



U.S.NRC

UNITED STATES NUCLEAR REGULATORY COMMISSION

Protecting People and the Environment

Training and Experience (T&E) Requirements

April 29, 2008

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**Advisory Committee on the Medical Uses
of Isotopes (ACMUI)**

ACMUI Recommendation

- **Nuclear Regulatory Commission (NRC) staff should remove the attestation requirement for board certified individuals**
- **NRC staff should rewrite the attestation requirement for individuals seeking authorization under the alternate pathway**
 - **The rewritten attestation should not include the word “competency” but should instead read “has met the training and experience requirements.”**

The Competency Problem

- **Competency is difficult to *quantitatively* define**
- **Competency cannot be taught**
- **Competency cannot be reliably measured**
- **Competency cannot be guaranteed**
 - **How long does a competency attestation last?**
- **Competency has legal liability risk**
 - **Preceptors are reluctant to accept this risk**

Board Certification

- **Approved boards have agreed to meet NRC requirements**
 - **Certification processes are reviewed and recognized by NRC**
- **A curriculum and a body of knowledge can be defined**
- **Progress toward meeting defined requirements can be measured**
- **Board certification indicates that T & E requirements have been met.**
 - **Maintenance of Certification provides ongoing evidence of current knowledge**
- **An additional attestation is superfluous**

Preceptor Attestation

- **Training to board certification is a collective process.**
 - **The collective judgment of an entire residency program and the board examination process are employed**
- **Preceptor attestation is an individual process**
 - **An individual preceptor typically would provide only a small portion of the training and experience**
 - **Because of the liability, preceptors are reluctant to attest to training and experience not personally provided**

Preceptor Attestation

- **The problem is particularly acute for Radiation Safety Officers (RSO)**
 - **Any one license recognizes only one RSO**
 - **The regulation requires a RSO preceptor for a RSO candidate**
 - **RSO's are reluctant to precept individuals they did not personally train**

Preceptor Attestation

- **Although the regulation has been interpreted to allow a preceptor to attest to “indirect knowledge” of a candidate’s training and experience, the legal liability risk discourages this in practice**

ACMUI Recommendation

- **ACMUI recommends that NRC staff should remove the attestation requirement for board certified individuals**

Alternate Pathway

- **Most boards provide final certification following residency**
 - **The range is a few months to 2 years**
 - **American Board of Radiology is the only board that certifies residents by the completion of residency**
 - **This will change for residents entering training no later than 2010**
- **This forces boards to train to the “Alternate Pathway” requirements**
 - ***This was not the intent of the regulation***

Alternate Pathway cont.

- **Although the alternate pathway was designed to allow individuals who are not (or not yet) certified by a recognized board to achieve authorized user status, the current regulation functionally limits the availability of the pathway**

Alternate Pathway cont.

- **Preceptors are reluctant to write Alternate Pathway preceptor statements in part because of the attestation of “competence”**
- **The result will be that graduates of residency programs will be unable to become authorized users for a variable amount of time after completion of residency**

Alternate Pathway cont.

- **Graduates may be unable to work until they achieve board certification**
- **Small and rural practices will be most disadvantaged**
- **Diagnostic nuclear medicine studies may be unavailable in some areas**

ACMUI Recommendation on Alternate Pathway

- **ACMUI recommends that the standard used be both measurable and achievable**
 - **ACMUI recommends that the phrase “has met the training and experience requirements” replace the term “competency”**
- **This will permit graduates to practice clinical nuclear medicine between completion of residency and board certification**

Summary

- **ACMUI believes that the T&E requirements in 10 CFR Part 35 have had unintended consequences for residency training**
- **If not corrected, those consequences will ripple through to both the clinical practice and availability of clinical nuclear medicine**
- **ACMUI believes that its recommendations will mitigate the unintended adverse impact on both the regulated community and the general public**

Acronyms

- **ACMUI – Advisory Committee on the Medical Uses of Isotopes**
- **CFR – Code of Federal Regulations**
- **NRC – Nuclear Regulatory Commission**
- **RSO – Radiation Safety Officer**
- **T&E – Training and Experience**



Increased Controls & Fingerprinting Orders

April 29, 2008

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(ACMUI)**

Issues with Fingerprinting Orders

- **Cost to licensee**
- **Lack of justification**
- **Grandfathering of Trustworthy & Reliable (T&R) employees**
- **Limited opportunity for ACMUI input**

Cost to Licensee

Fingerprinting costs for one licensee:

- **Local fingerprinting:** <\$50
- **NRC/FBI costs:** \$36
- **Total per employee** <\$90
- **400 employees @ \$90:** \$36,000

Cost to Licensee cont.

Indirect costs (Salary & Benefits):

- Time away from work - 1 hour \$56**
- 400 lab employees @ \$50 \$20,000**
- Security (400 @ 0.25 hr) \$5000**
- Health Physics (set-up, training, communications, etc: 0.2 FTE) \$15,000**

Total: \$40,000

Cost to Licensee cont.

Cost to Licensee cont.

Budget: Outside Services

- **Annual license fees** **\$29,000**
- **Dosimeter service** **\$33,000**
- **Fingerprinting** **\$76,000**

- **If margin = 2.4%, gross needed = \$3.2M**
- **Repeat every 5 years??**

Justification

- **Unfunded mandate**
- **RSO must justify to management**
- **Not based on a vulnerability analysis**
- **No security issues with irradiators**
- **Nuclear Materials Events Database (NMED): 1 “lost” irradiator – 420 Ci; high school license expired 1986; inspection in 2000 failed to locate source (oversight).**

Example

Researcher must be fingerprinted

- **> 400 scientific publications**
- **Grants total \$ millions**
- **Current research:**
 - **collagen induced arthritis**
 - **HLA-B27 gene linked spondyloarthropathies**
 - **experimental autoimmune encephalomyelitis**
 - **allergen induced asthma**
 - **diabetes**
 - **lupus**
 - **coeliac disease**

Grandfathering of T&R Employees

- **Researcher should be grandfathered**
- **Current users passed T&R determination**
- **Fingerprint requirement disqualifies them**
- **All current users should be grandfathered**

ACMUI Input

- **This is first opportunity for ACMUI to address fingerprinting with The Commission**
- **Email to NRC Staff (5/23/07)**
- **Ralph Lieto & I met with NRC Implementation Task Force (7/31/07); briefed ACMUI by conference call 8/15/07**

Conclusions

- **Initial costs significant**
- **Lack of justification for Category 2 sources**
- **T&R employees should be grandfathered**
- **Lack of ACMUI input**

Acronyms

- **ACMUI – Advisory Committee on the Medical Uses of Isotopes**
- **FBI – Federal Bureau of Investigation**
- **NMED – Nuclear Materials Events Database**
- **NRC – Nuclear Regulatory Commission**
- **RSO – Radiation Safety Officer**
- **T&R – Trustworthy and Reliable**