

This is an amendment to 16.19.18 NMAC, Sections 1, 3, 7, 9, and 10 effective 12/17/2019

16.19.18.1 ISSUING AGENCY: Regulation and Licensing Department - Board of Pharmacy, 1650 University Blvd, NE Ste. 400B, Albuquerque, NM 87102, (505) 841-9102. [2/15/1889...2/15/1996; 16.19.18.1 NMAC - Rn, 16 NMAC 19.18.1, 3/30/2002; A, 12/17/2019]

16.19.18.3 STATUTORY AUTHORITY: ~~[Section 61-11-6.A.(1) NMSA 1978]~~ Paragraph (1) of Subsection (A) of Section 61-11-6 NMSA 1978 authorizes the Board of Pharmacy to adopt, regularly review and revise rules and regulations necessary to carry out the provisions of the Pharmacy Act. ~~[Section 61-11-6.A.(3)]~~ Paragraph (3) of Subsection (A) of Section 61-11-6 NMSA 1978 directs the Board to provide for the registration and annual renewal of licenses of pharmacists. Pursuant to ~~[61-11-6.A.(6)]~~ Paragraph (6) of Subsection (A) of Section 61-11-6 NMSA 1978, the Board is authorized to provide for the licensing of retail pharmacies, nonresident pharmacies and wholesale drug distributors and to provide for the inspection of their facilities and activities. [2/15/1996; A, 5/30/1998; 16.19.18.3 NMAC - Rn, 16 NMAC 19.18.3, 3/30/2002; A, 12/17/2019]

16.19.18.7 DEFINITIONS:

A. The "Practice of Nuclear Pharmacy" means a patient-oriented service that embodies the scientific knowledge and professional judgement required to improve and promote health through the assurance of the same and efficacious use of radiopharmaceuticals and other drugs.

B. "Nuclear Pharmacy" means a pharmacy which provides radiopharmaceutical services, and shall be licensed by the Board as a wholesaler ~~and~~ or retail pharmacy.

C. "Qualified Nuclear Pharmacist" means a pharmacist currently licensed by the Board who meets either of the following criteria:

(1) Must be currently certified as a Nuclear Pharmacist by the Board of Pharmaceutical Specialties; or

(2) Must have successfully completed the requirements of ~~[Paragraph 7.C.2.a.,]~~ Subparagraphs (a) and (b) of this Paragraph. ~~[and meet a minimum of 250 contact hours of didactic instruction in nuclear pharmacy and the safe handling and use of radioactive materials from a nationally accredited college of pharmacy or other training program sponsored by an ACPE accredited provider of continuing pharmaceutical education, with the minimum 250 contact hours apportioned according to 7.C.2.b. and 7.C.2.e.]~~

(a) Must have attained a minimum of 500 contact hours of experiential training in nuclear pharmacy under the supervision of a qualified nuclear pharmacist in, but not limited to, the following areas:

- (i) procurement of radioactive materials;
- (ii) compounding of radiopharmaceuticals;
- (iii) maintenance of a quality assurance program;
- (iv) dispensing of radiopharmaceuticals;
- (v) distribution of radiopharmaceuticals;
- (vi) implementation of basic health and safety practices and procedures; and
- (vii) provision of information and consultation related to the practice of

nuclear pharmacy and the use of radiopharmaceuticals.

~~[(viii) monitoring of outcomes in patients who receive radiopharmaceuticals and related ancillary medications;~~

~~[(ix) research and development of radiopharmaceuticals].~~

(b) 200 contact hours of didactic instruction in nuclear pharmacy and the safe handling and use of radioactive materials, from a nationally-accredited college of pharmacy or other training program sponsored by an ACPE-accredited provider of continuing pharmaceutical education, in the following five areas:

- (i) radiation physics and instrumentation;
- (ii) radiation protection;
- (iii) mathematics pertaining to the use and measurement of radioactivity;
- (iv) radiation biology; and
- (v) radiopharmaceutical chemistry. ~~[and~~

~~[(c) 50 hours in the clinical use of radiopharmaceuticals].~~

(3) Any pharmacist who has been legally listed on a radioactive material license for a nuclear pharmacy in the State of New Mexico for at least six months prior to the 1994 effective date of these regulations, is exempt from Paragraphs (1) and (2) of Subsection C of 16.19.18.7 NMAC.

~~[(3)]~~ **D. "Radiopharmaceutical Services"** means the procurement, storage, handling, compounding, labeling, quality control testing, dispensing, distribution, transfer, record keeping and disposal of radiochemicals, radiopharmaceuticals and ancillary drugs, and also includes quality assurance procedures, radiological health activities, any consulting activities associated with the use of radiopharmaceuticals, and any other activities required for provision of pharmaceutical care.

~~[(4)]~~ **E. "Quality Control Testing"** means the performance of appropriate chemical, biological and physical tests on compounded radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals.

~~[(5)]~~ **F. "Quality Assurance Procedures"** means all activities necessary to assure the quality of the process used to provide radiopharmaceutical services, including authentication of product history and maintenance of all records as required by pertinent regulatory agencies.

~~[(6)]~~ **G. "Authentication of Product History"** means identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical or other drug.

~~[(7)]~~ **H. "Radiopharmaceutical"** means any drug which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or protons and includes any nonradioactive reagent kit or nuclide generator which is intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides. The term 'radiopharmaceutical' also includes any biological product which is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

~~[D. — Any pharmacist who has been legally listed on a radioactive material license for a nuclear pharmacy in the State of New Mexico for at least six months prior to the effective date of these regulations, is exempt from Paragraphs 7.C.1 and 7.C.2.]~~

[5/29/1994, 5/30/1998; 16.19.18.7 NMAC - Rn, 16 NMAC 19.18.7, 3/30/2002; A, 12/17/2019]

16.19.18.9 REQUIREMENTS FOR OPERATION OF A NUCLEAR PHARMACY:

A. A nuclear pharmacy shall meet the requirements of ~~[16 NMAC 19.6]~~ 16.19.6 NMAC of the Board, except as provided for in this section.

B. A qualified nuclear pharmacist shall be in personal attendance when the nuclear pharmacy is open for business.

C. A nuclear pharmacy shall meet minimum space requirements established for all pharmacies in the state (see ~~[16 nmac 19.6.10]~~ 16.19.6.10 NMAC, with the exception that the space may be interrupted).

D. The nuclear pharmacy shall maintain records of procurement, inventory and disposition of all radioactive drugs and other radioactive materials.

E. A nuclear pharmacy shall have a current copy (paper or electronic) of city, state, and federal regulations governing the safe storage, handling, use, dispensing, transport and disposal of radiopharmaceuticals.

F. The following minimum equipment requirements ~~[for a nuclear pharmacy are in lieu of]~~, as appropriate for the scope of nuclear pharmacy services provided, are in addition to those contained in 16.19.6.11[-A] NMAC [Paragraphs 11.A.6-11.A.9; 11.A.12-11.A.14; 11.A.18; 11.A.20 and 11.1.21 (the remainder of Sub-Section 11.A remains in force)]:

- (1) Radionuclide Dose Calibrator;
- (2) Refrigerator;
- (3) Single or multiple channel scintillation counter with well-type NaI(Tl) or Ge(Li)

detector;

- (4) Radiochemical fume hood and filter system;
- (5) Area rate meter;
- (6) At least two (2) GM survey meters;
- (7) Microscope and hemacytometer;
- (8) Laminar air flow hood and/or biologic safety cabinet;
- (9) Syringe and vial radiation shields;
- (10) Lead-shielded drawing station;
- (11) Decontamination supplies;

(12) Other equipment as needed for radiation safety to workers and the public; or for performance of quality control/quality assurance specified by standards of practice for the individual setting and the products involved.

G. A nuclear pharmacy shall operate in conformance with the United States Pharmacopeia *General Chapters: <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging*, and all other applicable chapters numbered 1000 or less.

[5/20/1994; 16.19.18.9 NMAC - Rn, 16 NMAC 19.18.9, 3/30/2002; A, 12/17/2019]

16.19.18.10 REQUIREMENTS FOR PROVISION OF RADIOPHARMACEUTICAL SERVICES:

A. Medications shall be dispensed from a nuclear pharmacy in accordance with the requirements contained in ~~[16 NMAC 19.6]~~ **16.19.6 NMAC**, except as provided for in this section.

B. A radiopharmaceutical shall be dispensed only to a licensed practitioner authorized by the Nuclear Regulatory Commission or an equivalent agreement state agency to possess, use and administer such drug. A radiopharmaceutical shall be dispensed only upon receipt of a prescription from such licensed practitioner. Otherwise, a radiopharmaceutical may be transferred to a person who is authorized to possess and use such drug for non-clinical applications.

C. In addition to other labeling requirements of the Board for nonradioactive drugs, the outer container shield of a radiopharmaceutical to be dispensed or transferred shall also be labeled with the following information:

- (1) the standard radiation symbol;
- (2) the words "Caution -- Radioactive Materials";
- (3) the radionuclide;
- (4) the chemical form;
- (5) the amount of radioactivity and the calibration date and time;
- (6) the expiration date and time;
- (7) if a liquid, the volume;
- (8) if a solid, the number of dosage units or weight;
- (9) if a gas, the number of ampules or vials;
- (10) the name of the patient (required only for radiolabeled blood components and all

radiopharmaceuticals intended for therapeutic use).

D. The inner container (e.g., syringe, vial, etc.) used to dispense or transfer a radiopharmaceutical shall be labeled with the following information:

- (1) the standard radiation symbol;
- (2) the prescription or lot number;
- (3) the name of the radiopharmaceutical;
- (4) the name of the patient (required only for radiolabeled blood components and all

radiopharmaceuticals intended for therapeutic use).

E. A licensed nuclear pharmacy, upon receiving a verbal prescription for a radiopharmaceutical, shall immediately have the prescription reduced to writing or recorded in a data processing system. The writing ~~[and/]~~ or record shall contain at least the following information, in addition to other requirements of the Board:

- (1) the name of the institution represented;
- (2) the date of the prescription;
- (3) the name and dose of the radiopharmaceutical;
- (4) the name of the procedure;
- (5) the requested date/time of calibration (tentative date/time of administration) of the

prescribed radiopharmaceutical;

(6) the name of the patient (required for radiolabeled blood components and all radiopharmaceuticals intended for therapeutic use.);

- (7) any specific instructions, if required.

F. Whenever a radiopharmaceutical is dispensed under the authority of an Investigational New Drug Application (INDA), the nuclear pharmacy records shall include an investigator's protocol for the preparation of the radiopharmaceutical, a copy of the Institutional Review Board approval form (or letter), and a letter from the manufacturer (sponsor) indicating that the physician requesting the radiopharmaceutical is a qualified investigator.

~~[G. Pharmacists practicing at a facility licensed under 16 NMAC 19.18 are exempt from 16.19.4.22.5 NMAC through 16.19.4.22.7 NMAC.]~~

[5/20/1994; 16.19.18.10 NMAC - Rn, 16 NMAC 19.18.10, 3/30/2002; A, 12/17/2019]