

Glossary of Terms

Aerosol: a suspension of fine solid or liquid particles in gas.¹

Aerosolization: the process of dispersing in a fine mist.¹

Alcohol-Based Hand Rub (ABHR): Gels or liquids containing antimicrobial agents that decrease the number of microorganisms present on hands. The antimicrobial agents in most ABHRs are alcohols (ethanol, isopropanol, and n-propanol), available in varying concentrations. ABHRs do not remove organic material; they cannot be used if hands are visibly soiled. Also known as sanitisers.²

Ancillary Devices: auxiliary or supplementary devices.¹

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 another.³

Antimicrobial: destroying or inhibiting the growth of microorganisms and especially pathogenic micro-organisms.¹

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.⁴

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).⁴

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 cells.⁵

Aseptic Technique: steps in the aseptic process, including all manipulations performed inside a containment primary engineering control by compounding personnel.³

Auxiliary: additional; adding to what is already supplied or presented⁶ (labels).

Baseline: an initial set of critical observations or data used for comparison or a control.¹

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 piece.⁶

Beyond Use Date (BUD): the date and time after which a compounded sterile preparation cannot be used and must be discarded. Administration of the compounded sterile preparation must begin before the BUD has passed.³

Bioburden: is the number of microorganisms with which an object is contaminated. This unit is measured in CFU (colony forming units) per gram of product.⁶

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 biohazards.⁷

Biological Safety Cabinet: A type of containment primary engineering control. A ventilated cabinet or enclosure that uses directional airflow and HEPA filters to provide personnel, environmental and varying degrees of product protection.⁸

Carcinogen: any cancer-producing substance.⁹

Chemotherapy Drug: a chemical agent used to treat diseases. The term usually refers to a drug used to treat cancer.⁵

Chemotherapy Gloves: gloves worn to prevent dermal exposure to hazardous drugs. Chemotherapy gloves 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*).¹⁰ The reported breakthrough detection times must be used to determine if the gloves are appropriate and the length of time that each brand and type of chemotherapy glove may be worn while staff handles hazardous drugs. Chemotherapy gloves must be sufficient length to cover gown cuff, when worn in conjunction with a chemotherapy gown.³

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.⁸

Cleaning agent: an agent, usually containing a surfactant, used for the removal of substances (e.g., dirt, debris, microbes, and residual drugs or chemicals) from surfaces.⁸

Clean room (sterile preparation room): a room in which atmospheric properties (e.g., temperature, humidity, particle and microorganism content, pressure, airflow) 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 sterile preparations a clean room is an ISO Class 7 environment. For non-hazardous compounding, the clean room has positive pressure relative to adjacent areas. For hazardous compounding, the clean room has negative pressure relative to adjacent areas.³

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 system.⁵

Communities Oncology Network (CON): a collaborative voluntary partnership with hospitals in the Health Authorities and with the BC Cancer regional centres and its systemic and radiation therapy programs. The CON works with BC health authorities to ensure that cancer care throughout the province meets the standards of BC Cancer.¹¹

Compounded sterile preparation: A preparation intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance.⁸

Compounding: the process of combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance to create a sterile preparation.⁸ Compounding does not include mixing, reconstituting or any other manipulation that is performed in accordance with the directions for use on an approved drug's labelling material.¹²

Contact Time: the time a disinfectant is in direct contact with the surface or item to be disinfected. For surface disinfection, this period is framed by the application to the surface until complete drying has occurred.¹³ (Also known as wet time, dwell time.)

Container, inner: one of the layers of packaging which may be required for hazardous drug transportation, enclosing the primary container. Inner containers must be sealable, leak-proof, and see-through (unless contents are light sensitive).¹⁴

Container, outer: one of the layers of packaging which may be required for hazardous drug transportation, enclosing both the primary and inner containers. Outer containers must be robust enough to withstand typical conditions during transport.¹⁴

Container, primary: a container suitable for dispensing medication such as intravenous solution bag, elastomeric infusor, syringe, vial, ampoule, ointment jar, blister card, manufacturer supplied packaging, or prescription vial.¹⁵

Containment Primary Engineering Control (C-PEC): a device that provides an ISO Class 5 environment for the exposure of critical sites during aseptic compounding and that is designed to minimize airborne contamination of hazardous products to protect workers and the environment from exposure to hazardous drugs. For compounding of hazardous sterile preparations, C-PECs include biological safety cabinets and compounding aseptic containment isolators.³

Contamination: the deposition of potentially dangerous/hazardous material where it is not desired particularly where its presence may be harmful or constitute a hazard.¹⁶

Continuous Flow Emergency Shower Facility: a facility capable of delivering water with a spray pattern designed to effectively flush affected areas of the skin.¹⁷

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 eyes.¹⁷

Controlled Area: an enclosed workspace constructed and operated in such a manner and equipped with appropriate air-handling and filtration systems to reduce to a predefined level the introduction, generation, and retention of contamination.¹⁸ Atmospheric properties (e.g., temperature, humidity, particle and microorganism content, pressure, airflow) are controlled to meet and maintain specified parameters.³

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 spike.¹⁶

Critical Area: Work area inside a containment primary engineering control ensuring ISO Class 5 air quality, where personnel compound sterile preparations and where critical sites are exposed to unidirectional airflow from a high-efficiency particulate air filter.³

Critical Site: a surface likely to come into contact with a sterile drug or liquid (e.g., vial septa, injection sites) or any exposed opening (e.g., open vials/ampoules, needle hubs) and likely to be in direct contact with the ambient air, with air filtered by means of a high-efficiency particulate air filter or with humidity (oral secretions or mucous membranes) or likely to be contaminated by touch.³

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 drugs.¹⁹

Deactivation: treatment of a hazardous drug to create a less hazardous agent. One method is chemical deactivation.³

Decontamination: the transfer of a hazardous drug from a fixed surface (e.g., counter, bag of solution) to a disposable surface (e.g., wipe, cloth). The wipe is then contained and discarded as hazardous waste.³

Demarcation line: A visible line on the floor that separates the clean and dirty sides of the anteroom.⁸

Designated person(s): One or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of CSPs.⁸

Di(2-ethylhexyl)phthalate (DEHP): A chemical additive that is used to make polyvinyl chloride in medical devices soft, flexible and kink-resistant.²⁰

Direct Compounding Area: a critical area within the ISO Class 5 PEC/C-PEC where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air.⁸

Disinfectant / Disinfecting Agent: a chemical that destroys microorganisms or other pathogens, but not necessarily their bacterial or fungal spores. Refers to substances applied to inanimate objects.³

Disinfection: treatment that eliminates most of the pathogens present on an object or surface.³

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 skin.¹⁷

Dwell time: the amount of time that a sanitizer or disinfectant must be in contact with the surface, and *remain wet*, in order to achieve the product's advertised kill rate.¹³

Dynamic Airflow Smoke Pattern Test: A PEC/C-PEC test in which a visible medium (smoke source), which is close to neutrally buoyant, is used to observe air patterns within the unidirectional space (i.e., the DCA) under dynamic operating conditions.²¹

Dynamic Operating Conditions: Conditions in the compounding area in which operating personnel are present and simulating or performing compounding. The conditions should reflect the largest number of personnel and highest complexity of compounding expected during routine operations as determined by the designated person(s).²¹

Engineering Controls: devices designed to eliminate or reduce worker exposures to chemical, biological, radiological, ergonomic, or physical hazards.⁵

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 temperature.⁸

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 intensity.¹⁶

Extravasation: escape of drug from a blood vessel into subcutaneous tissues, possibly leading to tissue damage.²²

First air: the air exiting the high-efficiency particulate air filter in a unidirectional air stream that is essentially particle free.³

Genotoxic: capable of damaging DNA and leading to mutations.⁵

Gloved fingertip sampling (GFS): a method of assessing whether an employee is meeting the standards for aseptic technique. 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 a contact plate (one agar plate for each hand). The agar plates are then incubated and the colony-forming units counted.³

Gowning: putting on personal protective equipment and clothing to help contain both the viable (micro-organisms) and nonviable particles that are generated by employees¹⁶ and to protect individual workers from hazardous physical or chemical exposure.⁵

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.²³

Hazardous Drug (HD): a drug that exhibits at least one of the following characteristics in animals or humans: (1) carcinogenicity, (2) teratogenicity or other developmental toxicity, (3) reproductive toxicity, (4) organ toxicity at low doses, (5) genotoxicity OR the drug (1) has a structure and toxicity profile that mimics an existing drug previously determined hazardous by the five previous criteria,³ (2) is or contains a living organism with the potential to cause infections in humans, (3) has insufficient information to properly evaluate the characteristics of the drug but the drug is primarily used to treat cancer.²⁴

Hazardous Drug Group 1: a drug will be classified HD Group 1 on the BC Cancer HD List if:

1. It is included on the current NIOSH List in Table 1
2. It is evaluated by the Provincial Pharmacy HD Review Committee or BC Cancer as hazardous and meets one or more of the following criteria for a hazardous drug:
 - i. meets the NIOSH criteria for carcinogenicity animals or humans
 - ii. meets the NIOSH criteria for genotoxicity/mutagenicity animals or humans
 - iii. has Manufacturer's Safe Handling Information (MSHI) in the product information
 - iv. is classified by the National Toxicology Program (NTP) as "known to be a human carcinogen"
 - v. is classified by the International Agency for Research on Cancer (IARC) as "carcinogenic" or "probably carcinogenic"
 - vi. is evaluated as "cytotoxic" or is described as having a "cytotoxic mechanism of action" by the Provincial Pharmacy Hazardous Drug Review Committee per the Guiding Principles for the BC Hazardous Drug List
 - vii. drug contains a living organism with the potential to cause infection in humans (i.e., biohazardous)
 - viii. is a new drug with a structure and toxicity profile that mimics an existing drug previously determined to be a HD Group 1 by the previous criteria

Hazardous Drug Group 2: A drug will be classified as HD Group 2 on the BC Cancer HD List if:

1. It is included on the current NIOSH List in Table 2
2. It is evaluated by the Provincial Pharmacy HD Review Committee or BC Cancer and does NOT meet one of the criteria for a Group 1 drug, but does meet one or more of the following criteria:
 - i. meets the NIOSH criteria for teratogenicity/developmental toxicity animals or humans
 - ii. meets the NIOSH criteria for reproductive toxicity animals or humans
 - iii. meets the NIOSH criteria for low dose organ toxicity animals or humans
 - iv. is a new drug with a structure and toxicity profile that mimics an existing drug previously determined to be a HD Group 2 by the previous criteria
3. There is insufficient information to properly evaluate the characteristics of the drug (e.g., investigational drug, drug only available via Health Canada Special Access program, etc.) but the drug is primarily used to treat cancer

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.²⁵

Hepatotoxic: relating to or causing injury to the liver.¹

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 liquid.²⁶

Hydrophobic: lacking affinity for water.¹ Hydrophobic filters lack an affinity for water and are best suited for venting applications.²⁶

Incubator: a device used in microbiology to keep cultures at a constant temperature.³

Intrathecal: introduced into or occurring in the space under the arachnoid membrane of the brain or spinal cord.¹

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 particles.⁶

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 C-PEC).⁸

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., clean room).⁸

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., anteroom adjacent to a non-hazardous compounding cleanroom).⁸

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 clean.⁶

Laminar Airflow Workbench (LAFW): see Primary Engineering Control

Line of Demarcation: A visible line on the floor that separates the clean and dirty sides of the anteroom. In some cases, different colored flooring is used.²¹

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 fitting⁶ secured using a twisting motion.

Media Fill Test (MFT): a test used to quality aseptic techniques 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.³

Mutagenic: capable of increasing the spontaneous mutation rate by causing changes in the DNA.⁵

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 safety.⁶

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 room.⁸

Nonporous: impermeable to outside influences such as fluids.¹

Occupational Exposure: anticipated contact with cytotoxic/hazardous agents that may result from the performance of a worker's regular or assigned job duties.¹⁹

Particulate: alternatively referred to as particulate matter (PM) or fine particles, are tiny particles of solid or liquid suspended in a gas⁶ (air).

Pascal: SI unit of measure for pressure.³

Pass-through: An enclosure with sealed doors on both sides that should be interlocked or procedures in place to assure only one door is opened at a time. The pass-through is positioned between two spaces for the purpose of minimizing particulate transfer while moving materials from one space to another.²¹

Personnel contamination: contamination of personal protective equipment (PPE) or clothing, or direct skin or eye contact.⁷

Personal Protective Equipment (PPE): all garb and accessories such as masks, gloves, gowns, respirators, goggles, face shields, and others that protect both the sterile preparation and the personnel. It enables compliance with the expected specifications of a controlled environment and protect personnel from exposure to physical or chemical risks.³

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.⁴

Positive Pressure Room: a room that is at a higher pressure than the adjacent spaces and therefore the net airflow is out of the room.⁸

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 products.⁸

Primary Engineering Control (PEC): a device that provides an ISO Class 5 environment for the exposure of critical sites during aseptic compounding. The air flows horizontally toward the worker or vertically towards the work surface. PEC options for non-hazardous compounding include laminar airflow workbenches (LAFWs) and compounding aseptic isolators (CAIs).³

Priming: to fill or load. To put into working order by filling or charging with something.⁶ 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 (i.e., its shelf-life), the same properties and characteristics that it possessed at the time of its manufacture.⁸

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".²⁷

Public Areas: areas within a facility which are commonly accessed by the public (i.e. hallways, elevators, and stairways) but which are not considered part of the patient treatment areas.

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 drugs.⁵

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 available.¹⁹

Spill: an unintentional, uncontained dispersal of a compound.⁷

Spill Kit: a container of supplies, warning signage, and related materials used to contain the spill of an HD.²⁸

Sporicidal: a chemical or physical agent that destroys bacterial and fungal spores when used in sufficient concentration for a specified contact time.⁸

State of Control: The practice of controlling variables to achieve the expected results. For the purposes of sterile compounding facility certification, a state of control is achieved when critical parameters used to achieve an appropriate environment for sterile compounding are managed and under control. Adequate HEPA filtered air is supplied to the room or PEC and the cleaner space is protected from less clean spaces by overpressure or displacement airflow.²¹

Sterile: free from bacteria or other living organisms.^{1, 6}

Sterile Preparation Room: see Clean Room

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.²⁹

Tempered: maintained at temperatures from 15° C to 30° C (60° F to 85° F).¹⁷

Teratogenic: relating to or causing developmental malformations.¹

Trough: drain spillage trough. An area below the biological safety cabinet's work surface, provided to retain spillage from the work area.²⁷

Unclassified Space: A space not required to meet any air cleanliness classification based on the ISO classification.²¹

Unidirectional Airflow: airflow moving in a single direction in a robust and uniform manner and at sufficient speed to reproducibly sweep particles away from the critical site.⁸

Vapour: 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 matter.⁶

Vapourization: the process by which molecules in a liquid or solid state spontaneously become gaseous-(evaporation).⁶

Vent: an outlet that allows the exchange of air.⁶

Vesicant: an agent that induces blistering, local or extensive tissue necrosis with or without ulceration.²²

Virucidal: to have the capacity to or tending to destroy or inactivate viruses.¹

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