

3701:1-58-25     **Determination of dosages of unsealed radioactive material for medical use.**

- (A) A licensee shall determine and record the activity of each dosage before medical use.
- (B) For a unit dosage, this determination must be made by:
  - (1) Direct measurement of radioactivity; or
  - (2) A decay correction, based on the activity or activity concentration determined by:
    - (a) 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;
    - (b) 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
    - (c) A PET radioactive drug producer licensed under paragraph (I) of rule 3701:1-40-14 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements.
- (C) For other than unit dosages, this determination must be made by:
  - (1) Direct measurement of radioactivity;
  - (2) Combination of measurement of radioactivity and mathematical calculations; or
  - (3) Combination of volumetric measurements and mathematical calculations, based on the measurement made by:
    - (a) 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
    - (b) A PET radioactive drug producer licensed under paragraph (I) of rule 3701:1-40-14 of the Administrative Code, or equivalent United States nuclear regulatory commission or agreement state requirements.
- (D) Unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than twenty per cent.
- (E) A licensee shall retain a record of the dosage determination required by this rule in accordance with rule 3701:1-58-79 of the Administrative Code.

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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