This is an amendment to 16.19.9 NMAC, Section 1, 3, 7, 8, 9 and 14 effective 11/18/2025

16.19.9.1 ISSUING AGENCY: [~~Regulation and Licensing Department~~] Board of Pharmacy.[~~, 1650 University Blvd, NE - Ste. 400B, Albuquerque, NM 87102, (505) 841-9102.~~]
[02-15-1889...02-15-96; 16.19.9.1 NMAC - Rn, 16 NMAC 19.9.1, 03-30-02; A, 11/18/2025]

16.19.9.3 STATUTORY AUTHORITY: Paragraph (6) of Subsection (A) of Section 61-11-6 [~~A(6)~~] NMSA 1978 directs the Board of Pharmacy to provide for the licensing of drug manufacturers and for the inspection of their facilities and activities. Subsection (A) of Section 61-11-6 [~~(A)~~] NMSA 1978 authorizes the Board to enforce the provisions of all state laws pertaining to the practice of pharmacy and the manufacture, production, sale or distribution of drugs, cosmetics or poisons, including the New Mexico Drug, Device and Cosmetic Act, Chapter 26, Article I NMSA 1978. Pursuant to Section 26-1-18 of the Drug, Device and Cosmetic Act, the Board is authorized to promulgate regulations for the efficient enforcement of the Act.
[02-15-96; A, 03-14-98; 16.19.9.3 NMAC - Rn, 16 NMAC 19.9.3, 03-30-02; A, 11/18/2025]

16.19.9.7 DEFINITIONS: For the purpose of defining Section 26-1-11 A(3) NMSA Comp. the following definitions apply:

A. "[~~Manufacturer~~] Manufacturing" means the steps in the preparation, propagation, processing or compounding of a drug - the making by chemical, physical, biological or other procedures of any articles which meet the definition of drugs and includes manipulation, sampling or control procedures resulting in the finished dosage form. [~~Manufacture~~] Manufacturing includes all the steps performed on the product itself, which do not affect intrinsically the safety, purity or potency of the product.

B. "[~~Manufacturers~~] Manufacturer" means the person or company who [~~manufacturer~~] manufactures a drug in its' finished dosage form.

C. "Packager" or "Packer" means a person or firm, other than a wholesaler, who distributes drugs.

D. "Distributor" means the original selling agent, other than a wholesaler, who distributes drugs.

E. "The finished dosage form" of a prescription drug is defined as that form of the drug which is or is intended to be dispensed or administered to the patient and requires no further manufacturing or processing other than packaging and labeling.
[03-07-80...08-27-90; 16.19.9.7 NMAC - Rn, 16 NMAC 19.9.7 NMAC, 03-30-02; A, 11/18/2025]

16.19.9.8 MINIMUM STANDARDS:

A. The following minimum standards shall apply to all manufacturing establishments and repackaging firms for which licenses have been issued by the Board:

(1) All drugs and chemicals used in the manufacturing process or held for sale shall conform to the New Mexico Drug and Cosmetic Act and shall be stored, preserved and disposed of as prescribed by laws regulating the labeling and manufacture of drugs. When necessary, and/or according to label requirements, all drugs and chemicals which require refrigeration shall be stored and preserved under proper temperature.

(2) All manufacturers must conform to current good manufacturing practices as set forth in Title 21, CFR, Subsection 211.1 to 211.208 inclusive. The definitions and interpretations contained in Section 201 of the Federal Food and Drug Act shall be applicable.

(3) All manufacturers must conform to [~~(1141) Packaging, Storage, and Distribution of Pharmacopeial Articles, the United States Pharmacopeia.~~] USP/NF <1079> *(USP General Chapters: <1079> Risks and Mitigation Strategies for the Storage and Transportation of Finished Drug Products).* [~~These include the following stability protocols:~~]

(4) Stability of manufactured dosage forms must be demonstrated by the manufacturer with [~~by the use if the~~] methods adequate for the purpose. Monograph assays may be used for stability testing if they are stability-indicating (i.e., if they accurately differentiate between the intact drug molecules and their degradation products). Stability considerations should include not only the specific compendial requirements, but also changes in physical appearance of the product that would warn users that the product's continued integrity is questionable.

(5) Stability studies on active substances and packaged dosage forms must be conducted by means of "real time," long-term tests at specific temperatures and relative humidities representing storage and shipping conditions experienced in the distribution chain of the climatic zones of the country or region of the world

concerned. Labeling of the packaged active substance or dosage form shall reflect the effects of temperature, relative humidity, air, and light on its stability. Label temperature storage warnings will reflect both the results of the real-time storage tests and also allow for expected seasonal excursions of temperature during distribution.

(6) All persons in the distribution or dispensing chain shall comply with the manufacturer's directions.

B. RADIOACTIVE PHARMACEUTICALS

(1) Radioactive pharmaceuticals require specialized techniques in their handling and testing in order that correct results may be obtained and hazards to personnel be minimized.

(2) The following minimum requirements must be met for a manufacturing establishment preparing radiopharmaceutical products: equipment, accessories and space as necessary for the manufacture of radiopharmaceuticals as specified by the agencies in this paragraph. These requirements are in addition to the regulatory requirements of 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. [~~**Minimum equipment and accessory standards:**~~

~~**(a)** Fume hood - minimum of 30 inches~~
~~**(b)** Laminar flow hood~~
~~**(c)** Dose calibrator~~
~~**(d)** Refrigerator (lead lined)~~
~~**(e)** Mettler balance~~
~~**(f)** Spectrophotometer~~
~~**(g)** Drawing Station (lead glass and lead)~~

~~**(3) Glassware:**~~

~~**(a)** 3 beakers 50 ml~~
~~**(b)** 3 beakers 150 ml~~
~~**(c)** 1 beaker 500 ml~~
~~**(d)** 2 volumetric flasks 50 ml~~
~~**(e)** 6 volumetric flasks 100 ml~~
~~**(f)** 2 graduated cylinders 10 ml~~
~~**(g)** 2 graduated cylinders 100 ml~~

~~**(4) Radiochromatographic strip scanner and/or well counter**~~

~~**(5) Supplies:**~~

~~**(a)** disposable syringes 1,3 and 5 cc~~
~~**(b)** multidose vials 10, 20 and 30 cc~~
~~**(c)** disposable alcohol swabs~~
~~**(d)** disposable gloves~~

~~**(6) Reference books:**~~

~~**(a)** American Hospital Formulary Service~~
~~**(b)** National Formulary~~
~~**(c)** United States Pharmacopoeia~~

~~**(7) Space:** The radiopharmaceutical manufacturing or preparation area shall be an undivided area of not less than 240 square feet for the hot lab and storage area. The area shall contain adequate sink with hot and cold water facilities.~~]

[03-07-80...08-27-90;A, 03-14-98; 16.19.9.8 NMAC - Rn & A, 16 NMAC 19.9.8, 03-30-2002; A, 11/18/2025]

16.19.9.9 LICENSURE OR REGISTRATION - MANUFACTURERS: [~~Wholesale distributor and manufacturer distributor or manufacturer.~~]

A. No manufacturer shipping dangerous drugs into New Mexico or who sells or distributes dangerous drugs in this state through any person or media, other than a wholesaler who has obtained a license, shall conduct the business of selling or distributing dangerous drugs without obtaining an out-of-state drug license from the Board.

B. Applications for an out-of-state drug distributor's license under this section shall be made on a form furnished by the Board of Pharmacy. The Board may require such information as it deems is reasonably necessary [~~to carry out the purposes of this section~~]. This requirement does not include the licensure of a parent corporation of a corporation or division.

C. The license and renewal fee shall be as specified in 16.19.12 NMAC. [~~, Fees, and shall be renewed annually before the last day of December each year.~~

~~**D.** No person acting as principal or agent (detail man) for any out-of-state manufacturer, wholesaler~~

~~or distributor who has not obtained a license from the Board shall conduct the business of selling or distributing dangerous drugs within the state.~~

~~**E.** Any person acting as principal or agent for any manufacturer, wholesaler or distributor who is licensed by the Board and who possesses or distributes dangerous drugs, shall register as principal or agent for the licensed manufacturer, wholesaler or distributor.~~

~~**F.** Registration of persons under this section shall be made on a form furnished by the Board. The Board may require such information as it deems is reasonably necessary to carry out the purpose of this section, including, but not limited to, the name and address of the registrant and the name and address of the manufacturer whose drugs he is they are selling or distributing.~~]

[~~**G.**~~] **D.** The Board may deny, revoke or suspend such person's registration for any violation of [~~the~~] Federal or State Drug Laws.

[03-07-80...08-27-90; Rn, 16.19.9.10.7, 03-14-98; 16.19.9.9 NMAC - Rn, 16 NMAC 19.9.9, 03-30-02; A, 12-01-2003; A, 11/18/2025]

16.19.9.14 FINISHED DOSAGE FORMS - PLACE OF BUSINESS: If a person manufactures, packs or distributes a drug at a place other than [~~his~~] their principle place of business, the label may state the principle place of business in lieu of the actual place where such drug is manufactured or packed or is to be distributed, unless such statement would be misleading.

[03-07-80...08-27-90; Rn, 16.19.9.15.1, 03-14-98; 16.19.9.14 NMAC - Rn, 16 NMAC 19.9.14, 03-30-02; A, 11/18/2025]