



North Carolina Department of Environment and Natural Resources
Division of Environmental Health
Radiation Protection Section

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April 8, 2005

Azzie Conley, Assistant Section Chief
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N.C. Division of Facility Services
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SUBJECT: Citing of 42 CFR Part 482.53(b)(1) Condition of Participation: Nuclear Medicine Services

42 CFR 482.53(b)(1) Inconsistent with State Regulations 15 A NCAC 11.0318(a)(3) and (c-g), 15A NCAC 11.0361(a)(2); and Federal Regulations 10 CFR 35.100(b) and 10 CFR 35.27(b-c); and 42 CFR 482.25 (b)(1);

Dear Ms. Conley:

Thank you for speaking with me Tuesday, March 8, about your Branch's inspection of several North Carolina radioactive material licensees' sites. These inspections took place Feb. 22 and Feb. 24 of this year.

I am writing to you because I have received a portion of your inspection report, completed Feb. 25, which cited the licensees with a deficiency under 42 CFR Part 482.53(b)(1). This was cited as evidenced by both facilities receiving Technetium generators in which Certified Nuclear Medicine Technologists routinely prepare diagnostic doses during off-hours (after normal business hours and/or on weekends) without the direct supervision of a radiopharmacist or physician.

I would like to take this opportunity to clarify and resolve any conflicting information regarding the state and federal regulations on medical use of radioactive materials. The regulation referenced in your inspection report, 42 CFR Part 482.53(b)(1) states:

(b) Standard: Delivery of service. Radioactive materials must be prepared, labeled, used, transported, stored, and disposed of in accordance with acceptable standards of practice.

(1) In-house preparation of radiopharmaceuticals is by, or under, the direct supervision of an appropriately trained registered pharmacist or a doctor of medicine or osteopathy.

Acceptable standards of practice are those found in the regulations in the governing bodies that license facilities to receive, prepare, use, store and dispose of radioactive material. The governing bodies in this country that regulate radioactive material and set standards of practice are the U.S. Nuclear Regulatory Commission, and in the case of North Carolina being an Agreement State, the N.C. Radiation Protection Section. In both instances, the regulations of these two agencies do not require a direct supervisory relationship in preparation of radiopharmaceuticals.

The state's 15 NCAC 11.0318(a)(3) and (c-g) and 15A NCAC 11.0361(a)(2) regulations neither require nor define "direct supervision." They do, however, outline an understanding of what is implied and intended for an individual "under the supervision" of a nuclear pharmacist or authorized user. This understanding is in direct correlation with federal regulations 10 CFR 35.100(b) and 10 CFR 35.27 set forth by the NRC. I have included the language from each below.

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10 CFR 35.100(b)

Except for quantities that require a written directive under § 35.40(b), a licensee may use any unsealed byproduct material prepared for medical use for uptake, dilution, or excretion studies that is—

(b) Prepared by:

- (1) An authorized nuclear pharmacist;
- (2) A physician who is an authorized user and who meets the requirements specified in §§ 35.290, 35.390, or, before October 24, 2005, § 35.920; or
- (3) An individual **under the supervision**, as specified in § 35.27, of the authorized nuclear pharmacist in paragraph (b)(1) of this section or the physician who is an authorized user in paragraph (b)(2) of this section; or

10 CFR 35.27

(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(b)(2), shall--

- (1) In addition to the requirements in § 19.12 of this chapter, instruct the supervised individual in the preparation of byproduct material for medical use, as appropriate to that individual's involvement with byproduct material; and
- (2) Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of byproduct material for medical use, written radiation protection procedures established by the licensee, the regulations of this chapter, and license conditions.

(c) A licensee that permits supervised activities under paragraphs (a) and (b) of this section is responsible for the acts and omissions of the supervised individual.

North Carolina regulations 15A NCAC 11.0318 (a)(3) and (c-g)

(a)(3) An individual may prepare unsealed radioactive material for medical use in accordance with the rules of this Section **under the supervision** of a pharmacist who is an authorized user or physician who is an authorized user as provided in this Section unless prohibited by license condition.

(c) Subject to the provisions of Subparagraph (b)(4) and Paragraphs (d) to (g) of this Rule, **an authorized physician may permit technicians and other paramedic personnel to perform** the following activities:

- (1) **preparation and quality control testing of radiopharmaceuticals and sources of radiation;**
- (2) **measurement of radiopharmaceutical doses prior to administration;**
- (3) **use of appropriate instrumentation for the collection of data to be used by the physician;**
- (4) **administration of radiopharmaceuticals and radiation from radioisotope sources to patients.**

(d) Authorized physicians who permit activities to be performed by technicians and other paramedical personnel pursuant to Paragraph (c) of this Rule shall:

- (1) prior to giving permission, determine that the technicians and other paramedical personnel have been properly trained to perform their duties with specific training in the following subjects, as applicable to the duties assigned:
 - (A) general characteristics of radiation and radioactive materials;
 - (B) physical, chemical, and pharmaceutical characteristics of each radiopharmaceutical to be used;
 - (C) mathematics and calculations basic to the use and measurement of radioactivity, including units of radiation dose and radiation exposure;
 - (D) use of radiation instrumentation for measurements and monitoring including operating procedures, calibration of instruments, and limitations of instruments;
 - (E) principles and practices of radiation protection;
 - (F) additional training in the above subjects, as appropriate, when new duties are added.
- (2) assure that the technicians and other paramedical personnel receive appropriate retraining in the subjects listed in Subparagraph (d)(1) of this Rule to maintain proficiency and to keep abreast of developments in the field of nuclear medical technology;

- (3) keep records showing the bases for the determinations of proper training;
- (4) retain responsibility as licensee or authorized user for the satisfactory performance of the activities; and
- (5) review the work of the supervised individual and the records kept reflecting that work.

(e) Certification in nuclear medicine technology by the American Registry of Radiologic Technologists or in nuclear medical technology by the Registry of Medical Technologists of the American Society of Clinical Pathologists or the Society of Nuclear Medicine shall be deemed to satisfy the training requirements in Subparagraphs (d)(1) and (2) of this Rule.

(f) An applicant for a license or for amendment or renewal of a license shall state whether he desires to permit technicians or other paramedical personnel to perform activities pursuant to Paragraph (c) of this Rule and, if so, shall include in his application for license, license amendment, or license renewal a statement of the activities to be so performed and a description of an adequate program for training the personnel, including retraining as required to keep abreast of developments in technology, or for otherwise determining that the personnel are properly trained to perform their duties.

(g) Whenever a technician or other paramedical person administers a radiopharmaceutical to a patient by injection, a physician shall be immediately accessible, but not necessarily a physician authorized by the agency to be a user of radioisotopes.

North Carolina regulations 15A NCAC 11.0361(a)(2)

(a) A licensee may use for diagnostic or therapeutic administration any unsealed radioactive material prepared for medical use that is either:

- (1) obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72 or equivalent agreement state requirements; or
- (2) prepared by a pharmacist who is an authorized user, a physician who is an authorized user or an individual under the supervision of either.

Even the language in federal regulation 42 CFR 482.25(b)(1) "Condition of participation: Pharmaceutical services" seems to be inconsistent with the cited regulation. It states:

(b) Standard: Delivery of services. In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law.

(1) All compounding, packaging, and dispensing of drugs and biologicals must be under the supervision of a pharmacist and performed consistent with State and Federal laws.

The phrase, "under the supervision," is adequately addressed in the referenced state and federal regulations responsible for establishing acceptable standards of practice and licensing, inspecting, and regulating radioactive material facilities. Our position on this matter is summarized best in the Statements of Consideration for 10 CFR Part 35.27, dated March 31, 2003, which states "The Aus and ANPs are best suited to determine what tasks supervised individuals are capable of performing and the degree of supervision that each needs."

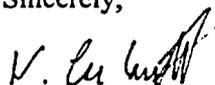
In 42 CFR 410.32(b)(3)(ii), there was one reference to the definition of direct supervision. It states: "Direct supervision in the office setting means the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed."

During your inspections on Feb. 22, and Feb. 24, our licensees were informed by the inspection team that a physician or a properly-trained registered pharmacist must be present in the room during the dose preparation to satisfy "under the direct supervision" requirement. If this statement is accurate of the qualifications used to inspect those particular licensees, then I would like to request further conversation with members of your agency, and other state and federal agencies to develop coherent guidelines void of inconsistencies.

We are all working toward what is best for the health and safety of our citizens. Together, I am sure we can achieve this with a better understanding of one another's regulations, roles and responsibilities regarding enforcement.

I thank you for your time and look forward to your response.

Sincerely,



W. Lee Cox, III, Manager
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cc: Beverly Hall, Chief
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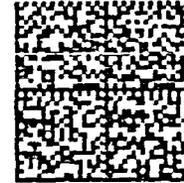
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