

RULEMAKING ISSUE NOTATION VOTE

August 21, 2003

SECY-03-0145

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

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

PURPOSE:

To request Commission approval to publish a proposed rule, in the *Federal Register*, that would amend 10 CFR Part 35, "Medical Use of Byproduct Material," to modify training and experience requirements related to recognition of specialty board certifications.

SUMMARY:

This paper transmits a proposed rule to amend 10 CFR Part 35 to the Commission for consideration. The proposed rule would amend the regulation governing the medical use of byproduct material to change requirements for recognition of specialty boards whose certification may be used to demonstrate the adequacy of the training and experience of individuals to serve as authorized users, authorized medical physicists, authorized nuclear pharmacists or radiation safety officers. The proposed rule would also revise the requirements for demonstrating the adequacy of training and experience for pathways other than the board certification pathway. A draft regulatory analysis and environmental assessment have been completed to support this rule.

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BACKGROUND:

During development of proposed and final rules for Part 35 [August 13, 1998 (63 FR 43516) and April 24, 2002 (67 FR 20249), respectively], there was a general belief that the specialty boards recognized by the U.S. Nuclear Regulatory Commission (NRC) would meet, or could make adjustments to meet, the new requirements, established by that rulemaking, governing NRC recognition of specialty boards, and that they would continue to be recognized by NRC. However, when applications for recognition were received, the NRC staff determined that, except for one board, the boards did not meet all the requirements in the final rule for preceptor certification and work experience.

On February 19, 2002, the Advisory Committee on Medical Uses of Isotopes (ACMUI) briefed the Commission and expressed a concern that if the final rule, as drafted, became effective there could be a potential shortage of individuals qualified to serve as radiation safety officers (RSOs), authorized medical physicists (AMPs), authorized nuclear pharmacists (ANPs) and authorized users (AUs). The ACMUI also expressed the concern that the boards might become "marginalized." To resolve these concerns, the NRC modified the final rule by reinserting Subpart J (as contained in the proposed rule) for a 2-year transition period (i.e., Subpart J continues to be effective for two years for NRC licensees) during which the NRC could work to resolve the problem. Subpart J provides for continuing recognition of the specialty boards listed therein during the transition period. The final rule was published in the *Federal Register* on April 24, 2002 (67 FR 20249), with an effective date of October 24, 2002. The transition period will end on October 24, 2004. In a staff requirements memorandum (SRM-COMSECY-02-0014) dated April 16, 2002, the Commission directed the NRC staff to develop options for addressing the training and experience (T&E) issue related to recognition of specialty board certifications.

The ACMUI formed a subcommittee to develop recommendations on this issue. After considering comments received during a public meeting conducted on June 21, 2002, along with letters from stakeholders, the subcommittee developed a final recommendation that the full ACMUI approved during a public tele-conference meeting, on July 8, 2002. These recommendations were submitted to the NRC on August 1, 2002. The NRC staff presented three options for addressing T&E requirements in SECY-02-0194, dated October 30, 2002, two of which included recommendations of the ACMUI. In SRM-02-0194, issued February 12, 2003 (Attachment 1), the Commission approved preparation of a proposed rule to modify the T&E requirements, based on the ACMUI's recommendations, with certain specific exceptions as discussed in more detail, below.

DISCUSSION:

In accordance with SRM-02-0194, the NRC staff has developed a proposed rule (Attachment 2), based on the ACMUI's recommendations. However, the Commission did not agree with the ACMUI's recommendations to change the preceptor statement and to list recognized boards in the rule itself. In SRM-02-0194, the Commission directed that the preceptor statement remain as written in the final rule; that the staff clarify that preceptor statement language does not require an attestation of general clinical competency, but does require sufficient attestation to demonstrate that the candidate has the knowledge to fulfill the

duties of the position for which certification is sought; and that the names of recognized boards be posted on the NRC's web site. The proposed rule was developed by a working group, formed in March 2003, which included a representative of the Organization of Agreement States (OAS) and Conference of Radiation Control Program Directors (CRCPD). On May 20, 2003, a public meeting was also held to solicit early input on the proposed rule from representatives of professional speciality boards and other interested parties.

The current regulations in 10 CFR Part 35 offer three pathways for individuals to satisfy training and experience requirements to be approved as an RSO, AMP, ANP, or AU. These pathways are: (1) approval of individual who is certified by a specialty board whose certification has been recognized by the NRC or an Agreement State as meeting the NRC's requirements for training and experience (a "recognized board"); (2) approval based on an evaluation of an individual's training and experience; or (3) identification of an individual's approval on an existing NRC or Agreement State license. For the sake of this discussion, pathway 1 will be referred to as the "certification pathway;" pathway 2 as the "alternate pathway." Discussion of rule changes are organized according to changes in criteria for recognition of specialty boards, termed the "certification pathway," and changes dealing with the "alternate pathway" (i.e., the listings in the rule of requirements for T&E for those who do not choose the certification pathway). The principal rule changes would involve revising the criteria for the certification pathway so that the requirements are less prescriptive than those in the current rule.

The proposed rule would revise the criteria that a board must meet to be recognized by the NRC or an Agreement State. The proposed criteria for RSOs, AMPs, and ANPs include requirements for a degree from an accredited college or university, professional experience, passing an examination administered by the board, obtaining a written preceptor statement, and clarifying that individuals are to have T&E related to the type of use (termed "modality" by the ACMUI) for which they would be responsible. The required degree (baccalaureate, masters, or doctorate) and the amount of professional experience varies depending on what type of approval is sought (for RSO, AMP, or an ANP). The certification pathway also includes a specification for number of hours of T&E for ANPs and AUs for uses of certain byproduct material under 10 CFR 35.100, 35.200, 35.300 (in 35.390, 35.392, 35.394, for uses under 35.300), and 35.500.

The proposed rule would provide the boards more latitude in making the determination that an individual is fully trained and capable of performing duties related to radiation safety. The NRC staff believes that the specialty boards will be able to apply to candidates the T&E criteria contained in the proposed rule. The proposed changes to the certification pathway would continue to ensure the safe use of byproduct material by medical licensees by establishing criteria for specialty boards to use in granting certification.

The proposed rule also contains revised requirements for some of the alternate pathways. Most of these changes are minor and would clarify the requirements for T&E.

The staff did not adopt certain recommendations made by the ACMUI. The staff made changes to be consistent with NRC's approach to regulatory language and to make the regulations internally consistent. These changes have been discussed with the Chairs of the full ACMUI and ACMUI's subcommittee on T&E, during development of the proposed rule, and they agreed with the staff's changes in these areas. The draft proposed rule was distributed to the ACMUI in June 2003, for review during the period of Agreement State review.

At a teleconference held on July 17, 2003, the full ACMUI discussed the draft proposed rule. During the teleconference, the ACMUI approved the NRC staff recommendation to broaden the requirement that supervised clinical experience be received in a "radiation facility" rather than in a "radiation oncology facility" for individuals to qualify as AMPs, in § 35.51(b)(1) of the proposed rule, and to change the requirement for experience in "radiation oncology" in paragraph § 35.690(b)(2) to allow for experience in "radiation therapy." Parallel changes were made to the certification pathway for AMPs in the proposed rule in § 35.51(a)(2)(ii) and in § 35.390(a)(1) for uses under § 35.600. Secondly, the ACMUI recommended that the experiential requirements, described in the current rule in § 35.390(b)(1)(ii)(G), not be included in criteria for recognition of specialty board certifications, but, that they continue to be required for AUs meeting T&E requirements for both the certification and alternate pathways. This recommendation was not adopted because the NRC staff believes that the requirements for work experience in § 35.390(b)(1)(ii)(G) are essential for an individual to be able to function independently as an AU for administration of byproduct material for which a written directive is required. Furthermore, if the requirement were removed from the certification pathway, individuals and applicants for licenses, or amendments, would be required to provide documentation of completion of requirements for experience required under § 35.390(b)(1)(ii)(G), in addition to evidence of board certification, to gain approval as AUs. Therefore, this requirement was retained in the proposed rule. Thirdly, the ACMUI recommended that the requirement for a preceptor statement be separated from the board certification pathway and the alternate pathway, and specified separately as a new paragraph in each training section. Lastly, the ACMUI recommended that the word "attest" should be used in place of certify (certification) in preceptor statements. The last two recommendations are discussed in detail below. They were not adopted because, in SRM-02-0194, the Commission stated that the preceptor statement should remain in the current regulations. Further, Agreement States who commented on the proposed rule agreed with the Commission's directive to keep the preceptor statement as written. With regard to the use of the word "attest" rather than "certify," the NRC staff believes placing this matter before all stakeholders and receiving their input is appropriate and, therefore, a question is posed in the FRN to seek stakeholder input on whether this change should be made.

Preceptor Certification

Part 35 currently requires that the preceptor who signs the certification be an RSO, AMP, ANP, or AU, as appropriate to the type of approval sought by a candidate to serve in one of these capacities. This requirement applies to both board certification and the alternate pathway. The ACMUI expressed concern that the existing preceptor statement could be viewed as a testament to clinical competence and recommended that the preceptor concept be modified to become documentation for completion of a training program.

On May 20, 2003, during an open meeting of the ACMUI, the NRC staff briefed the ACMUI on its approach to drafting the proposed rule. This briefing included a discussion of the requirement in SRM-02-0914 to retain, in the proposed rule, the preceptor statement, as written in the current Part 35. During its meeting with the Commission on May 28, 2003, the ACMUI expressed concern regarding the NRC's intent to retain requirements in Part 35 for certifications by preceptors. As a result of this meeting, the Commission issued an SRM dated June 20, 2003 (M030528B), indicating that, as the Commission directed in a Staff Requirements Memorandum on SECY-02-0194, dated February 12, 2003, the staff, with appropriate interactions with the ACMUI, should continue its development of a proposed rule to

modify the training and experience requirements in 10 CFR 35 so that the revised rule can be in place as promptly as possible. The Commission also instructed the NRC staff, in SRM-02-0194, to clarify that the preceptor language does not require an attestation of general clinical competency, but requires an attestation sufficient to demonstrate that the candidate has the knowledge to fulfill the duties of the position for which certification is sought. This clarification is included in the "Supplementary Information" for the proposed rule.

During the teleconference with ACMUI, conducted on July 17, 2003, ACMUI members continued to voice concern about having recognition of boards conditioned on requiring candidates for certification to obtain written attestation of competency signed by a preceptor. Concern was also expressed by the ACMUI about the NRC's requirements that an authorized user must sign the preceptor statement rather than a program director. During the teleconference, ACMUI proposed that, if the Commission maintained it was necessary to include a preceptor statement, that this requirement be separated ("decoupled") from the criteria for recognition of board certifications, as well as the alternative pathway. Specifically, ACMUI suggested that the requirement be set forth as a new paragraph in each "training section." This would place the responsibility upon the individual seeking authorized status to obtain a preceptor statement in addition to fulfilling the requirements for board certification (the condition currently applies for the alternate pathway). Agreement State representatives participating in the teleconference agreed with this recommendation. During the teleconference, the NRC staff agreed that if ACMUI documented its position, the staff would provide that documentation to the Commission.

In a letter dated July 23, 2003, Dr. Manuel Cerqueira, Chair of the ACMUI, advised the NRC Staff that the ACMUI had restated its consensus position that a preceptor attestation should not be a requirement for specialty boards to qualify under 10 CFR Part 35 sections. He stated further that ACMUI recommended that requirements for a preceptor statement be removed from the certification pathway; however, if the Commission still felt it necessary to include a preceptor statement for all authorized positions named in Part 35, the ACMUI recommended that this requirement be separated from the board certification pathway and from the alternate pathway and specified separately as a new paragraph in each "training section." In accordance with statements by the NRC staff made during the July 17 teleconference, this letter, containing ACMUI's recommendation, is being provided to the Commission as the ACMUI's alternative (Attachment 3). Alternate wording for appropriate sections of the FRN appears in Attachment 4 for consideration by the Commission if it adopts ACMUI's recommendation.

The ACMUI also recommended, during the teleconference, that the word "attest" should be used in place of "certify" in preceptor statements. ACMUI explained that the reason for this recommendation was that preceptors do not "certify" individuals, but "attest." This proposal has not been adopted by the staff because, in SRM-02-0194, the Commission stated that the preceptor statement should remain as currently written in the regulations. As noted above, a question on this change is posed in the FRN.

Listing/De-listing of Specialty Boards

All current and new boards whose certification process meets the NRC's criteria for recognition would be listed on the NRC's web site rather than in the rule. This approach has the advantage of avoiding the necessity to amend Part 35 to effect recognition each time a new board is added to the listing. The ACMUI and stakeholders participating in a public meeting on May 20,

2003, (attended primarily by specialty board representatives) agreed with this approach. The staff is developing a procedure for both the listing and de-listing of specialty boards and will discuss the draft procedure with the ACMUI at its October 2003 meeting, as well as with the OAS. The staff plans to place the procedure on the NRC web page before the effective date of the final rule.

The procedure will include a mechanism for requesting additional or clarifying information from a specialty board, criteria for de-listing a board, and steps to notify a board of the NRC's action. The staff plans to consult with the ACMUI, if needed, before a decision on recognition of a board is made and before a final decision to de-list a board is made. The procedure will also include a step for Commission notification before de-listing a board.

Authorized Medical Physicists as RSOs.

Current regulations provide, in § 35.50(c), that an AMP identified on a licensee's license can serve as an RSO. However, the current regulations only require services of an AMP for uses under §§ 35.433 and 35.600; a few AMPs are also named on licenses for uses under § 35.1000. Therefore, individuals who may have adequate T&E to serve as AUs for types of use licensed under §§ 35.100, 35.200, 35.300, 35.400 and 35.500, are not listed on an NRC or Agreement State license under current rules. The NRC staff believes that medical physicists who are certified by a specialty board recognized by the Commission or an Agreement State have training and experience in radiation safety aspects of the use of byproduct material for medical purposes. Therefore, the proposed rule includes a change to the regulations in § 35.50(c) that would allow medical physicists, who are certified by a specialty board recognized by the NRC or an Agreement State, to serve as RSOs, while retaining the requirement that individuals have experience specific to the types of use for which they would be responsible. This change would remove an impediment for individuals who have adequate T&E to becoming approved as RSOs. It would also avoid placing a burden on licensees to apply for an exemption to the regulations and on NRC and Agreement State staff who would be required to process an application for an exemption to regulations in order to approve a licensee's request to have a medical physicist, certified by a recognized specialty board, serve as an RSO.

AGREEMENT STATE ISSUES:

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" approved by the Commission on June 30, 1997, and published in the *Federal Register* on September 3, 1997 (62 FR 46517), this proposed rule would be a matter of compatibility between NRC and the Agreement States, thereby providing consistency among Agreement State and NRC requirements. The proposed rule changes would all be classified as Category B. A Compatibility Category "B" designation means the requirement has significant direct transboundary implications. Compatibility Category "B" designated Agreement State requirements should be essentially identical to those of NRC. A person from the State of Alabama represented the OAS and participated as a member of the working group with the NRC staff in development of this proposed rule.

Agreement States must adopt the current rule, published in April 2003, by October 24, 2005, (3 years from the effective date of the rule). Adoption by Agreement States of the proposed rule under discussion in this paper is tentatively planned to coincide with the date by which they

must adopt the current rule, that is, by October 24, 2005. However, this would result in a shortening of the time available to States to develop compatible T&E requirements. During the OAS meeting in October 2002, the Agreement States voiced their concern regarding the adoption of compatible T&E requirements by October 24, 2005. The staff is soliciting comments from all stakeholders on the issue of the timing of the adoption of compatible T&E requirements by Agreement States.

AGREEMENT STATE COMMENTS ON THE PROPOSED RULE:

The proposed rule was distributed for Agreement State comment, and comment letters were received from Alabama, Florida, Illinois, Maine, Washington and Wisconsin. All States voiced support for the Commission's decision to continue to require a preceptor statement as written in the current regulations. As noted above, Agreement States who participated in the teleconference agreed with the ACMUI's recommendation to "decouple" the requirement for a preceptor statement from the requirements for recognition of board certifications. One State also indicated support for the addition of requirements for training specific to type-of-use. Three States indicated that they should have 3 years to adopt the rule. As discussed in SECY-02-0194, the NRC is soliciting input on this subject in the FRN containing the proposed rule. One State suggested that the term "high energy," used in the section of the proposed rule in which requirements for training of candidates for AMPs are discussed, should be defined. The NRC staff believes that defining the term would be overly prescriptive and might be misinterpreted. Discussion of this point was included in the supplementary information in the FRN. One State asked for clarification related to processes for keeping records of training related to specific type-of-use, suggesting that this duty be placed on specialty boards. The NRC staff believes this would impose an unnecessary burden on boards and has not incorporated this suggestion in the proposed rule. Two States expressed concern about enacting a rule which included reference to the NRC's web site as the source for listing the names of specialty boards recognized by the NRC or an Agreement State, indicating that there is a need for public involvement in their rulemaking process. The staff notes that the criteria for board recognition are contained in this proposed rulemaking and, thus, will have public involvement. The staff has only proposed that the names of these boards that meet the proposed criteria will be listed on the NRC website. The issue will also be raised with Agreement States during the OAS meeting in October, 2003. Agreement States who commented on the proposed rule agreed with the Commission's direction that attestations should be signed by an individual who is approved by the NRC or an Agreement State as an RSO, AMP, ANP or AU (for the corresponding category of approval). The NRC staff is in agreement with the rationale of the Agreement States, i.e., that these individuals are well suited to offer an independent, informed opinion about the knowledge and skills needed to fulfill the duties for which approval is sought.

COORDINATION:

The Office of the General Counsel has no legal objection to the proposed rulemaking. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections.

RESOURCES:

To complete and implement the rulemaking, 0.4 full-time equivalent positions will be required. No contractual support is anticipated. These resources are included in the current budget.

RECOMMENDATIONS:

That the Commission:

1. Approve for publication, in the *Federal Register*, the proposed amendments to Part 35 (Attachment 2).
2. Certify that, based on the information currently available, the proposed rule, if adopted, is not likely to have a significant economic impact on a substantial number of small entities.
3. Note that:
 - a. The proposed amendments will be published in the *Federal Register*, allowing 75 days for public comment.
 - b. The Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification and the reasons for it, as required by the Regulatory Flexibility Act, 5 U.S.C. 605(b).
 - c. A draft Regulatory Analysis has been prepared for this rulemaking (Attachment 5).
 - d. Appropriate Congressional committees will be informed of this action.
 - e. A press release will be issued by the Office of Public Affairs when the proposed rulemaking is filed with the Office of the Federal Register.

/RA/

William D. Travers
Executive Director
for Operations

Attachments:

1. SRM Dated February 12, 2003
2. Draft *Federal Register* notice
3. Letter From ACMUI Chair, Manuel D. Cerqueira,
to Thomas Essig, Dated July 23, 2003
4. Alternative language for FRN
5. Draft Regulatory Analysis

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