Ohio Administrative Code

Rule 3701:1-46-43 Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing radioactive material for medical use.

Effective: August 15, 2021

(A) An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing radioactive material for use by persons authorized pursuant to Chapter 3701:1-58 of the Administrative Code or equivalent regulations of an agreement state will be approved if:

(1) The applicant satisfies the general requirements specified in rule 3701:1-40-15 of the Administrative Code;

(2) The applicant submits evidence that the applicant is at least one of the following:

(a) Registered with the United States food and drug administration as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 C.F.R. 207.20(a) (as in effect on the effective date of this rule);

(b) Registered or licensed with a state agency as a drug manufacturer;

(c) Licensed as a pharmacy by a state board of pharmacy;

(d) Operating as a nuclear pharmacy within a federal medical institution; or

(e) A positron emission tomography (PET) drug production facility registered with a state agency.

(3) The applicant submits information on the radionuclide; the chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radioactive drugs by medical use licensees; and

(4) The applicant commits to the following labeling requirements:

(a) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL"; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half-life greater than one hundred days, the time may be omitted.

(b) A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

(B) A licensee described by paragraph (A)(2)(c) or (A)(2)(d) of this rule:

(1) May prepare radioactive drugs for medical use, as defined in rule 3701:1-38-01 of the Administrative Code, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in paragraphs (B)(2) and (B)(3) of this rule, or an individual under the supervision of an authorized nuclear pharmacist as specified in rule 3701:1-58-14 of the Administrative Code.

(2) May allow a pharmacist to work as an authorized nuclear pharmacist if:

(a) This individual qualifies as an authorized nuclear pharmacist as defined in rule 3701:1-58-01 of the Administrative Code,

(b) This individual meets the requirements specified in paragraph (B) of rule 3701:1-58-20 of the Administrative Code and rule 3701:1-58-22 of the Administrative Code and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist, or

(c) This individual is designated as an authorized nuclear pharmacist in accordance with paragraph (B)(4) of this rule.

(3) The actions authorized in paragraphs (B)(1) and (B)(2) of this rule are permitted in spite of more restrictive language in license conditions.

(4) May designate a pharmacist as an authorized nuclear pharmacist if:

(a) The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material, and

(b) The individual practiced at a pharmacy at a government agency or federally recognized indian tribe before November 30, 2007 or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the United States nuclear regulatory commission.

(5) Shall provide to the director a copy of:

(a) A copy of each individual's certification by a specialty board whose certification process has been recognized by the United States nuclear regulatory commission or an agreement state as specified in paragraph (A) of rule 3701:1-58-20 of the Administrative Code; or

(b) The United States nuclear regulatory commission or agreement state license; or

(c) The permit issued by a United States nuclear regulatory commission master materials licensee; or

(d) The permit issued by a licensee or United States nuclear regulatory commission master materials permittee of broad scope; or

(e) The authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist; or

(f) Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a government agency or federally recognized indian tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the United States nuclear regulatory commission; and

(g) State pharmacy licensure or registration, no later than thirty days after the date that the licensee allows, under paragraphs (B)(2)(a) and (B)(2)(c) of this rule, the individual to work as an authorized nuclear pharmacist.

(C) A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

(1) Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

(2) Check each instrument for constancy and proper operation at the beginning of each day of use.

(D) A licensee shall satisfy the labeling requirements in paragraph (A)(4) of this rule.

(E) Nothing in this rule relieves the licensee from complying with applicable United States food and drug administration, other federal, and state requirements governing radioactive drugs.