

4731.4422 DETERMINATION OF DOSAGES; UNSEALED RADIOACTIVE MATERIAL.

A. A licensee must determine and record the activity of each dosage before medical use.

B. For a unit dosage, the determination under item A 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 part 4731.3395 or equivalent requirements of the NRC or an agreement state;

(b) an NRC or agreement state licensee for use in research according to the radioactive drug research committee-approved protocol or an investigational new drug protocol accepted by the Food and Drug Administration; or

(c) a PET radioactive drug producer licensed according to part 4731.3065, subpart 7, or equivalent requirements of the NRC or an agreement state.

C. For other than unit dosages, the determination under item A must be made by:

(1) direct measurement of radioactivity;

(2) a combination of measurement of radioactivity and mathematical calculations;

(3) a combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer or preparer licensed under part 4731.3395 or equivalent requirements of the NRC or an agreement state; or

(4) a PET radioactive drug producer licensed according to part 4731.3065, subpart 7, or equivalent requirements of the NRC or an agreement state.

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 20 percent.

E. A licensee must retain a record of the dosage determination required under this part according to part 4731.4503.

Statutory Authority: *MS s 144.1202; 144.1203*

History: *29 SR 755; 33 SR 1440*

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