# Summary of BCCA Pharmacy Practice Standards for Hazardous Drugs

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September 2016
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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.\(^1,2\)

Module 1 – Safe Handling of Hazardous Drugs

Section A

A.1 Potential Hazards of Handling Hazardous Drugs

Hazardous Drug (HD) safe handling policies and procedures must be developed to address the following:\(^3,4\)

- Receipt\(^2-4\)
- Storage\(^1-4\)
- Preparation\(^3,4\)
- Labelling\(^1-3\)
- Safety equipment\(^5\)
- Use of Personal Protective Equipment (PPE)\(^2,6\)
- Emergency procedures for treating accidental contact and spills\(^2,4\)
- Packaging\(^1,3\)
- Transport\(^1-3\)
- Drug administration\(^4\)
- Disposal\(^2-4\)

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.\(^2,4\) There must be established work practices related to both drug manipulation techniques and to general hygiene practices.\(^2\) Workplace procedures must be developed for using and maintaining all equipment that functions to reduce hazardous drug exposure.\(^4\)

Warning signs, which are clearly visible and clearly state the identified hazards, must be posted in all areas where hazardous drugs are received, stored, prepared and administered.\(^7\)

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.\(^2,4\)

The facility’s hazardous drug list must be posted in all areas where these drugs are received, stored, prepared and administered.\(^7,8\)

A.4 Personal Exposure Records

WorkSafe BC Occupational Health and Safety (OH&S) Regulation 6.52 states: “the employer must maintain a record of all workers who prepare or administer cytotoxic (hazardous) drugs, including the name of the drugs handled, and when practicable, the number of preparations or administrations per week. Exposure records must be maintained for the duration of employment plus 10 years, and training records for 3 years from the date that the training occurred.”
A.5 Work Re-Assignment

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

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

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

Section B

B.2 Controlled Work Area

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

Doors leading into controlled work areas must not be left open.

B.2.1 Hazardous Drug Cleanroom

The hazardous drug cleanroom must maintain an ISO Class 7 environment and be negative pressure to the anteroom. The cleanroom must retain at least 30 air changes per hour (ACPH) of HEPA-filtered air.

A warning sign must clearly identify the hazard and state that access to the cleanroom is controlled and limited to authorized personnel only.

B.2.2 Hazardous Drug Anteroom

The hazardous drug anteroom must maintain an ISO Class 7 environment and be positive pressure to both the hazardous drug cleanroom and the rest of the pharmacy. The anteroom must maintain at least 20 air changes per hour (ACPH) of HEPA-filtered air.

B.3 Equipment

B.3.1 Biological Safety Cabinets

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

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

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

B.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. 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.

B.3.1.2 Class II BSC

Because there is a possibility that HEPA-filtered air recirculated back into the cleanroom may be contaminated with hazardous drug, Class II Type A cabinets must not be used during preparation of hazardous drugs.
A minimum Class II Type B BSC that is exhausted to the outside atmosphere with no recirculation into any work area must be used for the preparation of sterile hazardous drugs.  

B.3.1.3 HEPA Filter

HEPA filters must be present in BSCs 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. 

B.3.1.4 Airflow

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

Manipulations must be performed at least six inches in from the front opening of the cabinet, behind the air ‘split’. Contaminated air must be able to escape via the rear grill, not via the front opening.

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

Note:
- Horizontal laminar airflow hoods must not be used for the preparation of hazardous drugs

B.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 BSC, or in the cleanroom.

B.3.1.6 Viewing Window

To protect the upper body and face from any splashes or aerosols produced inside a BSC; the viewing window must be kept at the manufacturers' recommended height during hazardous drug preparation.

B.3.1.7 Location

A biological safety cabinet used for hazardous drug preparations must be located away from doorways, traffic corridors, and air conditioning and heating vents inside a restricted access ISO Class 7 cleanroom.

B.3.1.8 Monitoring

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

For the safety of the patient and the operator, hazardous drug compounding must not take place when a BSC alarm is sounding or the lights and/or gauges indicate the cabinet is not functioning within the manufacturer’s specifications.

Site specific procedures must be created and posted for workers so that when the gauges, lights or alarms indicate that the BSC 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.

B.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) when installed. Certification procedures used must meet the requirements of the NSF Standard 49-Biosafety CabINETry: Design, Construction, Performance, and Field Certification (current version). The BSC must be re-certified every six months and when the cabinet is altered or repaired or the HEPA filter is changed. 

Testing and certifying the biological safety cabinet must occur during dynamic operating conditions.

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

After field certification, the BSC must have certification information posted on the front of the cabinet housing in a readily visible location.
B.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.9

Appropriate personal protective equipment must be worn when replacing HEPA filters and the contaminated filters must be handled and disposed of as hazardous waste.7,17

B.3.1.11 Turning off a Biological Safety Cabinet

If it is necessary to turn off a BSC for testing and certifying or for maintenance, the entire inner cabinet must be decontaminated first.3

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

B.3.1.12 Cleaning Biological Safety Cabinets

To maintain an aseptic environment and to protect against possible contact with hazardous drug particles, interior surfaces of the BSC must be cleaned and disinfected regularly throughout the day11 using an aqueous antibacterial agent (e.g., chlorhexidine 0.05%, CaviWipe™) followed by sterile 70% alcohol.11

Prior to cleaning a BSC, proper hand hygiene procedures must be followed and full personal protective equipment (PPE) must be donned.1

B.3.1.12a Cleaning All Interior Biological Safety Cabinet Surfaces

Prior to commencing daily compounding, all interior surfaces of the biological safety cabinet (except under the work surface) must be cleaned and disinfected using an aqueous antibacterial agent (e.g., chlorhexidine 0.05%, CaviWipe™) followed by sterile 70% alcohol.11 If the viewing window has been raised during cleaning and disinfecting, it must be lowered to the manufacturers recommended operating level and the BSC must purge for at least fifteen minutes3 afterwards.

Following hazardous drug compounding, the BSC must purge for at least five minutes15 and then all interior surfaces (except under the work surface) must be cleaned and disinfected using an aqueous antibacterial agent (e.g., chlorhexidine 0.05%, CaviWipe™) followed by sterile 70% alcohol11:

- after preparations within the BSC are completed for the day3
- prior to compounding ‘latex-free’ preparations3
- prior to compounding sterile HD preparations in a BSC once it has been used to compound non-sterile HD preparations3
- prior to resuming compounding in a BSC that is turned off between aseptic processes for any reason (e.g., power interruption, maintenance)3

If cleaning interior surfaces of a BSC with the viewing window raised, additional PPE is required including a NIOSH-approved respirator (e.g., N95) appropriately fit-tested for the operator and safety goggles with side shields3 to prevent splashing into the eyes.

To protect others from potential exposure to hazardous drugs, pharmacy personnel who must be present in the cleanroom or in the area of the biological safety cabinet15 must wear an N95 or better respirator in addition to all other PPE if the viewing window is raised.

B.3.1.12b Cleaning the Work Surface of the BSC

The work surface of the BSC must be cleaned and disinfected using an aqueous antibacterial agent (e.g., chlorhexidine 0.05%, CaviWipe™) followed by sterile 70% alcohol:11

- after a completed preparation has been cleaned and removed from the BSC
- before leaving the BSC for an extended period of time (e.g., for a break)
- upon returning to the BSC after an extended period of time
- after a minor spill involving the working surface
At least 30 seconds of surface contact time must be allowed for the alcohol to act before beginning the next sterile preparation.11

B.3.1.13 Decontaminating Biological Safety Cabinets

Decontamination of the BSC must occur once a week, after a HD spill in the BSC, and before maintenance/certification/servicing if shutdown of the BSC is required.6

Prior to decontaminating the BSC, proper hand hygiene procedures must be followed and full personal protective equipment (PPE) must be donned.1

When decontaminating interior surfaces of the BSC with the viewing window raised, additional PPE is required, including a NIOSH-approved respirator (e.g., N95) appropriately fit-tested for the operator and safety goggles with side shields9 to prevent splashing into the eyes.

To protect others from potential exposure to hazardous drugs, pharmacy personnel who must be present in the cleanroom or in the area of the biological safety cabinet11 must wear an N95 or better respirator in addition to all other PPE when the viewing window has been raised.

After decontamination is completed, the viewing window is lowered to the manufacturers recommended operating level and the BSC must purge for at least thirty minutes prior to sterile preparation.7

B.3.2 Communication System

Verbal communication between personnel in the cleanroom and the anteroom or between personnel in the cleanroom and the general pharmacy must not be through open doors or pass-throughs.19

Section C

C.1 General Protective Guidelines

Personnel must follow protective guidelines 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 personal exposure to hazardous drugs.8,11

There must be procedures and directives available for safe and aseptic handling of hazardous drugs. There must be strict adherence to safe handling procedures and directives.2

C.2 Personal Protective Equipment (PPE) and Cleanroom Garb

Personal protective equipment and cleanroom garb must be provided to minimize or prevent healthcare workers exposure to hazardous drugs.4 All personnel entering the controlled work areas must follow appropriate hand hygiene and garbing procedures.1

C.2.1 Scrubs

Scrubs / low lint clothing must be worn by all personnel working in the controlled work area.1 Pants must fully cover the legs.1 A buttoned lab coat or isolation gown must be donned over scrubs upon exiting the controlled work area.3

C.2.2 Footwear

Each facility must be in compliance with WorkSafe BC regulations to help reduce preventable injuries due to inappropriate footwear.6

WorkSafe BC Regulation 8.22 states:

1. “A worker’s footwear must be of a design, construction and material appropriate to the protection required.”
2. “To determine appropriate protection, the following factors must be considered; slipping, uneven terrain, abrasion, ankle protection and foot support, crushing potential, temperature extremes, corrosive substances, puncture hazards, electrical shock and any other recognizable hazard.”

Personnel entering the controlled work area must wear socks that are long enough to reach above the bottom of the pant legs as well as closed shoes.1
C.2.3 Shoe Covers

One (inner) pair of shoe covers must be donned by all personnel upon stepping from the dirty side of the demarcation line in the anteroom to the clean side.1 In facilities that have incorporated a gowning room in the controlled work area, the inner pair of shoe covers is donned upon stepping from the dirty side of the demarcation line in the gowning room to the clean side.3

A second (outer) pair of shoe covers must be donned on the clean side of the anteroom before stepping inside the hazardous drug cleanroom.2 The outer pair of shoe covers must be removed with gloved hands upon exiting the hazardous drug cleanroom.2

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.1 In facilities that have incorporated a gowning room in the controlled work area, the inner pair of shoe covers is removed in the gowning room upon stepping from the clean side of the demarcation line to the dirty side, not in the anteroom.3

Shoe covers must be disposed of in hazardous waste containers and not saved for reuse.2

C.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(3,683),(86,683)(91,683),(155,683)(160,683),(224,683)(229,683),(293,683)(297,683),(361,683)(365,683),(429,683)(434,683),(498,683)(503,683),(567,683)(572,683),(636,683)(641,683),(705,683)(710,683),(774,683)(779,683),(843,683)(848,683),(912,683)(917,683),(981,683) must be worn by all personnel working in the controlled work area.1,3

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 work area, the hair cover must be donned on the dirty side of the demarcation line in the gowning room.3

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 work area, the hair cover is not in the anteroom. The hair cover is removed on the dirty side of the demarcation line in the gowning room.3

Hair and beard covers are single use only and must not be saved for reuse.11 Hair and beard covers worn in the hazardous drug cleanroom must be disposed of in hazardous waste containers.2

C.2.5 Surgical Masks

Surgical masks must be worn by all personnel present in the hazardous drug cleanroom1,3 unless cleaning or decontaminating the biological safety cabinet with the viewing window raised. Masks must be donned on the dirty side of the demarcation line in the anteroom.1 Masks must cover from the bridge of the nose down to include the chin.11

Masks must be disposed of in hazardous waste containers.2 Masks must not be saved for reuse.11

C.2.6 Respirators

A NIOSH-approved respirator must be worn when cleaning up HD spills outside of the BSC, when decontaminating or cleaning the BSC with the viewing window raised, or when working in a cleanroom when a BSC is being cleaned or decontaminated with the viewing window raised.7,8,10

Personnel wearing a NIOSH-approved respirator (e.g., N95, P100) must be fit-tested prior to initial use and 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.6

WorkSafe BC 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.

A respirator must not be worn over a surgical mask.6

Once removed, disposable respirators must be discarded into HD waste containers2, not saved for reuse.11
C.2.7 Chemotherapy Gowns

To decrease particulate levels in the preparation area and to decrease the risk of direct skin contact with hazardous drugs, workers must wear non-linting, impermeable, disposable chemotherapy gowns with long sleeves and tight-fitting cuffs, a closed front, and tied around the waist. Chemotherapy gowns must be worn for all activities that may result in the worker’s direct exposure to hazardous drugs.

Chemotherapy gowns worn when mixing hazardous drugs in the biological safety cabinet must be removed for storage or disposal while still in the cleanroom to help prevent the spread of hazardous drug contamination to areas outside of the cleanroom.

Personnel leaving the hazardous drug cleanroom to work in another room in the controlled work area (e.g., the anteroom, set-up room) or intending to leave the controlled work area through a gowning room must remove chemotherapy gloves, wash hands and don an isolation gown or a new chemotherapy gown and a new pair of chemotherapy gloves (sterile or non-sterile) while still in the anteroom.

Lab coats or isolation gowns must not be worn in the hazardous drug cleanroom by personnel working in the biological safety cabinet in place of chemotherapy gowns.

Used chemotherapy gowns must be discarded into hazardous waste containers.

C.2.8 Isolation Gowns

Isolation or chemotherapy gowns must be worn by all personnel working in the controlled work areas.

Isolation gowns must be low-shedding with long sleeves and tight fitting cuffs, a closed front, and tied around the waist.

C.2.9 Chemotherapy Gloves

Chemotherapy gloves worn when mixing hazardous drugs in the biological safety cabinet must be sterile and be long enough to cover the cuff of the chemotherapy gown. If powder-free gloves are not available, powdered gloves must be wiped with a clean, low-lint wipe pre-moistened with sterile 70% alcohol prior to entering the cleanroom. Alcohol must not be sprayed onto gloves to remove powder.

Gloves approved for use with hazardous drugs must be tested with nine chemotherapy drugs as required in the American Society for Testing and Materials (ASTM) Standard D6978-05. 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.

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. Two pairs of disposable chemotherapy gloves must be worn at all times by all personnel working in the hazardous drug cleanroom.

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

One (inner) pair 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. In facilities that have incorporated a gowning room in the controlled work area, an inner pair of non-sterile gloves is donned by all personnel on the clean side of the demarcation line in the gowning room after performing hand hygiene.

To minimize the spread of hazardous drug contamination outside the cleanroom, outer chemotherapy gloves worn during hazardous drug compounding must not be worn outside of the cleanroom.

The inner pair of chemotherapy gloves worn during hazardous drug compounding must be removed in the anteroom (e.g., on the clean side of the demarcation line immediately prior to washing hands). In facilities that have incorporated a gowning room in the controlled work 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 chemotherapy gloves (sterile or non-sterile) must be donned prior to leaving the anteroom.
When leaving the controlled work area, the new pair of gloves is removed on the clean side of the demarcation line in the gowning room (immediately prior to washing hands).³

Chemotherapy gloves must be disposed of in hazardous waste containers.⁴

Hands must be washed with soap and water every time gloves are removed.²

Latex-free ‘chemotherapy-approved’ gloves must be made available to staff.⁴

C.2.10 Eye Protection

Eye shields or safety goggles with side shields must be worn for splash protection when cleaning or decontaminating a BSC with the viewing window raised or when cleaning up a hazardous drug spill outside the BSC.⁷,⁸

Table 1: Summary of Process for Donning Personal Protective Equipment and Cleanroom Garb
(For controlled work area with anteroom and cleanroom only)

Removing a respirator (e.g., after cleaning or decontaminating the BSC) and replacing with a surgical mask must not occur in the cleanroom.³

C.3 Hand Hygiene

Hand hygiene must be performed by all personnel prior to entry into the cleanroom to minimize microbial contamination of sterile products. After handling hazardous drugs and removing chemotherapy gloves, hand washing is performed² to remove possible drug contamination.

C.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.²¹

C.3.2 Hand Washing After Handling Hazardous Drugs

Personnel handling hazardous drugs must wash their hands with soap and water immediately after removal of chemotherapy gloves.²

C.3.2.1 Compounding personnel

Personnel compounding sterile hazardous drug preparations must perform hand hygiene before donning two pairs of sterile chemotherapy gloves.³ 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.⁷ Hands must be dried with a clean, low lint towel.¹¹

C.3.3 Nails and Nail Polish

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

C.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.⁵

Personnel that are required to use emergency eyewash and shower facilities must be adequately trained in their location and proper use.⁵

For potential exposure to high risk materials: WorkSafe BC Occupational Health and Safety (OHS) Regulation 5.89 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”

C.4.1.2 Hand Held Portable

Portable eyewash stations must be capable of delivering a minimum flush duration of 15 minutes.5

C.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.22

C.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.5

Hand held portable eyewash equipment must be inspected and maintained according to the manufacturer's instructions.22

Section D

D.1 Supplies

D.1.3 Alcohol Swabs and Solutions

Single use, individually packaged sterile 70% isopropyl alcohol swabs must be used to disinfect a critical site prior to accessing.11 Gauze pads or other particle-generating material moistened with alcohol must not be used to disinfect critical sites of containers prior to accessing.11

Partially emptied containers of alcohol must not be topped up.7

D.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.3

Staff must be trained to use the proper aseptic technique required with each device utilized in the safe preparation of hazardous drugs.10

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 manufacturer19
- Venting devices used during preparation of parenteral hazardous drugs must have filters7,17
- Luer-lock fittings must be used for all hazardous drug connections made during manipulation and dispensing4

D.2.1 Syringes

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.3

A syringe must not be used more than five times for a single compounding procedure (e.g., reconstitution).10
D.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).11

D.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.23

Safety Engineered Needles (SEN) must not be used in the preparation of hazardous drugs. There is a risk that the HD will spray droplets off of the needle point when the SEN cap is engaged.19

Placing the open end of the needle cap directly on the work surface of the BSC must be avoided.11

D.2.7 Filters
Solutions prepared for parenteral administration must be filtered when there is a possibility that glass particles10 or particulate matter (e.g., core from a vial stopper) may be present and the solution is filterable.

D.2.7.1 Filter Needles
The same filter needle must not be used for both withdrawing and expelling solution.13,24

D.2.7.2 Filter Discs
A filter disc used for hazardous drugs must be equipped with proximal and distal luer-locking connections.4

D.2.8 Filter Venting Devices
Negative pressure technique must not be used for hazardous drug reconstitution or withdrawal if filter venting devices7 or closed system drug transfer devices7,9 are available.

D.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 integrity25 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 solution19
- Chemotherapy dispensing pins must be disposed of in a HD sharps waste container if removed from a HD vial19
- A new chemotherapy dispensing pin must be used for each vial. Spraying of the solution or touch contamination can occur upon removal of the pin26

D.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.11

D.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 connections5 which allow transfer of solution from one syringe to another without leakage.
D.2.14 Closed System Drug Transfer Devices

Closed System Drug Transfer Devices must be used within the ISO Class 5 environment of a biological safety cabinet. 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.

D.3 Containers

The length of time between opening an ampoule and transferring the solution into a closed-system (e.g., syringe) must be minimized. 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. Glass particles in solutions must be filtered prior to administration unless the manufacturer indicates the solution cannot be filtered. Solution must not be withdrawn and injected using the same filtration equipment.

D.3.2 Vials

Removal of a flip top cap from a hazardous drug vial must be performed carefully inside the BSC to 'contain' and avoid spreading HD contamination to areas outside of the BSC. 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 BSC. The date and time of puncture or the beyond use 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.

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

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

D.3.5 Empty Sterile Infusion Bags

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

D.4 Ambulatory Drug Delivery Infusion Devices

D.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. To decrease the risk of accidental exposure to HD, the delivery tubing of the INFUSOR™ must be primed with HD-free solution.

D.4.1.3 INFUSOR™ Volume Capacities and Fixed Flow Rates

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.

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

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

Section E

E.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 preparation and storage areas.
Operational standards must be adhered to when preparing sterile HD admixtures.³

E.1.1 Personnel Hygiene in the Controlled Work Area

- Eating, drinking, smoking, chewing gum, or storing food in the controlled work area is strictly prohibited¹,⁴
- Personnel with rashes, burns to the skin (including sunburn), weeping sores, conjunctivitis, cold sores, active respiratory infection and wearing cosmetics are prohibited from preparing sterile admixtures¹,¹¹
- Compounding personnel must remove:
  - jewellery, studs, and other accessories from fingers, wrists, forearms, face including nose, tongue and ears, and neck¹
  - 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 contamination¹
  - nail polish and other nail applications (nail extensions, synthetic nail-lengthening products), natural nails must be kept neat and trimmed¹
  - personal outer garments (e.g., bandanas, coats, hats, jackets, scarves, sweaters, vests) because they shed flakes and particles¹,¹¹

E.1.2 Personal Protective Equipment and Cleanroom Garb in the Controlled Work Area

- Personnel must wear scrubs or clean, low-lint clothing to enter the controlled work area¹
- Hair covers (covering hair and ears completely) and beard covers (as applicable), must be worn by all personnel working in the controlled work area¹
- Hair covers and beard covers (as applicable) must be donned on the dirty side of the demarcation line in the anteroom¹
  Or
- Hair covers and beard covers (as applicable), must be donned on the dirty side of the demarcation line in the gowning room³
- A surgical mask (or N95 or better respirator depending on the work being performed) must be donned on the dirty side of the demarcation line in the anteroom¹
- Pharmacy personnel who must be present in the cleanroom or in the area of the biological safety cabinet must wear an N95 or better respirator in addition to all other PPE¹³ if the viewing window is raised
- One pair of shoe covers must be donned by all personnel upon stepping from the dirty side of the demarcation line in the anteroom to the clean side¹
  Or
- One pair of shoe covers must be donned by all personnel upon stepping from the dirty side of the demarcation line in the gowning room to the clean side³
- A second (outer) pair of shoe covers must be donned on the clean side of the anteroom before stepping inside the hazardous drug cleanroom²
- 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)³
  Or
- A chemotherapy or isolation gown must be donned on the clean side of the demarcation line in the gowning room (depending on the work being performed)³
- A chemotherapy gown must be worn any time there is a risk of hazardous drug exposure (e.g., when working in the biological safety cabinet, when cleaning up a HD spill)²
- Hand hygiene must be performed and gloves donned on the clean side of the demarcation line in the anteroom¹
  Or
- Hand hygiene must be performed and gloves donned on the clean side of the demarcation line in the gowning room³
The outer pair of shoe covers must be removed with gloved hands upon exiting the hazardous drug cleanroom and be disposed of into HD waste.

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.

Or

The inner pair of shoe covers is removed upon stepping from the clean side of the demarcation line in the gowning room to the dirty side and is disposed of into HD waste.

Chemotherapy gowns worn when preparing hazardous drugs must be non-linting, impermeable and disposable with long sleeves, tightly-fitting cuffs, a closed front, and tied around the waist.

Chemotherapy gowns worn in the cleanroom must be removed for storage or disposal while still in the HD preparation area, to prevent the spread of HD contamination from one area to another.

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.

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 the BSC). Both pairs of chemotherapy gloves must be inspected for visible defects. Gloves that have visible defects must not be worn.

Gloves must be powder-free because powder can contaminate the work area and can absorb and retain hazardous drug.

Gloves must be disinfected by wiping with a low lint towel moistened with sterile 70% alcohol. The gloves must be completely dry before performing aseptic compounding activities inside the BSC.

Gloves worn during hazardous drug compounding must be changed every 30 minutes unless otherwise recommended by the manufacturer’s documentation or when torn, punctured or in the event of suspected contamination. Hands must be washed with soap and water every time gloves are removed.

E.1.3 Biological Safety Cabinet

The UV light may cause eye damage and must not be turned on when personnel are working in the cleanroom.

All interior surfaces of the BSC (except under the work surface) must be cleaned and disinfected using an aqueous antibacterial agent (e.g., chlorhexidine 0.05%, CaviWipe™) followed by sterile 70% alcohol 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 BSC must purge for at least 15 minutes after cleaning.

The viewing window must be kept at the manufacturer’s recommended level during HD preparation.

Rapid arm movements that could disrupt the air curtain must be minimized.

The front air intake grill and the rear air exhaust route must not be blocked.

Manipulations must be performed at least six inches in from the front opening and side walls of the BSC.

Following hazardous drug compounding, the BSC must purge for at least five minutes and then all interior surfaces (except under the work surface) must be cleaned and disinfected using an aqueous antibacterial agent (e.g., chlorhexidine 0.05%, CaviWipe™) followed by sterile 70% alcohol:

- after preparations within the BSC are completed for the day
- prior to compounding ‘latex-free’ preparations
- prior to compounding sterile HD preparations in a BSC once it has been used to compound non-sterile HD preparations
- prior to resuming compounding in a BSC that is turned off between aseptic processes for any reason (e.g., power interruption, maintenance)
E.1.4 General Procedures

- Unnecessary items must not be taken into the BSC since airflow is disrupted in an overcrowded BSC.
- HD vials must be wiped with low-lint towels or gauze moistened with sterile 70% alcohol to disinfect and physically remove HD contamination prior to placement inside the BSC.
- Prior to placement inside the BSC, the outer wrapping of unopened supplies (e.g., syringes) must be disinfected by wiping with a low lint towel moistened with sterile 70% alcohol.
- Best practice standards for aseptic technique in vertical airflow must be adhered to when preparing sterile hazardous drug admixtures.
- Compounding must occur in the critical area (work zone) of the BSC such that critical sites are exposed to first air. Supplies not immediately required for use must not be kept in the critical area of the BSC.
- To decrease particle generation inside the BSC, paper coverings must be peeled away from needle hubs (critical sites) rather than pushing them through.
- Critical sites must be protected as soon as possible after being exposed and must not be touch contaminated.
- Infusion solution bag ports and vial stoppers must be disinfected with sterile 70% alcohol prior to accessing.
- A new sterile alcohol swab must be used to disinfect each critical site.
- When reconstituting, the drug must be completely dissolved before withdrawing a dose or storing for future use.
- Syringes must not be overfilled with hazardous drug. In most cases, syringes should not be more than three-quarters (75%) full, although some preparations require accurate volume measurements that necessitate the use of a smaller volume syringe.
- Negative pressure technique must not be used for hazardous drug reconstitution or withdrawal if filter venting devices or closed system drug transfer devices are available.
- A puncture-proof sharps container must be used for disposal of all sharp objects including needles, chemotherapy dispensing pins, and chemotherapy vents.
- 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 BSC for later removal and disposal.

E.1.5 Removing Products from the BSC

- Infusion solution bag ports that have been accessed must be wiped with an alcohol swab prior to removal from the BSC 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 biological safety cabinet (and prior to covering the port with a foil seal if the injection port was used to add drug to the infusion solution bag).
- Outer chemotherapy gloves worn when compounding hazardous drugs must be removed, discarded within the BSC replaced with a new pair of sterile chemotherapy gloves or wiped with a new towel moistened with an aqueous antibacterial agent (e.g., CaviWipe™) prior to touching items for removal from the BSC.
- Surfaces of final preparation(s) may be contaminated with HD and must be cleaned using a new towel moistened with an aqueous antibacterial agent (e.g., CaviWipe™) prior to removal from the BSC.
- The final preparation must be labelled immediately after it is removed from the BSC with the patient specific and required warning labels.
To remove a vial of HD that will be saved for reuse from the BSC:

- the vial stopper must be wiped with a sterile 70% alcohol swab\textsuperscript{11} to remove possible HD residue (if there is not a chemotherapy dispensing pin or CSDTD inserted)
- the puncture date and time or beyond use date and time must be written directly on the vial with a thin-tipped permanent marker\textsuperscript{3}
- the vial must be cleaned with a new towel moistened with an aqueous antibacterial agent (e.g., CaviWipe™)\textsuperscript{3}
- the vial must be placed inside a zip lock bag that is sealed inside the BSC or above the front grill upon removal from the BSC\textsuperscript{24}

Containers used for HD waste (sharp and non-sharp) must be sealed and cleaned using a new towel moistened with an aqueous antibacterial agent (e.g., CaviWipe™) inside the BSC before removal from the cabinet\textsuperscript{9}

E.1.6 Warning Labels

- All hazardous drugs and hazardous drug preparations must be easily identifiable by personnel involved in their handling\textsuperscript{4}
- The container of hazardous drug must be appropriately labelled\textsuperscript{4} indicating the contents are hazardous in nature

E.1.7 Exiting the Cleanroom

- PPE must be appropriately removed upon exiting the controlled work area\textsuperscript{2,4}
  - Removal of chemotherapy gowns for storage or disposal must be done with care to avoid spreading HD contamination to other non-contaminated garments\textsuperscript{2}
  - Outer gloves must be discarded in a hazardous waste container (inside or outside of the BSC)\textsuperscript{2} prior to exiting the cleanroom – outer gloves must NOT be worn outside the cleanroom once compounding hazardous drugs in the BSC has occurred\textsuperscript{3}
  - The outer pair of shoe covers worn in the hazardous drug cleanroom must be removed with gloved hands upon exiting the cleanroom into the anteroom and must be discarded as hazardous waste\textsuperscript{5}
  - Mask and hair cover(s) must not be removed inside the cleanroom\textsuperscript{1}
  - Mask, hair cover(s) and inner gloves must be discarded in a hazardous waste container\textsuperscript{2}
  - Hands must be washed immediately with soap and water every time gloves are removed\textsuperscript{2}
  - A buttoned lab coat (or isolation gown) must be donned over scrubs upon exiting the anteroom\textsuperscript{10,24}

E.2 Aseptic/Protective Routines

E.2.1 Critical Sites

Critical sites must be protected as much as possible and must not be touch-contaminated.\textsuperscript{11} Protection of critical sites by precluding physical contact and airborne contamination must be given the highest priority in aseptic compounding practice.\textsuperscript{11}

E.2.2 First Air

While working in the BSC, 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.\textsuperscript{1,11}

E.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.\textsuperscript{11}
The correct technique to disinfect a critical site is to make several firm strokes in the same direction over the rubber closure. A new sterile swab must be used to disinfect each new surface. 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.

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

E.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.

E.2.5 Capping Needles Safely
Needles are a critical site and therefore must be capped when not being used for injection or withdrawal. 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.

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

E.3 Safe Handling Aseptic Techniques

E.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.

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

E.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 BSC.

E.3.3 Attaching and Priming Solution / Administration Sets
Priming any intravenous administration set with hazardous drug solution in an uncontrolled environment must be avoided.

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).

Section F

F.1 Clean Up and Waste Disposal

F.1.1 Biological Safety Cabinet 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.

F.1.2 Hazardous Waste Disposal
Hazardous waste containers must be available in all areas where hazardous drugs are received, stored, prepared and administered.

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

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

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 without being crushed or clipped. 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.

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.

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

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

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

Section G

G.1 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. 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.

G.1.1 Oral Preparations

- Two pairs of chemotherapy gloves must be worn when handling hazardous drug tablets and capsules and when pouring HD oral solutions or suspensions in a designated area of the pharmacy dispensary.
- 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.
- 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 to reduce the risk of HD exposure.
- Dedicated ‘chemotherapy’ counting trays and spatulas must be used to count loose HD tablets and capsules.
- Hands must be washed with soap and water immediately after removing chemotherapy gloves.
- Gloves worn when handling hazardous drugs must be discarded in HD waste.
- Automated counting machines must not be used to count hazardous drug tablets and capsules.

G.1.2 Topical Preparations

- Two pairs of chemotherapy gloves must be worn when handling hazardous drug topical preparations that have been removed from the original packaging.
- 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.

All interior surfaces of a BSC (except under the work surface) used for both sterile and non-sterile HD preparations must be cleaned and disinfected following non-sterile HD preparations using an aqueous antibacterial agent (e.g., chlorhexidine 0.05%, CaviWipes™) and disinfected using sterile 70% alcohol. Once cleaned, the BSC must purge for at least 15 minutes prior to compounding sterile HD products.
Section H

H.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. Spill kits must be located in all areas where exposures may occur.4

H.1.1 Recommended Spill Kit Contents
New employees must be advised of hazardous drug spill control procedures4 and be required to demonstrate competency in spill handling.17

Training and competency assessments should be documented.2

H.2 Accidental Exposure to Hazardous Drugs
Healthcare workers must be made aware of how to manage accidental exposure to hazardous drugs.4

Any accidental HD exposure as a result of a spill, needle stick or other accident must be reported immediately to the professional practice leader/department manager31 and by calling the Provincial Workplace Health Call Centre reporting line at 1-866-922-9464. Appropriate documentation must be completed.3

H.2.2 Ingestion
Personnel must not take food, gum, drinks, cigarettes or personal medication into an area where hazardous drugs are handled4 (e.g., received, stored, prepared, administered and disposed).

Section I

I.1 Receipt and Unpacking
Personnel receiving and unpacking hazardous drugs must be made aware of precautions and follow special handling procedures.2

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.3

I.1.1 Receipt

- Two pairs of chemotherapy gloves must be worn when packing and unpacking boxes containing hazardous drugs3
- The outside of cartons must be examined for possible damage prior to opening2
- Hazardous drugs requiring refrigeration must be unpacked and refrigerated immediately upon receipt8,13

I.1.2 Receipt of a Damaged Shipment
Policies and procedures must be in place for handling damaged shipments of hazardous drugs.2

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 respirator and safety goggles to handle the package34 following procedures outlined in the BCCA Directive VI-10 Hazardous Spill Control in Pharmacy.

When cartons, totes, and/or packages are opened unknowingly with damaged contents inside, the receiver must don full PPE including a respirator and safety goggles34 and follow procedures outlined in the BCCA Directive VI-10 Hazardous Spill Control in Pharmacy.

HD spill kits with written procedures for use must be located in all areas where hazardous drugs are received.9,10
I.2 Storage

- Containers, shelves and bins used for HD storage must be properly labelled with hazard warning labels identifying the drugs that require special handling.
- 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.
- Hazardous drugs must be stored in a manner that prevents spillage or breakage if the container falls.
- Antineoplastic HDs requiring manipulation other than counting or repackaging of final dosage forms must be stored separately from other inventory in a manner that prevents HD contamination and personnel exposure.
- Standard: Refrigerator temperatures must maintain a cold temperature range of 2°C to 8°C.
- 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.
- Access to areas where hazardous drugs are stored must be limited to authorized personnel.
- Hazardous drugs spill kits with written procedures for use must be readily available in areas where hazardous drugs are stored.

I.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.

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

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:

- 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;
- the drug volume(s) added to a final container must match the dose prescribed on the medication order;
  - reconstitution solution and volumes must be checked by any qualified person other than the individual who measured the solution;

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

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.

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.

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.

- 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;
- 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;
- the person performing the final product check must indicate by documenting on a permanent record that they have performed a complete final product check.

Module 3 – Hazardous Drug Cleanroom Standards

Section A

A.3 Hazardous Drug Cleanroom

The hazardous drug cleanroom must maintain an ISO Class 7 environment and be negative pressure to the anteroom. The cleanroom must retain at least 30 air changes per hour (ACPH) of HEPA-filtered air.

A.4 Hazardous Drug Anteroom

The hazardous drug anteroom must maintain an ISO Class 7 environment and be positive pressure to both the hazardous drug cleanroom and the rest of the pharmacy. The anteroom must maintain at least 20 air changes per hour (ACPH) of HEPA-filtered air.

A.5 Specifications of the Controlled Work Area

- Access to the controlled work area must be limited to authorized personnel who are assigned to work there.
- Doors leading into controlled work areas must not be left open.
- A differential of at least 0.01 inch water column (negative pressure) must be maintained between the cleanroom and the anteroom.
Floors, walls, ceilings and all exposed surfaces in the controlled work area must be nonporous and washable.

Cleaning must take place in the cleanroom at a time when no aseptic operations are in progress.

Essential furniture in the controlled work area must be nonporous, smooth, non-shedding, impermeable, cleanable, and resistant to disinfectants.

A warning sign must clearly identify the hazard and state that access to the cleanroom is controlled and limited to authorized personnel only.

The door opening into the cleanroom and the door leading to the anteroom should not be opened at the same time in order to maintain pressure differential between the two rooms.

Appropriate personal protective equipment (PPE) must be donned by all personnel prior to entering the controlled work area to minimize the spread of skin particles that may shed.

Lab coats must not be worn in the cleanroom in place of chemotherapy gowns.

No shipping or other external cartons may be taken into the controlled work area.

Antineoplastic HDs requiring manipulation other than counting or repackaging of final dosage forms must be stored separately from other inventory in a manner that prevents HD contamination and personnel exposure.

Refrigerator temperatures must maintain a cold temperature range of 2°C to 8°C.

A.6 Location of Biological Safety Cabinets

A BSC used for HD compounding must be located away from doorways, traffic corridors, and air conditioning and heating vents inside a restricted access negative pressure ISO Class 7 cleanroom.

Section B

B.1 Cleaning

Staff must be instructed on how to safely carry out their cleaning responsibilities within the controlled work area including in the vicinity of the BSC in order to minimize HD exposure to themselves and the environment.

Section C

C.1 Documentation

Documentation records of routine BSC, cleanroom and anteroom cleaning must be completed and maintained.

Module 4 – 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.

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. 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
- All drug used MUST be labelled ‘for intrathecal use’ by the manufacturer
- Gloves MUST be changed immediately prior to preparing the intrathecal dose

**Section B**

**B.1 Vinca Alkaloids**

All Vinca Alkaloids should be dispensed in a 50 mL minibag to be given within 5-15 minutes and labelled with an auxiliary label with the words ‘WARNING: FOR INTRAVENOUS USE ONLY – FATAL IF GIVEN BY OTHER ROUTES’

**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.

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

**Section E**

**E.1 Latex Allergies**

Medication for patients allergic to latex must be prepared and administered in a latex-free environment. All surfaces of the biological safety cabinet must be cleaned and disinfected prior to compounding hazardous drug (HD) admixtures for latex-sensitive patients.
References


19. BCCA Division of Pharmacy. BCCA Best Practice Safe Handling Standards. 2008.
29. BCCA Division of Pharmacy. BCCA Systemic Therapy Update - Elastomeric Infusors. 2008 June;2(11).
34. BCCA Safe Handling Group/P4C. BCCA Pharmacy Directive Number VI-10 - Hazardous Drug Spill Control in Pharmacy. 2013 September 11.