

February 12, 2003

COMMISSION VOTING RECORD

DECISION ITEM: SECY-02-0194

TITLE: OPTIONS FOR ADDRESSING PART 35
 TRAINING AND EXPERIENCE ISSUES
 ASSOCIATED WITH RECOGNITION OF
 SPECIALTY BOARDS BY NRC

The Commission (with Chairman Meserve and Commissioners McGaffigan and Merrifield agreeing) approved the subject paper as recorded in the Staff Requirements Memorandum (SRM) of February 12, 2003. Commissioners Dicus and Diaz disapproved the subject paper.

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 Meserve
 Commissioner Dicus
 Commissioner Diaz
 Commissioner McGaffigan
 Commissioner Merrifield
 OGC
 EDO
 PDR

VOTING SUMMARY - SECY-02-0194

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. MESERVE	X					1/16/03
COMR. DICUS		X				1/14/03
COMR. DIAZ		X				1/22/03
COMR. McGAFFIGAN	X					2/3/03
COMR. MERRIFIELD	X					1/16/03

COMMENT RESOLUTION

In their vote sheets, Chairman Meserve and Commissioners McGaffigan and Merrifield agreeing) approved the subject paper. Commissioners Dicus and Diaz disapproved the subject paper. Subsequently, the comments of the majority of the Commission were incorporated into the guidance to staff as reflected in the SRM issued on February 12, 2003.

Commissioner Comments on SECY-02-0194

Chairman Meserve

I agree with Option 3, subject to the following comments. Under Option 3, the staff will develop a proposed rule governing the training and experience (T&E) requirements of Part 35 along the lines of a recommendation submitted by the Advisory Committee on the Medical Uses of Isotopes (ACMUI), but with all specialty boards recognized by the NRC to be listed on a website, rather than listing certain existing boards.

The final rule for Part 35 requires written certification by a preceptor that the individual seeking certification has completed the relevant requirements and “has achieved a level of radiation safety knowledge sufficient to function independently as a _____.” See 10 C.F.R. 35.50(b)(2) (radiation safety officer); 35.51(b)(2) (medical physicist); 35.55(b)(2) (nuclear pharmacist); 35.190(c)(2), 35.290(c)(2), 35.390(b)(2), 35.392(c)(3), 35.394(c)(3), 35.490(b)(3), 35.690(b)(3) (authorized user). This evidently has been interpreted by the ACMUI as requiring a testament of general clinical competence. ACMUI Recommendations, at 1 (SECY-02-0194, Att. 2); see Letter from J.G. Klinger, Illinois Department of Nuclear Safety, to L.M.Psyk, NRC (Sept. 11, 2002)(SECY-02-0194, Att. 3). As a result, the ACMUI has recommended that the preceptor attest only to the completion of the training and experience requirements. I believe this weakens the intended certification too significantly. In my view, the whole point of the certification is to obtain a bottom-line assessment that the candidate has the knowledge and ability to fulfill the duties required by the license. The existing language of Part 35 may encompass this concept adequately, but staff might clarify that this language does not require an attestation of general clinical competency. This form of attestation should be preserved for both pathways of certification (i.e., through board certification or through training and experience).

One consequence of the acceptance of Options 2 or 3 is that the requirements that now exist in the revised Part 35 concerning didactic training and experience in specific subject areas will no longer be applicable to those who obtain board certification. These requirements are presumably intended as an indirect measure of competence and, so long as there is an adequate attestation of actual competence from an approved specialty board, I conclude it is appropriate to relieve these prescriptive requirements.

As noted above, the chief difference between Option 2 and Option 3 is that Option 2 would list certain existing boards in the rule, whereas under Option 3 all boards that are recognized would be listed only on the NRC website. Staff recommends Option 3 on the basis that there is efficiency in having only one source of information -- the website -- for the list of acceptable certification boards. This seems a weak justification because staff would not be prohibited in Option 2 from listing all boards on the website. There is another major difference in the two approaches, however. The ACMUI approach would effectively grandfather certain existing boards, while Option 3 would require the staff to determine that both existing and new boards meet the criteria for recognition. In this connection, the ACMUI notes that “[t]o the best of our knowledge, those specialty boards that are listed in these recommendations meet [the] specific criteria [for listing as approved boards].” ACMUI Recommendations, at 5 (emphasis added). Because of the important role of Board certification, a clear regulatory determination that all Boards, both new and existing, meet the relevant criteria should be required. I thus favor Option 3, but for different reasons than those expressed by staff.

In order to speed the modification of the rule, I endorse the staff's proposal that the staff proceed directly to the development of a proposed rule without the generation of an additional rulemaking plan. The ACMUI, the Board, and the Agreement States that assisted in the development of the proposal should be commended for their assistance.

Commissioner Dicus

I disapprove the staff's recommendation to prepare a proposed rule to modify the training and experience based on the recommendations submitted by the ACMUI and do not agree with the staff's or the ACMUI's proposal to modify 10 CFR Part 35 to accommodate the certification boards.

When the revisions to Part 35 were drafted and debated over the past several years, one of the Commission's main initiatives was to increase the level of awareness and documentation of experience regarding basic radiation safety training and knowledge for those individuals involved with the use or handling of radioactive materials in medical applications. During this very open, public rulemaking process, all parties, including the Certification Boards, were able to provide comments on the viability of this change to the training and experience requirements of Part 35. At the time the Commission approved Part 35, many of the Boards participating in our rulemaking workshops agreed that their exams should include more radiation safety-related questions for certification. Since being established, these requirements represent the minimum radiation safety requirement applicable to all users, including Board certified individuals, and in my view, should be required for all.

The Certification process, if properly designed, could be used to assess the competency of an individual licensed to use radioactive material for medical use. The primary concern that I have, along with those of several Agreement States, is that the proposal before the Commission appears to be proposing a lesser training and experience requirement for physicians with a Board certification. Based on SECY-02-0194, it would appear that the proposed ACMUI proposal for Board certifications would not even meet the reduced requirements, despite a 500-hour reduction for training and experience. I would like to point out that the only Board that currently meets the revised requirements is the Certification Board of Nuclear Cardiology, because it took the initiative, time, and effort to develop its certification program based on the final rule. They are to be commended for their efforts.

I recommend that the training and experience requirements stay as they are currently as written, but that changes to the certification (preceptor) requirement be clarified as proposed by the ACMUI. This will clarify that radiation safety, which is clearly within the NRC's purview, rather than clinical skills, are the focus of these regulatory requirements. In addition, I would recommend that the ACMUI set specific training requirements for new devices or modalities that can build upon the basic requirements for other existing modalities. Lastly, I would support the staff's proposed use of the website for publication of NRC-approved Boards.

Commissioner Diaz

I continue to support the existing training and experience requirements in Part 35, which focus on radiation safety. Therefore, I disapprove staff's recommended Option 3. Board certification, in most cases, is the preferred path to meet the requirements in this part; however, before a board is

recognized by NRC, the board should be able to certify that individuals who are board-certified by their respective board meet the training and experience requirements in Part 35. In addition, the ACMUI-proposed requirements for NRC recognition of new boards include areas involving the practice of medicine, which is contrary to the 2000 Medical Policy Statement that specifically states that "NRC will minimize intrusion into . . . areas traditionally considered to be a part of the practice of medicine." We should uphold the principles in the Medical Policy Statement in all areas of our medical regulations, including recognition of new boards.

The staff should work with stakeholders to seek resolution of specific problems with the training and experience requirements, such as: (1) the requirement for a preceptor statement for radiation safety officers; and (2) the requirements for authorized medical physicists.

Commissioner McGaffigan

I agree with the staff's recommendation and approve the staff to move forward with Option 3 which incorporates the recommendations of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) except that all boards that meet the criteria for recognition by the NRC will be listed on the NRC website rather than in the rule itself. I also agree with Chairman Meserve that the preceptor statement should remain as written in the final Part 35 rule.

In 1997, the Commission directed the staff to revise Part 35 to be more risk-informed and, where appropriate, more performance based while maintaining radiation safety. I believe that the staff accomplished this task admirably and developed a more risk informed regulation with a great deal of coordination with external stakeholders. The ACMUI, however, has recently stated that the medical boards would like Part 35 to be less prescriptive in the area of Training and Experience (T&E) requirements. The ACMUI has offered modifications to the rule which would allow the boards to have more latitude in making the determination that an individual is sufficiently trained and capable of performing his or her duties in radiation safety. I believe that the ACMUI proposed revisions would make the final rule more performance based but this must be balanced with NRC's statutory obligations regarding the radiation safety of workers and the public, including patients. I believe Chairman Meserve's vote is a good compromise between these two issues.

The Chairman's vote stated that the rule should allow certain approved board certifications to be one path an individual could take to demonstrate sufficient knowledge and training in radiation safety. It also stated that the rule should maintain the current preceptor statement as written in the final Part 35. I agree. If the boards are willing to take on the responsibility for determining that an individual is fully trained in radiation safety and is capable of performing his/her duties, then the boards should be required to sign a preceptor statement to that effect. The preceptor statement, in addition to the NRC's review of a board's program prior to approving that board to be listed on the web site, will give NRC the assurance that a board certified individual has sufficient radiation safety training to handle radioactive material safely.

I also agree with the staff and the Chairman that all specialty boards should be listed on NRC's web site rather than in Part 35. Changes to the regulations can be burdensome and time consuming. I think it is most beneficial for the NRC, the boards, and the medical professionals that are seeking board certification for the NRC's list of approved boards be current and that changes be completed quickly and efficiently.

Commissioner Merrifield

I approve the staff's recommended option 3 and the proposal to direct the staff to proceed with rulemaking without generating a separate rulemaking plan as stated in SECY-02-0194.

I recognize that training associated with 10 CFR Part 35 is a controversial area. In the last revision to Part 35, some Agreement State representatives were particularly concerned when we significantly reduced the number of training hours and focused the training on radiation safety. The old Part 35 recognized training provided by speciality boards listed in the regulations. However, these previously approved speciality boards (with one exception) do not meet the detailed training requirements in the new Part 35. The ACMUI reviewed the existing speciality boards and concluded, with concurrence by the NRC staff, that the existing speciality boards meet the intent of the required training even if they do not meet the exact wording in the regulations. The ACMUI and staff have recommended an alternative rule which would resolve the dilemma by approving existing boards reviewed by the ACMUI and providing criteria for qualifying new speciality boards in the future. The new training criteria also requires authorized users, besides being certified by a speciality board or receiving other general training, to also receive training for the equipment or function for which the licensee is seeking authorization. Given the fact that a significant majority of past medical events (formally known as misadministrations) were attributed to technicians, equipment, or procedures and not inadequate training by the speciality boards of authorized users, I will accept the staff recommendations.

I also approve the staff recommendation that approved speciality boards be listed on our web site as opposed to being listed in the regulations. It is a more timely and efficient process to add or remove items from our web site than it is to change our regulations for issues which can be adequately addressed in this manner.

The draft rule contains criteria for new speciality boards to achieve recognition by the NRC. As part of the rulemaking process, I would expect the staff to discuss implementing procedures both for adding new speciality boards to the approved listing and for removing boards from the approved list. While I do not expect NRC staff to conduct inspections of the approved speciality boards, I do expect staff to monitor trends in medical events. If a particular speciality for some reason has a series of medical events that can be attributed to inadequate training, the staff will need to determine if the training should have been site specific or should have been provided by the speciality boards. If the staff determines that changes in training by an approved speciality board are necessary and the speciality either cannot or will not make adequate changes to its training program to address our needs, then that speciality board should be removed from our approved list. However, appropriate due process would require that the procedures are established in advance for removing a speciality board from the approved list. In addition, the Commission should be informed of any staff decision to remove a board from the approved list.