



Informational Briefing to ACMUI Revisions to Part 35 – Recognition of Board Certifications

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Final Rule, Revise Part 35

Training and Experience (T&E)

- Published in the Federal Register
 - March 30, 2005 (70 FR 16335)
- Effective 30 days after publication
 - April 29, 2005
- Licensees to implement by October 24, 2005
 - Coincides with extended, effective date of Subpart J
- Agreement States have 3 years to adopt final rule

Key Changes to Requirements for T&E

- Revises requirements for recognition of specialty board certifications by the NRC and Agreement States (AS)
- Applies to qualifications for individuals to serve as
 - Authorized user (AU)
 - Radiation safety officer (RSO)
 - Authorized medical physicist (AMP)
 - Authorized nuclear pharmacist (ANP)
- Also revises some requirements for “alternate pathway”

More Highlights

- Preceptor statements
 - Changed to *attest* and *attestation* from *certify* and *certification*
 - Required for board and alternate pathways
 - Requirement ‘de-coupled:’ NOT required for a board’s certification to be recognized

Highlights (cont'd)

- Added requirements for use-specific training
 - For RSOs, AMPs, AUs for high-risk uses
- Removed requirement for experience with elution, etc., of generators (old 35.390(b)(1)(ii)(F))
- Decoupled requirements for experience with oral and parenteral administrations from requirements for recognition of certifications
 - former 35.390(b)(1)(ii)(G)

Highlights (cont'd)

- New Section 35.396 – parenteral administration of unsealed byproduct material for which a written directive (WD) is required
- Provides pathway for non-AMP, medical physicists to become RSOs
- Final Rule resolves petition PRM-35-17 filed on behalf of the Organization of Agreement States (OAS)

Resolution of PRM-35-17

- AS recommended requirements for minimum hours of classroom and laboratory training for
 - Nuclear pharmacists (ANPs, 35.55)
 - Authorized Users (AUs)
 - Uptake, dilution and excretion studies, 35.190
 - Imaging and localization studies, 35.290
 - Uses for which a WD is required, 35.390

Requirements for Classroom and Laboratory Training (hr)

	Total	Classroom + Lab
35.55 (ANPs)	700	200
35.190 (AUs)	60	8
35.290 (AUs)	700	80
35.390 (AUs)	700	200

- Applies only to alternate pathway
- “Classroom and laboratory,” not “didactic”

Implementation of Final Rule

- Licensees have until Oct 24, 2005 to implement final rule
- Letter to boards inviting application for recognition of certifications
 - Implemented by Material Safety and Inspection Branch (MSIB)
- Licensing guidance for medical use
 - NUREG-1556, Vol. 9, Rev. 1
- Revised NRC Form 313A, “Medical Use Training and Experience and Preceptor Attestation”

Implementation – Resources

- NUREG-1556, Vol. 9, Rev. 1 available on the NRC's web site via the Medical Uses Licensee Toolkit
 - <http://www.nrc.gov/materials/miau/med-use-toolkit.html>
- Federal Register Announcement and related documents
 - <http://www.nrc.gov/what-we-do/regulatory/rulemaking.html>
- Red-line / strike-out comparison – highlights changes