This is an amendment to 16.19.9 NMAC, Section 1, 7 and 9 effective 11/18/2025

Explanatory paragraph: Sections 2, 3, 4, 5, 6, 8 and 10 were not published as there are no changes

TITLE 16 OCCUPATIONAL AND PROFESSIONAL LICENSING
CHAPTER 19 PHARMACISTS
PART 18 NUCLEAR PHARMACY

16.19.18.1 ISSUING AGENCY: ~~Regulation and Licensing Department~~ Board of Pharmacy.
[2/15/1889...2/15/1996; 16.19.18.1 NMAC - Rn, 16 NMAC 19.18.1, 3/30/2002; A, 12/17/2019; A, 11/18/2025]

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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 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)**~~**(1)** Must have successfully completed the requirements of Subparagraphs (a) and (b) of this Paragraph.

(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.

(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.

~~**(3)**~~**(2)** 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 Paragraph~~s~~ (1) ~~and (2)~~ of Subsection C of 16.19.18.7 NMAC.

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.

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.

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.

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.

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.

[5/29/1994, 5/30/1998; 16.19.18.7 NMAC - Rn, 16 NMAC 19.18.7, 3/30/2002; A, 12/17/2019; A, 11/18/2025]

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16.19.18.9 REQUIREMENTS FOR OPERATION OF A NUCLEAR PHARMACY:

A. A nuclear pharmacy shall meet the requirements of 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 16.19.6.10 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. A nuclear pharmacy shall have the minimum equipment, accessories and space as necessary for the manufacture of radiopharmaceuticals as specified by the Federal Atomic Energy Commission, the Federal Food and Drug Administration, the U.S. Public Health Service regulations and the New Mexico Radiation Protection Act administered by the Environmental Improvement Agency. ~~The following minimum equipment requirements, as appropriate for the scope of nuclear pharmacy services provided, are in addition to those contained in 16.19.6.11 NMAC:~~

~~**(1)** Radionuclide Dose Calibrator;~~
~~**(2)** Refrigerator;~~
~~**(3)** Single or multiple channel scintillation counter with well-type NaI(T1) 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; A, 11/18/2025]

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