

3701:1-58-37 **Use of unsealed radioactive material for which a written directive is required.**

A licensee may use any unsealed radioactive material prepared for medical use and for which a written directive is required that is:

(A) Obtained from:

- (1) A manufacturer or preparer licensed under rule 3701:1-46-43 of the Administrative Code or equivalent United States nuclear regulatory commission or agreement state requirements; or
- (2) A PET radioactive drug producer licensed in accordance with paragraph (I) of rule 3701:1-40-14 of the Administrative Code or equivalent United States nuclear regulatory commission or agreement state requirement; or

(B) Prepared by, excluding production of PET radionuclides:

- (1) An authorized nuclear pharmacist;
- (2) A physician who is an authorized user and who meets the requirements specified in rule 3701:1-58-36 or 3701:1-58-40 of the Administrative Code; or
- (3) An individual under the supervision, as specified in rule 3701:1-58-14 of the Administrative Code, of the— authorized nuclear pharmacist in paragraph (B)(1) of this rule or the physician who is an authorized user in paragraph (B)(2) of this rule;

(C) Obtained from and prepared by an United States nuclear regulatory commission or agreement state licensee for use in research in accordance with an investigational new drug protocol accepted by United States food and drug administration; or

(D) Prepared by the licensee for use in research in accordance with an investigational new drug protocol accepted by United States food and drug administration.

Five Year Review (FYR) Dates: 06/12/2015 and 06/01/2020

CERTIFIED ELECTRONICALLY

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Certification

06/12/2015

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Date

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