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(68FR 68549)

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February 23, 2004

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Ms. Annette Vietti-Cook
 Secretary of the Commission
 U.S. Nuclear Regulatory Commission
 Attention: Rulemakings and Adjudications Staff
 Washington, DC 20555-0001

RE: RIN 3150-AH19

Dear Ms. Vietti-Cook:

The American College of Cardiology (ACC) welcomes the opportunity to comment upon revisions to 10 CFR Part 35, Medical Use of Byproduct Material-Recognition of Specialty Boards (RIN 3150-AH19) published in the *Federal Register*, December 9, 2003, Vol. 68, No. 236, pages 68549-68563. ACC is a 28,000 member nonprofit professional medical society and teaching institution whose purpose is to foster optimal cardiovascular care and disease prevention through professional education, promotion of research, and leadership in the development of standards and formulation of health care policy. ACC represents over 90 percent of the cardiologists practicing in the United States.

The ACC comments will focus upon the following issues:

- (1) compatibility timing and the Agreement States;
- (2) status of the Certification Board of Nuclear Cardiology;
- (3) the preceptor letter and the specialty board application;
- (4) the preceptor letter and licensure application;
- (5) revisions to 10 CFR Part 35.290;
- (6) use of "attestation" rather than "certification"; and
- (7) listing approved boards on the NRC Web Site.

DISCUSSION

(1) The most important issue raised in this rulemaking is the timing of Agreement State compatibility. Agreement States can and should comply with the training and experience requirements published in the revised 10 CFR Part 35 on April 24, 2002 by October 24, 2005. The issues in this proposed rule are limited and do not affect the core of the training and experience requirements. Agreement States have had three years to develop a ("essentially identical") compatible rule. Progress on implementing compatibility in the Agreement States has been agonizingly slow. Giving Agreement States three years from implementation of this rule to have compatible training and experience requirements in place constitutes a reward for obfuscation and inefficiency. In some states these changes will require legislative action, and the process needs to be

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The mission of the American College of Cardiology is to foster optimal cardiovascular care and disease prevention through professional education, promotion of research, leadership in the development of standards and guidelines and the formulation of health care policy.



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started immediately in order to achieve compliance with the federal mandate. Further delay in the adoption of training and experience requirements will inject added uncertainty into the process and delay unnecessarily the final resolution of the training and experience issue. **Recommendation:** Order Agreement States to comply with the requirements of this rule by October 24, 2005.

(2) ACC strongly objects to applying the terms of this rule to the CBNC, the only board that took the time and made the effort to comply with the NRC requirements in 10 CFR Part 35 as promulgated on April 24, 2002. Under the terms of this proposed rule, an efficient and well-run board will have to meet new requirements and endure regulatory uncertainty. CBNC's reward for complying with the NRC's original requirements is to repeat the recognition process. **Recommendation:** Permit the CBNC to stand as organized and recognized by the NRC following publication of 10 CFR Part 35 on April 24, 2002.

The College believes there are very good reasons to require a preceptor letter with the application to sit for the board examination. A preceptor letter is required for the authorized user license. What is to be gained by dropping the requirement of a preceptor letter in the board application process? **Recommendation:** Retain the preceptor letter requirement as a prerequisite to the board application. See discussion in the next paragraph for recommended revisions in the required language.

(4) ACC agrees with the commission's suggestion that the preceptor should "attest to the candidate's ability to handle radioisotopes in preserving the health and safety of the patient and the provider." Since the NRC has made it very clear that it is not in the business of regulating medicine, this language fulfills the commission's mandate to protect public health and safety. **Recommendation:** Include the verbiage "attest to" in connection with the candidate's ability to handle byproduct material safely.

(5) The College agrees with the ACMUI recommendation that the "the requirements for work experience for authorized users in Part 35.290 be changed to require experience with performing quality control check of instruments rather than with calibrating instruments." This revision reflects practices in nuclear laboratories and therefore constitutes a more realistic regulatory requirement. **Recommendation:** Make the changes proposed on page 68552 of the *Federal Register*.

(6) ACC agrees with the commission that the word "attestation" is superior to "certification" in the preceptor statement. The word certification applies to a process which boards like the Certification Board of Nuclear Cardiology use in connection with its examination. In making a statement the preceptor does in fact "attest" to the candidate's qualifications. **Recommendation:** Require the preceptor to "attest to" the candidate's qualifications.



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(7) The College concurs with the NRC that the recognized specialty boards should be listed on the commission's web site rather than be included within the rule text. Listing approved specialty boards on the web site gives the commission more flexibility and eliminates the need for a new rulemaking procedure should the approved boards change for any reason. **Recommendation:** List the NRC-recognized specialty boards on the NRC web site.

ACC appreciates this opportunity to submit these comments. Please feel free to contact either me or James A. Boxall, Jr., Associate Director, Regulatory and Legal Affairs, at (301) 493-2366 or jboxall@acc.org with any questions regarding the College's comments.

Thank you for considering the American College of Cardiology's views.

Sincerely yours,

Carl J. Pepine, MD, MACC
President

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