuroendocrine tumors
- $^{177}$Lu – lutetium-177
- T&E – Training and Experience