201 KAR 2:215. Nuclear pharmacy services.

RELATES TO: KRS Chapter 315
STATUTORY AUTHORITY: KRS 315.191(1)
NECESSITY, FUNCTION, AND CONFORMITY: The Kentucky Board of Pharmacy shall be responsible for imposing minimum standards in all settings where drug products are dispensed and to ensure the safety of all drug products provided to the citizens of the Commonwealth. This administrative regulation applies to pharmacies as defined in KRS 315.010. The requirement of these administrative regulations are in addition to, and not in substitution of, other applicable administrative regulations promulgated by the Cabinet for Human Resources for radioactive materials and applicable administrative regulations promulgated by the Kentucky Board of Pharmacy.

Section 1. Definitions. (1) "Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.

(2) "Radiopharmaceutical services" means those acts, services, operations and transactions necessary in the conduct, operation, management and control of a nuclear pharmacy, including, for example:

(a) The compounding, dispensing, labeling and delivery of radiopharmaceuticals;

(b) The participation in radiopharmaceutical utilization reviews; and

(c) The proper and safe storage and distribution of radiopharmaceuticals.

(3) "Radiopharmaceutical" means any substance defined as a drug in Section 201(g)(1) of the Federal Food, Drug and Cosmetic Act which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any of those drugs intended to be made radioactive. This includes nonradioactive reagent kits and nuclide generators which are intended to be used in the preparation of any such substance, but does not include drugs which are carbon-containing compounds or potassium-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.

(4) "Radiopharmaceutical quality assurance" means the performance of appropriate chemical, biological and physical tests on radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals, and it shall include, for example, internal test assessment, authentication of product history and the keeping of proper records.

(5) "Internal test assessment" means conducting those tests necessary to insure the integrity of the test.

(6) "Authentication of product history" means identifying the purchase source, the ultimate use or disposition and any intermediate handling of any components of a radiopharmaceutical.

(7) "Authorized practitioner" means a practitioner duly authorized by applicable federal and state law to possess, use and administer radiopharmaceuticals. This person shall be named on a radioactive materials license issued by the Radiation Control Branch of the Cabinet for Human Resources.

(8) "Designated agent" means an individual who shall be under the direct supervision of an authorized practitioner and who shall be authorized to communicate that practitioner's instructions to a nuclear pharmacy.

(9) "Nuclear pharmacist" means a pharmacist licensed to practice in the Commonwealth of Kentucky and who meets minimal standards of training and experience in the handling of radioactive materials in accordance with the requirements of the Radiation Control Branch of the Cabinet for Human Resources.

(10) "Direct supervision" means that the supervising nuclear pharmacist shall be physically present in the general area or location where the supportive personnel are performing supportive duties and shall conduct in-process and final checks.

Section 2. General Requirements for Pharmacies Providing Radiopharmaceutical Services. (1) A license to operate a pharmacy providing radiopharmaceutical services shall only be issued to a pharmacy operating under the direct supervision of a nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radioactive drugs shall be under the direct supervision of a nuclear pharmacist. A nuclear pharmacist shall be responsible for all operations of the licensed area and in personal attendance at all times that the pharmacy is open for business.

(2) Nuclear pharmacies may be exempted from the general space requirements for pharmacies, but shall:

(a) Have adequate space, commensurate with the scope of services required and meeting Radiation Control Branch, Cabinet for Human Resources, requirements established for all radioactive material licensees in the Commonwealth;

(b) Be separate from the pharmacy areas for nonradioactive drugs;

(c) Be inaccessible to all unauthorized personnel; and

(d) Have a radioactive storage and decay area.

(3) The process used for handling radioactive materials by any license holder shall involve appropriate procedures for the purchase, receipt, storage, manipulation, compounding, distribution and disposal of radioactive materials as approved in a Kentucky radioactive materials license. In order to ensure the public health and safety in this respect, a nuclear pharmacy shall first meet the following general environmental requirements where the handling of radiopharmaceutical materials takes place:

(a) Proper ventilation so that radioactive materials cannot be airborne from that environment to other nonoccupationally unrestricted areas;

(b) Proper location so that the receipt and dispersal of radioactive materials do not result in inadvertent and undesired contamination of other nonoccupationally labeled areas; and

(c) Proper design to allow radioactive materials to be contained in given areas to ensure adequate safety and protection to personnel working in or near them and to ensure proper operation of the corresponding assay equipment.

(4) Nuclear pharmacies shall maintain records of acquisition and disposition of all radioactive drugs in accordance with administrative regulations of the Radiation Control Branch of the Cabinet for Human Resources.

(5) A nuclear pharmacy, upon receiving an oral prescription for a radiopharmaceutical, shall immediately have the prescription reduced to writing or recorded in a data processing system, which writing or record shall contain at least the following:

(a) The name of the authorized user or his agent;

(b) The date of distribution and the time of administration of the radiopharmaceutical;

(c) The name of the procedure;

(d) The name of the radiopharmaceutical;

(e) The dose or quantity of the radiopharmaceutical;

(f) The serial number assigned to the order for the radiopharmaceutical;

(g) Any specific instructions; and

(h) The patient's name, whenever an order is for a therapeutic or blood-product radiopharmaceutical.

(6) The immediate outer container (shield) of a radioactive drug to be dispensed shall be labeled with the:

(a) Standard radiation symbol;

(b) Words, "Caution-Radioactive Material";

(c) Radionuclide;

(d) Chemical form;

(e) Amount of radioactive material contained in millicuries or microcuries;

(f) Volume in cubic centimeters, if a liquid;
(g) Requested calibration time for the radioactivity contained;
(h) Name, address, and telephone number of the nuclear pharmacy;
(i) Prescription number;
(j) Date; and
(k) Space for patient's name.
(7) The immediate container shall be labeled with the:
(a) Standard radiation symbol;
(b) Words, "Caution-Radioactive Material";
(c) Prescription number; and
(d) Name of the radiopharmaceutical.
(8) Nuclear pharmacies shall only dispense radiopharmaceuticals which comply with acceptable professional standards of radiopharmaceutical quality assurance.
(9) A nuclear pharmacist may transfer to authorized persons, in accordance with the provisions of a Kentucky radioactive materials license, radioactive materials not intended for drug use and radiopharmaceuticals intended for individual patient use.
(10) Nuclear pharmacies shall comply with all applicable laws and regulations of federal and state agencies including those laws and regulations governing nonradioactive drugs. For nuclear pharmacies handling radiopharmaceuticals exclusively, the Kentucky Board of Pharmacy may waive regulations pertaining to pharmacy licenses for nonradiopharmaceuticals which requirements do not pertain to the practice of nuclear pharmacy.
(11) Radioactive drugs are to be dispensed only upon a nonrefillable prescription order from a Radiation Control Branch, Cabinet for Human Resources, licensed medical practitioner (or the designated agent) authorized to possess, use and administer radiopharmaceuticals.
(12) Prescription orders for delivery of radioactive drugs for use in the medical practice of a Radiation Control Branch, Cabinet for Human Resources, licensed medical practitioner may be placed on a telephone answering and recording device, only if the practitioner (or the designated agent) is identified in such a manner that is clearly recognized by the nuclear pharmacist dispensing the radioactive drug.
(13)(a) A nuclear pharmacist in charge of a nuclear pharmacy shall have the authority to delegate to any qualified and properly trained person or persons, acting under his direct supervision, any nuclear pharmacy act which a reasonable and prudent nuclear pharmacist would find is within the scope of sound pharmaceutical judgment to delegate.
(b) The delegation shall only occur if, in the professional opinion of the delegating nuclear pharmacist-in-charge, the act may be properly and safely performed by the person to whom the act is delegated.
(c) The delegated act shall only be performed in its customary manner and not in violation of other statutes.
(d) Persons to whom nuclear pharmacy acts are delegated shall not hold themselves out to the public as being authorized to practice pharmacy.

Section 3. Minimum Requirements for Space, Equipment, Supplies, and Library. (1) Each nuclear pharmacy must meet the following requirements for space:
(a) The area for the storage, compounding, and dispensing of radioactive drugs shall be completely separate from pharmacy areas for nonradioactive drugs;
(b) Hot lab and storage area shall be a minimum of 120 square feet; and
(c) The compounding and dispensing area shall be a minimum of 300 square feet.
(2) Each nuclear pharmacy shall be equipped with at least the following items of equipment:
(a) Dose calibrator;

(b) Refrigerator;
(c) Drawing station;
(d) Well scintillation counter;
(e) Microscope;
(f) Chromatagraphic apparatus or comparable means of effectively assuring tagging efficiency;
(g) Portable radiation survey meter; and
(h) Other equipment deemed necessary for radiopharmaceutical quality assurance for products compounded or dispensed as shall be determined by the Radiation Control Branch, Cabinet for Human Resources, and the Kentucky Board of Pharmacy.

(3) Each nuclear pharmacy shall have on the premises current editions or revisions of the following reference materials:
(a) United States Pharmacopedia-National Formulary with supplements;
(b) State statutes and administrative regulations relating to pharmacy;
(c) State and federal regulations governing the use of applicable radioactive materials; and
(d) Text relating to the practice of nuclear pharmacy and radiation safety.

Section 4. Radiopharmaceutical Quality Assurance. The holder of a nuclear pharmacy license shall be responsible for the radiopharmaceutical quality assurance of all radiopharmaceuticals, including biologicals, dispensed or manufactured. (19 Ky.R. 1462; 1742; eff. 1-27-1993; Crt eff. 4-17-2019.)