



**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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**Radiation Safety Officer (RSO) Representative  
Advisory Committee on the Medical Uses of Isotopes  
(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**

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**Total:** **\$40,000**

## **Cost to Licensee cont.**

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## **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**