

October 9, 2003

COMMISSION VOTING RECORD

DECISION ITEM: SECY-03-0145

TITLE: PROPOSED RULE: MEDICAL USE OF
BYPRODUCT MATERIAL - RECOGNITION OF
SPECIALTY BOARDS

The Commission (with all Commissioners agreeing) approved the subject paper as recorded in the Staff Requirements Memorandum (SRM) of October 9, 2003.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commission.

Annette L. Vietti-Cook
Secretary of the Commission

Attachments:

1. Voting Summary
2. Commissioner Vote Sheets

cc: Chairman Diaz
 Commissioner McGaffigan
 Commissioner Merrifield
 OGC
 EDO
 PDR

VOTING SUMMARY - SECY-03-0145

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. DIAZ	X				X	9/10/03
COMR. McGAFFIGAN	X				X	10/3/03
COMR. MERRIFIELD	X				X	9/26/03

COMMENT RESOLUTION

In their vote sheets, all Commissioners approved the staff's recommendation and provided some additional comments. Subsequently, the comments of the Commission were incorporated into the guidance to staff as reflected in the SRM issued on October 9, 2003.

Commissioner Comments on SECY-03-0145

Chairman Diaz

I approve staff publishing the proposed amendments to Part 35 in the Federal Register for public comment, subject to my comments below.

I strongly believe that NRC's training and experience requirements for the medical use of byproduct material should be focused on radiation safety. On the other hand, I also recognize the importance of the certifying boards in assessing an individual's clinical/professional competency. However, if we rely on board certification as one pathway to determine if an individual meets NRC's training and experience requirements, we must be certain that the certification pathway provides reasonable assurance that authorized users (AUs), radiation safety officers (RSOs), authorized medical physicists (AMPs), and authorized nuclear pharmacists (ANPs) have adequate training and experience in the safe use of radioactive materials. I do not believe that the Federal Register notice (FRN) provides an adequate description of this reasonable assurance nor provides sound justification for the proposed revision to the rule text.

Therefore, prior to publication of the proposed rule, the Federal Register should be revised to:

- ! 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."
- ! Add a separate section in the FRN that lists the questions that NRC is soliciting public comment on.
- ! 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.
- ! Comment on the ACMUI's position that candidates "might bypass the board certification pathway. . ." I do 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 need for board certification for practicing physicians versus certification for an RSO, AMP, or ANP.
- ! Provide a brief discussion on NRC's proposal for oversight of the boards. This should specifically include NRC's plans for assessing whether the examinations provided by the certifying boards adequately assess the knowledge/skills reflected in the proposed rule text. This discussion should be consistent with the guidance for monitoring medical events attributed to inadequate radiation safety training provided in the SRM for SECY-02-0194.

- ! 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.
- ! Provide the rationale for the change in the training criteria for authorized medical physicists in §35.51(a)(2).
- ! 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.
- ! Provide examples of what additional tests would be required under "quality control" that would not be required under "calibration."
- ! 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.
- ! 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."
- ! 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:

- ! On page 3, the last sentence, provide the outcome of the discussions with the boards.
- ! 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 . . ."
- ! On pages 18 and 19, §§ 35.390 and 35.490, include the new requirement for review of the training programs.
- ! 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,..."
- ! On page 39, §35.490(a)(2), revise the rule text to read ". . . clinical use of **manual** ~~high and low dose-rate~~ brachytherapy . . ."
- ! On page 41, §35.690(a)(2), revise the text to read ". . .radiosurgery, **remote afterloaders** ~~high and low dose-rate brachytherapy~~, and

Commissioner McGaffigan

I approve the staff publishing the proposed amendments to Part 35 in the Federal Register for public comment, subject to the following comments.

I agree with the changes to the FRN contained in the Chairman's vote. I also agree with Commissioner Merrifield's vote concerning the preceptor statement. I believe that a preceptor statement should be required as part of the training regardless of the training pathway which is chosen. If the boards believe it is too burdensome for them to collect preceptor statements from individuals who choose the board certification pathway, that is acceptable, as long as these individuals are still required to have a preceptor statement.

It was not clear to me from the proposed rule language that ACMUI's proposed changes would continue to require a preceptor statement from individuals that followed either the board certification route or the "alternate" pathway. Therefore, 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.

Commissioner Merrifield

I approve the staff publishing the proposed amendments to Part 35 in the Federal Register for public comment subject to the following comments.

First, I support the Chairman's vote concerning revisions necessary for the Federal Register notice.

Second, I approve the recommendation of the ACMUI concerning the preceptor statement. In the staff's proposal, the board certification pathway requires the medical board to obtain the preceptor statement before completing its certification process and the alternative qualification pathway requires the individual to obtain the preceptor statement and provide it to the licensee. Multiple medical boards (with one exception) objected to placing this requirement on the board certification process and many objected to requiring a preceptor statement at all. However, I still believe the requirement to obtain an appropriate preceptor statement is valid. Although the ACMUI, like the medical boards, objects to the proposed requirement, the ACMUI has offered an alternative which I find acceptable and which should be somewhat more acceptable to the medical boards. The ACMUI alternative places the requirement on the individual to obtain the preceptor statement regardless of which training pathway is chosen. This change is particularly appropriate given the Chairman's vote to revise §35.14 to require licensees to submit a copy of the board certification as well as the preceptor statement(s) to the Commission.

Finally, on page 10 of the Federal Register notice, the first sentence of the third paragraph (which begins with "Training requirements for authorizations as a medical physicist ...") should be modified by deleting the word "credit" and replacing it with "specific requirements". As the sentence reads now, it states the NRC would not give credit for a degree in biophysics, radiological physics, or health physics. The intent of the sentence is to state that the NRC will accept certain more general educational requirements but degrees in those three specific areas are certainly still acceptable.