



Proposed Rule to Amend 10 CFR Part 35: Requirements for Training and Experience

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Defining the Problem

- Revised 10 CFR Part 35 scheduled for publication Spring, 2002
- ACMUI briefed Commission, Feb 2002
- Boards did not meet criteria in rule to have certifications recognized by the NRC
- Concerned that shortage of authorized users (physicians), RSOs, AMPs, ANPs would develop

NRC's Solution

- Subpart J was retained in rule for 2 years from effective date of rule – until Oct 24, 2004
- Staff work with ACMUI to develop solution
- ACMUI subcommittee developed proposal
- 3 options to Commission, Oct 2002
- Commission approved Option 3, as communicated in SRM-02-0194

Commission Direction

SRM-02-0914 directed staff to:

- Modify T&E requirements based on ACMUI's recommendations (SECY-02-0194, Attachment 2)
- List recognized specialty boards on NRC's web site
- Keep preceptor statement "as written" in current rule
- Clarify preceptor statement:
 - Attestation of clinical competency not required
 - Require attestation to be sufficient to demonstrate that a candidate has knowledge to fulfill the duties of position for which certification is sought

Key Points in SRM

- Require a clear regulatory determination that all boards meet criteria
- Provide implementing procedures for the addition to / removal from list of recognized boards
- When de-listing boards, consider:
 - No inspections of boards
 - Monitor trends in medical events

Drafting the Proposed Rule

- Using ACMUI's recommendations in Att. 2 to SECY-02-0194 as basis for proposed rule
- Staff's evaluation:
 - Need for some wording changes
 - Review recommendations that also introduced changes in 'alternate pathway' for satisfying NRC's T&E requirements

ACMUI Recommendation to Add A Residency Approving Entity

- Added the “Royal College of Physicians and Surgeons of Canada” to the list of approving entities for recognition of residency training programs in:
 - 35.390, 490, 690 board cert. pathway, and
 - ‘alternate pathway’ in 490(b)(2), 690(b)(2)
 - Basis?

Additions to ACMUI

Recommended Rule Text

- Preceptor statement from 'alternate pathway' adopted to board-certification pathway, while retaining original rule language
- Retain option for board to satisfy 'alternate pathway' – adds an "or" to board cert. path

Staff Changes to ACMUI's Wording

- Added “radiation dosimetry” to list of subject areas for training in 35.50(a)(1)(iii)
- Retained “Radiation dosimetry” in 35.50(b)(1)(i)(E)
- “permit issued by a Commission master material licensee” retained in 35.50(b)(1)(ii)

Wording (cont.)

- 35.51 Terminology: medical physics vs. radiation oncology physics
 - Is use of more general, medical physics, term more appropriate?
 - Some boards use more general term; others the more specific term
- 35.390: staff recommends: “quantities for which a written directive is required” rather than “therapeutic quantities”

Wording (cont.)

- ACMUI recommended changing "calibrate" to "performing quality control procedures" in several sections on requirements for experience, e.g., 35.190(c)(1)(ii)(B)
 - ACMUI Draft - no change in 35.392(c)(2)(ii) and 35.394(c)(2)(ii)
 - For parallelism, staff changed to "performing quality . . ." in 392 & 394

Wording (cont.)

- Retained “running” in “running inventories”
- 35.490(b)(1)(ii)(D)
- Retained “handling” in “basic radionuclide handling techniques” - 35.490(b)(2):

Implementation

- Listing of a board
 - Board submits to NRC an application describing certification process – application form w/ check list
 - Staff compares to requirements in rule
 - Consult with ACMUI if needed
- Maintenance of recognition
 - Boards notify NRC of changes in their requirements for certification

Implementation (cont.)

- De-listing (possible reasons):
 - Medical events increase / trace to fault in cert process
 - Board changes requirements, no longer meets regulatory requirement
- Agreement States List / De-list

Process for “De-listing” of a Board

- NRC identifies a potential problem
- Board contacted – opportunity to respond
- NRC evaluates response
- Consult with ACMUI
- Notify Commission of findings
- Notify board of determination

Path Forward

- Distribute draft proposed rule to Agreement States for 30-day comment period: June 2003
- Proposed Rule to Commission: July 2003
- Commission Decision
- Publish in FR, Sep. – 75 day comment period
- Final Rule
- Obtain input from boards & ACMUI on staff approach by May 30th