

4731.4440 UNSEALED RADIOACTIVE MATERIAL; WRITTEN DIRECTIVE REQUIRED.

A licensee may use any unsealed radioactive material identified in part 4731.4443, subpart 1, item B, subitem (1), unit (b), subunit vi, prepared for medical use and for which a written directive is required 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 an authorized nuclear pharmacist, a physician who is an authorized user and meets the requirements under part 4731.4436 or 4731.4443, or an individual under the supervision of either, as specified under part 4731.4407;

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

D. prepared by the licensee for use in research according to an investigational new drug protocol accepted by the Food and Drug Administration.

Statutory Authority: *MS s 144.1202; 144.1203*

History: *29 SR 755; 33 SR 1440; 46 SR 791*

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