**Section 335.2030 Assay of Radiopharmaceutical Dosages**

a) A licensee shall determine and record the activity of each dosage before medical use.

b) For a unit dosage, this determination shall be made by:

1) Direct measurement of radioactivity by the licensee; or

2) For radiopharmaceuticals with a photon emitting radionuclide not requiring a written directive, a decay correction based on the activity or activity concentration determined by:

A) A manufacturer or preparer authorized under Section 335.30 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

B) An Agency, U.S. 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 (IND) protocol accepted by FDA; or

C) A PET radioactive drug producer licensed under 32 Ill. Adm. Code 330.260(c)(23) or the equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State.

c) For other than unit dosages, this determination shall be made by:

1) Direct measurement of radioactivity by the licensee;

2) A combination of measurement of radioactivity and mathematical calculations; or

3) A combination of volumetric measurements and mathematical calculations based on the measurement made by a manufacturer or preparer licensed under Section 335.30 or equivalent U.S. 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 20 percent.

e) A licensee shall maintain a record of dosage determinations required by subsection (a) of this Section for 5 years.

f) The record shall contain:

1) The radiopharmaceutical;

2) The patient's or human research subject's name, or identification number if one has been assigned;

3) The prescribed dosage, the determined dosage, or a notation that the total activity is less than 1.1 MBq (30 μCi);

4) The date and time of the dosage determination;

5) If more than 15 minutes have elapsed between the time of dosage determination and dosage administration, the date and time of dosage administration; and

6) The name of the individual who determined the dosage.

AGENCY NOTE: If a unit dose has been manipulated in any way, it is no longer considered a unit dose and shall be measured by the licensee before administration.

(Source: Amended at 35 Ill. Reg. 884, effective December 30, 2010)