April 13, 2006

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

SUBJECT: LETTER DATED FEBRUARY 9, 2006

Dear Mr. Rose:

I am responding to your February 9, 2006, letter in which you requested a response from the Nuclear Regulatory Commission (NRC) as to whether NRC would accept two positions of the Institute for Nuclear Medical Education (INME). Specifically, you stated that INME is taking the position that the training provided in the Radiopharmaceutical Chemistry section of INME's training program constitutes adequate training as stipulated in 10 CFR 35.290(ii)(G). You also state that INME takes the position that the INME administration is authorized to certify the Radiopharmaceutical Chemistry portion of the training.

10 CFR 35.290(c)(1)(ii)(G) requires that a physician seeking to become an authorized user of unsealed byproduct material for uses authorized under (AU) section 35.200 must complete 700 hours of training and experience including work experience involving "[e]luting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs...." 10 CFR 35.290(c)(1)(ii) lists all of the required work experience topics and states that the work experience must be obtained under the supervision of an authorized user who meets the requirements in 10 CFR 35.290, or 10 CFR 35.290(c)(1)(ii)(G) and 10 CFR 35.390 or equivalent Agreement State requirements. Accordingly, it is *not* acceptable for INME students to be obtaining their work experience, to include eluting generators, from radiopharmacists or physicists or anyone else unless the training program is under the supervision of an authorized user who meets the requirements in 10 CFR 35.290, or 10 CFR 35.290(c)(1)(ii)(G) and 10 CFR 35.390 or equivalent Agreement State requirements.

Further, 10 CFR 35.290(c)(2) requires, in part, that the individual who provides the written attestation must be a preceptor AU who meets the requirements of 10 CFR 35.290, or 10 CFR 35.290(c)(1)(ii)(G) and 10 CFR 35.390, or equivalent Agreement State requirements. Therefore, it is *not* acceptable for the INME administration to "certify" the Radiopharmaceutical Chemistry where the generator elution work experience is obtained unless the INME administration is an authorized user who meets the requirements in 10 CFR 35.290, or 10 CFR 35.290(c)(1)(ii)(G) and 10 CFR 35.390 or equivalent Agreement State requirements.

In addition, I noted that your letter states that INME's training program is "recognized by the NRC ...." We would like to clarify that NRC does not "recognize" any training programs as meeting the training and experience criteria in 10 CFR 35. The supporting documentation to an

amendment request is reviewed by the appropriate NRC Regional office on a case-by-case basis for all physicians seeking AU status under the alternate pathway to determine whether the proposed AU meets the training and experience requirements in 10 CFR 35.

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

Sincerely,

/RA/

Thomas H. Essig, Chief
Materials Safety & Inspection Branch
Division of Industrsial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

amendment request is reviewed by the appropriate NRC Regional office on a case-by-case basis for all physicians seeking AU status under the alternate pathway to determine whether the proposed AU meets the training and experience requirements in 10 CFR 35.

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

Sincerely,

/RA/

Thomas H. Essig, Chief
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Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

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