**Section 335.3010 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 subsection 335.1110(a), a licensee may use any unsealed radioactive material prepared for medical use for uptake, dilution or excretion studies that is:

a) Obtained from a person specified in Section 335.30, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

b) Excluding production of PET radionuclides, prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements in Section 335.9040, or a combination of Section 335.9050 and subsection 335.9040(c)(1)(B)(vii) or an individual under the supervision of either as specified in Section 335.1050; or

c) Obtained from and prepared by 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 application or protocol accepted by the FDA; or

d) Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an application or a protocol accepted by the FDA.

AGENCY NOTE: Participation in FDA research trials involving human subjects does not relieve the licensee from following all Agency regulations, whether or not they are included in the trial protocols. This includes participation in trials using "blind" research protocols.

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