

July 20, 2000

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

SUBJECT: 10 CFR 35.25 REQUIREMENTS

Dear Mr. Rose

I am responding to your March 3, 2000, letter (Enclosure 1), requesting whether a hypothetical case involving the absence of an authorized user physician would comply with NRC requirements for supervision of individuals by an authorized user.

Several provisions of Title 10 Code of Federal Regulations (10 CFR) such as, but not limited to, sections 35.25, "Supervision," and 35.32, "Quality management program," are applicable to this specific issue. Section 35.25 (Enclosure 2), spells out the requirements for the supervision of individuals who perform the medical use tasks specified in section 35.11(b) (i.e., receipt, possession, use, or transfer of byproduct material). For administration of sodium iodine-131 in quantities greater than 30 microcuries, the licensee and authorized user must meet, among other things, the provisions in 10 CFR 35.2, "Definitions," and requirements in 35.32 relating to written directives (Enclosure 3).

The 1986 statement of considerations (SOC) for 10 CFR Part 35 (51 FR 36932) (Enclosure 4) provides clarification on the authorized user's duties with respect to supervision, delegation of tasks, and delegation of responsibility, all issues related to your letter. It states, "[T]he purpose of supervision is to provide assurance that technologists and physicians do not use byproduct materials in a manner that is contrary to the requirements of the license, the regulations, or that is hazardous to the public health and safety." The SOC clarifies that, "[T]he licensee cannot delegate responsibility to supervised individuals. If a supervised individual, through misunderstanding, negligence, or commission, acts contrary to the requirements of the license, the regulations, or an order, the licensee remains responsible." Thus, "[T]he authorized user physician identified on the license is responsible for delivering quality medical care, and is best situated to determine what tasks a certain physician or technologist is capable of performing and the amount of personal supervision that each needs."

The 1986 SOC also states, "a licensee may delegate to unnamed individuals performance of any task associated with the medical use of byproduct material from package receipt through quality control, prescription, administration, interpretation or follow-up for individual clinical procedures, and radioactive waste disposal. The delegations must be consistent with other institutional requirements and the state's regulation of medicine." However, with the subsequent promulgation of section 35.32, the authorized user must sign and date a "written directive." Thus, this is a task that cannot be delegated. Therefore, when the only authorized

user is absent, the licensee may have difficulties meeting the requirements for making and documenting any changes to the written directive.

The regulations do not address the issue of the authorized user's presence or availability while a supervised individual administers byproduct material for medical use. Licensee commitments are used for specific high-risk medical uses (e.g., gamma stereotactic radiosurgery and high dose rate afterloader uses) to assure the authorized user and other designated personnel are present or immediately available when these devices are used for patients or human research subjects.

A question similar to the one you raised is addressed in the 1986 SOC. That question is whether a license amendment or notification of NRC is required if an authorized user, Radiation Safety Officer, or teletherapy physicist is absent for illness, vacation, sabbatical, or continuing education. In answer to that question, the SOC states that "[B]ecause the specific facts and circumstances would dictate the appropriate action by the licensee, it would be impossible for the NRC to make generic determinations in advance of the situation." The SOC further states that "[T]he point cannot be reiterated sufficiently that the licensee, despite the absence of personnel, remains responsible for assuring continued compliance with NRC radiation safety requirements." As a result, the Commission rejected requirements that "the authorized user be immediately available by telephone and physically present on one hour's notice as an attempt at a prescriptive definition of supervision in the medical setting."

Although it may be possible in the hypothetical scenario you described for the licensee to comply with NRC requirements (because the authorized user can delegate certain tasks), we cannot speculate on actual compliance without specific facts. Similarly, we cannot speculate on what enforcement may be appropriate if there were a violation. For information on appropriate levels of enforcement, you may refer to NUREG -1600, "General Statement of Policy and Procedure for NRC Enforcement Actions, Enforcement Policy - November 9, 1999," which is available in the "Reference Library" of NRC's web page (www.nrc.gov).

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

Sincerely,

/RA/Frederick C. Sturz, for
John W. Hickey, Chief
Materials Safety and
Inspection Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

Enclosures:

1. Incoming ltr. dtd. 3/3/2000
2. 10 CFR 35.25
3. 10 CFR 35.2 & 35.32
4. Statement of consideration
For final rule revising 10CFR35

Supervision Requirements for NRC Medical Use Licensees

10 CFR 35.25, Supervision.

(a) A licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user as allowed by §35.11(b) of this part shall:

(1) Instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of byproduct material and in the licensee's written quality management program;

(2) Require the supervised individual to follow the instructions of the supervising authorized user, follow the written radiation safety and quality management procedures established by the licensee, and comply with the regulations of this chapter and the license conditions with respect to the use of byproduct material; and

(3) Periodically review the supervised individual's use of byproduct material and the records kept to reflect this use.

(b) A licensee that permits the preparation of byproduct material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by §35.11(c), shall:

(1) Instruct the supervised individual in the preparation of byproduct material for medical use and the principles of and procedures for radiation safety and in the licensee's written quality management program, as appropriate to that individual's use of byproduct material;

(2) Require the supervised individual to follow the instructions given pursuant to paragraph (b)(1) of this section and to comply with the regulations of this chapter and license conditions; and

(3) Require the supervising authorized nuclear pharmacist or physician who is an authorized user to periodically review the work of the supervised individual as it pertains to preparing byproduct material for medical use and the records kept to reflect that work.

(c) A licensee that supervises an individual is responsible for the acts and omissions of the supervised individual.

[51 FR 36951, Oct. 16, 1991, as amended at 56 FR 34121, July 25, 1991; 59 FR 61782, Dec. 2, 1994]

Nuclear Medicine Written Directive and Quality management requirements

10 CFR 35.2 Definitions.

Authorized user means a physician, dentist, or podiatrist who is:

- (1) Board certified by at least one of the boards listed in Paragraph (a) of §§35.910, 35.920, 35.930, 35.940, 35.950, or 35.960;
- (2) Identified as an authorized user on a Commission or Agreement State license that authorizes the medical use of byproduct material; or
- (3) Identified as an authorized user on a permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of byproduct material.

Physician means a medical doctor or doctor of osteopathy licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine.

Written directive means an order in writing for a specific patient or human research subject, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, except as specified in paragraph (6) of this definition, containing the following information:

- (1) For any administration of quantities greater than 30 micro curies of either sodium iodide I - 125 or I - 131: the dosage;

10 CFR 35.32 Quality management program.

(a) Each applicant or licensee under this part, as applicable, shall establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user. The quality management program must include written policies and procedures to meet the following specific objectives:

- (1) That, prior to administration, a written¹ directive is prepared for:

¹If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision.

Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next teletherapy fractional dose.

(iv) Any administration of quantities greater than 30 micro curies of either sodium iodide I - 125 or I - 131; or

(2) That, prior to each administration, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive;

(4) That each administration is in accordance with the written directive; and

(5) That any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

[56 FR 34121, July 25, 1991, as amended at 59 FR 61783, Dec. 2, 1994]

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

PART 35 STATEMENTS OF CONSIDERATION

Section 35.25 Supervision.

Comment: There may be only one authorized user on a hospital's license. If the authorized user is absent, the hospital has to hire an authorized user from another area to care for the patients. There may be capable residents at a nearby medical college who cannot be hired only because they are not listed as authorized users on a license. Yet, they may have been supervised by the authorized user before and found capable of delivering proper care for patients.

Comment: The NRC should require that each physician authorized user and technologist be certified by the appropriate board. This would help assure that individuals have been trained.

Comment: Requiring the authorized user to be physically present on one hour's notice is arbitrarily stringent. Choose a more reasonable time.

Comment: There should be a time limit on use of the supervision clause with respect to a physician-in-training in order to avoid use of the supervision clause in lieu of licensure.

Response: The purpose of supervision is to provide assurance that technologists and physicians do not use byproduct materials in a manner that is contrary to the requirements of the license, the regulations, or that is hazardous to the public health and safety. The proposed requirement that the authorized user be immediately available by telephone and physically present on one hour's notice was an attempt at a prescriptive definition of supervision in the medical setting.

NRC recognizes that medical practice is regulated differently in each state, but that, in the end, the physician is responsible for providing quality medical care. A prescriptive definition that describes delegatable tasks, timely response in case of untoward events, and training requirements that are suited for one setting may hinder the delivery of medical care in another setting. The authorized user physician identified on the license is responsible for delivering quality medical care, and is best situated to determine what tasks a certain physician or technologist is capable of performing and the amount of personal supervision that each needs.

Under the final regulation, a licensee may delegate to unnamed individuals performance of any task associated with the medical use of byproduct material from package receipt through quality control, prescription, administration, interpretation or follow-up for individual clinical procedures, and radioactive waste disposal. The delegations must be consistent with other institutional requirements and the state's regulation of medicine. The NRC did not retain the "immediately available by telephone and physically present on one hour's notice" clause.

The licensee can not delegate responsibility to **supervised individuals**. If a supervised individual, through misunderstanding, negligence, or commission, acts contrary to the requirements of the license, the regulations, or an order, the licensee remains responsible.

The NRC believes this strikes the best balance between its responsibility to assure the public health and safety and a physician's responsibility to deliver quality medical care.

5. Temporary absence. Several commenters asked if a license amendment or notification was required if an authorized user, Radiation Safety Officer, or Teletherapy Physicist was absent for illness, vacation, sabbatical, or continuing education. Because the specific facts and circumstances would dictate the appropriate action by the licensee, it would be impossible for the NRC to make generic determinations in advance of the situation.

The point cannot be reiterated sufficiently that the licensee, despite the absence of personnel, remains responsible for assuring continued compliance with NRC radiation safety requirements.

user is absent, the licensee may have difficulties meeting the requirements for making and documenting any changes to the written directive.

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

Sincerely,
 /RA/
 John W. Hickey, Chief
 Materials Safety and
 Inspection Branch
 Division of Industrial and
 Medical Nuclear Safety, NMSS

Enclosures:

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2. 10 CFR 35.25
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4. Statement of consideration

For final rule revising 10CFR35

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