

657—13.1(124,126,155A) Purpose and scope. These rules establish standards and procedures for the preparation, labeling, and distribution of sterile preparations by licensed pharmacies pursuant to a practitioner's order or prescription; for sterile product quality and characteristics; for personnel training, environmental quality, and equipment standards; and for pharmaceutical care. Sterile compounding differs from nonsterile compounding primarily by requiring the maintenance of sterility when preparations are compounded exclusively with sterile ingredients and components and by requiring the achievement of sterility when preparations are compounded with nonsterile ingredients and components. The standards and procedures outlined in this chapter apply to pharmacy practice when a preparation:

1. Is prepared according to the manufacturer's labeled instructions and requires other manipulations that expose the original contents to potential contamination;
2. Contains nonsterile ingredients or employs nonsterile components or devices that must be sterilized before administration; or
3. Is a biologic, diagnostic, drug, or nutrient that possesses characteristics of either "1" or "2" above and includes, but is not limited to, the following preparations that are required to be sterile when they are administered to patients: baths and soaks for live organs and tissues, injections (e.g., colloidal dispersions, emulsions, solutions, and suspensions), aqueous bronchial and nasal inhalations, irrigations for wounds and body cavities, ophthalmic drops and ointments, and tissue implants.

Standards and safe practices for the compounding of radioactive preparations are identified in 657—Chapter 16.