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 and medical products that involves the separate sterilization of the product and of the package, the transfer of the product into the container, and closure of the container under at least ISO Class 5 conditions and 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 or transported and after which administration of the preparation shall not begin. The beyond-use date is determined from the date or time compounding of the preparation is completed.

"Biological safety cabinet" 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 where the primary engineering control device is physically located and in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class. Microorganisms in the environment are monitored so that a microbial level for air, surface, and personnel gear is not exceeded for a specified cleanliness class. Activities that occur in the buffer area include the preparation and staging of components and supplies used when sterile preparations are compounded.

"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 the air has first passed through a microbially retentive filter, HEPA minimum.

"Critical site" means a location that includes any component or fluid pathway surfaces or openings, such as vial septa, injection ports, beakers, opened ampoules, and needle hubs, exposed and at risk of direct contact with air, moisture, or touch contamination.

"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 or larger 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 or larger 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 or larger 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).

"Media-fill test" or *"MFT"* means a test used to validate aseptic technique of compounding personnel or of processes and to ensure that the processes used are able to produce sterile product without microbial contamination.

"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).

"Multiple-dose container" means a multiple-unit container for articles or preparations intended for parenteral administration only and usually containing antimicrobial preservatives.

"Negative pressure room" means a room that is at a lower pressure compared to adjacent spaces, creating a net airflow into the room.

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

"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.

"Segregated compounding area" means a designated space, either a demarcated area or room, which is restricted to preparing low-risk preparations with 12-hour or less beyond-use date. A segregated compounding area shall contain a device that provides unidirectional airflow of ISO Class 5 air quality for the compounding of sterile preparations and shall be void of activities and materials that are extraneous to sterile compounding.

"Single-dose container" means a single-unit container for articles or preparations intended for parenteral administration only, intended for a single use and labeled as such. Examples include prefilled syringes, cartridges, fusion-sealed containers, and closure-sealed containers when labeled for a single use or single dose.

"Sterile compounding" means the aseptic processing in a clean air environment of any pharmaceutical preparations that are required to be sterile when they are administered into patient body cavities, central nervous and vascular systems, eyes, and joints, and when used as baths for live organs and tissues, including by not limited to 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.

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