

Glossary of Terms

Aerosol: a suspension of fine solid or liquid particles in gas¹

Aerosolization: the process of dispersing in a fine mist¹

Ancillary Devices: auxiliary or supplementary devices¹

Anteroom: 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 another²

Antimicrobial: destroying or inhibiting the growth of microorganisms and especially pathogenic micro-organisms¹

Antimicrobial Soap: Antimicrobial soap is a detergent that contains an antimicrobial agent (e.g., chlorhexidine, hexachlorophene, iodine compounds, or triclosan) to reduce the numbers of micro-organisms on the skin.

NOTE: The hand hygiene agents most commonly employed today by healthcare workers are alcohols and detergent preparations containing chlorhexidine gluconate. The antimicrobial activity of chlorhexidine gluconate compared with alcohol is gradual in onset (e.g., activity within *one to two minutes rather than seconds*).³

Antineoplastic Drug: a chemotherapeutic agent that controls or kills cancer cells. Drugs used in the treatment of cancer are cytotoxic but are generally more damaging to dividing cells than to resting cells⁴

Aseptic Technique: steps in the aseptic process, including all manipulations performed inside a biological safety cabinet by compounding personnel²

Auxiliary: additional; adding to what is already supplied or presented⁵ (labels)

Baseline: an initial set of critical observations or data used for comparison or a control¹

Bevel: a **beveled edge/tip** refers to an edge/tip of a structure that is not cut perpendicular (but instead often at 45 degrees) to the faces of the piece⁵

Beyond Use Date: the date and/or time after which a CSP shall not be stored or transported. The date is determined from the date or time the preparation is compounded.⁶

Bioburden: is the number of microorganisms with which an object is contaminated. This unit is measured in CFU (colony forming units) per gram of product⁵

Biohazardous Drug: A drug containing living organisms with potential to cause infections in humans. Biohazardous drugs are considered hazardous drugs and will be included on the NIOSH HD List or BCCA HD List Addendum. Note: Biohazardous drugs may include gene therapy, biologicals and/or biohazards⁷

Biological Safety Cabinet: a ventilated cabinet or enclosure that uses directional airflow and HEPA filters to provide personnel, environmental and varying degrees of product protection⁶

Buffer Room: (sterile preparation/cleanroom): a compounding environment in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class (ISO Class 7 specifications) the access to which is limited to personnel trained and authorized to perform sterile compounding and facility cleaning.⁶

Carcinogen: any cancer-producing substance⁸

Chemotherapy Drug: a chemical agent used to treat diseases. The term usually refers to a drug used to treat cancer⁴

Chemotherapy Gloves: Gloves that have been tested with nine chemotherapy drugs as required in the American Society for Testing and Materials (ASTM) D6978-05 Standard (*Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Gloves*).⁹ Usually they are 0.1 mm or more in thickness and must be sufficient length to cover gown cuff, when worn in conjunction with a chemotherapy gown as outlined in BCCA Pharmacy Directive VI-30: Personal Protective Equipment.¹⁰

Clean: to rid of dirt, impurities, or inappropriate matter

Cleanroom (sterile preparation/buffer room): a compounding environment in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class (ISO Class 7 specifications) the access to which is limited to personnel trained and authorized to perform sterile compounding and facility cleaning.⁶

Closed System Drug Transfer Device: a drug-transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug or vapour concentrations outside the system⁴

Communities Oncology Network (CON): a collaborative voluntary partnership with 19 community-based Community Cancer Centres, 6 community-based Community Cancer Services and 10 Consultative Clinics across the province, in conjunction with the Regional Cancer Centres and the Systemic and Radiation Programs. The Network also supports appropriate delivery of cancer patient care and support in 27 other Community Hospitals¹¹

Compounding: the act of preparing a pharmaceutical preparation, through preliminary work, to put it into a usable state. The term “compound” also refers to the material that has been prepared (e.g., a chemical or pharmaceutical preparation)²

Compounded hazardous drug parenteral admixtures: Hazardous drugs that are prepared by pharmacy in a biological safety cabinet (BSC) for parenteral administration¹²

Contamination: the deposition of potentially dangerous/hazardous material where it is not desired particularly where its presence may be harmful or constitute a hazard¹³

Continuous Flow Emergency Shower Facility: a facility capable of delivering water with a spray pattern designed to effectively flush affected areas of the skin¹⁴

Continuous Flow Eyewash Facility: a plumbed or portable facility capable of delivering a minimum of 1.5 litres of water per minute (0.33 imp gal per min), with a water pressure not exceeding 175 kPa (25 psi) and with a spray pattern designed to effectively flush both eyes¹⁴

Controlled Work Area: an area with at least two separate controlled rooms enclosed and physically separated by a wall: a cleanroom where the BSC is located and an anteroom located next to the cleanroom.²

Coring: introduction of particulate matter into sterile fluid during the process of penetrating the outer seal of a vial or IV bag with a needle or a spike¹³

Critical Site: A location that includes any component or fluid pathway surfaces or openings exposed or at risk of direct contact with air, moisture, or touch contamination⁶ (opened ampoules, needle hubs etc.)

Cytotoxic Agent: a substance that possesses a specific destructive action on certain cells or that may be genotoxic, oncogenic, mutagenic, teratogenic or hazardous to cells in any way and includes most anti-cancer drugs¹⁵

Deactivation: treating a chemical agent (such as a hazardous drug) with another chemical, heat, ultraviolet light, or other agent to create a less hazardous or inactive product⁴

Decontamination: The removal or inactivation of hazardous drug from a surface, through chemical inactivation, or removal from a non-disposable surface to a disposable surface (e.g. gauze) by use of a cleaning agent. See also BCCA Pharmacy Directive VI-20; Biological Safety Cabinet (BSC) Decontamination.⁷

Di(2-ethylhexyl)phthalate (DEHP): A chemical additive that is used to make polyvinyl chloride in medical devices soft, flexible and kink-resistant.

Disinfect/Disinfection: The destruction and removal of disease-causing pathogens/microorganisms from surfaces or inanimate objects through the application and removal of a disinfecting agent.⁶

Disinfecting Agent: Agent capable of destroying (inactivating) disease-causing pathogens/microorganisms when applied to surfaces or inanimate objects⁷

Drench Hose: a flexible hose connected to a water supply and capable of delivering a minimum of 11.4 litres of water per minute (2.5 imp gal per min), for use to flush the eyes and/or skin¹⁴

Engineering Controls: devices designed to eliminate or reduce worker exposures to chemical, biological, radiological, ergonomic, or physical hazards⁴

Expiration Date: expiration dates for the chemical potency and stability of manufactured sterile products are determined from results of rigorous analytical and performance testing and they are specific for a particular formulation in its container and at stated exposure conditions of illumination and temperature⁶

Exposure: the condition of being subjected to something, as to chemicals, that may have a harmful effect. **Acute exposure** is exposure of short duration, usually of heavy intensity; **chronic exposure** is exposure of long duration, continuous or intermittent and usually referring to exposure of low intensity¹³

Extravasation: escape of drug from a blood vessel into subcutaneous tissues, possibly leading to tissue damage¹⁶

First air: the air exiting the HEPA filter in a unidirectional air stream that is essentially particle free⁶

Fluorescein dye: fluorescent dye which is illuminated with UV light

Genotoxic: capable of damaging DNA and leading to mutations⁴

Gowning: putting on personal protective equipment and clothing to help contain both the viable (micro-organisms) and nonviable particles that are generated by employees¹³ and to protect individual workers from hazardous physical or chemical exposure⁴

Graduated Cylinder: a tall narrow container with a volume scale used especially for measuring liquids¹

Hand hygiene: A comprehensive term that refers to hand washing, hand antisepsis and actions taken to maintain healthy hands and fingernails. Hand washing is a process for the removal of soil and transient micro-organisms from the hands using soap and water. Hand antisepsis is a process for the removal or destruction of resident and transient micro-organisms on the hands using an antiseptic agent, either by rubbing hands with alcohol-based hand rub or hand washing with an antiseptic soap. Hand antisepsis has also been referred to as antiseptic hand wash, antiseptic hand-rubbing, hand decontamination and hand disinfection.¹⁷

Hand Rub (Alcohol-Based): Gels or liquids containing antimicrobial agents that decrease the number of microorganisms present on hands. The antimicrobial agents in most hand rubs are alcohols (ethanol, isopropanol, and n-propanol), available in varying concentrations. Hand rubs do not remove organic material; they cannot be used if hands are visibly soiled. Also known as sanitisers.¹⁸

Hazardous Drug (HD): Drug that exhibits one or more of the following characteristics in humans and/or animals: carcinogenicity, teratogenicity or other developmental toxicity, reproductive toxicity, organ toxicity at low doses, genotoxicity and structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the five previous criteria.³ If there is no information found and the drug is primarily used as an antineoplastic agent, it will be deemed as hazardous. If a drug contains living organisms with potential to cause infections in humans it will be considered a hazardous drug and will be designated a biohazardous drug on the NIOSH HD List or BCCA HD List Addendum. Note: Hazardous drugs have been referred to as "cytotoxic, antineoplastic, hazardous, and/or chemotherapy".¹⁹

HEPA filter: High Efficiency Particulate Air filters found in most Biological Safety Cabinets that trap approximately 99.9% of particulate matter 0.3 micron size or greater to provide ultra clean air²⁰

Hepatotoxic: Relating to or causing injury to the liver¹

Horizontal Laminar Flow Hood: a device that provides an ISO Class 5 environment for the exposure of critical sites when sterile preparations are being compounded. The airflows horizontal toward the worker; the first air (exiting the HEPA filter) is free from airborne particulates²

Hydrophilic: relating to, or having a strong affinity for water.¹ Hydrophilic filters possess an affinity for water and can be wetted with almost any liquid²¹

Hydrophobic: lacking affinity for water.¹ Hydrophobic filters lack an affinity for water and are best suited for venting applications²¹

Intrathecal: introduced into or occurring in the space under the arachnoid membrane of the brain or spinal cord¹

ISO Classification: classification of air cleanliness was the first ISO 14644 International Standard prepared by ISO (International Organization for Standardization) Technical Committee 209 (ISO/TC 209). ISO 14644-1 covers the classification of air cleanliness in clean rooms and associated controlled environments. Classification in accordance with this standard is specified and accomplished exclusively in terms of concentration of airborne particles⁵

ISO Class 5: an environment containing not more than 3250 particles 0.5 μm and larger size per cubic meter of air. (e.g., interior of a functioning BSC)⁶

ISO Class 7: an environment containing not more than 352,000 particles 0.5 μm and larger size per cubic meter of air. (e.g., buffer area/cleanroom)⁶

ISO Class 8: an environment containing not more than 3,520,000 particles 0.5 μm and larger size per cubic meter of air (e.g., ante area adjacent to a non-hazardous compounding cleanroom)⁶

Lab Coat: an overcoat/smock worn by professionals in the medical field or by those involved in laboratory work to protect their street clothes. The garment is made from white cotton or linen to allow it to be washed at high temperature and make it easy to see if it is clean⁵

Luer-Lock: fittings used for making leak-proof connections between a male-taper fitting and its mating female part on medical and laboratory instruments, including hypodermic syringe tips and needles and other devices. Luer Lock fittings are joined by means of a tabbed hub on the female fitting which engages threads on the male fitting⁵ secured using a twisting motion

Mutagenic: capable of increasing the spontaneous mutation rate by causing changes in the DNA⁴

National Sanitation Foundation (NSF): NSF International, formerly National Sanitation Foundation, is a not-for-profit, non-governmental organization that develops standards and provides product certification and education in the field of public health and safety⁵

Negative Pressure Room: a room that is at a lower pressure than the adjacent spaces and therefore the net flow of air is into the room⁶

Nonporous: impermeable to outside influences such as fluids¹

Non-Tempered Drench Hose: a flexible hose connected to a water supply that is capable of delivering a minimum of 11.4 litres of water per minute (2.5 imp gal per min), for use to flush the skin.¹⁴ The water temperature must be adjusted before use

Occupational Exposure: anticipated contact with cytotoxic/hazardous agents that may result from the performance of a worker's regular or assigned job duties¹⁵

Particulate: alternatively referred to as particulate matter (PM) or fine particles, are tiny particles of solid or liquid suspended in a gas⁵ (air)

Personnel contamination: Contamination of personal protective equipment (PPE) or clothing, or direct skin or eye contact⁷

Personal Protective Equipment (PPE): Items such as gloves, gowns, respirators, goggles, face shields, and others that protect individual workers from hazardous physical or chemical exposures outlined in BCCA Pharmacy Directive VI-30: Personal Protective Equipment.¹⁰

Plain Soap: Plain soap is a detergent that does not contain antimicrobial agents or that contains very low concentrations of antimicrobial agents that are present only as preservatives.³

Positive Pressure Room: a room that is at a higher pressure than the adjacent spaces and therefore the net airflow is out of the room⁶

Preparation: a compounded product that is a drug or nutrient prepared in a licensed pharmacy or other healthcare-related facility pursuant to the order of a licensed prescriber; the article may or may not contain sterile products⁶

Priming: to fill or load. To put into working order by filling or charging with something.⁵ The replacement of air with a drug, or non-drug solution

Product Stability: the extent to which a preparation retains, within specified limits, and throughout its period of storage and use (ie, its shelf-life), the same properties and characteristics that it possessed at the time of its manufacture²²

Protective Air Curtain: the combined air that flows from the room and from the BSC interior into the front intake grill produces an "air curtain" that prevents particles from entering or leaving via the BSC's front opening. Penetration of this curtain by the arms of the operator, although unavoidable, decreases optimal function of the "air curtain".²³

Respirator: a type of PPE that prevents harmful materials from entering the respiratory system, usually by filtering hazardous agents from workplace air, and meeting NIOSH and OSHA standards for use with hazardous drugs⁴

Safety Needles: a needleless device or safety-engineered (SEN) hollow bore needle which must be used for the following procedures performed to care for or treat a person: withdrawal of body fluids; accessing a vein or artery; administration of medications or fluids; any other procedure involving the potential for an exposure to accidental parenteral contact for which a needleless system or safety-engineered hollow bore needle system is available¹⁵

Spill: an unintentional, uncontained dispersal of a compound⁷

Spill Kit Station: designated location where supplies and personal protective equipment are stored in preparation for cleaning up a spill. Each station should be clearly identified with a label that includes the words "Hazardous Drug Spill Kit". If kits are stored within a cupboard, the outermost door of the cupboard must be labelled⁷

Sterile: free from bacteria or other living organisms^{1,5}

Sterile Preparation Room (clean/buffer room) : a compounding environment in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class (ISO Class 7 specifications) the access to which is limited to personnel trained and authorized to perform sterile compounding and facility cleaning.⁶

TALLman lettering: a risk reduction strategy that reduces errors by printing sections of the drug name in capital letters to emphasize differences between similar pairs of drugs. TALLman lettering is recommended by the Institute for Safe Medication Practices (ISMP) for incorporation into all forms of drug communication. As such, it has become a widely accepted method for distinguishing confusing drug names in the healthcare setting in order to avoid unintended interchange of Look-Alike/Sound-Alike drugs.²⁴

Tempered: maintained at temperatures from 15° C to 30° C (60° F to 85° F)¹⁴

Teratogenic: relating to or causing developmental malformations¹

Trough: drain spillage trough. An area below the biological safety cabinet's work surface, provided to retain spillage from the work area²³

Vapour – is the gas phase component of another state of matter (e.g. liquid or solid). It is distinguished from the pure gas phase by the presence of the same substance in another state of matter⁵

Vapourization: is the process by which molecules in a liquid or solid state spontaneously become gaseous (evaporation)⁵

Vent: an outlet that allows the exchange of air⁵

Vesicant: an agent that induces blistering, local or extensive tissue necrosis with or without ulceration¹⁶

Virucidal: to have the capacity to or tending to destroy or inactivate viruses¹

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