

March 26, 2009

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

SUBJECT: RESPONSE TO LETTER DATED DECEMBER 3, 2008 AND E-MAIL DATED
NOVEMBER 13, 2008.

I am responding to your December 3, 2008, letter addressed to Ms. Cindy Flannery and your November 13, 2008, e-mail to Mr. Victor McCree in which you 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 authorized users (AUs) for imaging and localization studies (10 CFR 35.290).

In your December 3, 2008, letter, you expressed concerns about the course not meeting the U.S. Nuclear Regulatory Commission's (NRC's) training and experience (T&E) requirements for Certification Board for Nuclear Cardiology (CBNC) candidates. In response to these concerns, I would note that NRC does not specify that a certain number of the hours required to meet the T&E requirements must be spent on classroom and laboratory training for individuals seeking to become AUs under the board certification pathway (i.e., CBNC diplomates). The T&E requirements in 10 CFR 35.290 offer three pathways for individuals seeking to be recognized as an AU for imaging and localization studies: (1) approval of a physician who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State as meeting the NRC's requirements for T&E, referred to as the "certification pathway;" (2) approval of a physician who is an AU under 10 CFR 35.390 for the use of unsealed material requiring a written directive who has additional generator experience specified in 10 CFR 35.290(c)(1)(ii)(G) or equivalent Agreement State requirements; or (3) approval of a physician based on an evaluation of the physician's T&E against the requirements in 10 CFR 35.290(c)(1), referred to as the "alternate pathway." Please note that the 80-hour classroom and laboratory training requirement in the introductory text of paragraph (c)(1) only applies to the alternate pathway; not to the other pathways under 10 CFR 35.290. While classroom and laboratory training in each of the listed topics is required for physicians seeking AU status under the certification pathway, NRC's regulations do not require a minimum of 80 hours to be spent on those topics listed in 10 CFR 35.290(c)(1)(i) under that pathway.

As you alluded to in your December 3, 2008 letter, the NRC allows some flexibility to the manner in which proposed AUs can meet the minimum 80 hours of classroom and laboratory training hours under the alternate pathway. For example, NRC has advised the public that some of the clinical laboratory experience may be credited toward the "classroom and laboratory training" as long as it is related to radiation safety and safe handling of byproduct material for the uses for which authorization is sought, and those hours claimed are not also credited toward the "supervised work experience." If a proposed AU attends an 80-hour course that spends time on subject matter that is not related to radiation safety and safe handling of byproduct material, then the proposed AU must seek additional classroom and laboratory training to meet the T&E requirements. The documentation of the complete T&E is carefully reviewed on a case-by-case basis by NRC Regional license review staff to ensure that that the

proposed AU satisfies the specific clock hour requirements with subject matter that relates to the topics identified in the applicable sections of 10 CFR Part 35.

In your November 13, 2008, e-mail, you expressed your concern that the course is significantly devoted to topics not related to the subject matter required in the applicable T&E sections of 10 CFR Part 35 and you asked whether the NRC would accept it to meet the 80 hours of classroom and laboratory training requirement in 10 CFR Part 35.

The NRC does not approve training programs designed to meet the T&E requirements in 10 CFR Part 35 and it is acceptable for training courses to spend some of the course time on topics other than those related to radiation safety and safe handling of byproduct material. A physician seeking to become an AU under the alternate pathway must provide evidence to the NRC 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 the classroom and laboratory training requirements.

For further information or for questions, please contact Ms. Cindy Flannery, Team Leader of the Division of Materials Safety and State Agreements' Medical Radiation Safety Team at (301) 415-0223, or via e-mail at cindy.flannery@nrc.gov.

Sincerely,

/RA by James Luehman Acting/

Robert J. Lewis, Director
Division of Materials Safety and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

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For further information or for questions, please contact Ms. Cindy Flannery, Team Leader of the Division of Materials Safety and State Agreements' Medical Radiation Safety Team at (301) 415-0223, or via e-mail at cindy.flannery@nrc.gov.

Sincerely,

/RA by James Luehman Acting/

Robert J. Lewis, Director
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