CAPhO Safe Handling of Hazardous Drugs Definitions

⇨ A

Absorption	The process or action by which one thing absorbs or is absorbed by another. Absorption occurs through direct contact (for example, touching powder particles or liquid residue on surfaces, splashes into the eyes), and accidental skin puncture or injection.
Anteroom	From NAPRA: A room equipped with two doors, with a system/procedure that allows only one door to be open at any given time, which allows passage or movement of people or things from one environment to the other, while keeping the two environments isolated from one another.

⇨ B

Biological safety cabinet	A laminar airflow workbench that is ventilated to protect personnel, hazardous compounded sterile preparations and the immediate environment. The open front of a BSC has the following features: ➢ air intake, to protect compounding personnel from hazardous sterile preparations; ➢ descending air curtain filtered with a high-efficiency particulate air filter, to protect the hazardous sterile product; ➢ air evacuation system equipped with high-efficiency particulate air filters for environmental protection

⇨ C

Chemical cartridge respirator	A reusable respirator that filters gases, vapours and particles from the air - when fitted with an appropriate filter cartridge.
Chemotherapy gloves	Gloves worn to prevent dermal exposure to hazardous Drugs. Chemotherapy gloves have been tested to the ASTM International Standard D-6978 for permeability to hazardous drugs. The results of the permeability testing must be used to determine if gloves can be worn when handling hazardous drugs and for how long.
Chemotherapy gown	Gowns worn to minimize the risk of exposure to hazardous drugs by providing a physical barrier to extraneous drug particles. Chemotherapy gowns must close in the back, have long sleeves and tight-fitting cuffs. There must not be any seams or closures that could allow hazardous drugs to pass through.
Clean room	A room in which atmospheric properties (temperature, humidity, particle and microorganism content, pressure, airflow, etc.) are controlled. The room's functional parameters are kept at specified levels. The room is designed to minimize the introduction, generation and retention of particles. In the context of compounding hazardous sterile preparations, a clean room is an ISO Class 7 environment and has negative pressure relative to adjacent areas.
Cleaning	The process of removing substances (e.g., organic and inorganic material) from objects and surfaces, normally accomplished by manually or mechanically using water with detergents or enzymatic products

Closed-system drug transfer device (CSTD)	A drug-transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of HD or vapor concentrations outside the system.
Code brown	A spill of a chemical nature that is beyond the capacity of the facility to clean up. Examples include: 1) staff have not been properly trained in spill cleanup procedures; 2) the spill is of an unknown substance; 3) the spill has seeped into an inaccessible area (e.g., elevator shaft); 4) the spill is a volume that is greater than the spill kit capacity and department/site capability.
Compounding aseptic containment isolator (CACI)	A specific type of restricted access barrier system (RABS) that is designed for the compounding of sterile HDs. The CACI is designed to provide worker protection from exposure to undesirable levels of airborne drugs throughout the compounding and material transfer processes and to provide an aseptic environment with unidirectional airflow for compounding sterile preparations.
Compounding personnel	A pharmacist or pharmacy technician who compounds or supervises the compounding of sterile preparations.
Containment primary engineering control (C-PEC)	A containment primary engineering control (C-PEC) provides an ISO Class 5 environment for the exposure of critical sites during aseptic compounding. It is designed to minimize airborne contamination of hazardous products in order to protect workers and the environment from exposure to hazardous drugs. Biological safety cabinets (BSCs) and compounding aseptic containment isolators (CACIs) are examples of C-PECs.
Containment ventilated enclosure (CVE)	From USP 797: A non-ISO classified full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through HEPA filtration and prevent their release into the work environment.

⇨ D

Deactivation	The treatment of a hazardous drug to create a less hazardous agent, for example, by chemical deactivation - render compound inert or inactive.
Decontamination	The transfer of a hazardous drug contaminant from a fixed surface (e.g., counter, bag of solution) to a disposable surface (e.g., wipe, cloth).
Demarcation line	A visible line on the floor that separates the clean and dirty sides of the anteroom.
Disinfect	The process of inhibiting or destroying microorganisms.
Disinfectant	A disinfecting agent, typically of a chemical nature, that can destroy microorganisms or other pathogens, but not necessarily bacterial spores or fungal spores.

⇨ E

Environmental services staff (EVS)	Exclusive to healthcare, highly trained support service staff that conduct cleaning and disinfecting services for healthcare facilities.

⇨ G

Gloved fingertip sampling (GFS)	Method of assessing whether an employee is meeting the standards for aseptic technique. Using tryptic soy agar contact plates with lecithin and polysorbate, the assessor obtains thumbprints and prints of gloved fingertips from both hands of the employee, asking the employee to gently press and roll each thumb and fingertip on the agar in the contact plate (one agar plate for each hand). The agar plates are then incubated and the colony-forming units counted.

⇨ H

Hazardous drug	A drug that meets one or more of the NIOSH criteria for a hazardous drug and exhibits at least one of the following characteristics in animals or humans: ➢ Carcinogenicity ➢ Teratogenicity or other developmental toxicity ➢ Reproductive toxicity ➢ Organ toxicity at low doses ➢ Genotoxicity OR the drug: ➢ Has a structure and toxicity profile that mimics an existing drug previously determined hazardous by the above criteria ➢ Has insufficient information to properly evaluate the characteristics of the drug (e.g., investigational drug) but the drug is primarily used to treat cancer ➢ Is or contains a living organism with the potential to cause infections in humans
Hazardous drug spill	An unexpected or uncontrolled release of a hazardous drug. This can be in the form of a liquid or a powder.
Hazardous drugs list	A list of drugs that identifies which drugs handled by facility employees are considered hazardous.
Hazardous waste	Hazardous drugs that are no longer required during the course of treatment or disposable equipment / material that has been contaminated with a hazardous drug (includes unused drug solutions, intravenous tubing used to administer drug solution, absorbent towels used to clean up spills).
High efficiency particulate air (HEPA) filter	A filter that efficiently removes microscopic contaminants from the air. HEPA filters remove the most penetrating particle size (MPPS) of 0.3 µm with an efficiency of at least 99.97%. Particles both larger and smaller than the MPPS are removed with greater efficiency. Bacteria, spores and viruses are removed from the air by these filters.

⇨ I

Ingestion	The process of taking food, drink, or another substance into the body by swallowing or absorbing it.
Inhalation	Breathing or inhaling into the lungs (vapors, dusts, or aerosols).

⇨ M

Media fill testing	A test used to qualify the aseptic technique of compounding personnel and the organization's ability to produce preparations that are 'sterile'. For this test, a nutrient medium replaces the actual product during performance of the aseptic technique.

⇨ N

N95 respirator	A disposable respirator that filters particles from the air.
Non-viable particle	Non-living particulate matter. Includes dust, skin cells, clothing particles, pollen, etc.

⇨ P

Personal protective equipment (PPE)	All garb and accessories, such as mask, gloves, gown and safety goggles, that protect both the sterile preparation and personnel. It enables compliance with the expected specifications of a controlled environment and protects personnel from exposure to physical or chemical risks.

⇨ Q

Quality assurance program	A system of procedures, activities, and oversight that ensures that the compounding process consistently meets quality standards.

⇨ R

Restricted access barrier system (RABS)	An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air that allows for the ingress and/or egress of materials through defined openings that have been designed and validated to preclude the transfer of contamination, and that generally are not to be opened during operations. Examples of RABS include CAIs and CACIs.

⇨ T

Third party evaluator	A pharmacist or pharmacy technician with expertise in sterile compounding, at arm's length from the facility / pharmacy and free of any real or perceived conflict of interest with the personnel being evaluated.

⇨ V

Viable particles	Live microorganisms. These can include yeast, bacteria, mold, fungi, and more. Not only are these contaminants dangerous to an aseptic environment because they are general contamination, but they have the potential to grow.