

WAC 246-240-107 Determination of dosages of unsealed radioactive material for medical use. (1) A licensee shall determine and record the activity of each dosage before medical use.

(2) For a unit dosage, this determination must be made by:

(a) Direct measurement of radioactivity; or

(b) A decay correction, based on the activity or activity concentration determined by:

(i) A manufacturer, producer, or preparer licensed under WAC 246-235-100 or equivalent NRC or agreement state requirements; or

(ii) An agreement state or NRC licensee for use in research in accordance with a radioactive drug research committee-approved protocol or an investigational new drug protocol accepted by FDA.

(3) For other than unit dosages, this determination must be made by:

(a) Direct measurement of radioactivity;

(b) Combination of measurement of radioactivity and mathematical calculations; or

(c) Combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer, producer, or preparer licensed under WAC 246-235-100 or equivalent agreement state requirements.

(4) 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 percent.

(5) A licensee shall retain a record of the dosage determination required by this section in accordance with WAC 246-240-569.

[Statutory Authority: RCW 70.98.050. WSR 13-11-021, § 246-240-107, filed 5/7/13, effective 6/7/13. Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 09-06-003, § 246-240-107, filed 2/18/09, effective 3/21/09. Statutory Authority: RCW 70.98.050. WSR 06-05-019, § 246-240-107, filed 2/6/06, effective 3/9/06.]