February 23, 2007

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

SUBJECT: LETTER DATED DECEMBER 27, 2006

Dear Mr. Rose:

This letter is in response to your December 27, 2006 letter to Dr. Charles Miller, in which you request that we advise you as to U. S. Nuclear Regulatory Commission's (NRC) position on several issues. I am responding on behalf of Dr. Miller, in my capacity as the new Director of the Division of Materials Safety and State Agreements which, due to a recent reorganization, has the responsibility for the medical use of byproduct material.

Although the inquiries in your letter do not explicitly reference a specific medical use of byproduct material, please be aware that our response to your questions is limited to the use of unsealed byproduct material for imaging and localization studies for which a written directive is not required, regulated in 10 CFR Part 35, Subpart D, "Unsealed Byproduct Material--Written Directive Not Required." Your specific concerns are addressed below:

1. Under item 1 of your letter, you asked if an authorized user (AU) may order or prescribe a diagnostic radiopharmaceutical for a patient who has not been seen and whose case history is unknown to the authorized user and the authorized user's ability to prescribe is simply used by non physicians through "standing orders."

   It appears that your concern is related to whether NRC requires an AU to verify the appropriateness of a diagnostic nuclear medicine procedure for a patient prior to radiopharmaceutical administration, since frequently, such tasks as ordering radiopharmaceuticals from the radiopharmacy and radiopharmaceutical administrations are performed by individuals other than the AU. 10 CFR Part 35, Subpart D, does not require an AU to see the patient or review the case history prior to radiopharmaceutical administration. However, higher-risk administrations regulated under other Subparts to 10 CFR Part 35 do require the review and approval by an AU before administration through the requirements of the AU's signature on a written directive.

   If, instead, your concern is related to whether a non physician may refer a patient for a diagnostic nuclear medicine procedure or whether a non physician may order a radiopharmaceutical, that issue can best be addressed by the State Medical Boards/Licensure, certifying organizations, or various medical professionals. The training and experience requirements for AUs under 10 CFR Part 35 establish the qualifications of a physician to safely handle radioactive material for medical use. They do not establish requirements for general clinical or professional competency. The NRC does not regulate the practice of medicine.

2. Under item 2 of your letter, you questioned whether a physician has to be present or available within a given period of time for radiopharmaceutical administration and imaging and whether that physician must be an AU. You also asked what training would be required for a non-AU physician if the AU was not required to be present.

   10 CFR Part 35 does not require either a physician or an AU to be physically present or available for byproduct materials used under Subpart D. However, modalities regulated under Subpart H—Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units, do have requirements for physical presence, immediate availability and training and experience for AUs, physicians and authorized medical physicists because of the higher risk associated with the treatment administration of these modalities.

3. Under item 3 of your letter, you asked if interpretations must be performed by AUs, or whether interpretations can be performed by non-AU physicians, non physicians or physicians not licensed to practice medicine in your State.

   The training and experience requirements for AUs under 10 CFR Part 35 establish the qualifications of a physician to safely handle radioactive material for medical use. They do not establish requirements for the individual's clinical or professional competency. NRC does not regulate the practice of medicine including the interpretation of test results. Requirements related to the practice of medicine are best addressed by State Medical Boards/Licensure, certifying organizations or hospital credentialing committees. Please refer to State law on the regulations for various medical professionals such as physicians, medical physicists or technologists.

For further information or for questions, please contact me or Ms. Cynthia 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

2. Under item 2 of your letter, you questioned whether a physician has to be present or available within a given period of time for radiopharmaceutical administration and imaging and whether that physician must be an AU. You also asked what training would be required for a non-AU physician if the AU was not required to be present.

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Sincerely,

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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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