

ARTICLE XXVII NUCLEAR/RADIOLOGIC PHARMACY

Section 1. Purpose and Scope.

The Practice of Nuclear/Radiologic Pharmacy is hereby recognized as a specialty of Pharmacy practice, regulated by the State Boards of Pharmacy. As such, the following rules are included to address those areas specific or unique to this specialty practice.

Nuclear/Radiologic Pharmacy Practice refers to a patient oriented service that embodies the scientific knowledge and professional judgment required to improve and promote health through the assurance of the safe and efficacious use of radiopharmaceuticals and other Drugs.

Section 2. Definitions.

- (a) “Authentication of Product History” means, but is not limited to, identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical.
- (b) “Internal test assessment” means, but is not limited to, conducting those tests of quality assurance necessary to ensure the integrity of the test.
- (c) “Nuclear pharmacy” means a Pharmacy providing radiopharmaceutical services or, an appropriate area of any Institutional Facility. These services include but are not limited to storing, preparing, compounding, dispensing, labeling or distributing radiopharmaceuticals.
- (d) “Authorized Nuclear Pharmacist” (NP) means a currently licensed pharmacist in the state of Mississippi who is licensed by the Mississippi State Department of Health, Division of Radiological Health or by a certification Board recognized by the State Board of Pharmacy, or who meets the following standards:
 - (1) Minimum standards of training for "authorized user status" of radioactive materials as defined by Mississippi State Department of Health, Division of Radiological Health;
 - (2) Completed a minimum of two hundred (200) contact hours of instruction in nuclear pharmacy and the safe handling and the use of radioactive materials from a program approved by the Mississippi Board of Pharmacy or the United States Nuclear Regulatory Commission or Agreement State Agency, with emphasis in the following areas:
 - (i) Radiation Physics and Instrumentation;
 - (ii) Radiation Protection;
 - (iii) Mathematics of Radioactivity;
 - (iv) Radiation Biology;
 - (v) Radiopharmaceutical Chemistry.
 - (3) Attained a minimum of five hundred (500) hours of clinical nuclear pharmacy training under the supervision of an authorized nuclear pharmacist.
- (e) “Radiopharmaceutical Quality Assurance” means, but is not limited to, the performance of appropriate chemical, biological and physical tests on potential radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals including internal test assessment, authentication of product history and the keeping of proper records. Assurance that variances in the processes are clearly identified,

assessed and improved upon if necessary is required for adequate quality control. All quality control procedures must be a set of planned, defined, and systematic activities to provide adequate confidence that the product optimally fulfills professional expectations and requirements.

- (f) “Radiopharmaceutical Service” means, but shall not be limited to the procurement, storage, handling, compounding, preparing, Labeling, quality assurance testing, Dispensing, Delivery, recordkeeping, and disposal of radiopharmaceuticals and other drugs.
- (g) “Radiopharmaceuticals” are radioactive drugs as defined by the Food and Drug Administration and the Mississippi State Board of Pharmacy.
- (h) Practice of Nuclear Pharmacy means a patient oriented service that embodies the scientific knowledge and professional judgment required to improve and promote health through the assurance of the safe and efficacious use of radiopharmaceuticals and other related drugs.
- (i) Nuclear Pharmacy Technician (NPT) means a person who works under the supervision of an Authorized Nuclear Pharmacist, who is currently registered with the Mississippi Board of Pharmacy, and has successfully completed a training program affiliated with a public/private learning institution or a company sponsored Nuclear Pharmacy Technician training program.
- (j) Protocol Order is an order for a prescription diagnostic radiopharmaceutical that an Authorized User Physician has instituted at his/her institution or clinic via a written order/protocol for specific drug products for diagnostic use. This type of protocol order is analogous to a refill order, and therefore can be taken by a nuclear pharmacy technician. Therapeutic agents do not qualify as medication reorders.
- (k) STAT/Emergency Order means an order or protocol order that must leave the nuclear pharmacy in less than 60 minutes or as fast as reasonably achievable.
- (l) Therapeutic Order means a prescription drug order that is intended to treat an illness or condition of a patient and requires pharmacist judgement and therefore should be discussed with an ANP prior to order entry. Therapeutic Orders cannot be taken by an NPT.

Section 3. General Requirements for Pharmacies Providing Radiopharmaceutical Services.

- (a) Nuclear Pharmacy License. A license to operate a pharmacy providing radiopharmaceutical services shall only be issued to an Authorized Nuclear Pharmacist. All personnel performing tasks in the preparation and distribution of radioactive Drugs shall be under the direct supervision of an Authorized Nuclear Pharmacist. An Authorized Nuclear Pharmacist shall be responsible for all operations of the Pharmacy and shall be in personal attendance at all times that the Pharmacy is open for business. In the event an ANP has to leave the pharmacy while the Pharmacy is open for business, the restricted area and all prescription products have to be secured from unauthorized access
- (b) Nuclear pharmacies shall have adequate space and equipment, commensurate with the scope of services required and provided, meeting minimal space requirements established for all pharmacies in the State or as otherwise defined by the Mississippi State Board of Pharmacy.
- (c) The Nuclear Pharmacy area shall be secured from unauthorized personnel.
- (d) Nuclear pharmacies shall maintain records of acquisition, inventory, and disposition of all radioactive Drugs and other radioactive materials, in accordance with guidelines established by the Mississippi State Department of Health, Division of Radiological Health.

- (e) All pharmacies handling radiopharmaceuticals shall provide a radioactive storage and product decay area in accordance with guidelines established by the Mississippi State Department of Health, Division of Radiological Health. Detailed floor plans shall be submitted to the State Board of Pharmacy and the Mississippi State Department of Health, Division of Radiological Health before approval of the license.
- (f) Radiopharmaceuticals are to be Dispensed only upon receipt of a Prescription Drug Order or protocol order, from an Authorized User authorized by the Nuclear Regulatory Commission and/or the Mississippi State Department of Health, Division of Radiological Health to possess, use, and administer such drug.
- (g) Otherwise, a radiopharmaceutical may be transferred to a person who is authorized by federal or state law to possess and use such drug for non-medical applications and are exempt from the electronic ordering clause.
- (h) All prescriptions/orders shall be readily retrievable if requested by any governing agency.
- (i) The permit to operate a Nuclear Pharmacy is conditioned upon an approved State Radiation Control Agency (RCA) or NRC license. Copies of the RCA or NRC inspection reports shall be made available upon request for Board inspection.
- (j) Labeling
 - (1) No radiopharmaceutical may be Dispensed unless a label is affixed to the immediate container bearing the following information:
 - (i) the standard radiation symbol;
 - (ii) the words “Caution—Radioactive Material”;
 - (iii) for all therapeutic and blood-products, the patient name/identifier;
 - (iv) the patient name or “per physician order”
 - (v) the prescription number.
 - (2) No radiopharmaceutical may be Dispensed unless a label is affixed to the outer or Delivery container bearing the following information;
 - (i) the standard radiation symbol;
 - (ii) the words “Caution—Radioactive Material”;
 - (iii) for all therapeutic and blood-products, the patient name/identifier;
 - (iv) the radionuclide and chemical form;
 - (v) the radioactivity and date and time of calibration;
 - (vi) the volume or number of units dispensed (e.g., 2 capsules), as applicable;
 - (vii) product expiration or BUD, as applicable, and any special storage and handling instructions for non-immediate use (e.g., refrigeration resuspension);
 - (viii) the prescription number;
 - (ix) the patient name provided by the entity ordering the drug. If no patient name is given then the words, “per physician order” shall appear on the prescription.
 - (x) the name and address of the nuclear Pharmacy;
 - (xi) the name of the Practitioner; and
 - (xii) the lot number of the prescription.

Section 4. Other requirements

- (a) All Nuclear/Radiologic Pharmacies shall also adhere to the principles outlined in the Rules for Pharmacist Care as these pertain to the practice of Nuclear Pharmacy.
- (b) Radiopharmaceuticals shall only be handled in conformity with the standards of USP General Chapter <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging unless stated otherwise in this ARTICLE.
- (c) When a radiopharmaceutical is dispensed under the authority of an Investigational New Drug Application (IND) 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.
- (d) A pharmacy exclusively handling radiopharmaceuticals may be exempt from the general requirements of conventional pharmacies as regards to equipment and inventory.
- (e) Written procedure and policy showing proof of adequate space and equipment for all operations involving radioactive material must be submitted to the Mississippi Board of Pharmacy along with a certified copy of the RADIOACTIVE MATERIALS LICENSE issued by the Mississippi State Department of Health, Division of Radiological Health, before a permit to operate as a Nuclear Pharmacy is issued. Compliance with applicable radiation protection regulations of the Mississippi State Department of Health, Division of Radiological Health is further required. Violation of rules and regulations established by the Mississippi State Department of Health, Division of Radiological Health that directly affects public health and safety, shall serve as prima facie evidence of violation of this ARTICLE.