BC CANCER
Provincial Health Services Authority

Safe Handling of Hazardous Drugs

Module 1

Includes Recommended Procedures and Techniques

Table of Contents

Section A - Safe Handling Principles

A.1 Potential Hazards of Handling Hazardous Drugs

Hazardous drugs used to treat cancer may cause temporary or permanent changes in a patient's health. Temporary adverse effects that patients may experience during or after treatment are well documented- immunosuppression, nausea/vomiting, hair loss, etc. and may be reversible. Cancer treatment regimens that may cause permanent health problems include cardiotoxicity after cumulative doses of DOXOrubicin and peripheral nerve damage after high doses of vinCRIStine. In therapeutic doses, some hazardous drugs can lead to reproductive problems such as decreased fertility, fetal malformations, and spontaneous abortions.[1, 2]

Adverse effects similar to those seen in treated cancer patients may occur in healthcare workers who handle hazardous drugs regularly, especially if protective garb and equipment are not used.[3, 4] Various studies have demonstrated possible links between occupational exposure to hazardous drugs and menstrual dysfunction[5], infertility[6], miscarriages and stillbirths[1], low birth weights and congenital abnormalities.[7]

Many of the studies investigating occupational exposure to chemotherapy in healthcare workers were conducted prior to the development of safe handling standards for the preparation and administration of hazardous drugs. In the mid-1980's, international standards regarding sterile preparation rooms (clean rooms), personal protective equipment, biological safety cabinets, etc. were developed. Given the changes in the handling procedures for hazardous drugs, the risk of acute and long-term toxic effects in healthcare workers may have declined.[8] Nevertheless, the potential health risks for hospital staff still exist as suggested by recent environmental contamination studies showing the presence of hazardous drug contamination on multiple surfaces in the workplace.[9-11]

Standard:

Policies and procedures covering all activities related to hazardous Drug (HD) safe handling and compounding must be developed.[12] Refer to Appendix 1 of NAPRA's Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations for a list of required policies and procedures.

All pharmacy staff must be informed of HD policies and procedures, and receive training for handling hazardous drugs safely, cleaning up spills, and using all equipment and PPE properly.[12,13] There must be established work practices related to both drug manipulation techniques and to general hygiene practices.[14] Workplace procedures must be developed for using and maintaining all equipment that functions to reduce hazardous drug exposure.[13]

A.2 Hazardous Drug List

Standard:

Each facility must develop and maintain a hazardous drug list to ensure that healthcare staff working in the facility is made aware of which drugs are hazardous.[13, 14]

The National Institute for Occupational Safety and Health (NIOSH) Alert: *Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings* was published in September 2004. In Appendix A of the Alert, NIOSH identified a sample list of hazardous drugs (HD). NIOSH periodically publishes updates to the original list found in the 2004 NIOSH Alert. NIOSH's most recently published hazardous drug list is used as the basis for the BC Health Authorities Hazardous Drug List.

BC Cancer's Hazardous Drug List is comprised of the BC Health Authorities HD List and the BC Cancer Addendum which includes additional hazardous drugs evaluated by BC Cancer.

Standard:

The facility's hazardous drug list must be posted in all areas where these drugs are received,[15, 16] stored,[13, 16] prepared[13] and administered.[15, 16]

A.3 Medical Surveillance

Protection from hazardous drug exposure depends on adherence to safety programs established by employers and followed by workers.[17, 18] A comprehensive approach to minimizing worker exposure should be part of a safety and health initiative that includes safe work practices, proper engineering controls, and personal protective equipment supported by a medical surveillance program.[14, 19] Unfortunately, despite publication and implementation of guidelines for handling antineoplastic agents, studies have shown that compliance is an issue, implying that various guidelines are not followed aggressively enough.[20]

Medical surveillance involves collecting and interpreting data to detect changes in the health status of working populations potentially exposed to hazardous substances. Elements of a medical surveillance program are used to establish a baseline of workers' health and then monitor their future health as it relates to their potential exposure to hazardous agents.[14] Employers should encourage healthcare workers who must handle hazardous drugs while performing their work responsibilities to be monitored routinely by their family physician as part of a medical surveillance program.[19, 21]

Elements of a medical surveillance program as suggested by NIOSH include:

- Reproductive/general health questionnaires completed at the time of hire (baseline) and periodically thereafter
- Laboratory work including complete blood count (CBC) and urinalysis at the time of hire and periodically thereafter[12]
- Physical examination completed at the time of hire and then as needed for any worker whose health questionnaire indicates an abnormal finding[12]
- Follow-up for workers with health changes or a significant exposure or risk of exposure (e.g., substantial skin contact, eye contact, clean-up of a large spill)[12, 14]

Currently, no NIOSH recommended exposure limits, OSHA permissible exposure limits, or American Conference of Governmental Industrial Hygienists threshold limit values have been established for hazardous drugs in general. The likelihood that a worker will experience adverse effects from hazardous drugs increases with the amount and frequency of exposure and the lack of proper work practices.[4]

A.4 Personal Exposure Records

A record of how much drug each staff member handles may be useful in the future for group studies on the consequences, if any, of handling all hazardous drugs in the workplace.[22]

Standard:

WorkSafe BC Occupational Health and Safety (OH&S) Regulation 6.52 states:

1. ***"The employer must maintain a record of all workers who prepare or administer cytotoxic (hazardous) drugs, including the name of the drugs handled, and when practicable, the number of preparations or administrations per week.***
2. ***Exposure records must be maintained for the duration of employment plus 10 years, and training records for 3 years from the date that the training occurred."***

A copy of these records is maintained by the pharmacy professional practice leader or department manager in a permanent 'exposure record' for each staff member. If they wish, an individual resigning from the department may take a copy of their own exposure record with them to their future place of employment.

A.5 Work Re-Assignment

Standard:

WorkSafe BC Occupational Health and Safety (OH&S) Regulation 6.49 Reproductive toxins states:

1. ***"At any worksite where a worker is occupationally exposed to a cytotoxic drug that is a reproductive toxin, the employer must develop policy and procedures appropriate to the risk, which may include protective reassignment."***

2. ***"The policy and procedures must inform workers about the reproductive toxin and identify ways to minimize exposure to the reproductive toxin for a worker who has advised the employer of pregnancy or intent to conceive a child."***

It is the responsibility of the employee handling hazardous drugs to discuss with their immediate supervisor any desired change in work assignment as a result of their pregnancy, breast-feeding or attempt to reproduce. All attempts should be made by management to re-assign staff who are pregnant, breastfeeding or planning imminent parenthood to work in another area of the pharmacy in order to avoid working directly with hazardous drugs, if so requested.[4, 13]

Refer to BC Cancer Systemic Therapy Policy V-20: Employee Health: Management of Risks Related to Hazardous Drugs Practice Guidelines

Section B - Decontaminating, Cleaning, Deactivating, Disinfecting, and Sporicidals

B.1 General

Environmental contact is a major source of microbial contamination of compounded sterile preparations, and hazardous drug contamination on surfaces is a potential source of personal exposure for healthcare workers.[12, 14] Therefore, scrupulous attention to decontaminating, cleaning, deactivating, and disinfecting surfaces is required.[12]

Standard:

To minimize hazardous drug and environmental (e.g., microbial and particulate) contamination, surfaces must be appropriately decontaminated, cleaned, and disinfected by personnel trained and qualified to safely carry out their responsibilities.[12] All personnel performing these activities must wear appropriate personal protective equipment resistant to the solutions used.[14] Solutions selected must be appropriate for the type of hazardous drug contaminants, location, and surface materials.[14]

When selecting decontaminating, cleaning, deactivating and disinfecting solutions, consideration must be given to compatibility, effectiveness, and inappropriate or toxic residues.[12] Diluted solutions must be prepared and stored according to the manufacturer's directions[12] and kept in previously cleaned containers.

Partly emptied containers must not be topped up.[15]

Solutions should be applied through the use of wipes moistened with an appropriate solution, not delivered by a spray bottle to avoid dispersing particulate and spreading HD residue[14], and to minimize risk of inhaling the solution. Solution should be applied to the wipe in such a manner as to avoid contaminating the bulk solution.[15]

Standard:

Where applicable, the manufacturer's directions regarding the required contact time between the solution and the surface to be disinfected must be followed in order for the disinfectant to be effective (e.g., germicidal disinfecting detergents, sporicidals).[12] When sterile 70% isopropyl alcohol is used, it must be allowed to dry.[23]

B.1.1 Decontamination

Decontamination involves the transfer of hazardous drug residue from a fixed surface (e.g., counter, intravenous solution bag) to a disposable absorbent material (e.g., wipe). The disposable material is then contained and disposed of as hazardous waste. Decontaminating agents selected should also contain a germicidal disinfectant detergent.[12,14]

B.1.2 Cleaning

Cleaning is the removal of dirt, dust and other substances that may host microorganisms.[12] It is recommended that cleaning products selected also decontaminate and/or disinfect surfaces.

B.1.3 Deactivation

Deactivation is the treatment of a hazardous drug to create a less hazardous agent, for example, by chemical deactivation. The safety data sheets for some hazardous drugs recommend sodium hypochlorite for this purpose. Sodium hypochlorite will corrode stainless steel surfaces, so it must be neutralized with sodium thiosulphate or removed using a germicidal disinfectant detergent.[12] Sodium hypochlorite also has an additional germicidal effect for disinfection.[24]

BC Cancer recommends decontamination instead of deactivation because there is no known single non-toxic product available that will deactivate all hazardous drugs.

B.1.4 Disinfection

Disinfection is the process of destroying microorganisms or other pathogens, but not necessarily their bacterial or fungal spores.

B.1.5 Sporicidals

A sporicidal is a chemical or physical agent that destroys bacterial and fungal spores when used at a sufficient concentration for a specified contact time. It is expected to kill all vegetative microorganisms.[23]

Some sporicidals have required contact times of 5 to 10 minutes to be effective which is generally not possible to achieve in a controlled area. It is recommended to use a sporicidal that has a contact time of 3 minutes or less in the controlled areas.[25]

Alcohol does not kill bacterial spores.[26] Non-sterile alcohol may harbour resistant microbial spores.

B.1.5.1 Odor Limiting and Odor Containment Strategies

All sporicidals have a strong odor. When using a sporicidal, it is recommended to use odor limiting and odor containment strategies:[25]

Odor limiting and containment strategies may include:[25]

- placing the moistened wipes for use into a sealable container (e.g., canister with a spring-loaded lid, zip lock bag);
- discarding used moistened wipes into a sealable container (e.g., zip lock bag);
    - zip lock bags can be folded in half but not sealed during use for easier access to minimize the amount of odor that can escape.
- Wear a N95 or an elastomeric half or full face mask respirator with an appropriate filter when working with a sporicidal

Section C - Controlled Area

C.1 International Standards Organization (ISO) Classifications

To prevent microbial contamination of compounded preparations, particulate matter in compounding areas must be controlled and limited as much as possible. The International Standards Organization established a technical committee and several working groups to delineate clean room classifications and standards. The ISO classification standards for particulate matter in room air are rated according to the number of particles per cubic meter at a specified particle size (e.g., 0.5 um and larger).[26]

Standard:

The air quality in the clean room and anteroom must comply with ISO 14644-1 according to the specifications listed in the table below during dynamic operating conditions (e.g., the number of particles ≥0.5 µm diameter per cubic metre of air must be verified while compounding personnel perform or simulate preparation of a typical hazardous product).[12]

Table 1: ISO Classification of Particulate Matter in Room Air

Limits are in particles of 0.5 µm and larger per cubic meter [current ISO] and per cubic foot [former Federal Standard No. 209E, FS 209E].[26, 27]			
Class Name		**Particle Count**	
ISO Class	**U.S. FS 209E**	**ISO, m^3**	**FS 209E, ft^3**
3	Class 1	35.2	1
4	Class 10	352	10
5	Class 100	3,520	100
6	Class 1,000	35,200	1,000
7	Class 10,000	352,000	10,000
8	Class 100,000	3,520,000	100,000

C.2 Room Specifications

The Controlled Area (CA) consists of at least two separate controlled rooms, a clean room and an anteroom, enclosed and physically separated by a wall. Additional rooms in the controlled area may include a gowning room (for donning of personal protective equipment to work in the CA), a hazardous drug storage room, a staging or set-up room, and a checking room.

The activities taking place in the controlled area are directly related to the preparation of parenteral drugs. The controlled area is designed to minimize the introduction, generation, and retention of particulate and microbial contamination through the facility's Heating, Ventilation, and Air Conditioning (HVAC) System and the use of High-Efficiency Particulate Air (HEPA) filters.

Standard:

Controlled rooms must not have windows or doors opening directly to the exterior of the building. If any windows are present, they must be sealed. If any doors lead to the outside or to a non-controlled area (other than the doors designated for accessing the room), they must be sealed.[12]

Doors leading into controlled areas must not be left open.[12]

Access to the controlled area must be limited to authorized personnel who are assigned to work there. All personnel entering the controlled area must follow appropriate hand hygiene and garbing procedures as the first major step in preventing microbial contamination of compounded sterile preparations[12] and to minimize healthcare workers' exposure to hazardous drugs.[4]

C.2.1 Heating, Ventilation and Air Conditioning (HVAC) System for Controlled Rooms

Standard:

The air in controlled rooms must be clean and the levels of airborne particulates must be limited. Therefore, the facility's HVAC system must be designed both to minimize the risk of airborne contamination and to minimize the exposure of personnel to hazardous drugs.[12]

An air conditioning system must be included in the HVAC system to help ensure the comfort of personnel wearing personal protective equipment.[12]

C.2.2 High Efficiency Particulate Air (HEPA) Filter

A high efficiency particulate air filter traps approximately 99.9% of particulate matter 0.3 microns in size or greater to provide ultra-clean air.[22, 28] Airborne contamination control is achieved in the controlled area rooms through the use of HEPA filters. HEPA filters are effective at trapping particulates but do not capture volatile drugs or vapours.[28]

Standard:

The air supplied to rooms in the controlled area must pass through at least one HEPA filter to help ensure a very high level of cleanliness. The intake air must come from the ceiling via diffusers, each fitted with a terminal HEPA filter.[12]

C.2.3 Signage

Standard:

Each room in the controlled area must be identified with appropriate informative signs (e.g., restricted access, dress code).[12]

Warning signs, which are clearly visible and clearly state the identified hazards, must be posted in all areas where hazardous drugs are received,[15] stored,[13] prepared[13] and administered.[15]

The sign should contain wording such as:

CAUTION CHEMOTHERAPY
(OR hazardous drugs)
Authorized Personnel Only

C.2.4 Hazardous Drug Clean Room

The hazardous drug clean room is a room in which the atmospheric properties (temperature, level of particles and microorganisms, air pressure, airflow, etc.) are controlled.[12] The hazardous drug clean room houses the containment primary engineering control (e.g., biological safety cabinet) that is used for the preparation of hazardous drugs.

Standard:

The hazardous drug clean room must be physically separated from the rest of the pharmacy and from other non-controlled areas, to reduce the risk of introducing viable and non-viable contaminants into the room and the spread of hazardous drug contamination outside the room.[12]

The hazardous drug clean room must maintain an ISO Class 7 environment and be 2.5 Pa negative pressure to the anteroom. The clean room must also maintain at least 30 air changes per hour (ACPH) of HEPA-filtered air.[12]

The return air from the hazardous drug clean room must be exhausted to the exterior of the building.[12]

Return air exhausts should be installed at the bottom of walls, forcing the particles to flow downward.[12]

Standard:

If a refrigerator is placed in the hazardous drug clean room, an air exhaust must be placed behind the refrigerator to remove any particles generated by the unit.[12]

C.2.5 Hazardous Drug Anteroom

The hazardous drug anteroom acts as a transition space between the hazardous drug clean room and other areas of the pharmacy. It helps to maintain the ISO classification and pressure differential in the clean room. An anteroom may be used for storage of supplies and non-hazardous drug and for staging of components as long as these activities do not interfere with maintaining the ISO classification.[12]

The anteroom is divided into a ‘clean’ side (closest to the clean room) and ‘dirty’ side (closest to the other areas in the pharmacy) and is marked with a visible demarcation line on the floor.

Standard:

The anteroom must have doors between the clean room and the anteroom and between the anteroom and the rest of the pharmacy.[12] There must be a process in place that allows only one door leading into the anteroom to be open at one time.[12]

The hazardous drug anteroom must maintain an ISO Class 7 environment and be positive pressure to both the hazardous drug clean room(s) (2.5 Pa [0.01 inch water column]) and the rest of the pharmacy (5 Pa [0.02 inch water column]). The anteroom must maintain at least 30 air changes per hour (ACPH) of HEPA-filtered air.[12]

C.2.6 Other Rooms in the Controlled Area

Within the controlled area, some facility's physical design may include a separate hazardous drug storage room as well as a supply storage room, a set-up room, and a checking room. These rooms may maintain an ISO Class 8 environment. Alternatively, these rooms may be located outside of the controlled area. In this case, the environment does not need maintain any ISO Classification.

C.2.7 Specifications of the Controlled Area

- **Standard: Access to the controlled area must be limited to authorized personnel assigned to work there.[12, 29]**
- **Standard: Doors leading into controlled areas must not be left open.[12, 29]**
- **Standard: A pressure indicator must be installed that can readily monitor room pressurization.[12] A notification system must be installed in each pressure monitor to alert pharmacy staff when pressure differentials deviate from specifications.[12]**
- **Standard: Water sources, sinks, and drains must not be located in a clean room but are permitted in the anteroom.[12]**
- **Standard: Floors, walls, ceilings and all exposed surfaces in the controlled area must be smooth, impervious, non-friable, free from cracks and crevices, nonporous and resistant to damage from cleaning and disinfecting products.[12]**
- **Standard: Cleaning of the ceiling, walls and floor must take place in the clean room at a time when no aseptic operations are in progress.[30]**
- All new rooms in the controlled area should be equipped with floors that do not require waxing as dried worn wax can contribute to airborne particulates. If an existing clean room is equipped with a floor that requires waxing to ensure a nonporous surface, waxing should not take place at a time when aseptic operations are in progress.
- **Standard: Essential furniture in the controlled area must be nonporous, smooth, non-shedding, impermeable, cleanable, and resistant to disinfectants.[12]**
- **Standard: Shelves and supplies must be kept to a minimum in the clean room and anteroom to help limit the number of particulates.[12]**
- **Standard: Each room in the controlled area must be identified with appropriate informative signs (e.g., pictograms identifying the hazard, the need for special care, restricted access, dress code).[12]**
- **Standard: The door opening into the clean room and the door leading to the anteroom must not be opened at the same time in order to maintain pressure differential between the two rooms.[12]**
- Consideration should be given to include public address (PA) speakers in the controlled area rooms to alert workers in the case of an emergency.
- During parenteral admixture preparation, activities that will disrupt airflow in the vicinity of the C-PEC or transport contaminants into or out of the clean room and/or the C-PEC such as and opening and closing nearby doors should be minimized.[29]
- Telephones or hands-free intercoms should be used for communication with the staff in the clean room, to limit the frequency of doors opening and staff entering and leaving.
- **Standard: Appropriate personal protective equipment (PPE) and clean room garb must be donned by all personnel prior to entering the controlled area to minimize the spread of skin particles that may shed.[12]**

- **Standard: Lab coats and isolation gowns must not be worn in the controlled area in place of chemotherapy gowns.[14]**
- **Standard: No shipping box or other external cartons may be taken into the controlled area.[12]**

NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations

Summary of Engineering Control Requirements for Hazardous Drug Sterile Product Preparation and Storage Areas

	ISO Classification	HVAC (Heating, Ventilation and Air Conditioning)					
		Temperature	**Air Changes per Hour (ACPH)**	**Relative pressurization to adjacent area**	**Pressure monitoring device installed and monitored**	**Area exhaust ventilation**	**HEPA filtered supply air**
HD Clean Room	ISO Class 7 (under dynamic conditions)	≤ 20° Celsius	≥ 30 ACPH	**Negative**[12] (not less than 2.5 Pa [equivalent to 0.01-inch water column] negative pressure to adjacent anteroom)	Required	Required	Required
Anteroom (adjacent to HD clean room)	ISO Class 7 (under dynamic conditions)		≥ 30 ACPH	**Positive**[12] (not less than 2.5 Pa [equivalent to 0.01-inch water column] positive pressure to adjacent clean room; not less than 5.0 Pa [equivalent to 0.02 inch water column] positive pressure to the rest of the pharmacy)	Required (between anteroom and the rest of the pharmacy)		Required
HD Storage Room		≤ 30° Celsius	≥ 12 ACPH	**Negative**[12] (not less than 2.5 Pa [equivalent to 0.01-inch water column] negative pressure to adjacent area	Required	Required	

C.3 Equipment and Furniture

Standard:

All equipment and furniture brought into the controlled area must first be cleaned using a germicidal disinfectant detergent and then disinfected using sterile 70% isopropyl alcohol or a sporicidal before being placed into the controlled area. Equipment removed from corrugated cardboard must be

disinfected using a sporicidal, rather than sterile 70% isopropyl alcohol. Equipment must be re-disinfected using sterile 70% isopropyl alcohol before being brought into the clean room.[12]

Any equipment removed from the controlled area must be decontaminated first.[12]

C.3.1 Containment Primary Engineering Control

A Containment Primary Engineering Control (C-PEC) is a ventilated containment cabinet that may aid in the protection of the:[12]

- operator
- sterile admixture
- environment

It is imperative that during training, staff are told and understand that the C-PEC does not prevent the generation of hazardous drug contamination within the cabinet and that the effectiveness of containing HD contamination within the cabinet depends on the operator's use and proper technique.[15, 21]

A biological safety cabinet is a type of C-PEC that has an open front for access to the critical area (direct compounding area).

Standard:

WorkSafe BC Occupational Health and Safety (OH&S) Regulation 6.53(1) states:

"All mixing, preparation and priming of administration sets with a cytotoxic (hazardous) drug must be performed in one centralized area in a specially designated Class II Type B biological safety cabinet that:

- ***is exhausted to the outside atmosphere in a manner that prevents recirculation into any work area;***
- ***has exhaust and ventilation systems that remain in operation for a sufficient period of time to ensure that no contaminants escape from the biological safety cabinet into the workplace; and***
- ***is equipped with a continuous monitoring device to permit confirmation of adequate airflow and cabinet performance".***

An appropriate C-PEC should be selected based on the type of protection needed and the activity being performed.

C.3.1.1 Class I BSC

The Class I BSC provides personnel and environmental protection only. It does not provide an ISO Class 5 environment to protect the product from microbial contamination because unfiltered room air continually enters the cabinet front to flow across the work surface. Personnel protection is made possible by constant movement of air into the cabinet away from the worker. HEPA filtered air from the cabinet is re-circulated into the room or exhausted to the outside environment.

Standard:

Class I BSCs are used when there is a need for containment, but not aseptic product protection and therefore must not be used for sterile hazardous drug preparation.[15, 31] **A minimum Class I BSC that is located in a negative pressure room with at least 12 air changes per hour, and that fully exhausts to the outside environment must be used for manipulation of non-sterile hazardous drugs.**[14]

A BSC is not required when handling (e.g., counting or repackaging) final dosage forms of non-sterile hazardous drugs that do not produce particles, aerosols, or gases.[14]

C.3.1.2 Class II BSC

The Class II (types A1, A2, B1 and B2) BSCs provide personnel, product and/or environmental protection. The Class II BSC is classified according to the venting of exhaust air and has three key features:

- A front access opening with inward airflow
- HEPA-filtered, vertical unidirectional airflow within the work area

- HEPA-filtered air exhausted back into the room, back over the work surface, or out through a facility exhaust system

Class II Type A (A1 and A2) cabinets re-circulate 70% of HEPA filtered air down towards the work surface within the BSC and exhaust 30% of HEPA filtered air back into the room or out to a facility exhaust system. There is a possibility that the filtered air is contaminated with hazardous drug vapours when it is expelled back into the room.

Standard:

Because there is a possibility that HEPA-filtered air recirculated back into the clean room may be contaminated with hazardous drug, Class II Type A cabinets must not be used during preparation of hazardous drugs.[13]

Class II Type B (B1 and B2) cabinets do not exhaust filtered air into the room.

Standard:

A minimum Class II Type B BSC that is exhausted to the outside atmosphere with no recirculation into any work area must be used for the preparation of sterile hazardous drugs.[13]

C.3.1.2.a Class II Type B1 BSC

A Class II Type B1 cabinet draws room air in through the front intake grill where it is HEPA-filtered. The air is then drawn to the top of the cabinet; HEPA filtered a second time, and directed towards the work surface. From there it is drawn through the front intake and rear exhaust grills, filtered through a HEPA filter and re-circulated to the work area or exhausted to a facility's external exhaust system through another HEPA filter.

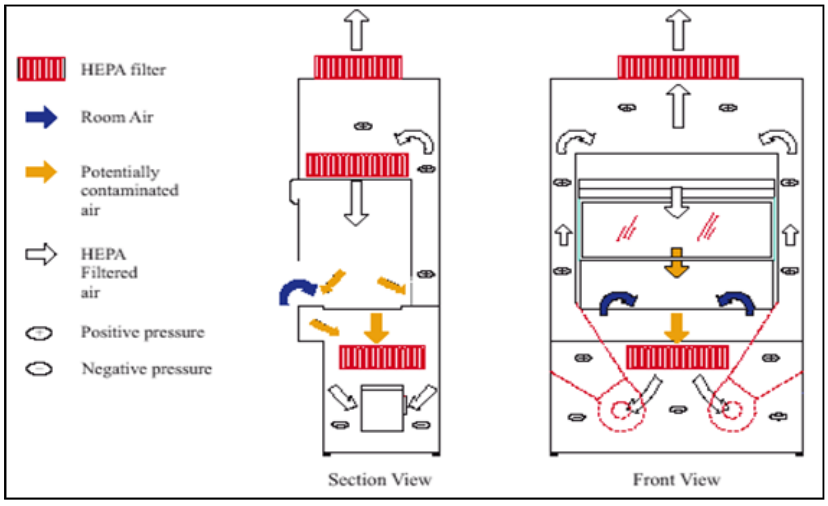
The major route for "used" air (60-70%), which may be contaminated with hazardous drug particles, to exit the work surface of the BSC is via the rear exhaust grill. This "contaminated" air is HEPA-filtered below the work surface and trough to remove drug particles and is then expelled from the top of the BSC through a second HEPA filter into an outside duct away from any air intake locations. This prevents recirculation into the room.

A portion (30-40%) of potentially contaminated air is drawn through the front intake grill. It combines with air that flows in from the room. This combined air is HEPA filtered below the work surface and then recycled through a second HEPA filter before it re-circulates to the work surface.

The combined air that flows from the room and from the BSC interior into the front intake grill produces a protective "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 protective "air curtain".[22, 32]

Due to the potential for HD contamination of the cabinet during the hazardous drug preparation process, it is preferable to choose a BSC that does not re-circulate air to the work surface (e.g., Class II B2).[33]

Airflow in a Class II Type B1 Biological Safety Cabinet (BSC)[34]



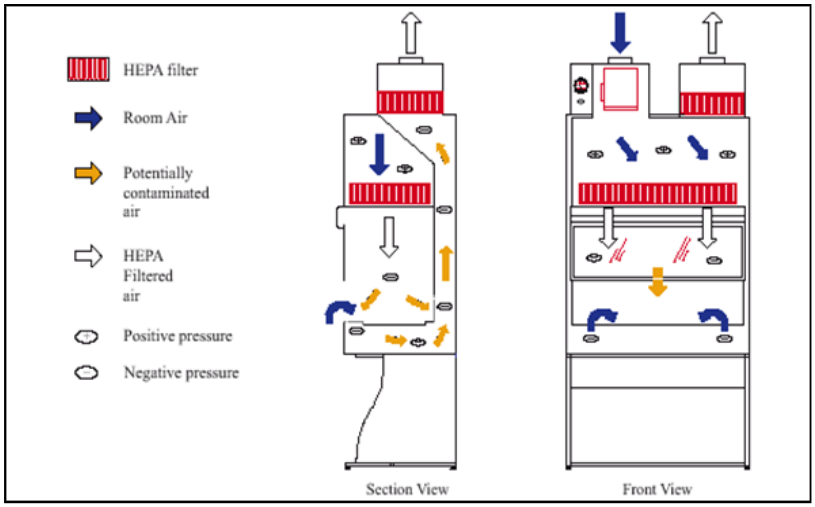
C.3.1.2.b Class II Type B2 BSC

A Class II Type B2 cabinet is a total exhaust cabinet. All potentially contaminated air from the BSC's work area is expelled directly to the facility's external exhaust system. Filtered air is not re-circulated to the work area inside the cabinet or into the room. Room air enters through the top of the cabinet and passes through a HEPA filter before it flows vertically towards the work surface. Just before the air meets the work surface, the now potentially contaminated air splits and is drawn towards the front and rear exhaust grills. Simultaneously, room air enters through the front opening and is pulled down through the front grill. The HEPA filtered air that flows vertically to the work surface along with air that is drawn in from the room through the front intake grill produces a protective "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 protective "air curtain".[22, 32] 100% of this air is filtered then drawn out to an exhaust vent and HEPA filtered a second time before exhausting to the facility's external exhaust system.

Where feasible, a total exhaust cabinet is preferred due to the increasingly complex nature of the chemotherapy preparations, the potential for vapourization and the possible aerosolization of hazardous drug products. Feasibility would be dependent on the ability to provide a location that supports the operating specifications of these cabinets.

It is recommended that cabinets with 100% exhausted and 0% recycled air be purchased for any new facilities, or when replacing existing cabinets.

Airflow in a Class II Type B2 Biological Safety Cabinet (BSC)[34]



C.3.1.3 HEPA Filter

A HEPA filter is a High Efficiency Particulate Air filter that traps approximately 99.9% of particulate matter 0.3 microns in size or greater to provide ultra-clean air.[22, 28] Airborne contamination control is achieved in the C-PECs through the use of HEPA filters. HEPA filters are effective at trapping particulates but do not capture volatile drugs or vapours.[28] HEPA-filtered air is not considered sterile; however, the presence of microorganisms in the filtered air stream is very unlikely. Contamination of a sterile product is most likely due to the introduction of foreign material (e.g., bacteria, particles) from supplies placed into the C-PEC and/or from the hands or arms of the operator. In addition to compromising the sterility of the drug, particulate matter may act as a carrier for hazardous drug particles or aerosols.[22]

Standard:

HEPA filters must be present in C-PECs used for the preparation of hazardous drug sterile preparations. Air that flows towards the work surface inside the cabinet and air that is expelled out to the environment must first pass through at least one HEPA filter.[13]

C.3.1.4 Airflow

Standard:

HEPA-filtered air inside the C-PEC must be supplied at a velocity sufficient to sweep particles away from the critical area and maintain unidirectional airflow during compounding.[33]

HEPA filtered air flows through the critical area (direct compounding area) from the top of the cabinet towards the work surface. As it descends, the air 'splits' with some air being drawn through the front intake grill and some through the rear exhaust grill.[35]

The unidirectional top to bottom flow of HEPA-filtered air in a C-PEC has a number of functions:[22]

- sweeps particles away from the compounding area
- filters out contaminants before releasing used air into the environment via ducts that open to the outside of the building
- keeps contaminated air inside the cabinet to protect the operator and nearby staff

Standard:

Manipulations must be performed in the critical area (direct compounding area), at least six inches in from the side walls and the front opening of a biological safety cabinet (BSC)[29] (behind the air 'split').[35] Contaminated air must be able to escape via the rear grill, not via the front opening.[31]

In order for the BSC to help protect the operator, paths of airflow must remain clear.[36]

It is important to avoid:[22, 28]

- overloading the BSC[16]
- crowding the BSC work space[21]
- rapid movements inside, or near the front opening of the BSC[16]
- unnecessary movements in and out of the front opening of the BSC
- activities that disturb or block the airflow inside the BSC

Note:

- In horizontal laminar airflow hoods, clean air flows from back to front, sweeping particles and organisms away from the drug but directly towards the operator.
- **Standard: Horizontal laminar airflow hoods must not be used for the preparation of hazardous drugs[14]**

C.3.1.5 Ultraviolet Lights

Most C-PECs have a built in ultraviolet (UV) light. The UV light is intended to destroy microorganisms in the air or on exposed surfaces when the blower is turned off. When the cabinet runs continuously, the UV light is not necessary.

Standard:

The ultraviolet light may cause eye damage and must not be turned on when personnel are working in or near the C-PEC, or in the clean room.[28, 37]

C.3.1.6 Viewing Window

Standard:

The viewing window must be kept at the manufacturers' recommended height when placing drug and supplies into the BSC and during hazardous drug preparation.[28, 37]

Each individual owner's manual should be consulted for recommended BSC viewing window height (normally eight to ten inches).

- If the viewing window height is above the manufacturer's recommended level, it could cause intake air velocity to drop too low for proper staff protection

- If the viewing window height is below the manufacturer's recommended level, it could cause intake air velocity to increase and allow unfiltered air to cross over the work surface and contaminate the product

C.3.1.7 Location

Standard:

A biological safety cabinet used for hazardous drug compounding must be located away from doorways, traffic corridors, and air conditioning and heating vents.[12, 37] To help ensure the safest preparation for the patient, best practice is to place the biological safety cabinet inside a restricted access ISO Class 7 clean room that is adjacent to an ISO Class 7 anteroom.[12]

If compounded sterile preparations are prepared in a C-PEC that is not placed in an ISO Class 7 clean room that is adjacent to an ISO Class 7 anteroom, the following conditions must be met:[12]

- The segregated area has walls to separate the room from other areas.
- The C-PEC is certified every 6 months and maintains ISO Class 5 air quality or better.
- The room maintains negative pressure of at least -2.5 Pa relative to adjacent spaces.
- Only low- or medium-risk preparations are compounded.
- Only one preparation is compounded at a time.
- The preparations are compounded in an area that is reserved for the compounding of sterile preparations that minimizes contamination.
- The sink is at least 1 metre away from the C-PEC.
- The preparation area has no unsealed windows or doors leading to the exterior of the building. Furthermore, the preparation area is not in a high-traffic area or adjacent to construction sites, warehouses or food preparation sites.
- Personnel are fully compliant with procedures for hand and forearm hygiene, asepsis, garbing, and cleaning and disinfecting.

C.3.1.8 Monitoring

Standard:

The C-PEC used for hazardous drug sterile compounding must be operated continuously with the blower turned on 24 hours a day, seven days a week[14, 29] **unless being serviced.**[29] **It must be equipped with a continuous monitoring device to allow confirmation of adequate airflow and cabinet performance.**[13]

Lights and gauges located on the front control panel above the viewing window of the C-PEC should be monitored. Staff working in and around the C-PEC should be informed of what the values on the gauges should read for a properly functioning cabinet. Most C-PECs have lights that indicate whether the blower, the internal fluorescent/UV lights and the internal outlet are turned on. As well, there are gauges to indicate airflow and exhaust readings. The values shown on the downflow and exhaust airflow gauges should be monitored on a regular basis. Large fluctuations in values on the gauges can be indicative of a malfunctioning system and must be evaluated immediately.

Some Class II Type B BSCs must have a remote or plant air exhaust system for proper operation. These systems are internally interlocked so that the internal blower will not start unless the exhaust flow is within 10% of the required airflow. Should the airflow fall below the 10% limit during operation, the cabinet initiates an audible alarm and visual error messages, de-energizing the internal blower.[38]

Standard:

For the safety of the patient and the operator, hazardous drug compounding must not take place when a C-PEC alarm is sounding or the lights and/or gauges indicate the cabinet is not functioning within the manufacturer's specifications.[37]

Site specific procedures must be created and posted for workers so that when the gauges, lights or alarms indicate that the C-PEC is not working properly or there is a power interruption, the safety of staff, the environment and the aseptic condition of the product (if possible) will be maintained.[16]

Note:

- Most C-PECs are wired to the facility's back-up generator, so a long term power shutdown would only occur when the cabinet is unplugged, or as the result of a catastrophic event.

C.3.1.9 Testing and Certifying Biological Safety Cabinets

Biological safety cabinets are essential components of the overall contamination control strategy for aseptic compounding. As such, it is imperative that they perform as designed.[33]

Standard:

Testing and certifying the biological safety cabinet must be completed by a qualified person (e.g., a person who has been accredited by the National Sanitation Foundation [NSF] to perform testing of biological safety cabinets) when installed.[39] Certification procedures used must meet the requirements of the NSF Standard 49- Biosafety Cabinetry: Design, Construction, Performance, and Field Certification (current version).[12, 39] The BSC must be re-certified every six months[12] and when the cabinet is altered or repaired or the HEPA filter is changed.[12, 37, 39] Testing and certifying the biological safety cabinet must occur during dynamic operating conditions.[12]

Prior to servicing a biological safety cabinet, service technicians or maintenance workers must be informed that the BSC may be contaminated with hazardous drugs.[4] Appropriate personal protective equipment and clean room garb must be worn when testing, certifying or servicing the BSC.[4, 12]

After field certification, the BSC must have certification information posted on the front of the cabinet housing in a readily visible location.[12, 39]

Before testing, servicing, and certifying of the BSC, all interior surfaces (including under the work surface) must be decontaminated, cleaned, and disinfected.[12]

C.3.1.10 Replacing HEPA Filters

HEPA filters will require replacement when they become loaded to the extent that sufficient airflow can no longer be maintained or if they are overtly contaminated by a breach in technique that causes hazardous drug to be introduced onto the clean side of the supply HEPA filter.[32]

Standard:

Only NSF certified technicians informed of the hazardous nature of the admixtures prepared in the biological safety cabinet shall replace HEPA and charcoal (if present) filters.[4]

Before replacement of a HEPA filter contaminated with hazardous drug occurs, the NSF technician and the pharmacy department should arrange a mutually acceptable procedure and time for replacing and subsequently disposing of a contaminated HEPA filter.[32]

Standard:

Appropriate personal protective equipment must be worn when replacing HEPA filters and the contaminated filters must be handled and disposed of as hazardous waste.[15, 21]

C.3.1.11 Turning off a Containment Primary Engineering Control (C-PEC)

Standard:

If it is necessary to turn off a C-PEC for testing and certifying or for maintenance, all surfaces inside the cabinet including under the work surface must be decontaminated, cleaned, and disinfected first.[12] If the decontaminating agent chosen contains a germicidal disinfectant detergent, then interior surfaces of the C-PEC may be decontaminated and cleaned in one step.

Pharmacy staff are responsible for decontaminating the C-PEC prior to shutting it down for repair or servicing. Once the C-PEC is decontaminated, the internal blower and the external exhaust fan may be turned off.

Standard:

If the internal blower and external exhaust fan of a BSC are both turned off, the work-access opening and the HEPA exhaust area must be covered with impermeable plastic and sealed with tape to prevent any remaining hazardous drug contamination from inadvertently escaping from the BSC until maintenance work begins. The BSC must be sealed with plastic whenever it is moved or left inoperative for a period of time.[35]

Refer to Checklists- Module 1 - Appendix 1: Weekly Decontamination of the Biological Safety Cabinet

C.3.2 Communication System

A communication system (intercom, telephone or other) should be installed to allow verbal communication between staff working in different rooms in the controlled area. These devices should be used in 'hands-free' mode, must be easy to clean and disinfect and must be resistant to damage from cleaning and disinfecting products. Personal electronic devices or accessories (e.g., cell phone, iPod, earbuds) are not permitted in the controlled area.[12]

Standard:

Verbal communication between staff in the clean room and the anteroom or between staff in the clean room and the general pharmacy must not be through open doors or pass-throughs to minimize the chance of introducing viable and non-viable contaminants into the rooms and the spread of hazardous drug contamination outside the rooms.[12]

C.3.3 Carts

Carts should be made of stainless steel, be smooth, non-friable, non-porous and resistant to damage from cleaning and disinfecting products, and should have easy-to-clean casters.[12]

If carts are used to transfer supplies into the clean room from the anteroom, one cart should be reserved for the "dirty" area of the anteroom. A second cart, dedicated to the 'clean' area of the anteroom may enter the clean room.[12]

Carts used to bring supplies into the anteroom from outside the controlled area should not cross over to the clean side of the demarcation line. Supplies are disinfected as they are being transferred onto the clean room cart. Likewise, carts taken into the anteroom from the clean room should not be moved past the clean side of the demarcation line.[12]

In facilities where the anteroom is too small to hold two carts, a cart may pass over the demarcation line in the anteroom into the clean room only after the entire cart including casters has been cleaned and disinfected.[33]

C.3.4 Chairs

Standard:

Chairs used in the controlled area must be made of smooth, non-friable, non-porous, washable materials that are resistant to damage from cleaning and disinfecting products.[12]

C.4 Decontaminating, Cleaning, Deactivating, and Disinfecting Surfaces in the Controlled Area

Decontaminating, cleaning, deactivating, and disinfecting should be conducted from the "cleanest" area to the "dirtiest" area and should also move in a direction that minimizes the spread of hazardous drug contamination. Use of an alternative disinfectant in the rotation is unnecessary. However, the daily use of a germicidal disinfectant should be augmented with monthly use of a sporicidal agent.[12]

Solutions used in the controlled area should be low-residue and low-foaming.

Standard:

Housekeeping activities must not take place in the clean room[14] or anteroom when compounding is occurring.

A germicidal disinfectant detergent must be used when cleaning surfaces and equipment in the controlled area.[12] A germicidal disinfectant detergent may be used to both clean and then disinfect surfaces. Sterile 70% isopropyl alcohol must be used to disinfect items just prior to placement into the clean room.[12] Sterile 70% alcohol must be used for disinfecting items just prior to placement into the C-PEC and for disinfecting surfaces of the C-PEC following decontamination or cleaning.[12]

Daily, weekly, and monthly decontaminating, cleaning, deactivating, and disinfecting procedures in the controlled area must be performed per Tables 2 to 4 (at a minimum).[12]

Note:

- If the decontaminating agent chosen contains a germicidal disinfectant detergent, then interior surfaces of the C-PEC may be decontaminated and then disinfected without the additional cleaning step.

Standard:

The required contact time for the selected agents used must be adhered to[12] (e.g., germicidal disinfectant detergents require a contact time ranging from 30 seconds to a few minutes; sporicidals require a contact time ranging from 3 to 10+ minutes).

Table 2: Daily Decontaminating, Cleaning, Disinfecting, and Sporicidal Use

Daily	Decontaminate / Deactivate	Clean	Sporicidal	Disinfect
Counter(s) and other horizontal surfaces	✓	✓	✓ (monthly)	✓
Set-up trays on days they are used	✓	✓		✓
All carts (e.g., transfer carts, carts beside the C-PEC used by compounding staff, etc.) that are not used for storage of bulk supplies and drugs	✓	✓		✓
The pass-throughs, inside and outside, including windows, walls and shelves	✓	✓	✓ (monthly)	✓
At the beginning of the day: interior surfaces of the C-PEC (above the work tray) on days the C-PEC is used		✓		✓
At the end of the day: interior surfaces of the C-PEC (above the work tray) on days the C-PEC is used	✓	✓		✓
Surfaces that are touched frequently (doorknobs; switches; armrest, back, and seat of chairs; communication system etc.)	✓	✓		✓
Floors	✓	✓	✓ (monthly)	✓
Sinks		✓	✓ (monthly)	✓

Standard:

Remove hazardous waste from controlled areas daily[12]

- **Tie the bag and/or seal the container before removing**
- **Do not compress contents as it may generate airborne HD particles**
- **Do not store new garbage bags in the bottom of the HD waste container**

Table 3: Weekly Decontaminating, Cleaning, Disinfecting, and Sporicidal Use

Weekly	Decontaminate / Deactivate	Clean	Sporicidal	Disinfect
All the items listed in the "Daily" section plus:				
Interior surfaces of the Containment Primary Engineering Control, including under the work surface	✓	✓	✓	✓

Table 4: Monthly Decontaminating, Cleaning, Disinfecting, and Sporicidal Use

Monthly	Decontaminate / Deactivate	Clean	*Sporicidal	**Disinfect
All the items listed in the "Daily" and "Weekly" sections plus:				
Interior refrigerator surfaces including shelves	✓	✓	✓	✓
All storage bins (e.g., hazardous drug and supply bins, etc.)	✓	✓	✓	✓
Storage shelves	✓	✓	✓	✓
Supply carts	✓	✓	✓	✓
Walls, door, and door frames[12]		✓	✓	✓
Ceilings		✓	✓	✓
Chairs, including base and castors	✓	✓	✓	✓
Exterior surfaces of the Containment Primary Engineering Control		✓	✓	✓
Any additional equipment not otherwise listed	✓	✓	✓	✓

*use of a sporicidal is recommended by NAPRA but not required.

**if a sporicidal is not used, an alternative disinfectant must be used.

Standard:

All decontaminating, cleaning, and disinfection activities must be recorded and retained in a general maintenance log.[12]

C.4.1 Decontaminating, Cleaning, and Disinfecting Interior Surfaces of the Containment Primary Engineering Control (C-PEC)

Decontamination is the physical removal of hazardous drug from a fixed surface to a disposable surface or the chemical inactivation of hazardous drug from a surface.[21] BC Cancer recommends physical removal because there is no known single non-toxic product available that will deactivate all hazardous drugs. Physical removal is achieved by wiping fixed surfaces using disposable wipes moistened with a decontaminating agent. This is followed by disinfection using sterile 70% isopropyl alcohol. Alcohol alone will not deactivate or remove hazardous drug from a surface and may result in the spreading of HD contamination.[21]

Routine decontaminating, cleaning, and disinfecting C-PEC surfaces is necessary to maintain an environment as free from contamination as possible and to reduce the potential health risks associated with exposure of healthcare workers preparing and handling hazardous drugs.

Standard:

To maintain an aseptic environment and to protect against possible contact with hazardous drug particles, interior surfaces of the C-PEC must be decontaminated, cleaned, and disinfected using a decontaminating agent, a germicidal disinfectant detergent, and sterile 70% isopropyl alcohol.[12]

If the decontaminating agent chosen contains a germicidal disinfectant detergent, then interior surfaces of the C-PEC may be decontaminated and disinfected without the additional cleaning step.

Standard:

Prior to decontaminating and cleaning a C-PEC, proper hand hygiene procedures must be followed and full personal protective equipment (PPE) must be donned.[12]

When cleaning, decontaminating, and disinfecting interior surfaces of the C-PEC (with or without raising the viewing window), additional PPE is required, including a NIOSH-approved elastomeric half face mask respirator (not a N95 respirator), a face-shield, and safety goggles or an elastomeric full face mask respirator. The respirator must be used with an appropriate filter cartridge and be fit-tested for the operator.[12] The compounder's head and upper body must remain outside of the C-PEC at all times; a cleaning tool may be used extend reach if necessary.[12]

To protect others from potential exposure to hazardous drugs, pharmacy staff who must be present in the clean room or in the area of the C-PEC must also wear a NIOSH-approved elastomeric half face mask respirator (with an appropriate filter cartridge) fit-tested for the operator (not a N95 respirator) in addition to all other PPE. If there is a risk of splash, other pharmacy staff must also wear safety goggles and a face shield or an elastomeric full face mask respirator.[12]

When decontaminating, cleaning or disinfecting interior surfaces of the C-PEC protective airflow into the cabinet is interrupted, so there is a chance that HD particles may be expelled. Also, the presence of others in the room while the C-PEC is being decontaminated and cleaned with the viewing window raised may increase the number of particles available to be drawn into and contaminate the interior of the C-PEC. To ensure others are aware, a sign on the outside of the door to the clean room must be hung indicating "DO NOT ENTER – Cleaning/Decontaminating the BSC / C-PEC".

See Personal Protective Equipment (PPE) and Clean Room Garb in Section D.2
See Hand Hygiene in Section D.3

C.4.2 Decontaminating, Cleaning, and Disinfecting the Work Surface of the Containment Primary Engineering Control (C-PEC)

The work surface of the C-PEC must be decontaminated, cleaned, and disinfected throughout the day; otherwise it will become the most contaminated area of the cabinet as hazardous drug admixtures are prepared.

Standard:

The work surface of the C-PEC must be decontaminated, cleaned, and disinfected using a decontaminating agent, a germicidal disinfectant detergent, and sterile 70% isopropyl alcohol:[12]

- **after completing each preparation**
- **before leaving the C-PEC for an extended period of time (e.g., for a break)**
- **upon returning to the C-PEC after an extended period of time**
- **after a minor spill involving the working surface**

Alcohol must be allowed to dry before beginning the next sterile preparation.[33]

If the decontaminating agent chosen contains a germicidal disinfectant detergent, then interior surfaces of the C-PEC may be decontaminated and then disinfected without the additional cleaning step.

C.4.3 Daily Decontaminating, Cleaning, and Disinfecting Interior Surfaces of the Containment Primary Engineering Control (C-PEC)

Standard:

Prior to commencing daily compounding, all interior surfaces of the C-PEC (except under the work surface) must be cleaned and disinfected using a germicidal disinfectant detergent followed by sterile 70% isopropyl alcohol.[12] If the viewing window has been raised during cleaning and disinfecting, it must be lowered to the manufacturers recommended operating level. The C-PEC must purge for at least fifteen minutes[16] afterwards unless otherwise recommended by the manufacturer.

Following hazardous drug compounding, the C-PEC must purge for at least five minutes[37] and then all interior surfaces (except under the work surface) must be decontaminated, cleaned, and disinfected using a decontaminating agent, a germicidal disinfectant detergent, and sterile 70% isopropyl alcohol:[12, 40]

- **after preparations within the C-PEC are completed for the day[29]**
- **prior to compounding 'latex-free' preparations[29]**
- **prior to compounding sterile HD preparations in a C-PEC once it has been used to compound non-sterile HD preparations[29]**
- **prior to resuming compounding in a C-PEC that is turned off between aseptic processes for any reason (e.g., power interruption, maintenance)[29]**

After testing, servicing, and certification of the C-PEC, all interior surfaces (except under the work surface) must be decontaminated, cleaned, and disinfected using a decontaminating agent, a germicidal disinfectant detergent, and sterile 70% isopropyl alcohol.[12, 40]

If the decontaminating agent chosen contains a germicidal disinfectant detergent, then interior surfaces of the C-PEC may be decontaminated and then disinfected without the additional cleaning step.

Note:

- Do not use 70% isopropyl alcohol on the viewing window if it is made of plastic (e.g., Plexiglas®) as this may cause permanent fogging. A low-lint wipe moistened with sterile water for irrigation may be used following use of a germicidal disinfectant detergent to remove residue or streaking[15]

Refer to Checklists- Module 1 - Appendix 1: Daily Decontamination of Interior Surfaces of the Biological Safety Cabinet

C.4.4 Weekly Decontaminating and Cleaning of all Interior Surfaces of the Containment Primary Engineering Control (C-PEC)

Standard:

Decontaminating, cleaning, and disinfecting of all surfaces inside the C-PEC including under the work surface, must occur once a week, after a HD spill in the C-PEC, and before maintenance, servicing, or certification of the C-PEC.[16] Disinfection of the C-PEC must be augmented with weekly use of a sporicidal agent.[41]

If hazardous drug compounding has taken place on the day weekly decontamination is scheduled, the C-PEC must purge for at least five minutes prior to decontaminating.[37]

To decontaminate, clean, and disinfect the C-PEC, use the following agents in the order listed:[40]

1. Decontaminating agent
2. Germicidal disinfectant detergent
3. Sporicidal (once weekly) (surface must remain wet for the required contact time in order for the sporicidal to be effective)
4. Sterile 70% isopropyl alcohol

If the decontaminating agent chosen contains a germicidal disinfectant detergent, then interior surfaces of the C-PEC may be decontaminated and then disinfected without the additional cleaning step.

Removable parts of the C-PEC are decontaminated within the cabinet and shall not be removed. When wiping the surfaces below the work surface in a C-PEC, staff must have a firm hold of all cleaning materials so that they are not drawn up the back of the C-PEC by the airflow causing damage to the HEPA filters.

Standard:

After decontamination and cleaning is complete, the viewing window is lowered to the manufacturers recommended operating level and the C-PEC must purge for at least thirty minutes (unless otherwise recommended by the manufacturer) prior to sterile compounding.[15]

See Personal Protective Equipment (PPE) and Clean Room Garb in Section D.2
See Hand Hygiene in Section D.3
Refer to Checklists- Module 1 - Appendix 1: Weekly Decontamination of the Biological Safety Cabinet

C.5 Movement of Supplies and Equipment into and Through the Controlled Area

Approximately 60% of packaging is contaminated with bacteria and 40% with bacterial spores. A standardized procedure for moving supplies and equipment through the controlled area contributes to a cleaner and safer environment for compounding sterile preparations.[42]

Standard:

When packaging integrity will not be compromised, supplies brought into in the controlled area must be disinfected using a sporicidal agent.[12] When packaging integrity will be compromised, supplies brought into the controlled area must be placed into zip lock bags prior to storage.[43]

Immediately before supplies are brought into the clean room and again before being placed into the C-PEC (if applicable), they must be (re-)disinfected using sterile 70% isopropyl alcohol.[12]

Before any furniture or equipment is used in the controlled area, it must be disinfected using a germicidal disinfectant detergent or a sporicidal agent. Immediately before furniture and equipment are brought into the clean room and again before being placed into the C-PEC (if applicable), they must be re-disinfected using sterile 70% isopropyl alcohol.[12]

Staff must wear at least one pair of gloves when disinfecting items (two pairs in the controlled area).[44] Disinfecting items must not compromise package integrity.[12]

When a germicidal disinfectant detergent or sporicidal agent is used, the packaging must remain wet for the minimum dwell time specified by the manufacturer. When sterile 70% isopropyl alcohol is used, it must be allowed to dry.[12]

The wiping procedure must not render the label or other pertinent information unreadable. The wipes must be changed regularly so the items remain wet for the required minimum dwell time.[12]

Cardboard has been found to harbour bacterial and mould spores.

Standard:

No shipping carton(s) or cardboard are permitted in the controlled area.[12]

Exceptions:

- Drug vials may remain in their manufacturer-supplied boxes for transport to, and storage in, the controlled area (e.g., HD storage room [hazardous drugs] and set-up/staging room [non-hazardous drugs]).
  - Boxes may be required by the manufacturer in the event that the drug will be returned to the manufacturer for credit.
  - Boxes provide an additional level of hazardous drug spill protection by limiting the spread of a hazardous drug spill.
- If a damaged hazardous drug shipping container needs to be opened to retrieve undamaged items, this must be done in a C-PEC.[12]

Refer to Supplemental Resources: Movement of Supplies and Equipment Into and Through the Pharmacy Controlled Area Procedure

Section D - Protective Measures

D.1 General

People generate approximately 100,000 particles per minute while sitting, 250,000 particles per minute while standing, and 5 million particles per minute while walking. Skin, hair, nails, cosmetics, and/or clothing may be sources of particulate contamination.[33] During manipulation, intravenous admixture products may be exposed to viable (e.g., carry bacteria) and non-viable particles.

Pharmacy staff handles hazardous drugs while receiving, storing, preparing, dispensing and disposing of oral, parenteral and topical dosage forms when involved in the delivery of cancer care. The work environment may become contaminated with hazardous drugs when they are handled.

Standard:

Staff must follow all established procedures to minimize the release of particles into the aseptic preparation environment leading to possible contamination of the final product(s) and to decrease the possibility of occupational exposure to hazardous drugs.[16, 33]

There must be policies and procedures that address the safe and aseptic handling of hazardous drugs. There must be strict adherence to safe handling policies and procedures.[12]

It is important to recognize that exposure requires direct contact with the drug particles, vapours or droplets. This is why most of the protective measures involve maintaining some form of barrier between the worker and the hazardous drug.[22]

Contact with hazardous drugs including drug contamination on vial surfaces, receipt of broken vials, compounding and administration, handling waste, and disposing of contaminated materials may cause hazardous drug contamination of the work environment, which may lead to exposure of workers.

The possible routes of hazardous drug (HD) exposure to avoid are:[13, 22]

- direct skin contact or puncture[32]
- inhalation of HD powders, sprayed droplets, aerosols,[32, 45] or vapours
- swallowing (ingestion) of HD powders or aerosols
- oral exposure from surface contact (hand to mouth)[32]

Activities which increase the potential for exposure to HD due to splattering, spraying, aerosolization, or skin puncture include but are not limited to:[13]

- withdrawing devices including needles from HD vials
- transferring HD from one container to another
- recapping HD needles (unsafely)
- breaking open glass HD ampoules

Activities to avoid due to the possibility of splattering, spraying, aerosolization, skin puncture, or ingestion include but are not limited to:

- expelling air from a syringe used for HD into the C-PEC environment, contaminating the air
- expelling any solution from a syringe into a HD waste container
- removing administration lines from infusion bags containing HD
- priming intravenous administration lines with HD solution
- placing gloved hands in or around the mouth or eyes
- eating, drinking, chewing gum, or applying cosmetics in or near areas where hazardous drugs are handled, received, stored, or administered

Despite all precautions, there may be occasions when drugs penetrate a protective barrier. This could include an accidental skin puncture or when a drug container breaks. It is important to follow established procedures for dealing with accidental HD contact and for cleaning up HD spills. Staff should locate and be familiar with these procedures before they are needed to help prevent panic when such an event occurs.[22]

See Personnel Hygiene in the Controlled Area in Section F.1.1

See Accidental Exposure to Hazardous Drugs in Section J

Refer to Checklists- Module 1 - Appendix 1: Personnel Contamination

Refer to BC Cancer Systemic Therapy Policy V-30: Hazardous Drug Spill Management

D.2 Personal Protective Equipment (PPE) and Clean Room Garb

To prevent transfer of hazardous drug particles to the outside environment, to assist in the overall cleanliness of the preparation area, and to minimize exposure to hazardous drugs, healthcare workers should be informed and understand the function, use and limitations of Personal Protective Equipment (PPE) and clean room garb.

Each article of PPE and clean room garb is worn to minimize or prevent one or more of the following:

- workers' exposure to hazardous drugs by providing a physical barrier to extraneous drug particles on surfaces or those generated during the compounding process
- particulate burden within the clean room
- spread of HD contamination to areas outside the HD work environment

Standard:

Personal protective equipment and clean room garb must be provided to minimize or prevent healthcare workers exposure to hazardous drugs.[13] All personnel entering the controlled areas must follow appropriate hand hygiene and garbing procedures.[12]

If disposable PPE and/or clean room garb become contaminated or are suspected of being contaminated with HD, they must be removed and disposed of in a HD waste container[12] or laundered per site-specific policy.[46]

Refer to Checklists- Module 1 - Appendix 1: Donning of Personal Protective Equipment to Enter a Hazardous Drug Clean Room When Not Working in a Biological Safety Cabinet

Refer to Checklists- Module 1 - Appendix 1: Donning of Personal Protective Equipment When Working in a Biological Safety Cabinet

D.2.1 Scrubs

Scrubs made of low-lint cotton or cotton/polyester material reduces the particle burden in the clean room environment[36] and helps to limit the spread of HD contamination.

Standard:

Street clothes must be replaced with fresh scrubs daily by all personnel when the work assignment will take place in the controlled area.[12] Scrubs worn into the controlled area must not have been worn outdoors. Scrub bottoms must fully cover the legs including while seated.[29]

Scrubs must not be worn home to ensure that no HD contamination is transported home and to ensure that the process of cleaning the clothing does not introduce lint onto the low-lint scrubs.[36]

Scrubs should be isolated and placed into a labeled laundry bag if hazardous drug contamination is known or suspected.[46]

Standard:

An isolation gown (enclosed at the neck and tied around the waist) or a buttoned lab coat must be worn over scrubs by staff that *will be* (re-)entering the controlled area.[36]

Scrubs contaminated with hazardous drug (e.g., as a result of a HD spill) must be isolated and placed into a separate laundry bag that is labelled as requiring special handling (e.g., 'Cytotoxic').[46]

D.2.2 Footwear

Pharmacy departments should develop a site specific policy determining appropriate footwear protection required in each work area of the pharmacy, taking into consideration the following risks: hazardous drug exposure, puncture hazards, slipping, tripping, spillage of liquids, and any other recognizable hazard.

Standard:

Each facility must be in compliance with WorkSafe BC regulations to help reduce preventable injuries due to inappropriate footwear.[47]

WorkSafe BC Occupational Health and Safety (OH&S) Regulation 8.22 states:

1. ***"A worker's footwear must be of a design, construction and material appropriate to the protection required and that allows the worker to safely perform the worker's work."***
2. ***"To determine appropriate footwear under subsection (1), the following must be considered: slipping; tripping; uneven terrain; abrasion; ankle protection and foot support; potential for musculoskeletal injury; crushing potential; temperature extremes; corrosive substances; puncture hazards; electrical shock; any other recognizable hazard."***

Personnel entering the controlled area must wear socks that are long enough to reach higher than the bottom of the pant legs at all times, including when seated, as well as closed shoes.[12]

D.2.3 Shoe Covers

Shoe covers help to minimize the spread of particulate contamination from footwear worn into the controlled area. Shoe covers also help to minimize the spread of hazardous drug (HD) particulate contamination from inside the HD clean room to areas outside.[14] The floor in hazardous drug clean rooms has been shown to be contaminated with hazardous drug.[20, 48, 49]

Standard:

At least one pair of disposable shoe covers must be worn in the controlled area.[29] When the controlled area comprises of rooms in addition to the anteroom and clean room, this pair of shoe covers is donned in the gowning room.

Two pairs of disposable shoe covers (or a second pair if already wearing one pair of shoe covers) must be donned when stepping from the dirty side of the demarcation line in the anteroom to the clean side. Two pairs of disposable shoe covers must be worn in the clean room.[12] The outer pair of shoe covers must be removed with gloved hands when stepping out of the hazardous drug clean room to the clean side of the anteroom.[14]

To minimize the spread of hazardous drug contamination to areas outside of the HD clean room, the outer pair of shoe covers is disposed of in a hazardous waste container inside the HD clean room.

Standard:

The inner pair of shoe covers is removed when stepping from the clean side of the demarcation line in the anteroom to the dirty side.[12] In facilities that have incorporated a gowning room in the controlled area, the inner pair of shoe covers is removed in the gowning room, not in the anteroom.[29]

Shoe covers must be disposed of in hazardous waste containers and not saved for reuse.[14]

D.2.4 Hair Covers

Personnel have been found to be a major source of particulate load in the sterile preparation area. Disposable hair covers (and beard covers if necessary) are worn to minimize the release of hair and skin particles into the controlled area.[33]

Standard:

A disposable hair cover (covering hair and ears completely) and beard cover (if necessary to cover facial hair or stubble) must be worn by all personnel working in the controlled area.[12]

The hair cover (and beard cover if necessary) must be donned on the dirty side of the demarcation line in the anteroom.[12] In facilities that have incorporated a gowning room in the controlled area, the hair and beard covers must be donned in the gowning room.[29]

Hair and beard covers must be removed on the dirty side of the demarcation line in the anteroom.[12] In facilities that have incorporated a gowning room in the controlled area, the hair and beard covers are removed in the gowning room, not in the anteroom.[29]

Hair and beard covers must be disposed of in hazardous waste containers after each removal and not saved for reuse. Beard covers must be changed after 3.5 hours of continuous use.[12]

D.2.5 Medical Masks

ASTM International Standard F2100 (*Standard Specification for Performance of Materials Used in Medical Face Masks*) specifies the performance requirements for medical masks (procedure [pictured] and surgical) using five basic criteria: bacterial filtration efficiency, particulate filtration efficiency, fluid resistance, pressure differential, and flame spread. In addition, all medical masks must be tested to ISO Standard 10993-5 for skin sensitivity and to ensure that no materials in the mask are harmful to the wearer. The results of all these tests determine the ASTM Level of Protection.[50]

Medical masks (surgical and procedure) protect the clean room environment from possible contamination by personnel.[33] To properly wear a medical mask, the outer pleats face down; the inner pleats (closer to the mouth) face up; the colored side of the mask faces out. Masks with a flexible nosepiece provide a better fit over the nose.

D.2.5.1 Ensuring proper fit

To make your medical mask fit properly:[51]

- Ensure the mask completely covers nose, mouth and chin.
- Check for gaps between face and mask.
  - Check the top, sides and bottom of the mask.
  - Check the edges of the mask for air leaks and adjust if necessary.
- Improve mask fit so it's snug and has no gaps.
  - Adjust the ties, bands or ear loops.
  - Adjust the nosepiece.

Standard:

Medical masks rated at least Level 1 by ASTM International Standard F2100[25] must be worn by all personnel present in a clean room, including personnel compounding in a PEC and in a C-PEC, unless decontaminating surfaces inside a C-PEC (see Section D.2.6 Respirators).[12, 41]

Medical masks do not provide respiratory protection against hazardous drug exposure and therefore must not be worn when respiratory protection from HD exposure is required.[12]

Medical masks must be donned on the dirty side of the demarcation line in the anteroom and must cover from the bridge of the nose down to below the chin.[36] Masks must not be saved for reuse. Masks must be changed after no more than 3.5 hours of use.[12]

Masks worn in the hazardous drug clean room must be disposed of in a hazardous waste container.[12]

D.2.6 Respirators

A respirator is a personal protective device worn on or over the face that covers at least the nose and mouth. A NIOSH-approved respirator reduces the wearer's risk of inhaling hazardous airborne particles, gases and/or vapours. N95, chemical cartridge, and Powered Air Purifying Respirator (PAPR) are types of NIOSH-approved respirators.

D.2.6.1 N95 Respirator

Disposable N95 respirators protect against inhalation of particles, not gases or vapours. N95 respirators are known as 'air-purifying respirators' because they clean particles out of the air as you breathe.[52]

D.2.6.2 Powered Air Purifying Respirator (PAPR)

A reusable Powered Air Purifying Respirator (PAPR) uses a fan to blow air through a filter to the user. It needs a fully charged battery to work properly. PAPRs require the same filter cartridge protection as chemical cartridge respirators.[52]

The PAPR does not require fit testing. It may be selected for use if the chemical cartridge respirator does not fit, if the employee has facial hair or a facial shape that interferes with the mask-to-face seal, or if chemical cartridge respirators are unavailable.

D.2.6.3 Chemical Cartridge Respirator / Elastomeric Half or Full Face-piece Respirator

Reusable chemical cartridge respirators (half mask or full face-piece) have a silicone, thermoplastic or rubber face-piece that is held against the face by two head straps. Filter cartridges attach onto each side of the face-piece.[53]

During inhalation, a one-way valve opens and allows air to be drawn in through the filter cartridge, where contaminants are removed. These valves close during exhalation preventing breath from contaminating the filter cartridges.[53]

During exhalation, a one-way valve opens, letting the air out. This valve closes during inhalation preventing contaminated air from entering the respirator.[53]

Reusable chemical cartridge respirators protect against inhalation of particles, gases and/or vapours depending on the type of filter cartridge they are worn with. There are filter cartridges that protect against more than one hazard, but there is no 'all-in-one' filter cartridge that protects against all substances.[52] To protect against personal exposure to particles, vapours, and gases from hazardous drugs and decontaminating/cleaning/sporicidal solutions, a minimum P100 filter cartridge approved by NIOSH for use against particles and organic vapours is recommended.

Standard:

A chemical cartridge respirator with an appropriate filter cartridge must be worn when cleaning up HD spills, when decontaminating or cleaning the C-PEC, or when working in a clean room when a C-PEC is being decontaminated or cleaned.[12]

A respirator is not required when unpacking a shipment of undamaged hazardous drug received from the supplier in impervious plastic.[12]

Standard:

A chemical cartridge respirator with an appropriate filter cartridge must be worn if unpacking HD shipments suspected of being damaged.[12]

Staff wearing a respirator that requires an effective seal with the face for proper functioning must be:[47]

- **fit-tested prior to initial use;**
- **retested at least once a year, when there is a change in the respirator face piece, or when a user's physical condition changes affecting the fit; and**
- **clean shaven where the respirator seals with the face.**

A respirator must not be worn over a medical mask.[47]

Other personal protective equipment that is to be worn at the same time as a respirator and which could interfere with the respirator fit must be worn during a fit test.[47]

WorkSafe BC Occupational Health and Safety (OH&S) Regulation 8.41states:

"Before each use of a respirator which requires an effective seal with the face for proper functioning, a worker must perform a positive or negative pressure user seal check in accordance with CSA Standard CAN/CSA-Z94.4-02, Selection, Use, and Care of Respirators."

Respirators worn in the clean room may be removed on the clean side of the demarcation line in the anteroom if **immediately** replaced with a medical mask (e.g., for re-entry into the clean room, or to clean the respirator).

Standard:

Disposable respirators must be disposed of in hazardous waste containers after each removal and not saved for reuse. Disposable respirators must be changed after no more than 3.5 hours of continuous use.[12]

Reusable respirators (including exterior surfaces of the filter cartridge casings) must be cleaned as per the manufacturer's recommendations daily after use. Filter cartridges must be changed per the maximum cumulative use time established by Occupational Health and Safety.[12]

A record of how long each pair of filters have been used should be maintained.

Standard:

Used filters and the cartridge housing they are supplied in must be disposed of in hazardous waste containers when replaced.[12]

Once cleaned and dry, reusable respirators should be stored in a new (clean) zip lock bag for future use. Filters should be removed from the respirator (before being cleaned) and stored in their own separate zip lock bag once dry.

See Receipt of a Damaged Shipment in Section K.1.2

Refer to Supplemental Resources: Elastomeric Half Face Mask Respirator Cleaning and Decontaminating Procedure

Refer to Supplemental Resources: Elastomeric Half Face Mask Respirator Donning and Doffing Procedure

D.2.7 Chemotherapy Gowns

Chemotherapy gowns help to minimize the risk of occupational exposure to hazardous drugs by providing a physical barrier to extraneous drug particles generated during the compounding process.[14]

Standard:

To decrease particulate levels in the preparation area and to decrease the risk of direct skin contact with hazardous drugs, compounding and cleaning personnel must wear a non-linting, impermeable, disposable chemotherapy gown with long sleeves and fitted cuffs, enclosed at the neck, closing at the back (no open front), and tied around the waist.[12] Chemotherapy gowns must be worn for all activities that may result in the worker's direct exposure to hazardous drugs.[12]

Chemotherapy gowns worn when mixing hazardous drugs in the C-PEC must be removed for disposal while still in the clean room to help prevent the spread of hazardous drug contamination to areas outside of the clean room.[13]

The chemotherapy gown is removed and disposed of into a hazardous waste container at the door leading out of the clean room immediately before stepping into the anteroom.

Standard:

Personnel leaving the hazardous drug clean room to work in another room in the controlled area (e.g., anteroom, set-up room) or leaving the controlled area through a set-up and/or gowning room must wear an isolation gown.[29]

A chemotherapy gown must be worn if unpacking a suspected damaged hazardous shipment or cleaning up a hazardous drug spill.[12]

Used chemotherapy gowns must be discarded into hazardous waste containers after:[12]

- **no more than 3 hours of continuous compounding**
- **contamination has occurred or is suspected**
- **each removal**

D.2.8 Isolation Gowns

Isolation gowns help to minimize particulate levels in the controlled area when protection from hazardous drug exposure is not a concern. Isolation gowns also help to minimize the spread of hazardous drug (HD) contamination from scrubs worn in the HD clean room to areas outside.

Standard:

An isolation or chemotherapy gown must be worn by all personnel working in controlled areas.[29] **Isolation gowns must be low-linting with long sleeves and fitted cuffs, enclosed at the neck, closing at the back (no open front), and tied around the waist.**[29]

Isolation gowns or lab coats must not be worn in the hazardous drug clean room by staff working in the C-PEC in place of chemotherapy gowns.[14]

Staff entering the anteroom from the gowning/set-up room or general pharmacy who will be changing into a chemotherapy gown to work in the clean room should hang the isolation gown in the anteroom for later use (i.e., when exiting the anteroom).

Standard:

An isolation gown (enclosed at the neck and tied around the waist) must be worn:

- **by staff compounding non-sterile non-hazardous drugs outside of the controlled area**[54]
- **by staff working in the controlled area unless wearing a chemotherapy gown**[29]
  - a buttoned lab coat may not be worn in the controlled area in place of an isolation or chemotherapy gown[14]
- **over scrubs by staff that *will be* (re-)entering the controlled area**[36]
  - a buttoned lab coat may be worn by staff that will be (re-)entering the controlled area in place of an isolation gown

Isolation gowns worn in the controlled area should not be worn out of the controlled area. Isolation gowns worn outside of the controlled area should not be worn in the controlled area.

Isolation gowns should be worn for a maximum of one day. Isolation gowns may be hung up for later use, disposed of (if disposable), or placed into a laundry bin (if reusable).

Standard:

Disposable isolation gowns contaminated with hazardous drugs must be disposed of into a HD waste container. Reusable isolation gowns contaminated with hazardous drugs (e.g., as a result of a HD spill) must be placed into a separate laundry bag that is labelled as requiring special handling (e.g., 'Cytotoxic').[46]

D.2.9 Chemotherapy Gloves

Chemotherapy gloves help to minimize the risk of occupational exposure to hazardous drugs by providing a physical barrier to extraneous drug particles on surfaces and to those generated during the compounding process.

Tiny holes or thinning of the gloves may occur during use. Gloves should be handled gently to avoid tearing or stressing the material.[22] Tweezers could be used to avoid activities which may tear or stress gloves, such as removing vial caps and handling adhesive surfaces of labels or seals.

Standard:

Gloves worn when touching surfaces that may be contaminated with hazardous drug must be tested with nine chemotherapy drugs as required in the American Society for Testing and Materials (ASTM) International Standard D6978-05 (*Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Gloves*).[55]

A report of the ASTM D6978-05 Standard test results indicating the minimum breakthrough detection time for each of the nine drugs tested must be provided to the facility by the glove manufacturer for each brand/type of chemotherapy glove to be worn by staff when handling hazardous drugs. 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.[14, 55]

Two pairs of disposable chemotherapy gloves must be worn for all activities that may result in hazardous drug exposure including handling all hazardous drugs and hazardous drug waste.[12] Two pairs of disposable chemotherapy gloves must be worn at all times by all personnel working in the hazardous drug clean room.[12]

Disposable chemotherapy gloves worn when mixing hazardous drugs in the C-PEC must be powder-free, sterile[29] and long enough to cover the cuff of the chemotherapy gown.[12] Two pairs of chemotherapy gloves must be donned by all personnel on the clean side of the demarcation line in the anteroom immediately after performing hand hygiene.[12] In facilities that have incorporated a gowning room in the controlled area, at least one pair of non-sterile gloves is donned by all personnel in the gowning room after washing hands.[29]

To minimize the spread of hazardous drug contamination outside of the clean room, outer chemotherapy gloves worn during hazardous drug compounding must not be worn outside of the clean room.[12]

The inner pair of chemotherapy gloves worn during hazardous drug compounding must be removed on the clean side of the demarcation line in the anteroom immediately prior to washing hands. In facilities that have incorporated a gowning room in the controlled area, the inner pair of gloves worn during hazardous drug compounding must be removed in the anteroom (immediately prior to washing hands). A new pair of non-sterile chemotherapy gloves must be donned prior to leaving the anteroom. When leaving the controlled area, the new pair of gloves is removed in the gowning room immediately prior to washing hands.[29]

Hands must be washed with soap and water every time chemotherapy gloves are removed.[14]

Recent concerns with healthcare workers' sensitivity to latex have prompted testing of newer glove materials.

Standard:

Latex-free chemotherapy gloves must be made available to staff.[13]

Both pairs of disposable chemotherapy gloves worn when handling hazardous drugs must be changed every 30 minutes (unless otherwise indicated by the manufacturer's documentation) or immediately if a tear, puncture or contamination is known or suspected.[14]

Note:

- Thiotepa and carmustine have been shown to have a very short break-through time when tested with certain gloves (less than 30 minutes). When working with thiotepa and carmustine, gloves worn must be changed according to the breakthrough time reported by the manufacturer when tested to ASTM International Standard D6978-05

Standard:

Chemotherapy gloves must be disposed of in hazardous waste containers.[14]

D.2.10 Eye Protection

Eye and face protection is not necessary when working in a C-PEC with the viewing window at the manufacturer's recommended operating level.

When selecting safety goggles, it is important to consider the type of ventilation the safety goggles provide.

Standard:

Safety goggles worn when working with cleaning agents or other liquids that pose a splash risk to the eyes must provide closed ventilation (non-ventilated) or indirect ventilation (preferred). Safety goggles must not provide direct ventilation.[56]

Closed-ventilation goggles protect against particles and liquids but are more likely to fog up. Indirect ventilation goggles contain angled vents to protect from splashes and particles and are ideal to wear during HD spill clean-up or when decontaminating and cleaning the C-PEC. Direct vent safety goggles only protect against large particle materials and therefore are not appropriate when protection from a splash to the eyes is required.[56]

Standard:

Safety glasses provide impact protection but do not provide the same level of splash or droplet protection as safety goggles and therefore must not be used when there is a risk of chemical splashes and/or sprays to the eyes.[57]

Face shields provide splash and spray protection for the eyes and other facial areas. To provide better face and eye protection from splashes and sprays, a face shield should have crown to chin protection and wrap around the face to the point of the ear. This reduces the likelihood that a splash or spray could go around the edge of the shield and reach the face or eyes.[57]

Standard:

When working with cleaning agents or other liquids that pose a splash risk to the face and eyes, a face shield must be worn in addition to safety goggles, not as a substitute.[58]

A face shield and safety goggles or a full face mask respirator must be worn for splash protection:[12]

- **when working at or above eye level**
- **when decontaminating or cleaning the containment primary engineering control**
- **when cleaning up a hazardous drug spill**
- **when performing manipulations with splash risk to the face and eyes**
- **when unpacking shipments suspected of containing damaged drugs**

Safety goggles, face shields, and reusable respirators must be decontaminated using a decontaminating agent daily after use.[14]

If safety goggles, a face shield, or a respirator becomes contaminated with hazardous drug, they should be disposed of in a hazardous waste container.

Contact lenses may absorb aerosolized drug and pose an extra potential hazard in the event of a splash of any hazardous solution into the eye. If possible, glasses should be worn for vision correction while preparing hazardous drug sterile preparations.[35]

Standard:

If glasses are worn for vision correction, a face shield and safety goggles or a full face mask respirator must be worn over them whenever there is a risk of splash to the eyes when using cleaning agents or other liquids.[14]

Table 5: Summary of Process for Donning Personal Protective Equipment and Clean Room Garb (For controlled area with anteroom and HD clean room only)

Personal Protective Equipment and Clean Room Garb (Summary)		
Before entering the Controlled Area (CA)	**To enter the anteroom:** **On the dirty side of the demarcation line in the anteroom**	**To work in the anteroom or enter the hazardous drug clean room:** **On the clean side of the demarcation line in the anteroom**
Scrubs	As per 'Before entering the CA' plus:	As per 'On the dirty side of the demarcation line in the anteroom' plus:
Clean shoes dedicated for use in the controlled area	Hair cover Beard cover (if applicable)	To work in the anteroom: Gown - isolation or chemotherapy Hand hygiene prior to donning chemotherapy gloves Gloves- two pairs of non-sterile chemotherapy gloves long enough to cover the cuff of the gown (inner pair under the cuff of the gown, outer pair over the cuff of the gown)
Remove: personal outer garments; jewellery; cosmetics, hair products; henna and paper tattoos; nail polish and other nail applications, etc. See Section F.1.1 for a more complete list	Medical mask- if working in the anteroom or if entering the clean room to perform duties other than decontaminating the C-PEC or cleaning up a HD spill Elastomeric half face mask respirator- if decontaminating the C-PEC or cleaning up a HD spill Full face mask respirator- if decontaminating the C-PEC or cleaning up a HD spill AND if not wearing safety goggles and a face shield	To enter the clean room: Safety goggles- if decontaminating the C-PEC or cleaning up a HD spill (worn with a face shield) Face shield- if decontaminating the C-PEC or cleaning up a HD spill (worn with safety goggles) Gown- chemotherapy gown if working in the C-PEC; isolation gown if not working in the C-PEC Perform appropriate hand hygiene prior to donning chemotherapy gloves Gloves- two pairs of sterile chemotherapy gloves if working in the C-PEC; 2 pairs of non-sterile chemotherapy gloves if not working in the C-PEC; ensure gloves are long enough to cover the cuff of the chemotherapy gown (inner pair under the cuff of the gown, outer pair over the cuff of the gown)
	Two pairs of shoe covers- as step over the demarcation line to the clean side of the anteroom	

Standard:

Removal of a medical mask to don a respirator, or removal of a respirator to don a medical mask (e.g., to decontaminate the C-PEC or after the C-PEC has been decontaminated) must not occur in the clean room.[29]

This activity may occur on the clean side of the demarcation line in the anteroom.

Table 6: Summary of Process for Donning Personal Protective Equipment and Clean Room Garb (For controlled area with other rooms in addition to anteroom and HD clean room)

<table>
<tr><th colspan="4">Personal Protective Equipment and Clean Room Garb (Summary)</th></tr>
<tr><td>Before entering the Controlled Area (CA)</td><td>In the gowning room</td><td>To enter the anteroom:
On the dirty side of the demarcation line in the anteroom</td><td>To work in the anteroom or enter the HD clean room:
On the clean side of the demarcation line in the anteroom</td></tr>
<tr><td>Scrubs</td><td>As per ‘Before entering the CA’ plus:</td><td>As per ‘In the gowning room’ plus:</td><td>As per ‘On the dirty side of the demarcation line in the anteroom’ plus:</td></tr>
<tr><td>Clean shoes dedicated for use in the controlled area</td><td>Hair cover
Beard cover (if applicable)</td><td>Medical mask- if working in the anteroom or if entering the clean room to perform duties other than decontaminating the C-PEC or cleaning up a HD spill
Elastomeric half face mask respirator- if decontaminating the C-PEC or cleaning up a HD spill
Full face-piece respirator- if decontaminating the C-PEC or cleaning up a HD spill AND if not wearing safety goggles and a face shield</td><td>To work in the anteroom:
Gown- keep on the gown that was donned in the gowning room
Gloves- keep on the gloves donned in the gowning room (ensure 2 pairs are worn if potential for exposure to HDs); ensure gloves are long enough to cover the cuffs of the gown (inner pair under the cuff of the gown, outer pair over the cuff of the gown)</td></tr>
<tr><td rowspan="3">Remove: personal outer garments; jewellery; cosmetics, hair products; henna and paper tattoos; nail polish and other nail applications, etc.
See Section F.1.1 for a more complete list</td><td>One (inner) pair of shoe covers</td><td>Remove isolation gown and hang up on the dirty side of the demarcation line in the anteroom for later use if donning a chemotherapy gown to enter the clean room</td><td rowspan="4">To enter the clean room:
Safety goggles- if decontaminating the C-PEC or cleaning up a HD spill (worn with a face shield)
Face shield- if decontaminating the C-PEC or cleaning up a HD spill (worn with safety goggles)
Gown- chemotherapy gown if working in the C-PEC; isolation gown if not working in the C-PEC
Perform appropriate hand hygiene prior to donning chemotherapy gloves
Gloves- two pairs of sterile chemotherapy gloves if working in the C-PEC; 2 pairs of non-sterile chemotherapy gloves if not working in the C-PEC; ensure gloves are long enough to cover the cuffs of the chemotherapy gown (inner pair under the cuff of the gown, outer pair over the cuff of the gown)</td></tr>
<tr><td>Isolation gown</td><td>Two pairs of shoe covers- as step over the demarcation line to the clean side of the anteroom</td></tr>
<tr><td>Wash hands and wrists for at least 30 seconds prior to donning inner pair of gloves</td><td></td></tr>
<tr><td></td><td>Two pairs of non-sterile chemotherapy gloves- one pair if going straight through the CA to the anteroom; ensure gloves are long enough to cover the cuffs of the gown (inner pair under the cuff of the gown, outer pair over the cuff of the gown)</td><td></td></tr>
</table>

D.3 Hand Hygiene

Standard:

Prior to donning gloves, hands must be cleansed using either soap and water or alcohol-based hand rub.[59]

D.3.1 Hand Hygiene Agents

Hand hygiene agents such as plain soap and water, should be designed to remove visible soil and hazardous drug contamination.[60] Plain soap has limited, if any, antimicrobial activity.[61]

Hand hygiene agents chosen for use by compounding staff who cannot use alcohol-based hand rub should be antimicrobial soaps containing detergent and an antimicrobial agent (e.g., chlorhexidine, iodine compounds) designed to rapidly kill the majority of transient skin flora.

Staff should work with their infection control department when choosing approved hand hygiene agents.

D.3.1.1 Alcohol-Based Hand Rub

Alcohol-Based Hand Rubs (ABHR) remove microorganisms more effectively, require less time to use, and irritate skin less often than hand washing with soap and water or other antiseptic agents.[62] Alcohols are preferred as a hand rub because of their effectiveness, immediate activity, excellent spreading on the surfaces of hands and quick evaporation.

The efficacy of the alcohol-based hand rub depends on the quality of the product, the amount of product used (one to two full pumps of product onto one palm)[63], the time spent rubbing (the volume should be such that a minimum of 15 seconds of rubbing is required for drying)[63] and the hand surface rubbed. Alcohol-based hand rubs should not be used with water, as water will dilute the alcohol and reduce its effectiveness.

Standard:

Alcohol-based hand rubs used to disinfect hands before compounding parenteral hazardous drugs must have a minimum alcohol concentration of 70%, and be used in conjunction with plain or an antimicrobial soap.[63]

See Table 7 - Hand Hygiene for Sterile Compounding Staff in Section D.3.3

D.3.2 Hand Washing After Handling Hazardous Drugs

Standard:

After handling hazardous drugs, hand washing must be performed[14] to remove possible drug contamination.

Note:

- ABHR will not remove hazardous residue from hands. ABHR is not appropriate to use to clean or disinfect hands after removal of chemotherapy gloves worn when handling hazardous drugs

D.3.3 Hand Hygiene Before Entering the Clean Room

Standard:

Hand hygiene must be performed by all personnel prior to donning gloves and entering the clean room to minimize the risk of microbial contamination of sterile products. Prior to performing hand hygiene, all jewellery including bracelets, rings and watches must be removed to prevent material from being trapped around or underneath them.[12]

Hands must be dried with a clean, low lint towel.[12]

Refer to Checklists- Module 1 - Appendix 1: Hand Hygiene for Personnel Working in the Clean Room

Refer to Checklists- Module 1 - Appendix 1: Donning of Personal Protective Equipment to Enter a Hazardous Drug Clean Room When Not Working in a Biological Safety Cabinet

Refer to Checklists- Module 1 - Appendix 1: Donning of Personal Protective Equipment When Working in a Biological Safety Cabinet

Table 7: Hand Hygiene for Sterile Compounding Staff

	Soap (Plain or Antimicrobial) & Alcohol-Based Hand Rub (ABHR)[12]	Antimicrobial Soap (Steps for staff who have sensitivities to ABHR only)
Step 1	Under running water, use a disposable nail pick to remove debris from underneath fingernails	Under running water, use a disposable nail pick to remove debris from underneath fingernails[12]
Step 2	Wash hands and arms to elbows with soap and water for at least 30 seconds (do not use the bristle side of scrub brushes on skin or nails)	Wash hands and arms to elbows for 2 to 3 minutes[64-68] with antimicrobial soap (e.g., 4% chlorhexidine, povidone-iodine)
Step 3	Rinse with water	Rinse with water
Step 4	Dry hands and forearms with low-lint towel; allow hands and arms to completely dry	Dry hands and forearms with low-lint towel; allow hands and arms to completely dry
Step 5	Use the towel to turn off the water taps (if applicable)	Use the towel to turn off the water taps (if applicable)
Step 6	Discard the towel (if disposable) or place into a laundry bag (if reusable)	Discard the towel
Step 7	Dispense a minimum of 2 full pumps of ABHR onto one palm	Don inner pair of sterile chemotherapy gloves
Step 8	Immerse fingertips of the opposite hand into the ABHR for several seconds	Don chemotherapy gown
Step 9	Cover the hand and forearm of the opposite hand with ABHR for a minimum of 15 seconds (until fully evaporated)	Don outer pair of chemotherapy gloves
Step 10	Repeat with other hand and forearm allowing the ABHR to fully evaporate	
Step 11	Don inner pair of sterile chemotherapy gloves	
Step 12	Don chemotherapy gown	
Step 13	Don outer pair of chemotherapy gloves	

D.3.4 Nails and Nail Polish

Long nails are difficult to clean, can pierce gloves and harbour more microorganisms than short nails. Healthcare workers who wear artificial nails are more likely to harbour gram-negative pathogens on their fingertips than those who have natural nails both before and after performing hand hygiene. Freshly applied nail polish does not increase the number of bacteria removed from skin under nails, but chipped nail polish may support the growth of large numbers of organisms on fingernails.[60]

Standard:

Wearing of artificial nails or other nail applications is prohibited while working in the controlled area. Natural nails must be kept neat, trimmed, and must be free of nail polish.[12]

D.4 Safety Stations

The first 10 to 15 seconds after exposure to a hazardous substance are critical. Delaying treatment, even for a few seconds, may cause serious injury. Emergency showers and eyewash stations provide on-the-spot decontamination. They allow workers to flush away hazardous substances that can cause injury.[69]

Standard:

Eyewash stations and emergency showers must be easily accessible and clearly identified by signs which indicate their location and provide clear directions for their use.[70]

The sign should be in the form of a symbol that does not require workers to have language skills to understand it.[69]

Standard:

Personnel that are required to use emergency eyewash and shower facilities must be adequately trained in their location and proper use.[70]

For potential exposure to high risk materials: ***WorkSafe BC Occupational Health and Safety (OHS) Regulation Table 5-3: Provision and location of emergency washing equipment states:***

"Eye Equipment: Tempered continuous flow eyewash facility with a minimum duration of 15 minutes (or more if required by the nature of the material)

Location: Within 5 seconds walking distance of the hazard area, but no further than 6 meters (20 feet).

Skin Equipment: Tempered, continuous flow emergency shower facility with a minimum duration of 15 minutes (or more if required by the nature of the material)

Location: Same location criteria as for high risk eyewash facility except that the shower may be located further than 6 meters, and

- ***(a) a supplementary emergency washing facility such as a non-tempered drench hose is located within 5 seconds walking distance of the hazard area but no further than 6 meters, and***
- ***(b) a tempered shower facility is available within the building to start emergency washing within 5 minutes of the contact"***

See Accidental Exposure to Hazardous Drugs in Section J

D.4.1 Eyewash Stations

Eyewash stations are designed to immediately flush contaminants out of the eyes after exposure. Tap water is not recommended for flushing the eyes as pressure damage can occur.[69]

D.4.1.1 Sink Mounted

To use a sink mounted eyewash station, follow these steps:

1. Push the handle away from you to start the water flow
2. With thumb and forefinger of each hand, hold eye lid(s) open allowing flushing water to bathe eye(s)
3. Look directly into the water stream and move eye(s) around to flush for at least 15 minutes
4. Seek medical advice as soon as possible

[71]

D.4.1.2 Hand Held Portable

Alternatives to a sink mounted eyewash station include hand held portable eyewash stations that may consist of an infusion bag of 0.9% NaCl solution (normal saline) or an irrigation bottle of water or normal saline with appropriate tubing.[32, 35] The portability means emergency equipment can be placed closer to potential hazards or taken to the contaminated worker. These eyewash stations are ideal quick first response eyewashes.[72]

[73]

Standard:

Portable eyewash stations must be capable of delivering a minimum flush duration of 15 minutes.[70]

D.4.2 Emergency Showers

Emergency showers are designed to flush the user's head and body.

Standard:

Emergency showers must not be used to flush the user's eyes because the high rate or pressure of water flow could possibly damage the eye.[69]

Any part of the body with known or suspected contamination should be rinsed for a minimum of 15 minutes but rinsing time can be up to 60 minutes. The temperature of the water should be one that can be tolerated for the required length of time. Water that is too cold or too hot will inhibit workers from rinsing or showering as long as they should.[69] A towel and gown should be made available to dry and replace contaminated clothing. Contaminated clothing should be discarded as HD waste or isolated and labelled for laundering according to site-specific policies and procedures.

[71]

When designing the safety shower area, consideration should be made to allow for proper drainage when the shower is running.

D.4.3 Safety Stations Maintenance

Standard:

Plumbed emergency eyewash and shower facilities must be full flow tested at least once per month, for a sufficient length of time to completely flush the branch of the water line supplying the eyewash.[70]

However, weekly activation of the plumbed eyewash station is recommended to ensure that there is flushing fluid available, to help clear the supply line of sediments and minimize microbial contamination caused by 'still' or sitting water.[69, 74] A complete inspection by maintenance on an annual (yearly) basis is also recommended.[69]

Standard:

Hand held portable eyewash equipment must be inspected and maintained according to the manufacturer's instructions.[69]

Consideration of expiry dates and shelf life of solution in the portable eyewash station is recommended to avoid bacterial and/or fungal growth.

Section E - Supplies and Devices

E.1 Supplies

E.1.1 Wipes/Towels

Wipes/towels pre-moistened with a germicidal disinfectant detergent may be used to physically remove HD particles from the work surface of the C-PEC, and the outside surfaces of gloves, products, and devices prior to removal from the C-PEC. Other wipes are commercially available however consideration when choosing these products is recommended due to the possibility of chemical interaction with approved solutions already in use.

Soap-free, disposable, low lint towels and gauze are available to be moistened with the various agents used for decontamination, cleaning, and disinfection.

E.1.2 Preparation Pad / Sterile Drape

Use of a preparation pad or sterile drape on the work surface of the C-PEC while compounding hazardous drugs comes with the following inherent problems and therefore is NOT recommended:

- introduction of particulates into the work area[75]
- uneven work surface may cause HD spills[75]
- increased difficulty of HD spill detection[75]

- additional HD contaminated material for disposal[75]
- compromises the containment properties of the biological safety cabinet[18]

E.1.3 Sterile Alcohol Swabs

Standard:

Single use, individually packaged sterile 70% isopropyl alcohol swabs must be used to disinfect a critical site prior to accessing.[33] Gauze pads or other particle-generating material moistened with alcohol must not be used to disinfect critical sites of containers prior to accessing.[33]

See Disinfecting Critical Sites in Section F.2.3

E.2 Devices

Standard:

Devices used in the safe and accurate reconstitution and withdrawal of hazardous drug in a vial must support minimizing the production and release of HD aerosols and vapours, maintaining the sterility of hazardous drugs, and preventing HD leaks/spills.[29]

Several devices are marketed for use in compounding hazardous drug preparations. There is no single device that is suitable for all hazardous drug sterile compounding. The choice of device must be based on minimizing the escape of hazardous drug particulates and limiting the production and release of HD aerosols and vapours into the environment and onto surfaces. Availability of devices and maintaining the safety of the patient and the worker are also important considerations.

Standard:

Staff must be trained to use the proper aseptic technique required with each device utilized in the safe preparation of hazardous drugs.[31]

The following criteria may be considered when deciding which devices are most suitable for the preparation of hazardous drugs.

- **Standard: Device must be approved for use with hazardous drugs by the manufacturer[43]**
- Venting devices equalize the pressure in a hazardous drug vial, minimizing the possibility of back spray and HD aerosolization
- **Standard: Venting devices used during preparation of parenteral hazardous drugs must have filters[15, 21]**
- Filters should have adequate pore size to remove the intended particulate. If removing glass particles from a solution in an ampoule, a 5 micron filter is recommended. For minimizing the release of HD aerosols into the environment a 0.2 micron filter may be used
- **Standard: When compatible, closed system drug transfer devices must be utilized for HD preparation to minimize the transfer of environmental contaminants into the system and the escape of hazardous drug out of the system[14]**
- **Standard: Luer-lock fittings must be used for all hazardous drug connections made during manipulation and dispensing[13]** (except some pediatric doses)
- To minimize exposure of critical sites to microorganisms, devices should be chosen which will reduce the number of required manipulations needed to compound admixtures

The above criteria are meant to provide guidance to pharmacy staff when evaluating which devices will provide safe and aseptic hazardous drug sterile preparations.

The following section contains information illustrating a number of devices currently being used by pharmacies in British Columbia that are preparing hazardous drugs. It would be impractical to describe every device currently being used. The devices available for compounding chemotherapy are numerous and are constantly changing.

E.2.1 Syringes

Syringes are made of either glass or plastic. Disposable plastic syringes are frequently used in compounding sterile preparations because they are inexpensive, durable and are in contact with substances only for a short time, which minimizes the potential for incompatibility with the plastic itself.[36]

Standard:

A luer-lock disposable syringe must be used in the preparation and administration of hazardous drugs to help prevent leakage and accidental separation of connections between devices such as syringes and needles.[13] Over tightening luer-lock connections could cause cracking or breaking of the device(s).

An appropriate size syringe must be selected so that no more than three-quarters (75%) of the syringe's maximum calibrated volume is filled with hazardous drug solution at any time during the compounding process.[29] This minimizes the risk of the plunger accidentally separating from the syringe barrel.

Exception:

- Becton Dickinson (BD) has informed customers that they are changing the graduation marking on their 60 mL syringes. The graduation marking will no longer extend beyond 50 mL. These syringes will now be labelled as 50 mL syringes.
- The only change to the device is the graduation marking and labelling of the packaging.
- There are no changes to device form, fit, function or raw material composition.
- As there are no other changes to these BD syringes, BC Cancer will continue to fill these syringes to no more than 45 mL of hazardous drug (75% of the previously marked 60 mL syringe).

There are three main parts of a syringe:

1. plunger
2. barrel
3. the tip/hub

The plunger and tip/hub are critical sites. Touching the plunger ribs of a multi-use syringe could result in contamination of the interior of the barrel and subsequent contamination of the drug or diluent inside the syringe.

See Critical Sites in Section F.2.1

Standard:

A syringe must not be used more than five times for a single compounding procedure (e.g., reconstitution).[31]

Syringes that have been used to withdraw and inject HD should not be re-used. Studies show HD contamination infiltrates onto the plungers of syringes after a single preparation.[76] There is a risk of contaminating the operator's gloves if the plunger is accidentally touched.

E.2.2 Syringe Tip Caps

A luer-lock syringe tip cap is used to protect the syringe tip/hub from contamination during storage or transport.[13] It also prevents HD solution from being accidentally ejected since the plunger cannot be pushed in or withdrawn when a luer-lock tip cap is in place.[22] A multi-function tip cap may be used on a chemotherapy dispensing pin if the original intermittent stopper cap is discarded.

Standard:

Care must be taken to avoid touch-contaminating the end of the multi-function tip cap that will be luer-locked to either the syringe or the chemotherapy dispensing pin (critical site).[33]

Tip caps may be packaged in multiples where each row of caps is sterile until the paper backing is peeled away. The paper should be peeled away at an angle to expose only one tip cap at a time. Tip caps packaged in a tray are single function with only one connection end (critical site).

Multi-Function Tip Cap

Single Function Tip Cap

Tray

In some cases, tip caps and syringes without luer-locks are used. For example, some hazardous pediatric medications must be dispensed in a slip tip syringe. Therefore, a slip tip syringe cap must be used. The dose should be appropriately packaged to ensure the plunger is not manipulated during transport causing HD solution to be accidentally ejected.

Non-luer-locking syringe tip caps can be attached to the tips of syringes used to prepare hazardous drugs to prevent leaking of HD contamination from the syringe tip during the manufacturing check prior to disposal.

E.2.3 Needles

Standard:

All parts of a needle are critical sites. Needles must be manipulated by handling their paper over-wrap and/or needle caps. Paper-covered needles must be unwrapped by peeling apart the sides of the package just enough to expose the needle's luer-lock hub. Airflow to the hub must be maintained as the needle is un-wrapped and luer-locked onto a syringe. The needle cap must be left in place until the needle is ready to be used.[36]

There are three main parts of a needle:

1. hub
2. shaft
3. bevel

Standard:

Aluminum-free needles and devices must be used in the preparation and administration of CISplatin, CARBOplatin and oxaliplatin.[77]

The aluminum/platin interaction causes a black precipitate to form due to an oxidation-reduction reaction.[77] To avoid confusion, the use of aluminum-free devices when preparing all hazardous drug sterile admixtures is recommended.

It is important to choose the appropriate needle gauge and length with consideration given to the type of intravenous bag port or vial stopper being punctured, the number of punctures, and the viscosity of the drug being withdrawn or injected. Correct selection of needle gauge and length helps to prevent hazardous drug leakage. The larger the needle gauge number, the smaller the needle bore size (e.g., the bore size of a 20G needle is smaller than the bore size of a 16G needle).

Standard:

Safety Engineered Needles (SEN) must not be used in the preparation of hazardous drugs. There is a risk that droplets of hazardous drug will spray off of the needle point when the SEN cap is engaged.[43]

E.2.4 Needle Caps

When the needle cap is removed from the needle it should be placed in a needle cap holder with the opening facing up. Alternatively, the open end of the needle cap could rest on an alcohol swab to the side of the working area.

Standard:

Placing the open end of the needle cap directly on the work surface of the C-PEC must be avoided.[33]

E.2.5 Needle Cap Holders

A needle cap holder is a device used to securely house the cap of the needle. It also helps to protect from needle stick injuries by enabling the worker to recap the needle without having to hold the needle cap. It allows for a one-handed recapping of the needle.

See Safely Capping Needles Used With Hazardous Drug in Section F.2.5

E.2.6 Seals

A seal may be affixed to vials that have been accessed during drug preparation. The presence of a seal indicates that the vial stopper has been accessed. Leakage from a poorly punctured entry may not be contained by the foil seal. Vials that have foil seals affixed should be handled carefully. The seal self-destructs upon attempted removal and cannot be effectively reapplied providing tamper evident security. They are available in a variety of sizes and colors.[78] A seal should not be affixed to an infusion solution bag port that has been accessed as this may hinder the ability to check for leaks during the final product check.

E.2.7 Filters

Filter sizes vary depending on the filtering device used. A hydrophilic filter allows solution to pass through and is used to trap particles/contaminants from solution up to a specific size. For example, the use of a 0.45 micron hydrophilic filter will remove microorganisms, particles, precipitates and undissolved powders 0.45 microns in size or larger. Filter devices must be luer-locking, compatible with the solution, and hydrophilic to allow the solution to pass through the filter membrane. Filter devices for sterile hazardous drugs are available in needle or disc form.

Particulate can be a potential risk to patient safety if present in the sterile product that is administered to a patient.

Standard:

Solutions prepared for parenteral administration must be filtered when there is a possibility that glass particles[31] or particulate matter (e.g., core from a vial stopper) may be present and the solution is filterable.

Refer to Checklists- Module 1 - Appendix 1: Filtering Particulate from Solution in Vials and Syringes Using a 5 Micron Hydrophilic Filter Disc and a Chemotherapy Vent

Refer to Checklists- Module 1 - Appendix 1: Filtering Particulate from Solution in a Syringe Using a 5 Micron Hydrophilic Filter Needle

Refer to Checklists- Module 1 - Appendix 1: Filtering Particulate from Hazardous Drug Solution in a Vial Using ChemoLock™

Refer to Checklists- Module 1 - Appendix 1: Filtering Particulate from Hazardous Drug Solution in Syringes Using ChemoLock™

E.2.7.1 Filter Needles

A filter needle contains a hydrophilic filter. To withdraw the solution, either start with a filter needle to withdraw solution into a syringe and change to a regular needle before expelling the contents into a container or start with a regular needle and change to a filter needle before expelling the contents.

Standard:

The same filter needle must not be used for both withdrawing and expelling solution.[22, 36]

E.2.7.2 Filter Discs

A hydrophilic filter disc is used for filtering withdrawn solution (e.g., from one syringe to another). Filter discs with slip tip connections are not recommended for use with hazardous drugs as accidental detachment can occur.

Standard:

A filter disc used for hazardous drugs must be equipped with proximal and distal luer-locking connections.[13]

E.2.8 Filter Venting Devices

A filter venting device should be used when reconstituting or withdrawing hazardous drug from a vial when closed system drug transfer devices are not available. Venting hazardous drug vials without a device with a built-in filter may lead to increased release of aerosolized hazardous drug into the work environment.

A hydrophobic filter is not meant for solution to pass through. A hydrophobic filter is used to filter the air that enters and leaves a container. The use of a hydrophobic filter venting device equalizes the pressure within a hazardous drug vial and prevents the release of aerosolized HD into the work environment. However, these devices may not prevent the release of HD vapours. The airflow in the C-PEC is designed to contain and remove HD vapours from the working environment.

There are various models of filter venting devices suitable for HD preparation. Chemotherapy dispensing pins and chemotherapy vents work differently, but both have a 0.22 micron or smaller hydrophobic filter that:

- allows air to enter and leave a vial to equalize pressure
- prevents particulate matter that may be present in the air from entering the vial
- prevents HD aerosols from leaving the vial

The choice of a filter venting device depends on the number of punctures to be made.

- A chemotherapy vent is not recommended for large volume vials that require multiple syringes for reconstitution and withdrawal.
- Use of a chemotherapy dispensing pin will produce only one puncture in the vial and may be accessed many times.

Standard:

Negative pressure technique must not be used for hazardous drug reconstitution or withdrawal if filter venting devices[15] or closed system drug transfer devices[4, 15] are available.

Care must be taken if negative pressure technique is used. Build-up of positive pressure within the vial will cause back spray of solution when the needle is removed. Excess negative pressure will result in spillage from the bevel of the needle when it is removed from the vial.[21]

Exception:

- Exposure to natural rubber latex (latex) can pose an important health concern to patients with a latex allergy.
- For vials with natural rubber latex stoppers or vials with stoppers of unknown composition, limit vial access to two punctures by using a chemotherapy vent (for medications already in solution) or use negative pressure technique (for medications requiring reconstitution)

E.2.8.1 Chemotherapy Dispensing Pins

The KENDALL CHEMOBLOC® and the BRAUN CHEMO DISPENSING PIN® are examples of hydrophobic venting devices that have a spike for entry into the vial allowing for reconstitution and multiple withdrawals of the drug with only one puncture. Equalization of pressure during use enables the reconstitution and withdrawal of solution from a vial to be performed with less risk of exposure to aerosolized hazardous drugs than with a needle and syringe alone.

KENDALL CHEMOBLOC®

BRAUN CHEMO DISPENSING PIN®

Chemotherapy dispensing pins should not be used for viscous drugs that could plug the filter before the total dose is withdrawn.

Standard:

Chemotherapy dispensing pins or similar devices with spikes must not be used with vials of TAXOL® since they can cause the stopper to collapse resulting in loss of the sterile integrity[79] and the possible release of hazardous drug.

Exposing the luer-lock end of a chemotherapy dispensing pin that is inserted into a hazardous drug vial creates an 'open system'. Hazardous drug-contaminated air or solution may pass freely in and out of the vial. Hazardous drug in an open system container is vulnerable to microbial contamination. Generation of environmental hazardous drug aerosol/vapour contamination is also a risk.

To maintain the sterility of the vial contents and protect the environment from possible hazardous drug contamination when a chemotherapy dispensing pin is inserted:

- The luer-lock end of a chemotherapy dispensing pin inserted into a HD vial (with or without drug inside) must be sealed with either a cap or an attached syringe
- When the original intermittent stopper cap or tip cap is removed, place it (connecting end up) on an alcohol swab outside the immediate working area so it does not become contaminated
- If the chemotherapy dispensing pin becomes plugged, carefully remove it from the vial stopper and discard into the HD sharps container. Re-disinfect the vial stopper and insert a new chemotherapy dispensing pin
- Do not withdraw drug from a vial once the vial has been removed from the C-PEC. There is a chance that movement of the spike in the vial stopper could contaminate the vial contents when the vial is removed from the ISO Class 5 environment, even when the vial is placed back into the C-PEC prior to the next withdrawal

Note:

- **Standard: Chemotherapy dispensing pins must be inspected for cracks prior to use. A cracked chemotherapy dispensing pin must be replaced prior to manipulation of HD solution[43]**
- **Standard: Chemotherapy dispensing pins must be disposed of in a HD sharps waste container if removed from a HD vial[43]**
- **Standard: A new chemotherapy dispensing pin must be used for each vial. Spraying of the solution or touch contamination can occur upon removal of the pin[80]**
- **Standard: A chemotherapy dispensing pin must not be used for multiple withdrawals from a vial if the vial is removed from the C-PEC between withdrawals[43]**

Refer to Checklists- Module 1 - Appendix 1: Reconstitution of Drug Using a Chemotherapy Dispensing Pin

Refer to Checklists- Module 1 - Appendix 1: Withdrawal of Drug Solution from a Vial Using a Chemotherapy Dispensing Pin

E.2.8.2 Chemotherapy Vents

A chemotherapy vent is a filtered venting device that has at least a 0.22 micron hydrophobic filter. It must be attached to a needle, which may be inserted into a vial stopper. A second needle attached to a syringe is required for reconstitution and/or withdrawal of the drug. As solution is added or as drug is withdrawn through the second needle, air escapes or enters through the filtered vent. Any air particles or drug aerosols 0.22 microns in size or larger are trapped in the filter. The equalization of pressure while using the chemotherapy vent enables the manipulation of a vial to be performed with less risk of exposure to aerosolized hazardous drugs than with a needle and syringe.

A CHEMO-VENT® is a 0.22 micron chemotherapy vent that is supplied with a permanently attached needle.

81

A PALL® Medical Hydrophobic Vent Filter is a 0.22 micron chemotherapy vent that must be attached to a needle just prior to use.

If the filter in a chemotherapy vent becomes wet, equalization of pressure inside the vial may not occur. A wet filter may cause the chemotherapy vent to become plugged.

Standard:

A new chemotherapy vent must be inserted prior to removal of a plugged chemotherapy vent.[35]

Multiple punctures of a HD vial stopper that has a chemotherapy vent inserted may be necessary.

Standard:

A hazardous drug vial stopper must be disinfected with sterile 70% alcohol prior to each puncture when multiple punctures are necessary.[33]

To disinfect a vial stopper that has a chemotherapy vent inserted:

- Ensure the needle of the chemotherapy vent is inserted into the vial stopper so that most of the needle shaft is not exposed. Do not touch the vial stopper with the hub of the needle
- With the vial in an upright position, disinfect the vial stopper using a sterile 70% alcohol swab around the needle of the chemotherapy vent
- Avoid touching the needle of the chemotherapy vent with the sterile alcohol swab

Refer to Checklists- Module 1 - Appendix 1: Reconstitution of Drug Using a Chemotherapy Vent

Refer to Checklists- Module 1 - Appendix 1: Withdrawal of Drug Solution from a Vial Using a Chemotherapy Vent

E.2.9 Syringe Fluid Dispensing Connectors/Syringe Tip Connectors

A syringe fluid dispensing connector/syringe tip connector facilitates a safe and efficient solution transfer technique.

Standard:

Both ends of the individually packaged fluid dispensing connector used with hazardous drugs must have luer-lock connections[13] which allow transfer of solution from one syringe to another without leakage.

E.2.10 NON-Hazardous Solution Dispensing Pins/Universal Spikes

The spike of a dispensing pin/universal spike is inserted into an administration port of a non-hazardous solution bag (e.g., diluent) to avoid multiple punctures into the medication port of the bag throughout the day. Both ends of these devices are critical sites.

Refer to Checklists- Module 1 - Appendix 1: Withdrawal of Solution from an Intravenous Solution Bag Using a Dispensing Pin / Universal Spike

E.2.11 Solution/Intravenous Administration Sets

A solution/intravenous administration set is a latex-free closed system infusion set used to transfer solution either from one container to another container or from a container to a patient. There is a spike for insertion into a container or a buretrol and a luer-lock or slip tip connection at the distal end for a needle or other attachment. The set has a drip chamber and a clamp to stop the flow of solution.

Refer to Checklists- Module 1 - Appendix 1: Priming Solution / Secondary Administration Sets Inside the Biological Safety Cabinet

E.2.12 Buretrols

A buretrol is used to transfer large volumes of solution either from one container to another container or from a container to a patient via gravity. The 150mL volumetric fill chamber is a control tube that allows for exact measuring of solutions to be transferred from one intravenous admixture bag to a second container without the use of syringes. Above the volumetric fill chamber is a spike for insertion, a clamp, and an air valve.

A releasable clamp sits on the tubing just below the fill chamber. An administration port that accepts a solution set spike is distal to the releasable clamp. When the releasable clamp is open, solution may flow from the volumetric fill chamber into the solution set.

A buretrol may be used to measure and add mannitol to a core preparation (e.g., high dose CISplatin/ mannitol solution). Site-specific procedures may be developed with attention to safe handling and aseptic technique.

E.2.13 Winged Infusion Sets

Winged infusion sets consist of a stainless steel needle with 'butterfly wings' at one end, a length of tubing, and a luer-lock adapter at the other end. A plastic cover must be discarded when removed from the needle.

To minimize the possibility of any leakage from an IV solution bag port when a hazardous drug has been injected, a maximum of two punctures is recommended for each port even though one manufacturer's study has shown that the port of an infusion solution bag will re-seal itself after 12 punctures with a 19 gauge needle.[82] If more than two punctures of a port will be necessary, the use of a luer-lock winged infusion set is recommended as it may be used for multiple transfers and withdrawals of solution using one puncture into a container.

Winged infusion sets may be designed with a safety mechanism that encapsulates the cannula minimizing the chance of a needle stick injury. A safety winged infusion set designed with a needle cap attachment that slides over the needle during removal from the container is recommended for use with hazardous drugs whenever possible.

Refer to Checklists- Module 1 - Appendix 1: Use of a Winged Infusion Set

E.2.14 Closed System Drug Transfer Devices

Use of Closed System Drug Transfer Devices (CSDTD) during preparation, administration and disposal of hazardous drugs has been shown to reduce surface contamination levels in work environments, decreasing healthcare workers' exposure[83-96] and reducing the calculated cancer risk for healthcare workers.[97]

There are many devices on the market claiming to be Closed System Drug Transfer Devices. NIOSH defines a CSDTD as a device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug or vapor concentrations outside the system.[4]

Standard:

Closed System Drug Transfer Devices must be used within the ISO Class 5 environment of a C-PEC during hazardous drug preparation.[14] Protective clothing must be worn and best practice safety measures must be adhered to when using a Closed System Drug Transfer Device to prepare, administer and dispose of hazardous drugs.[4]

To protect staff from hazardous drug exposure, BC Cancer has chosen to implement the ChemoLock™ Closed System Drug Transfer Device for use during preparation, administration, and disposal of parenteral hazardous drugs to meet the current best practice standard guidelines.[4]

The ChemoLock™ system is a needle-free, membrane-to-membrane closed system which mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug or vapor concentrations outside the system. It has a "click to lock" technology. The system snaps together with an audible click to ensure a safe and secure connection.

The ChemoLock™ is a two-piece system (Injector and Port). The female luer end of the Injector is compatible with all ISO syringes and tubing sets, while the male end will only connect to the ChemoLock™ Port. The Port accepts only the ChemoLock™ Injector. The ChemoLock™ Port is the access point on all Vial Spikes, Bag Spikes and Administration Sets (e.g., primary lines). The Injector is a stand-alone for use on syringes or administration sets (e.g., secondary lines).

E.2.14.1 ChemoLock™ Vial Spike

The ChemoLock™ Vial Spike allows access to vials having 13 mm, 20 mm, and 28 mm necks. The external balloon on the Vial Spike equalizes pressure inside the vial during reconstitution and withdrawal of drug. The vapour containment of the balloon on the 13 mm Vial Spike is 20 mL. The vapour containment of the balloon on the 20 mm and 28 mm Vial Spikes is 100 mL.

The priming volume of the ChemoLock™ Vial Spike CL-82 (13 mm) is 0.16 mL and the CL-80S (20 mm) is 0.18 mL. The Port on the ChemoLock™ Vial Spikes has been tested to and is approved for up to 10 activations.

E.2.14.2 ChemoLock™ Injector

The ChemoLock™ Injector is attached to a standard luer-lock syringe for withdrawal of hazardous drug from a vial. The Injector can also be attached to a solution/intravenous administration set during administration of hazardous drug. The Injector is available in a spinning and non-spinning design. The spinning design prevents accidental disconnection of the Injector during hazardous drug preparation and administration.

The priming volume of the ChemoLock™ Injector CL-2000 (non-spinning) is 0.22 mL and the CL-2000S (spinning) is 0.34 mL. The ChemoLock™ Injector has been tested to and is approved for up to 10 activations.

E.2.14.3 ChemoLock™ Bag Spikes

The ChemoLock™ Bag Spike has a built-in ChemoLock™ Port to facilitate a leak-proof connection for the addition of drug into an infusion solution bag. The Port on the Bag Spike is also used by nurses to attach a ChemoLock™ solution/intravenous administration set to the medication bag for administration of hazardous drug. The Port on the ChemoLock™ Bag Spike has been tested to and is approved for up to 10 activations.

The priming volume of the ChemoLock™ Bag Spike (CL-10) is 0.43 mL.

The priming volume of the ChemoLock™ Bag Spike (CL-12) is 0.39 mL.

When hazardous drugs are prepared in an infusion solution bag for intermittent or continuous infusion, the drug must dilute in the total volume of the solution bag. This ensures the concentration of the drug remains consistent over the ordered administered time. If the ordered dose results in a small volume of drug added to the infusion solution bag through the ChemoLock™ Bag Spike, there may be a statistically significant percentage of the dose trapped in the Bag Spike. Because of this, the Bag Spike should be flushed using a new syringe and Injector when a volume of 3 mL or less is injected into the infusion solution bag through the Bag Spike.

Refer to Checklists- Module 1 - Appendix 1: Flushing a ChemoLock™ Bag Spike that has been used to inject 3 mL or less of drug solution into an Intravenous Solution Bag

E.2.14.4 ChemoLock™ Port

The ChemoLock™ Port attaches to the access port on an Infusor™ for addition of hazardous drug during preparation or onto a port on a primary intravenous line for administration of hazardous drugs. The Port attaches to an Injector to provide a leak-proof connection for safe drug transfer via injection or infusion.

The priming volume of the ChemoLock™ Port (CL-2100) is 0.1 mL. The Port has been tested to and is approved for up to 10 activations.

E.2.14.5 ChemoLock™ Syringe Transfer Set with MicroClave and ChemoLock™ Port

The ChemoLock™ Syringe Transfer Set with MicroClave and ChemoLock™ Port has a Clave connection at one end and a ChemoLock Port™ at the other end to provide a leak-proof connection for safe transfer of hazardous drug into a diluent-filled syringe during preparation of an intrathecal (IT) dose.

The priming volume of the ChemoLock™ Syringe Transfer Set with MicroClave and ChemoLock™ Port (CL-34) is 0.21 mL. The Port on the ChemoLock™ Syringe Transfer Set has been tested to and is approved for up to 10 activations.

E.2.14.6 ChemoLock™ Syringe Transfer Set with Double ChemoLock™ Ports

The ChemoLock™ Syringe Transfer Set with Double ChemoLock™ Ports has a ChemoLock Port at each end to provide a leak-proof connection for safe hazardous drug transfer from one syringe to another.

The priming volume of the ChemoLock™ Syringe Transfer Set with Double ChemoLock™ Ports (CL-33) is 0.28 mL. The Ports on the ChemoLock™ Syringe Transfer Set have been tested to and are approved for up to 10 activations.

E.2.14.7 ChemoLock™ Secondary Set with Drip Chamber

The ChemoLock™ Solution/Intravenous Administration Set with Drip Chamber has a built-in Injector at each end to facilitate a leak-proof connection to the Port on the Bag Spike and the Port on the primary intravenous line for administration of hazardous drug to a patient.

The priming volume of the ChemoLock™ Secondary Set with Drip Chamber (CL-3520) is 5.2 mL.

E.3 Containers

E.3.1 Ampoules

An ampoule is a small glass container sealed to preserve the sterility of an injectable solution. Ampoules can be used to package drugs that may not be chemically compatible with plastic containers or rubber closures. The upper portion of the ampoule (head) is 'snapped' off creating an open-system.[31]

Drug in an open system container is vulnerable to microbial contamination. Environmental hazardous drug aerosol/vapour contamination is a risk when working with open system containers containing hazardous drug.

Standard:

The length of time between opening an ampoule and transferring the solution into a closed-system (e.g., syringe) must be minimized.[29]

To minimize the length of time the drug is exposed, the syringe and needle or filter device should be assembled prior to removing the top from of the ampoule.

Most ampoules are pre-weakened by the manufacturer around the neck. Ampoules often have a painted ring around the neck indicating where the weak point is. A second ring painted higher on the ampoule head indicates the point behind where fingers should be placed to help avoid injury when the ampoule is broken.

Standard:

The neck of the ampoule must be wiped to disinfect using a sterile 70% alcohol swab before breaking and must not be touch-contaminated after being disinfected.[33]

A new sterile alcohol swab may be wrapped around the neck of the glass ampoule before breaking it to protect the fingers from sharp edges. An ampoule breaker may be used in place of a new sterile alcohol swab. An ampoule breaker used to break off the upper portion of an ampoule containing a hazardous drug should be dedicated for this purpose and not be used on ampoules containing non-hazardous drug. A non-disposable ampoule breaker must be decontaminated after every use.[22]

Standard:

Glass particles in solutions must be filtered prior to administration[98] unless the manufacturer indicates the solution cannot be filtered. Solution must not be withdrawn and injected using the same filtration equipment.[29]

If a filter device (e.g., needle or disc) was used to withdraw a hazardous drug solution into a syringe, the filter device must be changed to a regular needle for injection into a solution container.

Drug solutions that are oily or too viscous to be filtered should be drawn up using a 20 gauge or smaller needle bore, leaving behind a residual volume of solution in the ampoule.

This residual volume should contain any glass particulate that was produced when the ampoule was broken. The residual volume from an ampoule containing hazardous drug should be withdrawn. The syringe must be tip capped and then discarded in a hazardous drug waste container.

Standard:

All parts of an opened ampoule must be discarded into a sharps container.[31]

There are two techniques for withdrawal of a hazardous drug from an ampoule using a filter device. Ampoule size, syringe size and operator preference will determine which to use.

E.3.2 Vials

A vial is either a glass or plastic container with a stopper secured to the top by a ring of metal banding. A flip-top cap protects the stopper. There may be traces of hazardous drug trapped between the flip top cap and the stopper of hazardous drug vials.

Standard:

Removal of a flip top cap from a hazardous drug vial must be performed carefully inside the C-PEC to 'contain' and avoid spreading HD contamination to areas outside of the C-PEC.[35]

Studies show HD surface contamination exists on commercially available vials of hazardous drugs as delivered from the manufacturer.[99-103]

Standard:

Hazardous drug vials must be wiped to disinfect (not sprayed) using a low-lint towel or gauze moistened with sterile 70% alcohol prior to placement inside the C-PEC.[33]

The puncture date and time must be written directly onto reconstituted and partial vials that will be saved for future use with ink that will not smudge or wipe off.[12] The product stability may be determined by referring to the BC Cancer Chemotherapy Preparation and Stability Chart.

Refer to Checklists- Module 1 - Appendix 1: Minimizing Core Formation When Using a Needle

Refer to the BC Cancer Chemotherapy Preparation and Stability Chart in the Cancer Drug Manual

E.3.3 Polyvinyl Chloride (PVC) Bags

Flexible bags made of polyvinyl chloride (PVC) are used for intravenous delivery of hazardous drugs. They are easy to store and eliminate the need for venting when adding or removing solution. Most PVC bags have one injection port which has two diaphragms that must be pierced. There are also PVC bags with one or two administration ports on the bag. Solutions come in volumes ranging from 25 mL to 5000 mL and include normal saline (NS), dextrose 5% in water (D5W), and mannitol. PVC bags are packaged in plastic over wraps to limit fluid loss. Bags smaller than 100 mL have a stability dating of 15 days out of the over wrap and bags 100 mL and larger have a stability dating of 30 days out of the over wrap.[104]

E.3.4 Non-Di(2-ethylhexyl)phthalate (Non-DEHP) Bags

Polyvinyl chloride (PVC) is a plastic polymer that is hard and brittle at room temperature. Di(2-ethylhexyl)phthalate (DEHP) is a chemical additive that is used to make polyvinyl chloride in medical devices soft, flexible and kink-resistant. The terms 'non-PVC' and 'non-DEHP' were once used interchangeably, but are now known to be different. As such, the term 'non-DEHP' has replaced the term 'non-PVC'.

Some drug solutions contain the surfactants Cremaphor EL (PACLitaxel) and Polysorbate 80 (DOCEtaxel and etoposide). These surfactants have been shown to extract DEHP from PVC containers and tubing into the hazardous drug solution.[79] The amount of DEHP leached into solution depends on the surfactant concentration, bag size and contact time. It is not known what level of DEHP is 'dangerous' to humans however DEHP is hepatotoxic and exposure should be minimized.

Standard:

PACLitaxel, DOCEtaxel, temsirolimus, teniposide, etoposide, cabazitaxel, cycloSPORINE and ixabepilone must be prepared in non-DEHP containers and administered using non-DEHP tubing.[77]

Polyolefin bags do not contain DEHP. They are biologically inert and non-toxic. Non-DEHP bags are available commercially as empty bags or filled with various volumes of standard infusion solutions.

E.3.5 Empty Sterile Infusion Bags

Empty sterile infusion bags may be used with programmable ambulatory infusion devices that require exact volumes of drug and diluent (e.g., Ambulatory Infusion Manager [AIM®] pump). Commercially available infusion solution bags with inconsistent overfill volumes are not suitable.

Empty sterile infusion bags may also be useful as 'waste containers' inside the C-PEC when contaminated air or excess HD solution needs to be removed from a syringe during HD drug preparation.

Standard:

Infusion bags used for hazardous drug solution waste must be disposed of as hazardous drug waste.[14]

Refer to Checklists- Module 1 - Appendix 1: Injection of Hazardous Drug Solution into an Intravenous Solution Bag Using ChemoLock™

Refer to Checklists- Module 1 - Appendix 1: Injection of Drug Solution into an Intravenous Solution Bag Using a Needle and Syringe

E.3.6 Evacuated Containers

An evacuated container is a sealed sterile glass bottle that has had the air removed creating a vacuum. Standard size bottles are 250 mL, 500 mL and 1000 mL. Sterilization of glass evacuated containers may be achieved through steam sterilization leaving a small amount of normal saline or water in the container. The label will indicate the expiry date and the solution used for steam sterilization.

Evacuated containers may be used when:

- The volume of drug to be added exceeds the capacity of the appropriate solution bag. Solution may be drained into an evacuated container prior to the addition of hazardous drug
- The drug may be more stable in glass than in PVC containers
- The drug is not compatible with plastic and the use of a polyolefin bag is not suitable

Once the drug and solution have been added to an evacuated container for patient administration, the excess vacuum should be aseptically removed using a 0.22 micron hydrophobic venting device.

E.4 Ambulatory Drug Delivery Infusion Devices

Elastomeric infusion devices are non-electric disposable ambulatory drug infusion devices. The use of a programmable ambulatory pump (e.g., Computerized Ambulatory Drug Delivery [CADD®], Ambulatory Infusion Manager [AIM®]) may occur with some clinical trials or in circumstances when an elastomeric infusion device is not deemed appropriate. Other fixed-rate infusion devices may be used, provided that they are able to administer the ordered dose over the ordered infusion duration.[105]

E.4.1 Elastomeric Infusion Devices

Based on the recommendations of the Institute for Safe Medication Practice (ISMP) Canada, BC Cancer has revised all treatments with 5-fluorouracil continuous infusions to minimize the potential for medication errors. The use of elastomeric infusion devices is one of several recommendations made by the ISMP to increase patient safety.[106] BC Cancer has chosen to implement this recommendation and has switched to elastomeric infusion devices for ambulatory delivery of continuous 5-fluorouracil infusions. These devices are available in a variety of sizes which have different flow rates.

BC Cancer has selected Baxter's elastomeric Infusors™ for ambulatory chemotherapy delivery because they are readily available and their performance standards meet the needs of BC Cancer. Baxter elastomeric Infusors™ consist of an elastomeric reservoir (balloon) inside a hard plastic outer casing (cover) with attached infusion delivery tubing.

E.4.1.1 Medication Delivery via Infusor™

Medication is delivered via a Baxter Infusor™ when the elastomeric balloon slowly deflates pushing solution through the tubing at a fixed-flow rate. The pressure on the fluid is generated by the force of the stretched elastomeric balloon. A fixed flow rate is inherent in the design of the device and programming is not required. The restriction of flow in an elastomeric Infusor™ is caused by narrow-bore tubing within the flow restrictor. The diameter of this tubing determines the device's flow rate. Flow restrictors may be made of either glass or PVC. Their dimensions should change little with temperature in order to maintain an accurate flow rate. The flow restrictor is always integral to the administration set.

E.4.1.2 Infusor™ Flow Rates

Elastomeric Infusors™ are available with flow rates ranging from 1.5 mL to 10 mL per hour and running times from 12 hours to 7 days.

To ensure the most accurate flow rate, Baxter Infusors™ should be filled to their labelled 'nominal fill volume'.[107] A reduction in fill volume (i.e., less than 81%) may result in an increased flow rate and therefore is not recommended. The potential increase in flow rate resulting from a reduction in fill volume is indicated below:[108]

- a 0% change in flow rate results when the fill volume is reduced to 81-100% of nominal
- a 5% increase in flow rate may result when the fill volume is reduced to 61-80% of nominal
- a 10% or greater increase in flow rate may result when the fill volume is reduced to 60% or less of nominal

In an effort to simplify dosing calculations and err on the side of caution, Baxter recommends Infusors be filled to a minimum of 90% of the nominal fill volume. This information has been added to the label on the Infusor. The previous instructions of filling to a nominal volume of equal or greater than 81% of the nominal fill volume remain valid and can be followed.

Note that nominal volume is not the same as maximum volume capacity. Maximum and nominal values for each Infusor™ size can be found in the Infusor's™ package insert. See Section E.4.1.3 for a summary table indicating maximum and nominal volumes for several Baxter elastomeric Infusors™.

Standard:

The correct size of elastomeric Infusor™ with the correct infusion rate must be selected when preparing hazardous drug medication.[43]

Flow rate is also affected by fluid viscosity and by pressure gradient across the flow restrictor. These factors may vary in clinical settings and significantly affect the accuracy and/or duration of infusion therapy.

Fluid viscosity is strongly affected by temperature and somewhat affected by drug concentration.[109] Infusors™ are designed to operate at the labelled flow rate when the diluent is D5W. Substituting a less viscous diluent such as normal saline may increase the flow rate by approximately 10%.[107]

Pressure gradient may be affected by vertical displacement of the device relative to the infusion site (e.g., patient), initial filling volume (e.g., under/overfilling), storage conditions (e.g., refrigeration/freezing), and variations in barometric pressure.[109]

Standard:

To decrease the risk of accidental exposure to hazardous drug, the delivery tubing of the Infusor™ must be primed with hazardous drug-free solution.[13, 107]

E.4.1.3 Infusor™ Volume Capacities and Fixed Flow Rates

There are two Infusor™ design shapes available from Baxter- tubular and rounded (baby bottle) shape. Both designs are available in different maximum volume capacities and fixed flow rates. Some examples of the two shapes of Infusors™ are:[107]

Table 8: Infusor™ Volume Capacities and Fixed Flow Rates

Baxter's Description	Shape	Color Code	Fixed Flow Rate	Maximum volume	Nominal Volume	Residual Volume
Two-Day Infusor™	Tubular	**Black**	2 mL/hr	105 mL	96 mL	2.5 mL
Infusor™ SV2	Baby bottle	**Yellow**	2 mL/hr	130 mL	96 mL	1 mL
Infusor™ LV1.5	Baby bottle	**Pink**	1.5 mL/hr	300 mL	252 mL	3 mL
Infusor™ LV2	Baby bottle	**Yellow**	2 mL/hr	300 mL	240 mL	3 mL
Infusor™ LV5	Baby bottle	**Maroon**	5 mL/hr	300 mL	240 mL	3 mL
Infusor™ LV10	Baby bottle	**Purple**	10 mL/hr	300 mL	240 mL	3 mL
Single Day Infusor™	Tubular	**White**	2 mL/hr	65 mL	48 mL	1.5 mL

'SV' = small volume; 'LV' = large volume. The number following indicates the fixed flow rate of that device.[105]

E.4.1.4 Hazardous Drug Medication Infusion Device Labels

Standard:

The intended infusion rate must be stated in millilitres per hour (mL/hour) on the medication label when hazardous drug is administrated via an infusion device.[105]

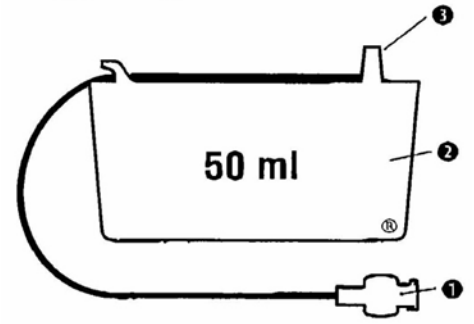
Refer to Checklists- Module 1 - Appendix 1: Elastomeric Infusor™ Preparation Using ChemoLock™

Refer to Checklists- Module 1 - Appendix 1: Elastomeric Infusor™ Preparation NOT Using ChemoLock™

E.4.2 Computerized Ambulatory Drug Delivery (CADD®) Pump and Medication Cassette Reservoir

The Computerized Ambulatory Drug Delivery (CADD®) pump is a programmable medication infusion device that provides measured drug therapy to patients in hospital or outpatient settings. The medication cassette reservoir for the CADD® pump is available in 50 mL or 100 mL volumes and is designed with standard luer-lock fittings. A CADD® extension set with an anti-siphon valve or a CADD® administration set with either an integral or an add-on anti-siphon valve must be used to protect against unregulated gravity infusion that can result from an improperly attached reservoir.

The CADD® Pump is indicated for intravenous, intra-arterial, subcutaneous, intraperitoneal use and infusions into epidural space, or subarachnoid space. It may be used for infusion of antibiotics, analgesics, anaesthetics, and chemotherapy medications.



1. Luer-Lock Fitting Access Port
2. Medication Bag
3. Pump Attachment

22

Standard:

To decrease the risk of exposure to hazardous drug, the tubing of a CADD® medication cassette reservoir must be primed with hazardous drug-free solution.[13]

Note:

- Avoid pressurizing the medication bag ❷ inside of the medication cassette reservoir (respect the maximum capacity of the medication bag). Over pressurizing or overfilling may cause the medication bag to rupture.

Section F - Aseptic and Protective Processes

F.1 Operational Standards for Sterile Hazardous Drug Preparation

Standard:

Hazardous drugs shall be prepared only under conditions that protect the healthcare workers and other personnel in the controlled area.[14]

Operational standards must be adhered to when preparing sterile HD admixtures.[29]

F.1.1 Personnel Hygiene in the Controlled Area

- **Standard: Eating, drinking, smoking, chewing gum or candy, or storing food in the controlled area is strictly prohibited[12, 13]**
- **Standard: Personnel with rashes, burns to the skin (including sunburn), weeping sores, cold sores, other fresh wounds, conjunctivitis, active respiratory infection with coughing, sneezing or runny nose, and wearing cosmetics are prohibited from entering the controlled area[12]**
- **Standard: Before entering the controlled area, personnel must remove:**
  - ✓ **personal outer garments (e.g., bandana, coat, hat, jacket, scarf, sweater, vest, boots, and outdoor shoes) because they shed flakes and particles[12]**
  - ✓ **jewellery, studs, and other accessories from fingers, wrists, forearms, face including nose, tongue and ears, and neck[12]**
  - ✓ **all cosmetics, false eyelashes, perfume, hair products such as hairspray, henna tattoos and paper tattoos, as these products can generate particles that are possible sources of contamination[12]**
  - ✓ **nail polish and other nail applications (nail extensions, synthetic nail-lengthening products), natural nails must be kept neat and trimmed[12]**

F.1.2 Personal Protective Equipment and Clean Room Garb in the Controlled Area

- **Standard: Street clothes must be replaced with fresh scrubs daily by all personnel when the work assignment will take place in the controlled area[12]**
- **Standard: Personnel entering the controlled area must wear socks (that are long enough to reach higher than the bottom of the pant legs at all times, including when seated) and closed shoes[12]**
- **Standard: One pair of shoe covers must be donned in the gowning room to enter the controlled area,[29] a second pair of shoe covers must be donned if stepping from the dirty side of the anteroom to the clean side[12]**

  OR
- **Standard: Two pairs of disposable shoe covers (or a second pair if already wearing one pair of shoe covers) must be donned when stepping from the dirty side of the demarcation line in the anteroom to the clean side[12]**
- **Standard: Hair covers (covering hair and ears completely) and beard covers (as applicable), must be worn in the controlled area[12]**
- **Standard: Hair covers and beard covers (as applicable) must be donned on the dirty side of the demarcation line in the anteroom[12]**

  OR
- **Standard: Hair covers and beard covers (as applicable), must be donned in the gowning room[29]**
- **Standard: At a minimum, an AAMI rated Level 1 medical mask must be worn by staff compounding hazardous sterile preparations in a containment primary engineering control[12, 50]**
- **Standard: When decontaminating interior surfaces of the C-PEC, when working in a clean room when a C-PEC is being decontaminated, or when cleaning up hazardous drug spills, additional PPE is required, including a NIOSH-approved elastomeric half face mask respirator with a face-shield and safety goggles or an elastomeric full face mask respirator. The respirator must be used with appropriate filter cartridges and be fit-tested for the operator[12]**
- **Standard: A respirator must be donned on the dirty side of the demarcation line in the anteroom[12]**
- **Standard: An isolation gown must be donned in the gowning room to enter the controlled area[29] when the controlled area comprises of rooms in addition to the anteroom and clean room**
- **Standard: A chemotherapy or isolation gown must be donned on the clean side of the demarcation line in the anteroom (depending on the work being performed)[29]**
- **Standard: A chemotherapy gown must be worn any time there is a risk of hazardous drug exposure (e.g., when working in the C-PEC, when cleaning up a HD spill)[12]**
- **Standard: Hands must be cleansed and gloves donned in the gowning room[29]**
- **Standard: Hand hygiene must be performed and gloves donned on the clean side of the demarcation line in the anteroom to enter the clean room[12]**
- **Standard: Gloves worn when touching surfaces that may be contaminated with hazardous drug must be tested with nine chemotherapy drugs as required in the ASTM International Standard D6978-05. 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[14, 55]**

- **Standard: Two pairs of disposable chemotherapy gloves must be worn at all times by all personnel when hazardous drug exposure is possible (e.g., when handling hazardous drug vials, when mixing hazardous drug in a C-PEC). Both pairs of chemotherapy gloves must be inspected for visible defects. Gloves that have visible defects must not be worn.[12]**
- **Standard: Gloves must be powder-free because powder can contaminate the work area and can absorb and retain hazardous drug.[14]**
- **Standard: Gloves must be disinfected before being placed into the C-PEC by wiping with a low lint towel moistened with sterile 70% isopropyl alcohol. The gloves must be completely dry before performing aseptic compounding activities inside the C-PEC[12]**
- **Standard: Both pairs of disposable chemotherapy gloves worn when handling hazardous drugs must be changed every 30 minutes (unless otherwise indicated by the manufacturer's documentation) or immediately if a tear, puncture or contamination is known or suspected.[14]**
- **Standard: Hands must be washed with soap and water every time gloves are removed.[14]**
- **Standard: Chemotherapy gowns worn when preparing hazardous drugs must be non-linting, impermeable, disposable chemotherapy gown with long sleeves and fitted cuffs, enclosed at the neck, closing at the back (no open front), and tied around the waist [12]**
- **Standard: Lab coats and isolation gowns must not be worn in place of chemotherapy gowns when protection from HD exposure is required because they permit the permeation of hazardous drug and can hold spilled hazardous drug against the skin, thereby increasing exposure[14]**

Refer to Checklists- Module 1 - Appendix 1: Donning of Personal Protective Equipment When Working in a Biological Safety Cabinet

Refer to Checklists- Module 1 - Appendix 1: Donning of Personal Protective Equipment to Enter a Hazardous Drug Clean Room When Not Working in a Biological Safety Cabinet

Refer to Checklists- Module 1 - Appendix 1: Exiting the Clean Room to Wash Hands Every 30 Minutes during Hazardous Drug (HD) Compounding

F.1.3 Containment Primary Engineering Control (C-PEC)

- **Standard: The UV light inside the C-PEC may cause eye damage and must not be turned on when personnel are working in the clean room[28, 37]**
- **Standard: All interior surfaces of the C-PEC (except under the work surface) must be cleaned and disinfected using appropriate agents followed by sterile 70% isopropyl alcohol[12] prior to commencing daily compounding. If the viewing window has been raised during cleaning and disinfecting, it must be lowered to the manufacturers recommended operating level and the C-PEC must purge for at least 15 minutes after decontaminating before beginning compounding.[16]**
- **Standard: The viewing window must be kept at the manufacturer's recommended level during HD preparation[28, 37]**
- **Standard: Rapid arm movements that could disrupt the air curtain must be minimized[28, 37]**
- **Standard: The front air intake grill and the rear air exhaust route must not be blocked[28, 37]**
- Materials required for the preparation should be placed as far in from the front grill as practical, without blocking the rear grill[28]
- **Standard: Manipulations must be performed at least six inches in from the front opening and side walls of the BSC[29]**
- **Standard: The work surface of the C-PEC must be decontaminated, cleaned, and disinfected between each preparation using appropriate agents followed by sterile 70% isopropyl alcohol[29]**

- **Standard: Following hazardous drug compounding, the C-PEC must purge for at least five minutes[37] and then all interior surfaces (except under the work surface) must be decontaminated, cleaned, and disinfected using appropriate agents followed by sterile 70% isopropyl alcohol:[12]**
  - ✓ **after preparations within the C-PEC are completed for the day[29]**
  - ✓ **prior to compounding 'latex-free' preparations[29]**
  - ✓ **prior to compounding sterile HD preparations in a C-PEC once it has been used to compound non-sterile HD preparations[29]**
  - ✓ **prior to resuming compounding in a C-PEC that is turned off between aseptic processes for any reason (e.g., power interruption, maintenance)[29]**

Refer to Checklists- Module 1 - Appendix 1: Morning Cleaning of Interior Surfaces of the Biological Safety Cabinet

Refer to Checklists- Module 1 - Appendix 1: Daily Decontamination of Interior Surfaces of the Biological Safety Cabinet

Refer to Checklists- Module 1 - Appendix 1: Weekly Decontamination of the Biological Safety Cabinet

F.1.4 General Procedures

- Chair height should be adjusted so that the operator's shoulders are level with the bottom of the front viewing window when seated. This provides face and eye protection while positioning the operator to compound within a biological safety cabinet[31]
- Only materials required to aseptically prepare a single dose for one patient should be placed into the C-PEC at one time[110] This creates a less crowded work space and improves patient safety by minimizing the chance that the wrong drug is selected and injected into the final container (e.g., diluent bag) which could then possibly go undetected during the final product check
- **Standard: Unnecessary items must not be taken into the C-PEC since airflow is disrupted in an overcrowded C-PEC[28]**
- **Standard: HD vials must be wiped with low-lint towels or gauze moistened with sterile 70% isopropyl alcohol to disinfect and physically remove HD contamination prior to placement inside the C-PEC[33]**
- **Standard: Prior to placement inside the C-PEC, the outer wrapping of unopened supplies (e.g., syringes) must be disinfected by wiping using a low lint towel moistened with sterile 70% isopropyl alcohol[33]**
- **Standard: Best practice standards for aseptic technique in vertical airflow must be adhered to when preparing sterile hazardous drug admixtures[12]**
- **Standard: Compounding must occur in the critical area (direct compounding area) of the C-PEC such that critical sites are exposed to first air.[12] Supplies not immediately required for use must not be kept in the critical area of the C-PEC;** supplies are stored to the side of the critical area in a 'storage zone'
- **Standard: To decrease particle generation inside the C-PEC, paper coverings must be peeled away from needle hubs (critical sites) rather than pushing them through[29]**
- Tweezers may be used to handle sticky surfaces of foil seals and to remove multiple or sharp vial caps to protect gloves from tearing and potential contamination[22]
- **Standard: Critical sites must be protected as soon as possible after being exposed and must not be touch contaminated[33]**
- **Standard: Infusion solution bag ports and vial stoppers must be disinfected using sterile 70% isopropyl alcohol prior to accessing[33]**
- **Standard: A new sterile alcohol swab must be used to disinfect each critical site[33]**

- **Standard: When reconstituting, the drug must be completely dissolved before withdrawing a dose[16] or storing for future use**
- **Standard: Syringes must not be overfilled with hazardous drug. In most cases, syringes should not be more than three-quarters (75%) full, although some preparations require accurate volume measurements that necessitate the use of a smaller volume syringe[29]**
  - Exception: BD syringes labelled as '50 mL syringes' may be filled to 45 mL with hazardous drug solution because BD removed the graduation markings on their 60 mL syringes past 50 mL and now label these syringes as '50 mL syringes'; no other changes were made to these syringes that were **previously labelled as '60 mL syringes'**
- **Standard: Verification of volumes measured in syringes during compounding must be performed prior to dispensing the final product in one of two ways:[12]**
  - ✓ **direct observation during compounding; or**
  - ✓ **review of photos taken of the solution-filled syringe(s)**
- **Standard: Verification of volumes measured in syringes during compounding must NOT be performed by marking syringes with a line indicating the volume of solution withdrawn while the solution is in the syringe with the check taking place after the volume has been injected into a final container.[12]**
- To modify the required volume in a syringe which has been out of the C-PEC, standard aseptic practice requires that the HD first be transferred from the original syringe to a new syringe using a transfer device.[43] The syringe plunger has been exposed to a non-ISO Class 5 environment and cannot be disinfected.
- **Standard: Negative pressure technique must not be used for hazardous drug reconstitution or withdrawal if filter venting devices[29] or closed system drug transfer devices[4] are available**
- **Standard: A puncture-proof sharps container must be used for disposal of all sharp objects including needles, chemotherapy dispensing pins, and chemotherapy vents[29]**
- **Standard: All non-sharp waste generated during compounding of hazardous drugs must be placed inside a HD waste container (e.g., zip lock bag or sharps container) in the C-PEC for later removal and disposal[14]**

F.1.5 Removing Products from the Containment Primary Engineering Control (C-PEC)

- **Standard: Infusion solution bag ports that have been accessed must be wiped with an alcohol swab prior to removal from the C-PEC[33] to remove possible HD residue**
- **Standard: Infusion solution bags that have had hazardous drug added must be checked for leaks and particulate prior to removal from the C-PEC (if the injection port was used to add drug to the infusion solution bag)[12]**
- Studies have shown that outer chemotherapy gloves may be contaminated with HD after compounding.[14]
- **Standard: Outer chemotherapy gloves worn when compounding hazardous drugs must be removed, discarded within the C-PEC and replaced with a new pair of sterile chemotherapy gloves or wiped with a new towel moistened with a decontaminating agent prior to touching items for removal from the C-PEC[29]**
- **Standard: Surfaces of final preparation(s) may be contaminated with HD and must be decontaminated using a new towel moistened with a decontaminating agent prior to removal from the C-PEC[29]**
- **Standard: The final preparation must be labelled immediately after it is removed from the C-PEC with the patient-specific label and any required warning labels[111]**
- To remove a vial of HD that will be saved for reuse from the C-PEC:
  - ✓ **Standard: the vial stopper must be wiped with a sterile 70% alcohol swab[33] to remove possible HD residue (if there is not a chemotherapy dispensing pin or CSTD inserted)**

- ✓ **Standard: the puncture date and time must be written directly on the vial with a thin-tipped permanent marker[29]**
- ✓ **Standard: the vial must be wiped with a new towel moistened with a decontaminating agent[29]**
- ✓ **Standard: the vial must be placed inside a zip lock bag that is sealed inside the C-PEC or above the front grill upon removal from the C-PEC[22]**

➢ **Standard: Containers used for HD waste (sharp and non-sharp) must be sealed and decontaminated using a new towel moistened with a decontaminating agent inside the C-PEC before removal from the cabinet[4]**

Refer to Checklists- Module 1 – Appendix 1: Removal and/or Disposal of Used Supplies and the Final Product from the Biological Safety Cabinet

Refer to Checklists- Module 1 – Appendix 1: Cleanup and Waste Disposal in the Biological Safety Cabinet

F.1.6 Warning Labels

➢ **Standard: All hazardous drugs and hazardous drug preparations must be easily identifiable by personnel involved in their handling[13]**

➢ **Standard: The container of hazardous drug must be appropriately labelled[13] indicating the contents are hazardous in nature**

F.1.7 Exiting the Clean Room

➢ **Standard: PPE must be appropriately removed upon exiting the controlled area:[13, 14]**

- ✓ **Outer chemotherapy gloves must be discarded into a hazardous waste container[14] (inside or outside of the C-PEC) prior to exiting the clean room; outer gloves must NOT be worn outside the clean room once compounding hazardous drugs in the C-PEC has occurred[12, 13, 47]**
- ✓ **The inner gloves must not be removed inside the clean room[43]**
- ✓ **Inner gloves must be disposed of into a hazardous waste container[12]**
- ✓ **Both pairs of chemotherapy gloves worn when handling hazardous drugs must be changed every 30 minutes (unless otherwise indicated by the manufacturer's documentation) or immediately if a tear, puncture, or contaminates is known or suspected. Gloves must be disposed of into a hazardous waste container[14]**
- ✓ **Removal and disposal of chemotherapy gowns must be done with care to avoid spreading HD contamination to other non-contaminated garments[14]**
- ✓ **Chemotherapy gowns must be discarded into hazardous waste containers after:[12]**
  - **no more than 3 hours of continuous compounding**
  - **contamination has occurred or is suspected**
  - **each removal**
- ✓ **Chemotherapy gowns worn in the clean room during hazardous drug compounding must be removed and disposed of in the clean room, to prevent the spread of HD contamination from one area to another.[13]**
- ✓ **The outer pair of shoe covers must be removed with gloved hands upon exiting the clean room into the anteroom and must be discarded as hazardous waste[14] inside the clean room**

- ✓ **The inner pair of shoe covers is removed upon stepping from the clean side of the demarcation line in the anteroom to the dirty side[12] and is disposed of into HD waste[14]**

  OR
- ✓ **The inner pair of shoe covers is removed in the gowning room[29] and is disposed of into a hazardous waste container[14]**
- ✓ **The medical mask or respirator and hair cover(s) must not be removed inside the clean room[12]**
- ✓ **Disposable masks, respirators and hair cover(s) must be disposed of into a hazardous waste container[12]**
- ✓ **Disposable masks, respirators and beard covers must be changed after no more than 3.5 hours of continuous use[12]**
- ✓ **Reusable respirators, safety goggles, and face shields must be decontaminated daily after use[12]**
- ✓ **Hands must be washed immediately with soap and water every time gloves are removed[14]**
- ✓ **An isolation gown must be donned over scrubs when exiting the anteroom[31] into another room within the controlled area. If the anteroom exits directly into the general pharmacy, or to leave the controlled area, an isolation gown or lab coat must be donned over scrubs upon exiting[31]**

Refer to Checklists- Module 1 - Appendix 1: Removal of Personal Protective Equipment to Exit the Clean Room after Working in a Biological Safety Cabinet

Refer to Checklists- Module 1 - Appendix 1: Removal of Personal Protective Equipment to Exit the Clean Room When Not Working in a Biological Safety Cabinet

F.2 Aseptic/Protective Routines

F.2.1 Critical Sites

Critical sites are surfaces or openings which may come in contact with sterile drug or surfaces which will be punctured that are at risk of direct contact with air, moisture, or touch contamination.

Standard:

Critical sites must be protected as much as possible and must not be touch-contaminated.[33] Protection of critical sites by precluding physical contact and airborne contamination must be given the highest priority in aseptic compounding practice.[33]

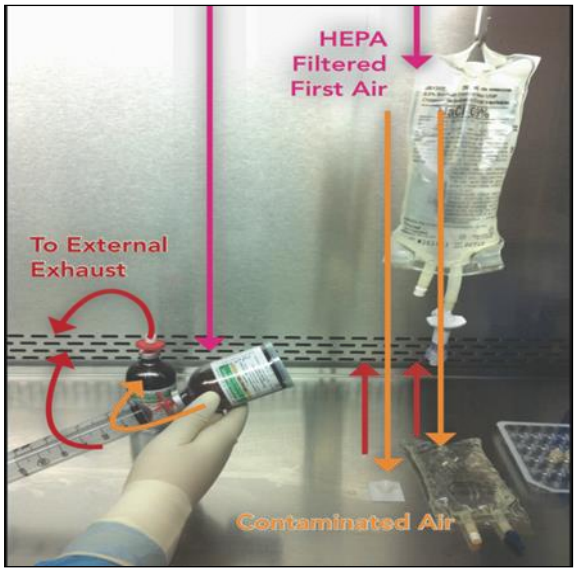
F.2.2 First Air

First air is unobstructed HEPA filtered air that washes over components (solution containers, syringes, gloves, etc.) in the work area of the C-PEC. Air that flows downstream from the HEPA filter may become contaminated with particles dislodged from components and PPE (e.g., chemotherapy gown sleeves and gloves) that are placed in the first air.[33]

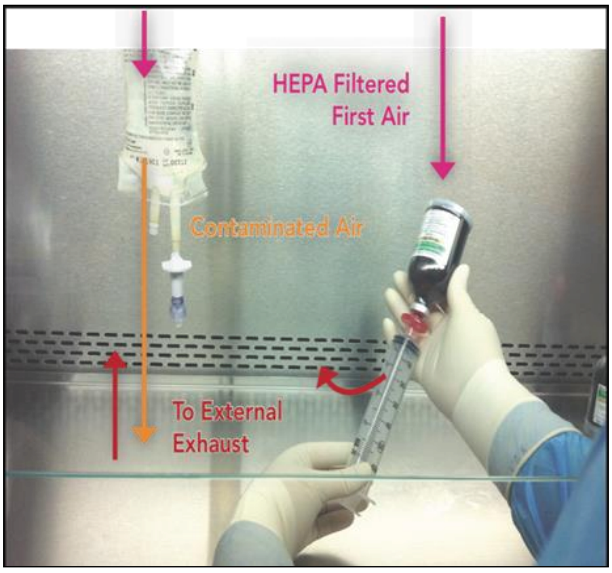
Standard:

While working in the C-PEC, a path of first air must be maintained to critical sites at all times. It is vital to avoid reaching over or working directly above or in front of exposed or previously disinfected critical sites.[12]

Path of First Air to Critical Sites Obstructed



Path of First Air to Critical Sites Maintained



F.2.3 Disinfecting Critical Sites

Standard:

The stopper on a vial or the port on an infusion solution bag must be disinfected using a sterile 70% alcohol swab just prior to penetration. At least 10 seconds must be allowed for the alcohol to dry (act) before manipulations begin.[33]

Wiping a critical site with a sterile alcohol swab is necessary for disinfection and the physical removal of particulates. The correct technique to disinfect a critical site is to make several firm strokes in the same direction over the rubber closure.[29]

Standard:

A new sterile swab must be used to disinfect each new surface.[29] The surface of sterile 70% alcohol swabs used to disinfect entry points on infusion solution bags and vials shall not contact any other object before contacting the surface of the entry point.[33]

Prior to removal from the C-PEC, the port of an infusion solution bag that has had drug added must be wiped with an alcohol swab[33] to remove possible HD residue.

F.2.4 Coring

When piercing infusion bag ports and vial stoppers with needles, it is important to avoid coring.[29] Coring occurs when the bevel tip and the bevel heel do not penetrate the port or stopper at the same point[36] causing particles of the port or stopper to end up in the diluent/HD solution.

Standard:

Each vial and final product must be checked for particulate (e.g., coring) after each puncture of a vial stopper or infusion solution bag port.[12]

Vials, syringes, and final products are checked for particulate by rotating upside down and right side up, while visually inspecting the contents.

F.2.5 Safely Capping Needles Used With Hazardous Drug

Standard:

Needles are a critical site and therefore must be capped when not being used for injection or withdrawal.[29] Prior to manipulation of a hazardous drug-filled syringe, the needle must be capped to reduce aerosol release and prevent splashes from the needle tip.[22]

For worker safety, two-handed recapping of a needle used for HD preparation is never an acceptable practice.[29] If recapping a needle is required, a one-handed 'scoop' method or a needle cap holder should be used.

In the event of a needle stick injury, see Accidental Exposure to Hazardous Drugs: Accidental Injection/Skin Puncture in Section J.1.4

Refer to Checklists- Module 1 - Appendix 1: Safely Capping Needles Used with Hazardous Drugs

F.3 Safe Handling Aseptic Techniques

F.3.1 Transfer of Hazardous Drug Solution from a Syringe

Standard:

If too much hazardous drug solution has been drawn into a syringe, care must be taken to minimize aerosol and vapour production, and to contain hazardous drug solution while removing the excess volume.[32, 75]

Excess drug may be injected back into the original drug vial, an empty sterile vial, or an empty infusion bag.[32, 75] Another option is to transfer the calculated hazardous drug volume to a fresh syringe via a syringe fluid dispensing connector. The syringe containing the excess drug should be capped using either a closed-system drug transfer device or a luer-lock tip cap and discarded into the HD waste container.

To modify the required volume in a syringe which has been out of the C-PEC, the HD should first be transferred from the original syringe to a new syringe[43] using a transfer device.[22] The syringe plunger has been exposed to a non-ISO Class 5 environment and cannot be disinfected. If excess drug remains in the original syringe, the labelled syringe may be recapped and saved for future use or discarded into the HD waste container.

Standard:

Excess hazardous drug must NOT be ejected into the needle cap, sharps container, or any other open container[32] as this could cause HD aerosolization, vaporization or contamination.

F.3.2 Removal of Bubbles/Air from a Syringe

The presence of bubbles/air in a syringe may prevent accurate measurement of solution.

Standard:

Bubbles and air must be removed carefully in a manner that prevents the release of HD solution and minimizes the production of HD aerosols in the C-PEC.[32, 75]

Refer to Checklists- Module 1 - Appendix 1: Removal of Air from a Syringe

F.3.3 Attaching and Priming Solution / Secondary Administration Sets

Standard:

Priming any intravenous administration set with hazardous drug solution in an uncontrolled environment must be avoided.[13]

To minimize exposure to HD, the administration tubing/line must be primed with HD-free solution whenever possible (e.g., unless contraindicated by the drug).[13]

Refer to Checklists- Module 1 - Appendix 1: Priming Solution / Secondary Administration Sets Inside the Biological Safety Cabinet

F.3.4 Withdrawal of Excess Solution from an Infusion Solution Bag

To prevent solution bags from becoming too full for safe administration after the addition of hazardous drug, it is sometimes necessary to withdraw solution from the intact bag before adding the drug. Maximum solution volumes for hazardous drugs contained in infusion solution bags should be established at each facility with consideration given to the type of bag and the fill capacity. This may be supplied by the manufacturer.

There are many acceptable methods for ensuring that infusion solution bags are not overfilled during HD preparation. Each facility should train pharmacy staff to perform a method that is aseptic, accurate, and consistent.

The withdrawn solution should be disposed of in a tip-capped syringe or injected into an empty infusion bag in the C-PEC - not expelled into a HD waste container.

Refer to Checklists- Module 1 - Appendix 1: Withdrawal of Solution from an Intravenous Solution Bag Prior to Adding Drug when Using ChemoLock™

Refer to Checklists- Module 1 - Appendix 1: Withdrawal of Solution from an Intravenous Solution Bag Using a Dispensing Pin / Universal Spike

Section G - Clean Up and Waste Disposal

G.1 Containment Primary Engineering Control (C-PEC) Waste Cleanup

Standard:

The entire aseptic preparation area must be kept clean so that aseptically prepared products remain as free from potential microbial and hazardous drug contamination as possible.[14, 33]

Procedures for decontaminating, cleaning, and disposing of waste from the C-PEC are intended to safely remove and minimize the transfer of HD from contaminated surfaces to areas where personnel may accidentally come into contact with them.

Waste generated throughout the decontamination or cleaning procedures should be collected in suitable zip lock bags that are sealed and decontaminated using a new towel moistened with a decontaminating agent inside the C-PEC, just prior to removal.[14]

Refer to Checklists- Module 1 - Appendix 1: Morning Cleaning of Interior Surfaces of the Biological Safety Cabinet

Refer to Checklists- Module 1 - Appendix 1: Daily Decontamination of Interior Surfaces of the Biological Safety Cabinet

Refer to Checklists- Module 1 - Appendix 1: Weekly Decontamination of the Biological Safety Cabinet

Refer to Checklists- Module 1 - Appendix 1: Cleanup and Waste Disposal in the Biological Safety Cabinet

G.2 Hazardous Waste Disposal

Standard:

Hazardous waste containers must be available in all areas where hazardous drugs are received, stored, prepared and administered.[13]

All disposable items that may have come in contact with hazardous drugs during receipt, storage, preparation or administration must be treated as hazardous waste including PPE.[13] Hazardous waste must be disposed of separately from general waste in hazardous waste containers with lids.[29] The hazardous waste container must be distinctly different from other types of waste containers[29] (e.g., bright red coloring with hazardous warning labels).

All disposable non-sharp HD waste must be disposed of in 4 mil thick plastic bags which are placed inside a rigid HD waste container or carton so that all waste is essentially 'double-bagged'.[29]

The HD waste containers must be labelled with an appropriate hazardous warning label. The HD waste containers must be leak proof and have a lid that seals securely.[12]

Hazardous waste container lids should be closed except when placing contaminated materials into the containers to reduce the risk of HD aerosols/vapours being released into the environment.[31]

The warning label must identify the contents as hazardous so that individuals transporting the waste are alerted to the need for special handling.[14]

All sharps used for the preparation and administration of hazardous drug admixtures must be placed into a puncture-proof hazardous drug sharps container for disposal[29] without being crushed or clipped.[31, 75] Chemotherapy dispensing pins and chemotherapy vents removed from HD vials must also be disposed of in a hazardous drug sharps container.

The HD sharps container must be sealed when it is no more than three-quarters full or at the indicated maximum fill line.[29]

HD waste containers must not be overfilled and the contents must not be pushed down to make more room due to the risk of HD exposure.[29]

Two pairs of chemotherapy gloves must be worn while handling hazardous waste.[4]

While awaiting removal from the facility for disposal, hazardous waste must be stored in a secure area in securely sealed and properly labelled containers.[31]

The handling of hazardous waste once it leaves the pharmacy is directed by the facility.

Standard:

Hazardous waste must be transported and disposed of according to Federal and Provincial regulations after leaving the facility.[14]

Section H - Safe Handling of Oral, Topical and Pre-Packaged Hazardous Drug Dosage Forms

Standard:

All drugs listed on the facility's hazardous drug list must be handled according to the facility's hazardous drug safe handling guidelines.[4] Oral, topical and pre-packaged hazardous drug dosage forms must be handled in a manner that prevents skin contact and minimizes the liberation of powdered or aerosolized HD into the air and cross contamination with other drugs.[15]

Some drugs defined as hazardous may pose less risk of direct occupational exposure because of their dosage formulation or packaging (manufacturer pre-packaged dosages, coated tablets, capsules, pre-filled syringes). However, altering the dosage form, packaging or opening the original container without utilizing the proper hazardous drug safe handling precautions may increase the worker's risk of direct exposure (e.g., dust from tablets and capsules). An assessment of risk may be performed for these dosage forms to determine alternative containment strategies.[14]

H.1 Oral Dosage Forms

- **Standard: Two pairs of chemotherapy gloves must be worn when handling hazardous drug tablets and capsules in a designated area of the pharmacy's outpatient dispensary[112]**
- **Standard: Hazardous oral solutions and suspensions must be compounded or prepared in a biological safety cabinet[54]**
- **Standard: All activities likely to result in particle generation, for example, weighing or mixing powder, crushing tablets/capsules, or filling capsules, must be performed in an externally vented, minimum Class I biological safety cabinet in a negative pressure room that maintains**

at least 12 APH to minimize the risk of spreading HD contaminated particulate throughout the rest of the pharmacy[14]

- **Standard: Counting of non-coated tablets or capsules that have visual evidence of HD powder residue on them or compounding HD oral solutions must be performed using containment strategies such as preparation inside an externally vented, minimum Class I biological safety cabinet[14] to reduce the risk of HD exposure**
- **Standard: Dedicated 'chemotherapy' counting trays and spatulas must be used to count loose HD tablets and capsules[29, 112]**
- "Chemotherapy" dedicated counting tray(s), spatula(s) and countertops should be decontaminated after each use using a decontaminating agent.[29] **Standard: The wipe used must be disposed of in HD waste[14]**
- **Standard: Hands must be washed with soap and water immediately after removing chemotherapy gloves[14]**
- **Standard: Gloves worn when handling hazardous drugs must be discarded in HD waste[14]**
- **Standard: Automated counting machines must not be used to count hazardous drug tablets and capsules[14]**

H.2 Topical Dosage Forms

- **Standard: Two pairs of chemotherapy gloves must be worn when handling hazardous drug topical preparations that have been removed from the original packaging[14]**
- **Standard: Compounding hazardous topical products, especially activities likely to result in particle generation, must be performed in an externally vented minimum Class I biological safety cabinet[14]**

H.3 Pre-filled Syringes

- Unopened HD injections packaged in pre-filled syringes from the manufacturer may be handled without donning chemotherapy gloves

Standard:

All interior surfaces of a C-PEC (except under the work surface) used for both sterile and non-sterile HD preparations must be decontaminated, cleaned, and disinfected following non-sterile HD preparations using a decontaminating agent, a germicidal disinfectant detergent, and sterile 70% isopropyl alcohol. Once decontaminated, the C-PEC must purge for at least 15 minutes prior to compounding sterile HD products[29]

If the decontaminating agent chosen contains a germicidal disinfectant detergent, then interior surfaces of the C-PEC may be decontaminated and then disinfected without the additional cleaning step.

Section I - Hazardous Drug Spills

I.1 Hazardous Drug Spills

Standard:

To minimize exposure of staff and patients to hazardous drugs, spills must be managed appropriately, according to established policies and procedures.[12] Clearly labelled spill kits must be located in all areas where exposures may occur.[13] These locations include hazardous drug preparation, dispensing, storage and receiving areas.

If a hazardous drug spill kit is stored within a cupboard or cabinet, the outmost door of the cupboard or cabinet should also be clearly labelled indicating the presence of a spill kit inside.

I.1.1 Recommended Spill Kit Contents

Spill kits purchased from a commercial source should be carefully reviewed to ensure they contain all required supplies. The contents of the kit should be, wherever possible, latex free.

Spill kits must contain a NIOSH-certified elastomeric half or full face mask respirator with appropriate filter cartridges. All employees who work in areas where HD spills could potentially occur must participate in a respiratory protection program that includes fit-testing of respirators available in the workplace. Arrangements for fit-testing should be made through Occupational Health or Workplace Health; Note that medical masks do not provide adequate protection from HD exposure.

PPE

1. Disposable chemotherapy gown
2. Two pair of chemotherapy gloves
3. Safety eye goggles and a face shield or a full face-piece respirator
4. Shoe covers
5. Hair cover
6. Elastomeric half or full face mask respirator with appropriate filter cartridges

Supplies

1. Disposable scoop and scraper
2. Sharps container
3. Incinerable, absorbent material (gauze pads, spill towels, absorbent polymer, etc.) in sufficient quantity
4. Two large plastic HD waste disposal bags (4 mil* or thicker) [*Note: 4 mil = 0.004 inches = 0.1 mm]
5. Decontaminating agent
6. Warning sign and plastic “caution” tape (to quarantine spill area)
7. Puncture and leak resistant HD waste container (e.g. Chemo-Gator)

Documents

1. Laminated copy of HD Spill Control Procedures

Standard:

Disposable PPE and the filter cartridge[113] attached to the elastomeric respirator worn during a hazardous drug spill clean-up must be disposed of after use into a hazardous waste container. The respirator and other reusable PPE must be decontaminated using an appropriate decontaminating agent per the manufacturer’s recommendation.[12]

New employees must be advised of hazardous drug spill control procedures[13] and be required to demonstrate competency in spill handling.[21]

Training and competency assessments must be documented.[14]

Refer to Checklists- Module 1 - Appendix 1: Hazardous Drug Spill Control in Pharmacy - Cleanup of a Spill Within a Biological Safety Cabinet

Refer to Checklists- Module 1 - Appendix 1: Hazardous Drug Spill Control in Pharmacy - Cleanup of a Spill Outside the Biological Safety Cabinet that may Reasonably Be Contained and Cleaned Within the Centre’s Capacity

Refer to Checklists- Module 1 - Appendix 1: Hazardous Drug Spill Control in Pharmacy - Cleanup of a Spill Outside the Biological Safety Cabinet that may be Beyond a Centre’s Capacity to Contain and Clean

Refer to the BC Cancer Pharmacy CON Educator’s Hazardous Drug Spill Control in Pharmacy In-service

Section J - Accidental Exposure to Hazardous Drugs

J.1 Accidental Exposure to Hazardous Drugs

Standard:

Healthcare workers must be made aware of how to manage accidental exposure to hazardous drugs.[13]

Any accidental hazardous drug exposure as a result of a spill, needle stick or other accident must be reported immediately to the professional practice leader/department manager[75] and by calling the Provincial Workplace Health Call Centre reporting line at 1-866-922-9464. Appropriate documentation must be completed.[29]

The exposure should be documented on the personal employee exposure record. The employee should inform their family doctor or general practitioner of the hazardous drug exposure.

Refer to BC Cancer Systemic Therapy Policy V-20: Employee Health: Management of Risks Related to Hazardous Drugs Practice Guidelines

J.1.1 Inhalation

Exposure through inhalation is greatest when particles of aerosolized or vaporized hazardous drug are released into the environment while injecting into a vial or infusion solution bag, and when expelling air from a hazardous drug-filled syringe. Studies have shown that some hazardous drugs tested may evaporate from liquid to gaseous forms or sublimate from solid to gaseous forms under normal working conditions.[45] Safe handling techniques and the proper use of a biological safety cabinet will reduce possible inhalation exposure. Selection and use of a respirator appropriate to the task being performed is necessary to minimize inhalation exposure to HD aerosols and vapours.

See Respirators in Section D.2.6

J.1.2 Ingestion

Exposure through ingestion may occur when hazardous drug particles or droplets enter the body through the mouth. This may occur when food, gum, cigarettes, beverages, or anything that may be ingested has become contaminated with a hazardous agent, and placed in the mouth.

Standard:

Personnel must not take food, gum, drinks, cigarettes or personal medication into an area where hazardous drugs are handled[13] (e.g., received, stored, prepared, administered and disposed).

In the event that inhalation or ingestion occurs, no management or treatment is required unless unusual symptoms occur.

1. Monitor for possible symptoms
2. Report any unusual symptoms to your professional practice leader/department manager and your family physician

J.1.3 Absorption/Skin Contact

Absorption into the body may occur when the skin comes in contact with hazardous drug through aerosolization, sprays or spills or when the skin touches a contaminated surface. The amount of absorption depends on the length of time the skin is exposed, the thickness of the skin, the amount of drug on the skin, and the drug involved. It is important to wear two pairs of chemotherapy gloves when there is a risk of hazardous drug exposure.

It is critical to always wear two pairs of gloves and protective clothing during sterile hazardous drug preparation and administration.

In the event of accidental skin contact:

1. Immediately remove contaminated Personal Protective Equipment (PPE) and / or clothing and discard or label indicating the need for special handling for laundry according to Site Procedure
2. Wash the area thoroughly with soap and water for at least fifteen minutes- use safety shower if appropriate
3. Notify supervisor
4. Call the Provincial Workplace Health Call Centre reporting line at 1-866-922-9464

In the event of accidental eye contact:

1. CALL FOR HELP
2. Remove gloves
3. Immediately proceed to the eyewash station and flush open eyes with copious amounts of water for at least fifteen minutes (or use bottled eyewash solution)
4. Hold eye(s) open with thumb and finger and look directly into the water stream – move eye(s) around to wash all around
5. Do NOT rub eye(s)
6. Do NOT use tap water as pressure damage may occur[15, 69]
7. Notify supervisor and report immediately to a physician
8. Note which hazardous drug was involved and the quantity of drug that the eye(s) were exposed to
9. Call the Provincial Workplace Health Call Centre reporting line at 1-866-922-9464

J.1.4 Accidental Injection/Skin Puncture

Accidental injection of a hazardous drug may occur if a contaminated needle or broken glass punctures the skin. Punctures can occur during capping and uncapping needles, during needle insertion and withdrawal, etc. To avoid punctures always proceed slowly and cautiously using the safest techniques during these procedures.

See Safely Capping Needles Used with Hazardous Drug in Section F.2.5

In the event of accidental injection/skin puncture:

1. Immediately remove contaminated PPE and/or clothing and discard or label indicating the need for special handling for laundry according to Site Procedure
2. Rinse the area with warm running water and allow the wound to bleed freely to flush out any drug. Do not squeeze the puncture area[13]
3. Wash the area thoroughly with soap and water for at least fifteen minutes
4. The HD and approximately how much was injected should be noted
5. The supervisor must be informed of an accidental injection/skin puncture immediately
6. The Occupational Health Nurse must be contacted as soon as possible
7. Call the Provincial Workplace Health Call Centre reporting line at 1-866-922-9464

Refer to Checklists- Module 1 - Appendix 1: Personnel Contamination

Section K - Receipt, Storage, and Transportation of Hazardous Drug

K.1 Receipt and Unpacking

The results of several studies show that surface contamination exists on commercially supplied vials of hazardous drugs supplied by manufacturers to pharmacies.[9, 101, 102, 114-116]

Standard:

Shipping cartons containing hazardous drugs must be unpacked outside of controlled areas to limit the introduction of dust and particles into the controlled area.[12]

Staff receiving and unpacking hazardous drugs must receive training to manage HD spills and be made aware of precautions and follow special handling procedures.[14]

Safe handling procedures must be followed to avoid breakage of hazardous drug containers, to minimize exposure to hazardous drugs, and to contain spills that occur when receiving and unpacking hazardous drugs within the pharmacy.[29]

K.1.1 Receipt

- Shipping containers, including re-packaged totes/containers from the facility's stores/distribution departments that contain HD deliveries to the pharmacy department from suppliers or vendors should have hazard warning labels on the outside packaging to identify the hazardous nature of the contents
- When hazardous drugs are received by the pharmacy department in totes/containers without hazard warning labels, the sender (e.g., suppliers, vendors or the facility's stores/distribution department) should be notified and encouraged to utilize warning labels to identify the hazardous nature of the contents
- Shipping containers and the packaging inside (e.g., bubble wrap, filling materials) that have not come into direct contact with hazardous drug vials may be considered not chemically contaminated and may be discarded in regular waste containers or returned to the supplier if so arranged. These materials should not be used for other purposes[12]
- **Standard: Manufacturer's boxes or individual packaging that has come in direct contact with hazardous drug vials is considered chemically contaminated and must be discarded as hazardous waste[12]**
- **Standard: Two pairs of chemotherapy gloves must be worn when packing and unpacking boxes containing hazardous drugs[29]**
- **Standard: The outside of shipping cartons must be examined for possible damage prior to opening[14]**
- **Standard: Hazardous drugs requiring refrigeration must be unpacked and refrigerated immediately upon receipt[16, 36]**

K.1.2 Receipt of a Damaged Shipment

Standard:

Policies and procedures must be in place for handling damaged shipments of hazardous drugs.[14]

Damaged cartons, totes, and/or packages containing hazardous drugs that are received must NOT be opened and the receiver must don full PPE including a NIOSH-approved elastomeric half face mask respirator with a face-shield and safety goggles or a full face-piece respirator to handle the package.[12]

When cartons, totes, and/or packages are opened with damaged contents inside, the receiver must immediately don full PPE including two pairs of chemotherapy gloves, a chemotherapy gown, hair, face, beard and shoe covers, a NIOSH-approved elastomeric half face mask respirator with a face-shield and safety goggles or a full face-piece respirator and follow HD spill clean up procedures.[12]

After proper containment of a damaged carton, tote, or package, the supplier should be notified of any damaged contents. It is not advisable to return damaged hazardous drug vials to the supplier but should instead be disposed of appropriately.[15]

Standard:

HD spill kits with written procedures for use must be located in all areas where hazardous drugs are received.[4, 31]

See Respirators in Section D.2.6

Refer to Checklists- Module 1 - Appendix 1: Hazardous Drug Spill Control in Pharmacy - Cleanup of a Spill Within a Biological Safety Cabinet

Refer to Checklists- Module 1 - Appendix 1: Hazardous Drug Spill Control in Pharmacy - Cleanup of a Spill Outside the Biological Safety Cabinet that may Reasonably Be Contained and Cleaned Within the Centre's Capacity

Refer to Checklists- Module 1 - Appendix 1: Hazardous Drug Spill Control in Pharmacy - Cleanup of a Spill Outside the Biological Safety Cabinet that may be Beyond a Centre's Capacity to Contain and Clean

Refer to the BC Cancer Pharmacy CON Educator's Hazardous Drug Spill Control in Pharmacy In-service

K.2 Storage

Standard:

Final compounded preparations must be stored at an appropriate temperature within the time specified by the beyond use date prior to dispensing.[12]

- **Standard: Hazardous drugs requiring manipulation other than counting or repackaging of final dosage forms must be stored:[12]**
  - ✓ **separately from other inventory in a manner that prevents HD contamination and occupational exposure[14]** Many hazardous drugs have sufficient vapour pressures that allow volatilization at room temperature[29]
  - ✓ **in a room that:**
    - **maintains at least 2.5 Pascals negative pressure relative to surrounding areas**
    - **maintains at least 12 air changes per hour with all air exhausted to the exterior**
    - **provides sufficient ventilation to prevent contamination from spreading to adjoining rooms**
- **Standard: Refrigerated hazardous drugs requiring manipulation other than counting or repackaging of final dosage forms must be stored in a dedicated refrigerator[12]**
- **Standard: Refrigerator temperatures must maintain a cold temperature range of 2°C to 8°C[12]**
- **Standard: Storage conditions specified by the manufacturer must be strictly adhered to (e.g., refrigerator versus room temperature). Alternative storage must be provided if the storage temperature exceeds acceptable variations and when refrigerators and freezers are being cleaned.[12]**
- **Standard: Containers, shelves and bins used for storage of hazardous drugs must be properly labelled with hazard warning labels identifying the drugs that require special handling[13]**
- **Standard: Barriers and other design features on bins and shelves must be present to contain accidental leakage and reduce the chance of drugs falling to the floor[29]**
- **Standard: Hazardous drugs must be stored in a manner that prevents spillage or breakage if the container falls[14]**
- **Standard: To prevent errors from occurring, medication that can be easily mistaken for another (sounds alike, looks alike, similar labelling) must be separated in all areas of the pharmacy[29]**
- Hazardous drugs should be stored at or below eye-level
- **Standard: Access to areas where hazardous drugs are stored must be limited to authorized personnel[29]**
- **Standard: Hazardous drugs spill kits with written procedures for use must be readily available in areas where hazardous drugs are stored.[13]**

The hazardous drug storage room may either be a separate room as described above or hazardous drugs may be stored in the hazardous drug clean room.[12]

Standard:

If hazardous drugs and the refrigerator in which they are stored are placed in the hazardous drug clean room, air exhausts must be placed in such a manner as to remove particles generated and must also ensure sufficient ACPH to maintain an ISO Class 7 clean room. An air exhaust must be placed behind the refrigerator to remove any particles generated by the unit.[12]

Hazardous drugs not requiring manipulation other than counting or repackaging of final dosage forms may be stored with other inventory.

K.3 Packaging and Transportation

Standard:

Hazardous drugs must be packaged and transported in a manner which minimizes the risk of HD exposure due to a spill or breakage during transit.[14] The packaging must be appropriate to maintain the stability and integrity of the preparation.[12]

Pneumatic tubes or other transport systems that produce stress on the contents must not be used for hazardous drug transport.[14]

All hazardous drugs must be dispensed in a suitable primary container such as intravenous solution bags, elastomeric infusors, syringes, vials, ampoules, ointment jars, blister cards, manufacturer supplied packaging, or prescription vials. Compounded hazardous drug-filled syringes must be transported with either a luer lock tip cap or closed system drug transfer device attached, unless specifically exempted.[29]

Packaging surrounding the primary container may consist of inner and outer containers depending upon the route of transport and the final destination of the hazardous drug. Inner containers must be sealable, leak-proof, and see-through (unless contents are light sensitive). Outer containers must enclose the HD and be robust enough to withstand typical conditions during transport.

See Table 9 Inner and Outer Containers Required for the Transport of Hazardous Drugs in Section K.3

In addition to mandatory prescription labeling requirements on the primary container, all containers (primary, inner, and outer) used in the dispensing and transporting of HDs must be clearly identified with distinctive warning labels meeting the College of Pharmacists of BC, WorkSafeBC, BC Health Authorities Exposure Control Program, and NAPRA requirements. Additionally, HD which are also biohazardous will be identified with a Bio-Hazard label.

Further considerations when determining hazardous drug packaging for transport include:

- package hazardous drugs separately from non-hazardous drugs
- protect from light where required
- contain any leakage if contents break or rupture
- use child-proof packaging for tablet containers (if appropriate e.g., patient-specific take home medications)
- label appropriately with auxiliary instructions (e.g., HD Group 1 or 2, storage requirements)
- use methods for maintaining the cold chain where appropriate (cold packs, dry ice)
- latex-free materials should be selected for the primary, inner, and outer containers whenever possible
- carts should be used to transport hazardous drugs through public areas of a facility (e.g., non-treatment areas) to the treatment area

Standard:

Take home medication must not be placed inside the same inner container as the compounded HD parenteral admixtures which are administered within the facility.[43]

Hazardous drugs should remain in their protective packaging until ready for use.

Reusable packaging should be designated for HD transport only[15] and must be decontaminated prior to re-use as per site-specific policies. Disposable HD packaging materials should be discarded as hazardous waste. Re-usable

cold packs used during transport must be separated from direct contact with HD by being placed in a sealable bag; the bag must be discarded as HD waste after use.

Site specific procedures for safe packaging, labelling, and transporting hazardous drugs should be developed and maintained. Personnel involved in transporting hazardous drugs must be properly trained to adhere to site specific HD transport procedures.

Personnel involved in the transport of hazardous drugs must receive appropriate training prior to transporting hazardous drugs. Personnel must be aware of:

- distinct identifying labels indicating the presence of hazardous drugs
- procedures required for handling damaged containers of hazardous drug
- the location of spill kits within the areas of the facility through which they are transporting hazardous drugs

Personnel transporting hazardous drugs should be aware of HD spill procedures. Spill kits should either accompany hazardous drug packages during transport or be easily accessible on the transport cart.[14]

Transportation within a Centre should be done via a direct route to minimize the number of areas within the facility which could be contaminated should a spill occur. All hazardous compounded sterile preparations transported from pharmacy through public areas of a facility (e.g., non-treatment areas) should have hazardous spill control information affixed to the outer containers.

For example:

IN THE EVENT OF A SPILL OR BREAKAGE:

- Isolate area and prevent anyone from going near the spill area.
- Call pharmacy at _____ and inform the supervisor that a hazardous drug spill has occurred.
- Stay with the spill until help arrives.

Staff mailing hazardous drugs should refer to Canada Post guidelines: ABCs of Mailing – Personal: Section 3.2.1. Staff shipping qualifying quantities of hazardous drugs listed as Dangerous Goods must observe all requirements specified in the Transport of Dangerous Goods Act. See http://www.tc.gc.ca/eng/tdg/clear-part2-339.htm

Standard:

Absorbent packaging material must be placed inside Type A and B outer containers to absorb any liquid in the event of leakage during transport.[30]

Table 9: Inner and Outer Containers Required for the Transport of Hazardous Drugs

Procedure	Inner Container Required	Type of Outer Container Required
1) Compounded HD Parenteral Admixtures		
Transport through public areas of a facility (non-treatment areas)	Yes	Type A or B
Transport within a treatment area or pharmacy department	Yes	None
Transport to another facility	Yes	Type A or B
Dispensed to outpatients	Yes	None
2) Solid, Liquid, Topical, & Injectable HD Dosage Forms		
Solid oral HD dosage forms (loose & blisterpack) dispensed to outpatients & inpatients	No	None
Solid oral HD dosage forms (loose tablets & capsules) transported via mail or courier	Yes	Type B or C
Blister-packaged solid oral HD dosage forms transported via mail or courier	Yes	Type B or C
Liquid oral HD dosage forms dispensed to outpatients & inpatients	Yes	None
Liquid oral HD dosage forms transported via mail or courier	Yes	Type B
Topical HD dosage forms dispensed to outpatients & inpatients	Yes	None
Topical HD dosage forms transported via mail or courier	Yes	Type B
Injectable HD dosage forms (e.g. vials) dispensed to outpatients and inpatients	Yes	None
Injectable HD dosage forms (e.g. vials) transported via mail or courier	Yes	Type B
Commercially supplied pre-filled syringes dispensed to outpatients and inpatients	No	None
Commercially supplied pre-filled syringes transported via mail or courier	No	Mail: Type B (only) Courier: Type B or C
3) Stock Inventory of Hazardous Drugs		
Transport within pharmacy department to storage area	Yes†	None
Movement of small quantities within the pharmacy department for dispensing or restocking	No	None
Transport through public areas of a facility	Yes†	Type A or B
Outside sales	Yes	Type A or B

Type A = hard-shell plastic box with secure lid

Type B = moulded foam or corrugated cardboard box

Type C = padded envelope

† = container may be original packaging from supplier

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