

Committee on Medical Uses of Isotopes (ACMUI) expressed concern about requirements for T&E in the revised 10 CFR part 35, approved by the Commission on October 23, 2000 (SRM-SECY-00-0118). The ACMUI was concerned that if the requirements for recognition of specialty board certifications were to become effective as drafted, there could be potential shortages of individuals qualified to serve as RSOs, AMPs, ANPs and AUs. The ACMUI indicated that, without changes to the requirements for T&E in the final rule approved by the Commission in October 2000, the boards would no longer be qualified for recognition by NRC and, therefore, a board's future diplomates could no longer be approved as RSOs, AMPs, ANPs or AUs.

The ACMUI also expressed the concern that the boards might be "marginalized." Specifically, under the draft final rule, to gain approval via the certification pathway, a candidate for certification would have been required to meet all of the requirements in the alternate pathway, thereby imposing more requirements, beyond those already required by boards, on candidates using the certification pathway for approval. The extra requirements of concern to the ACMUI, incorporated from the alternate pathway by reference, include a specification for length-of-training as well as obtaining a written certification signed by a preceptor. Taken together with other requirements of boards, such as requiring candidates for certification to take written and/or oral examinations, the concern was that candidates seeking approval might bypass the board certification pathway and select the alternate pathway.

Based on these concerns, the ACMUI urged the Commission to implement measures to address the training and experience issues associated with recognition of specialty boards by the NRC in the draft final rule and to find a permanent solution after publication of the final rule. Subsequently, the NRC modified the final rule by reinserting subpart J (as contained in the proposed rule) for a 2-year transition period. 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), and became effective on October 24, 2002. As specified in § 35.10(c), the 2-year transition period ends 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 issue. The intent is to have this new rule in place before the end of the 2-year transition period.

The issue in question concerns the requirements in the rule governing the recognition of specialty boards by the NRC. These requirements are located in the current regulations at 10 CFR 35.50, 35.51, 35.55, 35.190, 35.290, 35.390, 35.392, 35.394, 35.490, 35.590, and 35.690.

The ACMUI formed a subcommittee to develop recommendations on the training and experience issue. A public subcommittee meeting was held on June 21, 2002, at NRC headquarters in Rockville, Maryland. Representatives from 13 boards, associations, and societies participated in the meeting. In addition, 8 boards and societies provided written comments to the ACMUI subcommittee on its recommendations. After considering the comments from the meeting and letters, the subcommittee developed final recommendations and submitted them to the ACMUI for consideration.

The ACMUI full committee discussed the subcommittee's recommendations in a public teleconference meeting on July 8, 2002. Members of the public and representatives from the Society of Nuclear Medicine participated in the teleconference. The ACMUI approved the recommendations of the subcommittee and submitted them in a report to the NRC on August 1, 2002. The report provided a rationale for the recommendations accompanied by suggested rule language. The NRC staff presented three options to the Commission in a Commission paper, SECY-02-0194, dated October 30, 2002, which included the recommendations of the ACMUI at Attachment 2. The three options were: Option (1) retain the existing requirements in the current regulations; Option (2) prepare a proposed rule to modify training and experience requirements based on the recommendations submitted by the ACMUI; and, Option (3) the same as Option 2 with a minor modification (*i.e.*, listing all specialty boards recognized by NRC on the NRC's Web site rather than, as recommended by the ACMUI, listing some boards in the regulation and others on the Web site).

In SRM-02-0194 dated February 12, 2003, the Commission approved Option 3, directing the NRC staff to prepare a proposed rule based on the ACMUI's recommendations with certain exceptions. Current regulations in 10 CFR part 35 require that individuals obtain a written certification that they have satisfactorily completed

requirements for T&E and have achieved a level of competency sufficient to function independently (*see, e.g.*, § 35.50(b)(2)). For the sake of discussion, this certification will be referred to herein as a preceptor statement. (The term "preceptor" is defined in § 35.2.) The Commission directed that a list of recognized boards be posted on the NRC's web site, that the preceptor statement remain as written in the current regulations (published April 24, 2002), and that the staff should clarify that the preceptor 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. This form of attestation should be preserved both for the certification pathway and the alternate pathway.

The ACMUI briefed the Commission on May 28, 2003, and members conveyed their views regarding the Commission's direction to NRC staff, relating to preceptor statements, in SRM-02-0194. The Commission subsequently issued an SRM on June 20, 2003 (SRM-M030528B). This SRM directed that the staff continue its development of a proposed rule to modify the training and experience requirements in 10 CFR part 35, with appropriate interactions with the ACMUI, so that the revised rule can be in place as promptly as possible. The NRC staff met with the ACMUI via teleconference on July 17, 2003, to further discuss the ACMUI's comments on the proposed rule. This meeting was noticed in the **Federal Register** on July 14, 2003 (68 FR 41665).

During the teleconference with the ACMUI, conducted on July 17, 2003, the ACMUI members continued to voice concern about having recognition of board certifications conditioned on requiring candidates for certification to obtain written attestation of competency signed by a preceptor. The ACMUI recommended that if the Commission still maintained that it was necessary to include a preceptor statement for all authorized positions named in 10 CFR part 35, this requirement would be separated from the criteria for recognition of board certifications, as well as the alternative pathway. Agreement State representatives participated in the teleconference and agreed with this recommendation. In a letter, dated July 23, 2003, Dr. Manuel Cerqueira, Chair of the ACMUI, restated the ACMUI's recommendation that the requirements for a preceptor statement be removed from the certification pathway; however, if the Commission