

October 3, 2000

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

SUBJECT: 10 CFR 35.980 REQUIREMENTS

Dear Mr. Rose:

I am responding to your May 11, 2000, letter (Enclosure 1), requesting further clarification for a hypothetical case concerning the requirements for an authorized nuclear pharmacist (Enclosure 2).

As I indicated in my April 18, 2000 letter, NRC regulations require, among other things, that the pharmacist complete: (1) a structured educational program that includes supervised experience in a nuclear pharmacy involving a number of specific tasks [10 CFR 35.980(b)(1)]; and (2) a written certification, signed by a preceptor authorized nuclear pharmacist, that the training required in 10 CFR 35.980 (b)(1) was satisfactorily completed and that the individual achieved a level of competency sufficient to independently operate a nuclear pharmacy [10 CFR 35.980(b)(2)].

Your letter indicates the nuclear medicine facility will obtain a state pharmacy license. You have not indicated whether this license would qualify the pharmacy as a nuclear pharmacy. If it does, the pharmacist could meet criterion (1) if a structured educational program is provided at the nuclear pharmacy. With regard to criterion (2), the pharmacist still needs the written certification signed by a preceptor authorized nuclear pharmacist. Unless the physician is also an authorized nuclear pharmacist, the pharmacist's application will not meet criterion 2.

As I also indicated in my previous letter, if a licensee requested a specific exemption, pursuant to 35.19, from the training and experience requirements of 35.980, to have an individual that did not meet these requirements listed as an authorized nuclear pharmacist on the license, the individual's training and experience requirements could be reviewed on a case-by-case basis.

If you have additional questions, please contact Donna-Beth Howe, PhD, at (301-415-7848).

Sincerely,

/RA/
John W. N. Hickey, Chief
Materials Safety and
Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosures:

1. Letter dated May 11, 2000
2. Training Requirements For An
Authorized Nuclear Pharmacist

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TRAINING REQUIREMENTS FOR AN AUTHORIZED NUCLEAR PHARMACIST

10 CFR 35.980 Training for an authorized nuclear pharmacist.

The licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

- (a) Has current board certification as a nuclear pharmacist by the Board of Pharmaceutical Specialties, or
- (b)(1) Has completed 700 hours in a structured educational program consisting of both:
 - (i) Didactic training in the following areas:
 - (A) Radiation physics and instrumentation;
 - (B) Radiation protection;
 - (C) Mathematics pertaining to the use and measurement of radioactivity;
 - (D) Chemistry of byproduct material for medical use; and
 - (E) Radiation biology; and
 - (ii) Supervised experience in a nuclear pharmacy involving the following:
 - (A) Shipping, receiving, and performing related radiation surveys;
 - (B) Using and performing checks for proper operation of dose calibrators, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;
 - (C) Calculating, assaying, and safely preparing dosages for patients or human research subjects;
 - (D) Using administrative controls to avoid mistakes in the administration of byproduct material;
 - (E) Using procedures to prevent or minimize contamination and using proper decontamination procedures; and
- (2) Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

[59 FR 61786, Dec. 2, 1994]