6800.8100 DEFINITIONS.

Subpart 1. **Manufacturers of radiopharmaceuticals.** Any person, firm, or hospital compounding, mixing, deriving, repackaging, or otherwise preparing a radioactive drug shall be licensed as a manufacturer, unless the drug is prepared for use by:

A. the medical facility to which the facility preparing the product is physically attached; or

B. an individual patient when the drug is being dispensed on the order of a licensed practitioner.

Subp. 2. **Nuclear pharmacy.** A nuclear pharmacy is any area, place, or premises described in a license issued by the board with reference to plans approved by the board where radioactive drugs are stored, prepared, manufactured, derived, manipulated, compounded, or dispensed.

Subp. 3. **Radiopharmaceutical.** A radiopharmaceutical is any substance defined as a drug in section 201 (g) (1) of the Federal Food, Drug, and Cosmetic Act that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or protons and includes any nonradioactive reagent kit or nuclide generator which is intended to be used in the preparation of such substance, but does not include drugs such as carbon-containing compounds or potassium-containing salts that contain trace quantities of naturally occurring radionuclides.

Subp. 4. **Nuclear pharmacy practice.** "Nuclear pharmacy practice" refers to a patient-oriented pharmacy service that embodies the scientific knowledge and professional judgment required for the assurance of the safe and effective use of radiopharmaceuticals and other drugs.

Statutory Authority: *MS s 151.06*

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