

American Association for Nuclear Cardiology, Inc.

Professionals Dedicated to Diagnostic Accuracy

22 July 2011

U.S. Mail

Mr. Robert J. Lewis, Director
Division of Materials Safety
and State Agreements
Office of Federal & State Materials
and Environmental Management Programs
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Mr. Lewis:

Please assist us in determining the proper response to inquiries concerning this issue.

The Event

In the course of performing a diagnostic nuclear medicine procedure, it is common practice that the Authorized User (AU) may not be present, physically in the room, when the patient is injected with the radiopharmaceutical. In hospital settings, the AU is usually not present, during the injection, and, in fact, may not be physically present in the facility. A non-physician, i.e., nuclear medicine technologist, cardiac stress technologist, physicians assistant, nurse or other individual may administer the radiopharmaceutical prescribed by the AU.

Administration of the radiopharmaceutical may be given IV and for most procedures, the agent is administered via an existing IV line that is open through a saline solution drip. In this latter situation, the radiopharmaceutical is injected into the plastic IV tube not directly via a new IV puncture.

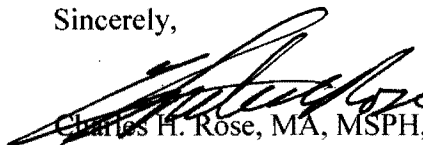
The Question

Are there any specific regulatory requirements, in your agency, that must be met by the individual administering the radiopharmaceutical? Who is permitted and what training/certification must they have to perform this activity?

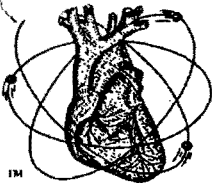
We assume that regulatory controls are exercised by the facility and established procedures are being followed. We also assume that none of the radiopharmaceuticals have the possibility of adverse reactions or contraindications.

Your response will be greatly appreciated.

Sincerely,



Charles H. Rose, MA, MSPH, D(ABSNM)
Executive Director



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