

October 9, 2003

MEMORANDUM TO: William D. Travers
Executive Director for Operations

FROM: Annette L. Vietti-Cook, Secretary **/RA by Andrew L. Bates
Acting For/**

SUBJECT: STAFF REQUIREMENTS - SECY-03-0145 - PROPOSED RULE:
MEDICAL USE OF BYPRODUCT MATERIAL - RECOGNITION
OF SPECIALTY BOARDS

The Commission has approved publication of the proposed amendments to Part 35 in the Federal Register subject to incorporation of the comments and changes noted below.

In addition, the Commission has approved the recommendation of the ACMUI concerning the preceptor statement which places the requirement on the individual to obtain the preceptor statement regardless of which training pathway is chosen. The staff should ensure that the proposed rule language is clear that a preceptor statement is required from individuals regardless of the training pathway chosen.

The Federal Register notice should be revised to:

1. Provide additional justification for the proposed rule changes to the "certification pathway." This needs to be done in the context that NRC has made a determination "that, except for one board, the boards did not meet all the requirements of the current rule. Specifically, the boards' certification programs failed to meet the requirements in the final rule regarding preceptor certification and work experience."
2. Add a separate section in the FRN that lists the questions that NRC is soliciting public comment on.
3. Include a question for public comment on whether commenters believe the revised requirements provide reasonable assurance that AUs, RSOs, AMPs, and ANPs will have adequate training in radiation safety.
4. Comment on the ACMUI's position that candidates "might bypass the board certification pathway" The Commission does not agree that the training and experience criteria in the current rule will result in candidates bypassing board certification. Board certification has been and will continue to be essential for practicing medicine. Staff's comments should recognize the difference needed for board certification for practicing physicians versus certification for an RSO, AMP, or ANP.
5. Provide a brief discussion on NRC's proposal for oversight of the boards. This

discussion should be consistent with the guidance in the SRM for SECY-02-0194 for monitoring trends in medical events that can be attributed to inadequate radiation safety training. Therefore, this discussion should address staff's plans to evaluate whether a medical event may have been due to inadequate radiation safety training related to the certification process, e.g., NRC's plans for assessing whether the examinations provided by the certifying boards adequately assess the knowledge/skills reflected in the proposed rule text.

6. Provide justification for adding the requirement for a degree in §35.50(a) and include a discussion that reinforces the Statements of Consideration for the final rule which noted that any individual, including a nuclear medicine technologist, who completes all of the training and experience requirements in the alternative pathway can be an RSO.
7. Provide the rationale for the change in the training criteria for authorized medical physicists in §35.51(a)(2).
8. Provide justification for deleting the minimum hour requirements in §35.490, "Training for use of manual brachytherapy sources," i.e., the requirements for 200 hours of classroom and laboratory training and 500 hours of work experience have been deleted.
9. Provide examples of what additional tests would be required under "quality control" that would not be required under "calibration."
10. To avoid confusion, provide a clear definition of what is meant by the different "rules" referenced in the FRN, e.g. the "draft final rule" referred to in paragraph 2 on page 4.
11. Standardize the language in the rule text, e.g. in §35.190(a)(1) it says to "meet the requirements" versus in §35.290(a)(1) it says to "satisfy the requirements."
12. In the Section by Section Analysis some of the rule changes were not discussed or were not fully justified. For example,
 - §35.50, include the new requirement for a degree.
 - §§35.390, 35.490 and 35.690, include the residency training

In addition, the following more specific changes need to be made to the FRN:

13. On page 3, the last sentence, provide the outcome of the discussions with the boards.
14. On page 7, last paragraph, second sentence, revise the sentence to read "The proposed rule would establish ~~separate~~ criteria for ~~that~~ a board ~~must meet~~ to be"
15. On page 10, last paragraph, revise line 2 to read ' ... to remove ~~specific requirements~~ ~~credit~~ for a degree in'
16. On pages 18 and 19, §§ 35.390 and 35.490, include the new requirement for review of the training programs.
17. On page 29, include a conforming change in §35.14 requiring the licensee to submit a copy of the preceptor statement as well as a copy of the board certification before permitting an individual to work as an AU, ANP, or AMP. Specifically, §35.14 should be

revised to state: “(a) A licensee shall provide the Commission a copy of the board certification and preceptor statement(s), the Commission or Agreement State license,…”

18. On page 39, §35.490(a)(2), revise the rule text to read “. . . clinical use of ~~manual high and low dose-rate~~ brachytherapy ... “
19. On page 41, §35.690(a)(2), revise the text to read “... radiosurgery, ~~remote afterloaders high and low dose-rate~~ brachytherapy, and

cc: Chairman Diaz
Commissioner McGaffigan
Commissioner Merrifield
OGC
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