Summary of BC Cancer's Pharmacy Practice Standards for Hazardous Drugs

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Pharmacy Oncology Certification

All pharmacy staff involved in the preparation and delivery of hazardous drugs must demonstrate knowledge and competency for the duties that they are required to undertake. Re-evaluation of competency and knowledge must take place on a regular basis with documentation of results.[1]

Module 1 – Safe Handling of Hazardous Drugs

Section A - Safe Handling Principles

A.1 Potential Hazards of Handling Hazardous Drugs

Policies and procedures covering all activities related to Hazardous Drug (HD) safe handling and compounding must be developed.[1]

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.[2, 3] There must be established work practices related to both drug manipulation techniques and to general hygiene practices.[3] Workplace procedures must be developed for using and maintaining all equipment that functions to reduce hazardous drug exposure.[2]

A.2 Hazardous Drug List

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.[2, 3]

The facility's hazardous drug list must be posted in all areas where these drugs are received,[4, 5] stored,[2, 5] prepared[2] and administered.[4, 5]

A.4 Personal Exposure Records

WorkSafe BC Occupational Health and Safety (OH&S) Regulation 6.58 Records states:

1. *"An employer must keep a record of all instruction and training provided under section 6.51 for a period of 3 years after the date the instruction or training is provided.*
2. *An employer must, for each worker who prepares a hazardous drug, keep a record that includes the following:*
    a. *the name of each hazardous drug prepared by the worker;*
    b. *if practicable, the number of preparations per week;*
    c. *each risk assessment prepared, and each exposure control plan developed, including any updates that*
        i. *is relevant to the worker's employment, and*
        ii. *applied to the worker at any time during the period of the worker's employment.*
3. *An employer must, for each worker who administers a hazardous drug, keep a record that includes the following:*
    a. *the name of each hazardous drug administered by the worker*
        i. *parenterally*
        ii. *orally, in the case of a hazardous drug in powder or liquid form or contained in a capsule that was opened, or*
        iii. *by topical application*
    b. *if practicable, the number of administrations per week;*
    c. *each risk assessment prepared, and each exposure control plan developed, including any updates, that*
        i. *is relevant to the workers employment, and*
        ii. *applied to the worker at any time during the period of the worker's employment*

4. *An employer must keep a record referred to in subsection (2) or (3) for the period of employment of the worker to whom the record relates and for the 10-year period after the end of that worker's employment."*

A.5 Work Re-Assignment

WorkSafe BC Occupational Health and Safety (OH&S) Regulation 6.47 Reproductive toxins states:

"If a worker is or may be exposed to a hazardous drug that is a reproductive toxin, an employer must develop

(a) a written policy about the availability of protective reassignment, and

(b) a procedure for determining if protective reassignment is appropriate for workers who advise the employer of a pregnancy or an intent to conceive a child."

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

B.1 General

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.[1] All personnel performing these activities must wear appropriate personal protective equipment resistant to the solutions used.[3] Solutions selected must be appropriate for the type of hazardous drug contaminants, location, and surface materials.[3]

When selecting decontaminating, cleaning, deactivating and disinfecting solutions, consideration must be given to compatibility, effectiveness, and inappropriate or toxic residues.[1] Diluted solutions must be prepared and stored according to the manufacturer's directions[1] and kept in previously cleaned containers.

Partly emptied containers must not be topped up.[4]

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).[1] When sterile 70% isopropyl alcohol is used, it must be allowed to dry.[6]

Section C - Controlled Area

C.1 International Standards Organization (ISO) Classifications

The air quality in the clean room and anteroom must comply with ISO 14644-1 according to the specifications listed in Table 1 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).[1]

C.2 Room Specifications

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.[1]

Doors leading into controlled areas must not be left open.[1]

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[1] and to minimize healthcare workers' exposure to hazardous drugs.[7]

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

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.[1]

An air conditioning system must be included in the HVAC system to help ensure the comfort of personnel wearing personal protective equipment.[1]

C.2.2 High Efficiency Particulate Air (HEPA) Filter

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.[1]

C.2.3 Signage

Each room in the controlled area must be identified with appropriate informative signs (e.g., restricted access, dress code).[1]

Warning signs, which are clearly visible and clearly state the identified hazards, must be posted in all areas where hazardous drugs are received,[4] stored,[2] prepared[2] and administered.[4]

C.2.4 Hazardous Drug Clean Room

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.[1]

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.[1]

The return air from the hazardous drug clean room must be exhausted to the exterior of the building.[1]

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.[1]

C.2.5 Hazardous Drug Anteroom

The anteroom must have doors between the clean room and the anteroom and between the anteroom and the rest of the pharmacy.[1]

There must be a process in place that allows only one door leading into the anteroom to be open at one time.[1]

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.[1]

C.2.7 Specifications of the Controlled Area

- Access to the controlled area must be limited to authorized personnel assigned to work there.[1, 8]
- Doors leading into controlled areas must not be left open.[1, 8]
- A pressure indicator must be installed that can readily monitor room pressurization.[1] A notification system must be installed in each pressure monitor to alert pharmacy personnel when pressure differentials deviate from specifications.[1]
- Water sources, sinks, and drains must not be located in a clean room but are permitted in the anteroom.[1]
- 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.[1]
- Cleaning of the ceiling, walls and floor must take place in the clean room at a time when no aseptic operations are in progress.[9]
- Essential furniture in the controlled area must be nonporous, smooth, non-shedding, impermeable, cleanable, and resistant to disinfectants.[1]
- Shelves and supplies must be kept to a minimum in the clean room and anteroom to help limit the number of particulates.[1]
- 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).[1]
- 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.[1]

- 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.[9]
- Lab coats and isolation gowns must not be worn in the controlled area in place of chemotherapy gowns.[3]
- No shipping box or other external cartons may be taken into the controlled area.[1]

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**[1] (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**[1] (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**[1] (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

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.[1]

Any equipment removed from the controlled area must be decontaminated first.[1]

C.3.1 Containment Primary Engineering Control

WorkSafe BC Occupational Health and Safety (OH&S) Regulation 6.50 Preparation and administration of certain hazardous drugs states:

(1) "In this section, 'IARC Monographs' means the IARC Monographs on the Identification of Carcinogenic Hazardous to Humans published by the International Agency for Research on Cancer, as amended from time to time.

(2) This section applies to the following hazardous drugs:

- *a. a hazardous drug that is identified in the NIOSH list as being antineoplastic;*
- *b. a hazardous drug for which the manufacturer recommends ventilated engineering controls;*
- *c. a hazardous drug that is classified by the IARC Monographs as Group1 or Group 2A carcinogen.*

(3) "An employer must ensure that all of the following work activities are performed in a ventilated enclosure that meets the requirements set out in subsection (4):

- *a. mixing a hazardous drug to which this section applies;*
- *b. preparing a hazardous drug to which this section applies;*
- *c. priming an intravenous administration set with a solution containing a hazardous drug to which this section applies.*

(4) For the purpose of subsection (3), a ventilated enclosure must

- *a. meet or exceed the requirements for a Class II Type B2 biological safety cabinet that conforms to NSF/ANSI Standard 49-2018 Biosafety Cabinetry: Design, Construction, Performance, and Field Certification,*
- *b. have exhaust and ventilation systems that remain in operation for a period of time sufficient to ensure that no contaminants escape into the workplace,*
- *c. be connected to the exhaust ventilation system, which system must discharge to the outdoors in a manner that prevents contaminants from being recirculated in the workplace or adjacent workplace, and*
- *d. be equipped with a continuous monitoring device to permit confirmation of adequate airflow and cabinet performance.*

C.3.1.1 Class I BSC

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.[10, 11] 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.[3]

C.3.1.2 Class II BSC

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.[2]

A minimum Class II Type B2 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.[2]

C.3.1.3 HEPA Filter

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.[2]

C.3.1.4 Airflow

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.[9]

Manipulations must be performed in the critical area (direct compounding area), at least six inches in from the front opening of a biological safety cabinet (BSC)[8] (behind the air 'split').[12] Contaminated air must be able to escape via the rear grill, not via the front opening.[11]

In order for the BSC to help protect the operator, paths of airflow must remain clear.[13]

Note:

- Horizontal laminar airflow hoods must not be used for the preparation of hazardous drugs[3]

C.3.1.5 Ultraviolet Lights

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.[14, 15]

C.3.1.6 Viewing Window

The viewing window must be kept at the manufacturers' recommended height when placing drug and supplies into the BSC and during hazardous drug preparation.[14, 15]

C.3.1.7 Location

A biological safety cabinet used for hazardous drug compounding must be located away from doorways, traffic corridors, and air conditioning and heating vents.[1, 15]

C.3.1.8 Monitoring

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[3, 8] unless being serviced.[8] It must be equipped with a continuous monitoring device to allow confirmation of adequate airflow and cabinet performance.[2]

The values shown on the downflow and exhaust airflow gauges must be monitored and recorded daily in the general maintenance log.[1] Staff working in and around the C-PEC must be informed of what the values on the gauges should read for a properly functioning cabinet.[1] Large fluctuations in values on the gauges can be indicative of a malfunctioning system and must be evaluated immediately.[16]

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.[15]

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 personnel, the environment and the aseptic condition of the product (if possible) will be maintained.[5]

C.3.1.9 Testing and Certifying Biological Safety Cabinets

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) before use after:[17]

- initial installation,
- change of the HEPA filter,
- maintenance or repairs are made to internal parts,[18]
- moving the unit, and
- any repair or maintenance that could affect the seal of the HEPA filter.

Certification procedures used must meet the requirements of the NSF Standard 49- Biosafety Cabinetry: Design, Construction, Performance, and Field Certification (current version)[1, 17]

Field testing of biological safety cabinets in accordance with NSF/ANSI 49 includes:[19]

- downflow velocity profile test;
- inflow velocity test;
- airflow smoke patterns test;
- HEPA filter leak test;
- site installation assessment tests; and
- cabinet integrity test (positive pressure plenum cabinets only).

Site installation assessment tests shall include:[19]

- alarm functions as required by NSF/ANSI 49;
- blower interlock; and
- exhaust system performance (proper exhaust duct negative pressure and canopy performance).

C.3.1.9.a Non-Viable Total Particle Counting

A count of non-viable particles (0.5 µm) in operational (dynamic) state must be performed each time the C-PEC is certified.[1, 18] Count of non-viable particles in at-rest state is optional.[1]

The BSC must be re-certified every six months.[1] Certification of the biological safety cabinet must occur during dynamic operating conditions.[1]

Prior to servicing a biological safety cabinet, service technicians or maintenance workers must be informed that the BSC may be contaminated with hazardous drugs.[7] Appropriate personal protective equipment and clean room garb must be worn when testing, certifying or servicing the BSC.[1, 7]

After field certification, the BSC must have certification information posted on the front of the cabinet housing in a readily visible location.[1, 17]

The information must include:[19]

- date of certification;
- date cabinet should be recertified: no later than;
- certifier's report number (reference document showing tests performed and results);
- name, address, and telephone number of certifying company; and
- signature of the person who performed the field certification tests.

All testing, servicing, and certifying of the BSC must be recorded in the general maintenance log.[1]

Before testing, servicing, and certifying of the BSC, all interior surfaces (including under the work surface) must be decontaminated, cleaned, and disinfected.[1]

C.3.1.10 Replacing HEPA Filters

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.[7]

Appropriate personal protective equipment must be worn when replacing HEPA filters and the contaminated filters must be handled and disposed of as hazardous waste.[4, 20]

C.3.1.12 Turning off a Containment Primary Engineering Control (C-PEC)

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.[1]

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.[12] Personnel involved in sealing the BSC and/or evaluating the service interruption must wear a chemical cartridge respirator with an appropriate filter in addition to all other clean room garb and PPE.[21]

C.3.2 Communication System

Verbal communication between personnel in the clean room and the anteroom or between personnel 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.[1]

C.3.4 Chairs

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.[1]

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

Housekeeping activities must not take place in the clean room[3] or anteroom when compounding is occurring.

A germicidal disinfectant detergent must be used when cleaning surfaces and equipment in the controlled area.[1] 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.[1] Sterile 70% isopropyl 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.[1]

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).[1, 9]

The required contact time for the selected agents used must be adhered to.[1]

Remove hazardous waste from controlled areas daily[1]

- 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

All decontaminating, cleaning, and disinfection activities must be recorded and retained in a general maintenance log.[1]

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

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.[1]

Prior to decontaminating and cleaning a C-PEC, proper hand hygiene procedures must be followed and full personal protective equipment (PPE) must be donned.[1]

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.[1] 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.[1]

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.[1]

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 using a decontaminating agent, a germicidal disinfectant detergent, and sterile 70% isopropyl alcohol:[1]

- after the C-PEC has purged for a minimum of 15 minutes post cleaning/decontaminating and disinfecting, before placing supplies into the C-PEC[16]
- 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.[9]

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

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.[1] 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[5] afterwards unless otherwise recommended by the manufacturer.

Following hazardous drug compounding, the C-PEC must purge for at least five minutes[15] 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:[1, 22]

- after preparations within the C-PEC are completed for the day[8]
- prior to compounding 'latex-free' preparations[8]
- prior to compounding sterile HD preparations in a C-PEC once it has been used to compound non-sterile HD preparations[8]
- prior to resuming compounding in a C-PEC that is turned off between aseptic processes for any reason (e.g., power interruption, maintenance)[8]

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.[1, 22]

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

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.[5] Disinfection of the C-PEC must be augmented with weekly use of a sporicidal agent.[23]

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.[15]

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.[4]

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

When packaging integrity will not be compromised, supplies brought into in the controlled area must be disinfected using a sporicidal agent.[1] When packaging integrity will be compromised, supplies brought into the controlled area must be placed into zip lock bags prior to storage.[16]

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.[1]

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.[1]

Staff must wear at least one pair of gloves when disinfecting items (two pairs in the controlled area).[24] Disinfecting items must not compromise package integrity.[1]

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.[1]

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.[1]

No shipping carton(s) or cardboard are permitted in the controlled area.[1]

Section D - Protective Measures

D.1 General

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.[5, 9]

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.[1]

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

Personal protective equipment and clean room garb must be provided to minimize or prevent healthcare workers exposure to hazardous drugs.[2] All personnel entering the controlled areas must follow appropriate hand hygiene and garbing procedures.[1]

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[1] or laundered per site-specific policy.[25]

D.2.1 Scrubs

Street clothes must be replaced with fresh scrubs daily by all personnel when the work assignment will take place in the controlled area.[1] Scrubs worn into the controlled area must not have been worn outdoors. Scrub bottoms must fully cover the legs including while seated.[8]

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.[13]

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.[13]

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').[25]

D.2.2 Footwear

Each facility must be in compliance with WorkSafe BC regulations to help reduce preventable injuries due to inappropriate footwear.[26]

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.[1]

D.2.3 Shoe Covers

At least one pair of disposable shoe covers must be worn in the controlled area.[8]

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.[1] 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.[3]

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.[1] 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.[8]

Shoe covers must be disposed of in hazardous waste containers and not saved for reuse.[3]

D.2.4 Hair Covers

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.[1]

The hair cover (and beard cover if necessary) must be donned on the dirty side of the demarcation line in the anteroom.[1] In facilities that have incorporated a gowning room in the controlled area, the hair and beard covers must be donned in the gowning room.[8]

Hair and beard covers must be removed on the dirty side of the demarcation line in the anteroom.[1] 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.[8]

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.[1]

D.2.5 Medical Masks

Medical masks rated at least Level 1 by ASTM International Standard F2100[27] 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).[1, 23]

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.[1]

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.[13] Masks must not be saved for reuse. Masks must be changed after no more than 3.5 hours of use.[1]

Masks worn in the hazardous drug clean room must be disposed of in a hazardous waste container.[1]

D.2.6 Respirators

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

A chemical cartridge respirator with an appropriate filter cartridge must be worn when cleaning up HD spills, when decontaminating or cleaning the C-PEC with the viewing window raised, or when working in a clean room when a C-PEC is being decontaminated or cleaned.[1]

A chemical cartridge respirator with an appropriate filter cartridge must be worn if unpacking HD shipments suspected of being damaged.[1]

Staff wearing a respirator that requires an effective seal with the face for proper functioning must be:[26]

- 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.[26]

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.[26]

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

"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."

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 use.[1]

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.[1]

Used filters and the cartridge housing they are supplied in must be disposed of in hazardous waste containers when replaced.[1]

D.2.7 Chemotherapy Gowns

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.[1] Chemotherapy gowns must be worn for all activities that may result in the worker's direct exposure to hazardous drugs.[1]

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.[2]

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.[8]

A chemotherapy gown must be worn if unpacking a suspected damaged hazardous shipment or cleaning up a hazardous drug spill.[1]

Used chemotherapy gowns must be discarded into hazardous waste containers after:[1]

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

D.2.8 Isolation Gowns

An isolation or chemotherapy gown must be worn by all personnel working in controlled areas.[8] 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.[8]

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.[3]

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[28]
- by staff working in the controlled area unless wearing a chemotherapy gown[8]
- over scrubs by staff that *will be* (re-)entering the controlled area[13]

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').[25]

D.2.9 Chemotherapy Gloves

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 International (ASTM) Standard D6978-05 (*Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Gloves*).[29]

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.[3, 29]

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.[1] Two pairs of disposable chemotherapy gloves must be worn at all times by all personnel working in the hazardous drug clean room.[1]

Disposable chemotherapy gloves worn when mixing hazardous drugs in the C-PEC must be powder-free, sterile[8]and long enough to cover the cuff of the chemotherapy gown.[1] 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.[1] 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.[8]

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.[1]

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.[8]

Hands must be washed with soap and water every time chemotherapy gloves are removed.[3]

Latex-free chemotherapy gloves must be made available to staff.[2]

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.[3]

Chemotherapy gloves must be disposed of in hazardous waste containers.[3]

D.2.10 Eye Protection

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.[30]

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.[31]

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.[32]

A face shield and safety goggles or a full face mask respirator must be worn for splash protection:[1]

- 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.[3]

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.[3]

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.[8]

D.3 Hand Hygiene

Prior to donning gloves, hands must be cleansed using either soap and water or alcohol-based hand rub.[33]

D.3.1.1 Alcohol-Based Hand Rub

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.[34]

D.3.2 Hand Washing After Handling Hazardous Drugs

After handling hazardous drugs, hand washing must be performed[3] to remove possible drug contamination.

D.3.3 Hand Hygiene Before Entering the Clean Room

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.[1]

Hands must be dried with a clean, low lint towel.[1]

D.3.4 Nails and Nail Polish

Wearing of artificial nails or other nail applications is prohibited while working in the controlled area. Natural nails must be kept neat and trimmed, and must be free of nail polish.[1]

D.4 Safety Stations

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.[35]

Personnel that are required to use emergency eyewash and shower facilities must be adequately trained in their location and proper use.[35]

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"*

D.4.1.2 Hand Held Portable

Portable eyewash stations must be capable of delivering a minimum flush duration of 15 minutes.[35]

D.4.2 Emergency Showers

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.[36]

D.4.3 Safety Stations Maintenance

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.[35]

Hand held portable eyewash equipment must be inspected and maintained according to the manufacturer's instructions.[36]

Section E - Supplies and Devices

E.1 Supplies

E.1.3 Sterile Alcohol Swabs

Single use, individually packaged sterile 70% isopropyl alcohol swabs must be used to disinfect a critical site prior to accessing.[9] Gauze pads or other particle-generating material moistened with alcohol must not be used to disinfect critical sites of containers prior to accessing.[9]

E.2 Devices

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.[8]

Staff must be trained to use the proper aseptic technique required with each device utilized in the safe preparation of hazardous drugs.[11]

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

- Device must be approved for use with hazardous drugs by the manufacturer[16]
- Venting devices used during preparation of parenteral hazardous drugs must have filters[4, 20]
- 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[3]
- Luer-lock fittings must be used for all hazardous drug connections made during manipulation and dispensing[2]

E.2.1 Syringes

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.[2]

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.[8]

A syringe must not be used more than five times for a single compounding procedure (e.g., reconstitution).[11]

E.2.2 Syringe Tip Caps

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).[9]

E.2.3 Needles

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.[13]

Aluminum-free needles and devices must be used in the preparation and administration of CISplatin, CARBOplatin and oxaliplatin.[37]

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.[16]

E.2.4 Needle Caps

Placing the open end of the needle cap directly on the work surface of the C-PEC must be avoided.[9]

E.2.7 Filters

Solutions prepared for parenteral administration must be filtered when there is a possibility that glass particles[11] or particulate matter (e.g., core from a vial stopper) may be present and the solution is filterable.

E.2.7.1 Filter Needles

The same filter needle must not be used for both withdrawing and expelling solution.[13, 38]

E.2.7.2 Filter Discs

A filter disc used for hazardous drugs must be equipped with proximal and distal luer-locking connections.[2]

E.2.8 Filter Venting Devices

Negative pressure technique must not be used for hazardous drug reconstitution or withdrawal if filter venting devices[4] or closed system drug transfer devices[4, 7] are available.

E.2.8.1 Chemotherapy Dispensing Pins

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[39] and the possible release of hazardous drug.

Note:

- 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[16]
- Chemotherapy dispensing pins must be disposed of in a HD sharps waste container if removed from a HD vial[16]
- 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[40]
- 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[16]

E.2.8.2 Chemotherapy Vents

A new chemotherapy vent must be inserted prior to removal of a plugged chemotherapy vent.[12]

A hazardous drug vial stopper must be disinfected with sterile 70% alcohol prior to each puncture when multiple punctures are necessary.[9]

E.2.9 Syringe Fluid Dispensing Connectors/Syringe Tip Connectors

Both ends of the individually packaged fluid dispensing connector used with hazardous drugs must have luer-lock connections[2] which allow transfer of solution from one syringe to another without leakage.

E.2.14 Closed System Drug Transfer Devices

Closed System Drug Transfer Devices must be used within the ISO Class 5 environment of a C-PEC during hazardous drug preparation.[3] 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.[7]

E.3 Containers

E.3.1 Ampoules

The length of time between opening an ampoule and transferring the solution into a closed-system (e.g., syringe) must be minimized.[8]

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.[9]

Glass particles in solutions must be filtered prior to administration[41] unless the manufacturer indicates the solution cannot be filtered. Solution must not be withdrawn and injected using the same filtration equipment.[8]

All parts of an opened ampoule must be discarded into a sharps container.[11]

E.3.2 Vials

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.[12]

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.[9]

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.[8]

E.3.5 Empty Sterile Infusion Bags

Infusion bags used for hazardous drug solution waste must be disposed of as hazardous drug waste.[3]

E.4 Ambulatory Drug Delivery Infusion Devices

E.4.1.2 Infusor™ Flow Rates

The correct size of elastomeric Infusor™ with the correct infusion rate must be selected when preparing hazardous drug medication.[16]

To decrease the risk of accidental exposure to hazardous drug, the delivery tubing of the Infusor™ must be primed with hazardous drug-free solution.[2, 42]

E.4.1.4 Hazardous Drug Medication Infusion Device Labels

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.[43]

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

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.[2]

Section F - Aseptic and Protective Processes

F.1 Operational Standards for Sterile Hazardous Drug Preparation

Hazardous drugs shall be prepared only under conditions that protect the healthcare workers and other personnel in the controlled area.[3]

Operational standards must be adhered to when preparing sterile HD admixtures.[8]

F.1.1 Personnel Hygiene in the Controlled Area

- Eating, drinking, smoking, chewing gum or candy, or storing food in the controlled area is strictly prohibited[1, 2]
- 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[1]
- 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[1]

- ✓ jewellery, studs, and other accessories from fingers, wrists, forearms, face including nose, tongue and ears, and neck[1]
- ✓ 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[1]
- ✓ nail polish and other nail applications (nail extensions, synthetic nail-lengthening products), natural nails must be kept neat and trimmed[1]

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

- Street clothes must be replaced with fresh scrubs daily by all personnel when the work assignment will take place in the controlled area[1]
- 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[13]
- 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[1]
- One pair of shoe covers must be donned in the gowning room to enter the controlled area,[8] a second pair of shoe covers must be donned if stepping from the dirty side of the anteroom to the clean side[1]

  OR
- 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[1]
- Hair covers (covering hair and ears completely) and beard covers (as applicable), must be worn in the controlled area[1]
- Hair covers and beard covers (as applicable) must be donned on the dirty side of the demarcation line in the anteroom[1]

  Or
- Hair covers and beard covers (as applicable), must be donned in the gowning room[8]
- At a minimum, an AAMI rated Level 1 medical mask must be worn by personnel compounding hazardous sterile preparations in a containment primary engineering control[1, 44]
- 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[1]
- A respirator must be donned on the dirty side of the demarcation line in the anteroom[1]
- An isolation gown must be donned in the gowning room to enter the controlled area[8] when the controlled area comprises of rooms in addition to the anteroom and clean room
- 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)[8]
- 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)[1]
- Hands must be cleansed and gloves donned in the gowning room[8]
- Hand hygiene must be performed and gloves donned on the clean side of the demarcation line in the anteroom to enter the clean room[1]
- 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[3, 29]
- 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.[1]
- Gloves must be powder-free because powder can contaminate the work area and can absorb and retain hazardous drug.[3]

- 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[1]
- 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.[3]
- Hands must be washed with soap and water every time gloves are removed.[3]
- 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 [1]
- 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[3]

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

- 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[14, 15]
- All interior surfaces of the C-PEC (except under the work surface) must be decontaminated, cleaned, and disinfected using appropriate agents followed by sterile 70% isopropyl alcohol[9] 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.[5]
- The viewing window must be kept at the manufacturer's recommended level during HD preparation[14, 15]
- Rapid arm movements that could disrupt the air curtain must be minimized[14, 15]
- The front air intake grill and the rear air exhaust route must not be blocked[14, 15]
- Manipulations must be performed at least six inches in from the front opening and side walls of the BSC[8]
- 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:[1]
  - ✓ after the C-PEC has purged for a minimum of 15 minutes post cleaning/decontaminating and disinfecting, before placing supplies into the C-PEC[16]
  - ✓ 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.[9]
- Following hazardous drug compounding, the C-PEC must purge for at least five minutes[15] 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:[1]
  - ✓ after preparations within the C-PEC are completed for the day[8]
  - ✓ prior to compounding 'latex-free' preparations[8]
  - ✓ prior to compounding sterile HD preparations in a C-PEC once it has been used to compound non-sterile HD preparations[8]
  - ✓ prior to resuming compounding in a C-PEC that is turned off between aseptic processes for any reason (e.g., power interruption, maintenance)[8]

F.1.4 General Procedures

- Unnecessary items must not be taken into the C-PEC since airflow is disrupted in an overcrowded C-PEC[14]
- 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[9]
- 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[1]

- Best practice standards for aseptic technique in vertical airflow must be adhered to when preparing sterile hazardous drug admixtures[1]
- Compounding must occur in the critical area (direct compounding area) of the C-PEC such that critical sites are exposed to first air.[1] Supplies not immediately required for use must not be kept in the critical area of the C-PEC
- To decrease particle generation inside the C-PEC, paper coverings must be peeled away from needle hubs (critical sites) rather than pushing them through[8]
- Critical sites must be protected as soon as possible after being exposed and must not be touch contaminated[9]
- Infusion solution bag ports and vial stoppers must be disinfected using sterile 70% isopropyl alcohol prior to accessing[9]
- A new sterile alcohol swab must be used to disinfect each critical site[9]
- When reconstituting, the drug must be completely dissolved before withdrawing a dose[5] or storing for future use
- 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[8]
- Verification of volumes measured in syringes during compounding must be performed prior to dispensing the final product in one of two ways:[1]
  - ✓ direct observation during compounding; or
  - ✓ review of photos taken of the solution-filled syringe(s)
- 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.[1]
- Negative pressure technique must not be used for hazardous drug reconstitution or withdrawal if filter venting devices[8] or closed system drug transfer devices[7] are available
- A puncture-proof sharps container must be used for disposal of all sharp objects including needles, chemotherapy dispensing pins, and chemotherapy vents[8]
- 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[3]

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

- Infusion solution bag ports that have been accessed must be wiped with an alcohol swab prior to removal from the C-PEC[9] to remove possible HD residue
- 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)[1]
- 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[8]
- 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[8]
- 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[45]
- To remove a vial of HD that will be saved for reuse from the C-PEC:
  - ✓ the vial stopper must be wiped with a sterile 70% alcohol swab[9] to remove possible HD residue (if there is not a chemotherapy dispensing pin or CSTD inserted)
  - ✓ the puncture date and time must be written directly on the vial with a thin-tipped permanent marker[8]
  - ✓ the vial must be wiped with a new towel moistened with a decontaminating agent[8]
  - ✓ 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[38]
- 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[7]

F.1.6 Warning Labels

- All hazardous drugs and hazardous drug preparations must be easily identifiable by personnel involved in their handling[2]
- The container of hazardous drug must be appropriately labelled[2] indicating the contents are hazardous in nature

F.1.7 Exiting the Clean Room

- PPE must be appropriately removed upon exiting the controlled area:[2, 3]
  - ✓ Outer chemotherapy gloves must be discarded into a hazardous waste container[3] (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[2]
  - ✓ The inner gloves must not be removed inside the clean room[16]
  - ✓ Inner gloves must be disposed of into a hazardous waste container[1]
  - ✓ 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[1]
  - ✓ Removal and disposal of chemotherapy gowns must be done with care to avoid spreading HD contamination to other non-contaminated garments[3]
  - ✓ Chemotherapy gowns must be discarded into hazardous waste containers after:[1]
    - 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.[2]
  - ✓ 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[3] 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 and is disposed of into HD waste[1]

    Or
  - ✓ The inner pair of shoe covers is removed in the gowning room[8] and is disposed of into a hazardous waste container[1]
  - ✓ The medical mask or respirator and hair cover(s) must not be removed inside the clean room[1]
  - ✓ Disposable masks, respirators and hair cover(s) must be disposed of into a hazardous waste container[1]
  - ✓ Disposable masks, respirators and beard covers must be changed after no more than 3.5 hours of continuous use[1]
  - ✓ Reusable respirators, safety goggles, and face shields must be decontaminated daily after use[1]
  - ✓ Hands must be washed immediately with soap and water every time gloves are removed[3]
  - ✓ An isolation gown must be donned over scrubs when exiting the anteroom[11] 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[11]

F.2 Aseptic/Protective Routines

F.2.1 Critical Sites

Critical sites must be protected as much as possible and must not be touch-contaminated.[9] Protection of critical sites by precluding physical contact and airborne contamination must be given the highest priority in aseptic compounding practice.[9]

F.2.2 First Air

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.[1]

F.2.3 Disinfecting Critical Sites

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.[9]

A new sterile swab must be used to disinfect each new surface.[8] 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.[9]

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[9] to remove possible HD residue.

F.2.4 Coring

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.[1]

F.2.5 Safely Capping Needles Used With Hazardous Drug

Needles are a critical site and therefore must be capped when not being used for injection or withdrawal.[8] 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.[38]

For worker safety, two-handed recapping of a needle used for HD preparation is never an acceptable practice.[8]

F.3 Safe Handling Aseptic Techniques

F.3.1 Transfer of Hazardous Drug Solution from a Syringe

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.[46, 47]

Excess hazardous drug must NOT be ejected into the needle cap, sharps container, or any other open container[47] as this could cause HD aerosolization, vaporization or contamination.

F.3.2 Removal of Bubbles/Air from a Syringe

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.[46, 47]

F.3.3 Attaching and Priming Solution / Secondary Administration Sets

Priming any intravenous administration set with hazardous drug solution in an uncontrolled environment must be avoided.[2]

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).[2]

F.4 Preparing Medications for Latex Allergic Patients

F.4.1 Determining Latex Content

When setting up a tray for the first treatment of a patient requiring latex precautions, the latex content of drug vials and supplies must be determined.[48]

F.4.2 Preparing the BSC

All items in the BSC must be removed from the BSC following site-specific procedures prior to the preparation of a medication requiring latex precautions. All interior surfaces of the BSC (above the work surface) must be cleaned, decontaminated, and disinfected[48] while wearing full personal protective equipment. The BSC must be left to purge for a minimum of 15 minutes before placing supplies for the latex-free preparation into the BSC. [8]

When camera verification is used during the final product check, the iPad (or other electronic device) must be disinfected prior to placement inside the BSC.[1]

F.4.3 Compounding

If the vial stopper is made with natural rubber latex or unknown composition, a new vial must be used for each dose and vial access must be limited to one puncture (for medications already in solution) or to two punctures (for medications requiring reconstitution). If a needle is used to withdraw the medication from the vial, it must be replaced with a new needle prior to injecting the medication into an infusion solution bag (if applicable).[48]

All sterile preparations compounded for patients identified as latex allergic must be prepared using latex precautions. Compounding personnel must wear latex-free gloves.[48]

F.4.4 Labelling and Packaging

In addition to other patient-specific and applicable auxiliary labels, final latex-free preparations must also be labelled with an auxiliary label that indicates the preparation was made following latex precautions (e.g., Prepared using latex precautions) and dispensed in a latex-free zip lock bag.[48]

Section G - Clean Up and Waste Disposal

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

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.[3, 9]

G.2 Hazardous Waste Disposal

Hazardous waste containers must be available in all areas where hazardous drugs are received, stored, prepared and administered.[2]

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.[2] Hazardous waste must be disposed of separately from general waste in hazardous waste containers with lids.[8] The hazardous waste container must be distinctly different from other types of waste containers.[8]

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’.[8]

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.[1]

The warning label must identify the contents as hazardous so that individuals transporting the waste are alerted to the need for special handling.[3]

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[8] without being crushed or clipped.[11, 46] 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.[8]

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.[8]

Two pairs of chemotherapy gloves must be worn while handling hazardous waste.[7]

While awaiting removal from the facility for disposal, hazardous waste must be stored in a secure area in securely sealed and properly labelled containers.[11]

Hazardous waste must be transported and disposed of according to Federal and Provincial regulations after leaving the facility.[3]

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

All drugs listed on the facility's hazardous drug list must be handled according to the facility's hazardous drug safe handling guidelines.[7] 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.[4]

A designated area of the pharmacy's outpatient dispensary must be dedicated to manipulating hazardous drug dosage forms (e.g., counting, blister packing).[49]

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[8]

H.1 Oral Dosage Forms

- At a minimum, one pair of (non-sterile) chemotherapy gloves must be worn when touching packaged hazardous drug (HD) products (e.g., boxes, bottles, blister strips) such as when picking/gathering HD to fill a prescription[50]
- Two pairs of (non-sterile) chemotherapy gloves must be worn when handling hazardous drug tablets and capsules (e.g., counting or blister-packing loose oral HDs)[49]
- At a minimum, one pair of (non-sterile) chemotherapy gloves must be worn when checking a filled HD prescription (including opening a lid or box-end to verify the contents)[50]
- At a minimum, one pair of (non-sterile) chemotherapy gloves must be worn when handling a filled and checked HD prescription (e.g., when dispensing a HD prescription to patient or representative)[50]
- Hazardous oral solutions and suspensions must be compounded or prepared in a biological safety cabinet[28]
- 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 (with at least 12 APH) to minimize the risk of spreading HD contaminated particulate throughout the rest of the pharmacy[3]
- 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[3] to reduce the risk of HD exposure
- Dedicated 'chemotherapy' counting trays and spatulas must be used to count loose HD tablets and capsules[8, 49]
- The wipe used to decontaminate "chemotherapy' dedicated counting tray(s), spatula(s) and countertops must be disposed of in HD waste[3]
- Hands must be washed with soap and water immediately after removing chemotherapy gloves[3]
- Gloves worn when handling hazardous drugs must be discarded in HD waste[3]
- Automated counting machines must not be used to count hazardous drug tablets and capsules[3]

H.2 Topical Dosage Forms

- At a minimum, one pair of (non-sterile) chemotherapy gloves must be worn when touching packaged topical HDs such as when picking/gathering HD to fill a prescription[50]
- Two pairs of chemotherapy gloves must be worn when handling hazardous drug topical preparations that have been removed from the original packaging[3]

- At a minimum, one pair of (non-sterile) chemotherapy gloves must be worn when checking a filled topical HD prescription[50]
- At a minimum, one pair of (non-sterile) chemotherapy gloves must be worn when handling a filled and checked topical HD prescription (e.g., when dispensing a HD prescription to patient or representative)[50]
- 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[3]

H.3 Pre-filled Syringes

- At a minimum, one pair of (non-sterile) chemotherapy gloves must be worn when touching pre-filled syringes such as when picking/gathering HD to fill a prescription[50]
- At a minimum, one pair of (non-sterile) chemotherapy gloves must be worn when checking a HD pre-filled syringe prescription[50]
- At a minimum, one pair of (non-sterile) chemotherapy gloves must be worn when handling a filled and checked HD pre-filled syringe prescription[50]

Section I - Hazardous Drug Spills

I.1 Hazardous Drug Spills

To minimize exposure of staff and patients to hazardous drugs, spills must be managed appropriately, according to established policies and procedures. Clearly labelled spill kits must be located in all areas where exposures may occur.[2] These locations include hazardous drug preparation, dispensing, storage and receiving areas.

I.1.1 Recommended Spill Kit Contents

Disposable PPE and the filter cartridge[51] 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.[1]

New employees must be advised of hazardous drug spill control procedures[2] and be required to demonstrate competency in spill handling.[20]

Training and competency assessments must be documented.[3]

Section J - Accidental Exposure to Hazardous Drugs

J.1 Accidental Exposure to Hazardous Drugs

Healthcare workers must be made aware of how to manage accidental exposure to hazardous drugs.[2]

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[46] and by calling the Provincial Workplace Health Call Centre reporting line at 1-866-922-9464. Appropriate documentation must be completed.[8]

J.1.2 Ingestion

Personnel must not take food, gum, drinks, cigarettes or personal medication into an area where hazardous drugs are handled[2] (e.g., received, stored, prepared, administered and disposed).

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

K.1 Receipt and Unpacking

Shipping cartons containing hazardous drugs must be unpacked outside of controlled areas to limit the introduction of dust and particles into the controlled area.[1]

Staff receiving and unpacking hazardous drugs must receive training to manage HD spills and be made aware of precautions and follow special handling procedures.[3]

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.[8]

K.1.1 Receipt

- 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[1]
- Two pairs of chemotherapy gloves must be worn when packing and unpacking boxes containing hazardous drugs[8]
- The outside of shipping cartons must be examined for possible damage prior to opening[3]
- Hazardous drugs requiring refrigeration must be unpacked and refrigerated immediately upon receipt[5, 13]

K.1.2 Receipt of a Damaged Shipment

Policies and procedures must be in place for handling damaged shipments of hazardous drugs.[3]

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.[1]

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.[1]

HD spill kits with written procedures for use must be located in all areas where hazardous drugs are received.[7, 11]

K.2 Storage

Final compounded preparations must be stored at an appropriate temperature within the time specified by the beyond use date prior to dispensing.[1]

- Hazardous drugs requiring manipulation other than counting or repackaging of final dosage forms must be stored:[1]
  - ✓ separately from other inventory in a manner that prevents HD contamination and occupational exposure[3]
  - ✓ 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
- Refrigerated hazardous drugs requiring manipulation other than counting or repackaging of final dosage forms must be stored in a dedicated refrigerator[1]
- Refrigerator temperatures must maintain a cold temperature range of 2°C to 8°C[1]
- 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.[1]
- Containers, shelves and bins used for HD storage must be properly labelled with hazard warning labels identifying the drugs that require special handling[2]
- 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[8]
- Hazardous drugs must be stored in a manner that prevents spillage or breakage if the container falls[3]
- 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[8]
- Access to areas where hazardous drugs are stored must be limited to authorized personnel[8]

- Hazardous drugs spill kits with written procedures for use must be readily available in areas where hazardous drugs are stored.[2]

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.[1]

K.3 Packaging and Transportation

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.[3] The packaging must be appropriate to maintain the stability and integrity of the preparation.[1]

Pneumatic tubes or other mechanical transport systems that produce stress on the contents must not be used for hazardous drug transport.[3]

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.[8]

Take home medication must not be placed inside the same inner container as the compounded HD parenteral admixtures which are administered within the facility.[16]

Absorbent packaging material must be placed inside Type A and B outer containers to absorb any liquid in the event of leakage during transport.[10]

Module 2 – Pharmacy Medication Checks

Section A

A.1 Clinical Medication Order Check

The following must be reviewed and verified by a pharmacist for all parenteral, oral and topical oncology prescriptions prior to dispensing:[52]

- pharmacy medication profile
- protocol code and cycle number (if appropriate)
- drug, dose (a maximum of a 5% variance is permitted in dose calculation unless a variance is prohibited by the treatment protocol), route, administration, timing and duration of each medication ordered; for cyclical therapies, no more than one cycle of medication will be dispensed at a time
- benefit status of the medication(s) and receipt of appropriate approval forms, if required
- patient-specific factors including allergies, alerts, and protocol required laboratory values; for new patients or patients beginning a new course of cancer treatment, baseline tests must have been conducted within four weeks of the start of therapy
- body surface area, calculated by the Mosteller equation, for the first treatment of each chemotherapy protocol only (based on actual body weight except for the designated high dose protocols described above, where ideal body weight is used) unless recalculated by the physician and documented in the patient's chart - if required for the cancer treatment being prescribed

A.2 Final Product and Computer Order Entry Check

The final product must be checked prior to dispensing:

- the volume/quantity calculation must be double checked, all components used must be appropriate and a visual inspection of the final product must be performed[1]
- the drug volume(s) added to a final container must match the dose prescribed on the medication order[4]
    - reconstitution solution and volumes must be checked by any qualified person other than the individual who measured the solution[5, 53]

The computer order entry on the patient-specific label must be checked for accuracy.[52]

The patient-specific label must be:

- affixed to the correct final product container;
- checked for completion; and
- checked that it accurately reflects what is written on the corresponding medication order.[5]

The final product must have the appropriate patient specific label, a HD warning label (if applicable) and any necessary auxiliary warning labels affixed to the container.[4, 53]

Section B

B.1 Documentation of Pharmacy Medication Checks

Standard operating procedures must be developed which include signed documentation that all the required pharmacy checks have been completed for each medication.[4]

- the pharmacist performing the clinical medication order review must indicate that the order is approved for preparation by documenting on the appropriate form prior to compounding[52]
- the person performing the computer order entry (e.g., patient label) check must indicate the computer order entry is accurate as per the medication order by documenting on a permanent record[4]
- the person performing the final product check must indicate by documenting on a permanent record that they have performed a complete final product check[4]

Module 3 – Improving Patient Safety and Compliance

Section A

A.1 Intrathecal (IT) Doses

Preparation of IT doses must be performed accurately given the limitations of syringe technology while following the principles of aseptic technique for the safety of the patient and to minimize exposure of staff to the hazardous drugs.[16]

All intrathecal doses will have a label stating the patient name, date, generic drug name, dose and route in full (i.e. By INTRATHECAL Injection). The route will be highlighted by using all upper case letters and/or a coloured highlighting pen. This labelling will be attached to the syringe and to the outer zip-lock bag. Intrathecal doses will be provided in luer lock syringes (WorkSafe BC Health and Safety Regulation 6.54). Intrathecal syringes and labels will have an auxiliary label stating 'IT' attached to the syringe and the outer zip-lock bag. These will be bright in colour and clearly visible.

Intrathecal doses will be packaged in separate outer containers for transport to the centre specific treatment location (i.e. intrathecal doses will be delivered separately from all other chemotherapy doses).

For protocols in which intrathecal drugs and drugs administered by other parenteral routes are all to be given in one same treatment cycle, the non-intrathecal drugs will NOT be released from pharmacy until the nurse or physician confirms that the intrathecal drug administration is completed.

Note:

- All drug and diluent used in the preparation of IT doses MUST be preservative free[37]
- All drug used MUST be labelled 'for intrathecal use' by the manufacturer[37]
- Gloves MUST be changed immediately prior to preparing the intrathecal dose[16]

Section B

B.1 Vinca Alkaloids

All Vinca Alkaloids must be dispensed in a 50 mL minibag to be given over 5-15 minutes and labelled with an auxiliary label with the words 'WARNING: FOR INTRAVENOUS USE ONLY – FATAL IF GIVEN BY OTHER ROUTES'[54]

Section D

D.1 Outpatient Hazardous Drug Prescription Labelling

All hazardous drugs dispensed for outpatient use must be labelled according to the current labelling standards found in the Health Professions Act (HPA) Bylaws; College of Pharmacists of BC.

A recognized strategy to improve comprehension of the directions on outpatient prescription labels and to reduce inadvertent medication errors is to standardize drug labelling practices.[55]

- All boxes/bottles must be individually labelled; multiple boxes must not be affixed together with a label on a single box[56]
- Vials, blister cards, boxes, bottles and jars containing hazardous drugs must be clearly labelled with a "Chemotherapy" warning auxiliary label[20, 56]

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