657—13.2(124,126,155A) Definitions. For the purposes of this chapter, the following definitions shall apply:

"Anteroom" or *"ante area"* means an ISO Class 8 or superior area where personnel perform hand hygiene and garbing procedures, staging of components, order entry, preparation labeling, and other high-particulate generating activities.

"Aseptic processing" means a method of preparing pharmaceutical products that involves the transfer of the product into the container and closure of the container using procedures designed to preclude contamination of drugs, packaging, equipment, or supplies by microorganisms during processing.

"Beyond-use date" means the date or time following compounding after which the preparation shall not be stored, transported, or administered.

"Biological safety cabinet, Class II" or *"BSC"* means a ventilated cabinet having an open front with inward airflow for personnel protection, downward HEPA-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection.

"Buffer area" or *"cleanroom"* means a room or area in which the concentration of airborne particles is controlled to meet an ISO Class 7 standard.

"Compounding" means the constitution, reconstitution, combination, dilution, or other process causing a change in the form, composition, or strength of any ingredient or of any other attribute of a product.

"Compounding aseptic isolator" or *"CAI"* means a form of barrier isolator specifically designed for compounding pharmaceutical ingredients or preparations. A CAI is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment should not occur unless it has first passed through a microbially retentive filter, HEPA minimum.

"Critical surface" means any area that provides an opportunity for exposure to contamination during aseptic processing, including sterilized products, devices, components, and containers used in the preparation, packaging and transferring of compounded sterile preparations.

"Hazardous drug" means a pharmaceutical that is antineoplastic, carcinogenic, mutagenic, or teratogenic.

"HEPA" means high efficiency particulate air.

"High-risk preparation" means a sterile preparation that is compounded from nonsterile ingredients; that is compounded with nonsterile components, containers, or equipment and requires terminal sterilization; or that meets the conditions of rule 13.13(155A).

"ISO Class 5" or *"Class 100 condition"* means an atmospheric environment that contains less than 100 particles, 0.5 microns in diameter per cubic foot of air, according to ISO standards.

"ISO Class 7" or *"Class 10,000 condition"* means an atmospheric environment that contains less than 10,000 particles, 0.5 microns in diameter per cubic foot of air, according to ISO standards.

"ISO Class 8" or *"Class 100,000 condition"* means an atmospheric environment that contains less than 100,000 particles, 0.5 microns in diameter per cubic foot of air, according to ISO standards.

"Laminar airflow workbench" or *"LAFW"* means an apparatus designed to provide an ISO Class 5 environment for the preparation of sterile products that uses air circulation in a defined direction that passes through a HEPA filter to remove the initial particles and the particles generated within the controlled environment.

"Low-risk preparation" means a sterile preparation that is compounded with sterile equipment, sterile ingredients, and sterile contact surfaces or that meets the conditions of rule 13.11(155A).

"Medium-risk preparation" means a sterile preparation that is compounded with sterile equipment, sterile ingredients, and sterile contact surfaces and involves complex or numerous manipulations of a sterile product or that meets the conditions of rule 13.12(155A).

"MFT" means a media-fill test as specified in rule 13.25(155A).

"Positive pressure room" means a room that is at a higher pressure compared to adjacent spaces, creating a net airflow out of the room.

"Preparation" or *"compounded sterile preparation"* means a drug or nutrient that is prepared in a licensed pharmacy or other health care-related facility pursuant to the order of a licensed prescriber, which preparation may or may not be sterile.

"Primary engineering control device" means a device or room that provides an ISO Class 5 environment during the compounding process. Such devices include, but may not be limited to, laminar airflow workbenches (LAFWs), biological safety cabinets (BSCs), and compounding aseptic isolators (CAIs).

"Product" means a commercially manufactured sterile drug or nutrient that has been evaluated for safety and efficacy by the FDA.

"Sterile compounding" means the aseptic processing in a clean air environment of any pharmaceutical including, but 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.