4731.4432 UNSEALED RADIOACTIVE MATERIAL; UPTAKE, DILUTION, AND EXCRETION STUDIES; WRITTEN DIRECTIVE NOT REQUIRED.

Except for quantities that require a written directive under part 4731.4408 or 4731.4409, a licensee may use any unsealed radioactive material prepared for medical use for uptake, dilution, or excretion studies that is:

A. obtained from a manufacturer or preparer licensed under part 4731.3395 or equivalent requirements of the NRC or an agreement state or a PET radioactive drug producer licensed according to part 4731.3065, subpart 7, or equivalent requirements of the NRC or an agreement state;

B. excluding production of PET radionuclides, prepared by:

(1) an authorized nuclear pharmacist;

(2) a physician who is an authorized user and who meets the requirements of part 4731.4436 or parts 4731.4436, subpart 1, item C, subitem (1), unit (b), subunit vii, and 4731.4443; or

(3) an individual under the supervision, according to part 4731.4407, of the authorized nuclear pharmacist in subitem (1) or the physician who is an authorized user in subitem (2);

C. obtained from and prepared for a commissioner, NRC, or agreement state licensee for use in research according to a radioactive drug research committee-approved protocol or an investigational new drug protocol accepted by the Food and Drug Administration; or

D. prepared by the licensee for use in research according to a radioactive drug research committee-approved application or an investigational new drug protocol accepted by the Food and Drug Administration.

Statutory Authority: *MS s 144.1202; 144.1203*

History: *29 SR 755; 32 SR 831; 33 SR 1440*

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