

4731.3055 EXEMPTION; RADIOACTIVE DRUGS.

Subpart 1. **Exemption.** Except as provided in subparts 2 and 3, a person is exempt from parts 4731.3000 to 4731.3245 and 4731.4400 to 4731.4527, if the person receives, possesses, uses, transfers, owns, or acquires capsules containing one μCi (37 kBq) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each, for in vivo diagnostic use for humans.

Subp. 2. **Research; license required.** A person who desires to use the capsules under subpart 1 for research involving human subjects must apply for and receive a specific license according to parts 4731.4400 to 4731.4527.

Subp. 3. **Specific license required.** A person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution the capsules under subpart 1 must apply for and receive a specific license under Code of Federal Regulations, title 10, section 32.21.

Subp. 4. **Other law.** Nothing in this part relieves a person from complying with applicable United States Food and Drug Administration or other federal and state requirements governing receipt, administration, and use of drugs.

Statutory Authority: *MS s 144.1202; 144.1203*

History: *29 SR 755*

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