

657—20.5(126,155A) Drug compounding facilities. Pharmacies engaged in compounding shall have a specifically designated and adequate area for the orderly placement of equipment and materials to be used to compound drugs. Sterile and nonsterile products shall not be compounded at the same time within the same area.

20.5(1) Component and bulk drug substance storage. Bulk drug substances and other materials used in the compounding of drug products shall be stored in adequately labeled containers in a clean, dry area or, if required, under proper refrigeration.

20.5(2) Facility requirements. Adequate lighting and ventilation shall be provided in all drug compounding areas. Adequate washing facilities, easily accessible to compounding areas of the pharmacy, shall be provided. These facilities shall include, but not be limited to, a sink with hot and cold running water, soap or detergent, and air dryers or single-source towels.

20.5(3) Facility maintenance. All areas used for the compounding of drug products shall be maintained in a clean and sanitary condition and in a good state of repair and shall be free of infestation by insects, rodents, and other vermin. Sewage, trash, and other refuse in and from the pharmacy and immediate drug compounding areas shall be maintained and disposed of in a timely, safe, and sanitary manner.