

657—20.8(126,155A) Equipment. Equipment used in the compounding of drug products shall be of appropriate design and adequate size and suitably located to facilitate operations for its intended use and for its cleaning and maintenance. Equipment used in the compounding of drug products shall be of suitable composition so that surfaces that come into contact with components, in-process materials, or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug product beyond that desired.

20.8(1) *Equipment maintenance.* Equipment and utensils used for compounding shall be cleaned and sanitized prior to use to prevent contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond that desired. In the case of equipment, utensils, and containers or closures used in the compounding of sterile drug products, cleaning, sterilization, and maintenance procedures as set forth in 657—Chapter 13 shall be followed.

20.8(2) *Specialized equipment.* If drug products with special precautions to prevent contamination are involved in a compounding operation, appropriate measures, including either the dedication of equipment for such operations or the meticulous cleaning of contaminated equipment prior to its return to inventory, shall be utilized in order to prevent cross-contamination.

20.8(3) *Use of automated equipment.* Automatic, mechanical, or electronic equipment, or other types of equipment or related systems that will perform a function satisfactorily, may be used in the compounding of drug products. If such equipment is used, it shall be routinely inspected and calibrated if necessary to ensure proper performance.

20.8(4) *Equipment storage.* Equipment and utensils used for compounding drugs shall be stored in a manner to protect them from contamination.