

3701:1-58-32 **Use of unsealed radioactive material for uptake, dilution, and excretion studies for which a written directive is not required.**

Except for quantities that require a written directive under paragraph (B) of rule 3701:1-58-15 of the Administrative Code, a licensee may use any unsealed radioactive material prepared for medical use for uptake, dilution, or excretion studies 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) Excluding production of PET radionuclides, prepared by:

- (1) An authorized nuclear pharmacist; or
- (2) A physician who is an authorized user and who meets the requirements specified in rule 3701:1-58-36, or rule 3701:1-58-40 and paragraph (C)(1)(b)(vii) of rule 3701:1-58-36 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; or

(C) Obtained from and prepared by an United States nuclear regulatory commission or agreement state licensee for use in research in accordance with a radioactive drug research committee-approved protocol or 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 a radioactive drug research committee-approved application or 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

Certification

06/12/2015

Date

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