

May 24, 2007

Mr. Charles H. Rose, Executive Director
American Association for Nuclear Cardiology, Inc.
5660 Airport Boulevard, Suite 101
Boulder, Colorado 80301

SUBJECT: RESPONSE TO LETTERS TO REGIONAL DIVISION DIRECTORS
DATED MARCH 19, 2007

Dear Mr. Rose:

This letter is in response to your March 19, 2007, letters to the Directors of the Division of Nuclear Materials Safety, U.S. Nuclear Regulatory Commission (NRC) in Regions I, III and IV, in which you request NRC's position on several issues related to the 80 hour classroom and laboratory training requirements stipulated for authorized users (AU) for imaging and localization studies (10 CFR 35.290). I am responding on behalf of the Regional Division Directors, in my capacity as the Director of the Division of Materials Safety and State Agreements, NRC Headquarters, which has the responsibility for coordinating issues involving the medical use of byproduct material.

In your letter, you provided information on and described concerns about a specific training course apparently purporting to satisfy the 80 hours of classroom and laboratory training requirements for physicians who are seeking to become AUs for imaging and localization studies (10 CFR 35.290). In general, your concerns related to physicians satisfying the training and experience (T&E) requirements, given the time allotted for each course as well as the lack of an exam, and the impact of the course on candidates of the Certification Board for Nuclear Cardiology (CBNC). In response to these concerns, I would note that NRC does not specify a minimum number of hours that shall be spent on classroom and laboratory training for individuals seeking to become AUs under the board certification pathway (i.e., CBNC diplomats). Further, NRC does not review and approve training programs to evaluate whether they meet the T&E criteria in 10 CFR Part 35, nor do NRC's regulations require individuals seeking to become AUs under the alternate pathway to pass an exam.

The following paragraphs respond to the specific questions raised in your letter:

In items a and e of your letter, you asked if the training program you describe, consisting of a 4-6 day course of 32-48 hours, is acceptable to the NRC. As stated above, NRC does not review and approve training programs to evaluate whether they meet the T&E criteria in 10 CFR Part 35. Rather, the documentation of T&E is reviewed by the appropriate NRC Regional Office on a case-by-case basis for all physicians seeking AU status under the alternate pathway in a particular regulation to determine whether the proposed AU meets the applicable requirements. For individuals seeking AU status under the alternate pathway, 10 CFR 35.290(c)(1) requires completion of 700 hours of T&E, with a minimum of 80 of those hours being classroom and laboratory training in the topics listed in 10 CFR 35.290(c)(1)(i)(A) through (E). The proposed AU may obtain the required classroom and laboratory training using a variety of instructional methods, including online training or home-study, as long as it meets the specific hour

requirements and the subject matter relates to radiation safety and safe handling of byproduct material for the uses requested.

In item b of your letter, you asked if NRC accepts a preceptor statement “on face value” or whether NRC asks for supporting documentation. Physicians seeking to become an AU under the alternate pathway are required to submit a written preceptor attestation *and* documentation of T&E, which can be accomplished either by completing the applicable NRC Form 313A or by submitting equivalent documentation. In either case, the proposed AU must provide information about the location and date of the training and the number of hours spent on each of the subject areas listed in the classroom and laboratory training requirements under 10 CFR 35.290(c)(1)(i).

In item c of your letter, you asked if NRC reviews the content and duration of the training beyond the preceptor statement. The NRC relies on preceptor statements to determine if an individual has satisfactorily completed the T&E requirements and is competent to function independently as an AU. The competency of proposed AUs to function independently as AUs is best assessed by AUs who have experience performing the duties of an AU. However, the proposed AU must still provide evidence that he or she has met the applicable T&E requirements by submitting information about the location, date, and the number of hours of training for each of the topics listed under classroom and laboratory training requirements. NRC license reviewer staff will carefully review this information before listing an individual on a license as an AU. The license reviewer may take additional measures or request additional information from the applicant if the license reviewer believes that the documentation of T&E originally submitted is inadequate (e.g., contacting the vendor providing the training, contacting the preceptor, or requesting a course syllabus).

In item d of your letter, you asked if NRC will accept “home study” to meet the 80 hour requirement. The proposed AU may obtain the required classroom and laboratory training using a variety of instructional methods. NRC will broadly interpret “classroom and laboratory training” to include various types of instruction, including online training or home-study, as long as it meets the specific hour requirements and the subject matter relates to radiation safety and safe handling of byproduct material for the uses requested.

For further information or for questions, please contact Ms. Cindy Flannery, Team Leader of the Medical Radiation Safety Team, at (301) 415-0223 or via e-mail at cmf@nrc.gov.

Sincerely,

/RA/

Janet R. Schlueter, Director
Division of Materials Safety
and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

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Janet R. Schlueter, Director
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Distribution:

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