Safe Handling of Hazardous Drugs

Module 1

Includes Recommended Procedures and Techniques
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Section A

A.1 Potential Hazards of Handling Hazardous Drugs

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

Adverse effects similar to those seen in treated cancer patients may occur in healthcare workers who handle hazardous drugs regularly, especially if protective garb and equipment are not used.3,4 Various studies have demonstrated possible links between occupational exposure to hazardous drugs and menstrual dysfunction5, infertility6, miscarriages and stillbirths, low birth weights and congenital abnormalities.7

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

Standard:

Hazardous Drug (HD) safe handling policies and procedures must be developed to address the following:12,13

- Receipt12-14
- Storage12-15
- Preparation12,13
- Labelling12,14,15
- Safety equipment16
- Use of Personal Protective Equipment (PPE)14,17
- Emergency procedures for treating accidental contact and spills13,14
- Packaging12,15
- Transport12,14,15
- Drug administration13
- Disposal12-14

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.13,14 There must be established work practices related to both drug manipulation techniques and to general hygiene practices.14 Workplace procedures must be developed for using and maintaining all equipment that functions to reduce hazardous drug exposure.13

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.18
A.2 Hazardous Drug List

Standard:

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

The National Institute for Occupational Safety and Health (NIOSH) Alert: Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings was published in September 2004. In Appendix A of the Alert, NIOSH identified a sample list of hazardous drugs (HD). NIOSH periodically publishes updates to the original list found in the 2004 NIOSH Alert.

The BCCA maintains a HD list for BCCA benefit drugs and drugs approved for use at BCCA regional centres via the Compassionate Access Program. The BCCA HD list is based on the NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings. New oncology drugs approved for use between updates of the NIOSH List will be evaluated by the Provincial Drug Information team and added to the BCCA HD List if deemed hazardous. For non-oncology drugs, refer to the latest NIOSH Hazardous Drug List.

A.2.1 BCCA Hazardous Drug Evaluation Criteria

Hazardous drugs include those drugs that exhibit one or more of the following characteristics in animals or humans:

1. Carcinogenicity4
2. Teratogenicity or other developmental toxicity4
3. Reproductive toxicity4
4. Organ toxicity at low doses4
5. Genotoxicity4
6. Structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the above criteria4 [In general, this means agents which share at least structural similarity (e.g., platinums, taxanes), with or without similar toxicity profiles]
7. Primary indication as antineoplastic agent in the absence of other information using the above criteria

Standard:

The facility’s hazardous drug list must be posted in all areas where these drugs are received,18,19 stored,13,19 prepared13 and administered.18,19

Refer to BCCA Pharmacy Directives – Module 1 – Appendix 2 – Number VI-80: Hazardous Drug List

A.3 Medical Surveillance

Protection from hazardous drug exposure depends on adherence to safety programs established by employers and followed by workers.20,21 A comprehensive approach to minimizing worker exposure should be part of a safety and health initiative that includes safe work practices, proper engineering controls, and personal protective equipment supported by a medical surveillance program.14,22 Unfortunately, despite publication and implementation of guidelines for handling antineoplastic agents, studies have shown that compliance is an issue, implying that various guidelines are not followed aggressively enough.23

Medical surveillance involves collecting and interpreting data to detect changes in the health status of working populations potentially exposed to hazardous substances. Elements of a medical surveillance program are used to establish a baseline of workers’ health and then monitor their future health as it relates to their potential exposure to hazardous agents.14 Employers should encourage healthcare workers who must handle hazardous drugs while performing their work responsibilities to be monitored routinely by their family physician as part of a medical surveillance program.22,24
Elements of a medical surveillance program as suggested by NIOSH include:

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

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

A.4 Personal Exposure Records

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

Standard:

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

A.5 Work Re-Assignment

Standard:

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

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

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

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

Refer to BCCA Systemic Therapy Policy V-20: Employee Health: Management of Risks Related to Hazardous Drugs
Section B

B.1 International Standards Organization (ISO) Classifications

As the need for international cleanroom classifications and standards grew, the International Standards Organization established a technical committee and several working groups to delineate a set of standards. The International Standards Organization (ISO) classification standards for particulate matter in room air are rated according to the number of particles per cubic meter at a specified particle size (e.g., 0.5 \( \mu \text{m} \) and larger).  

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B.2 Controlled Work Area

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

The activities taking place in the controlled work area are directly related to the preparation of parenteral drugs. The controlled work area is designed to minimize the introduction, generation, and retention of particulate and microbial contamination. Rooms in the controlled work area meet specific International Standards Organization (ISO) classification standards.

Standard:

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\(^{12,15}\) and to minimize healthcare workers’ exposure to hazardous drugs.\(^4\)

Doors leading into controlled work areas must not be left open.\(^{15}\)

B.2.1 Hazardous Drug Cleanroom

The hazardous drug cleanroom houses the biological safety cabinet that is used for the preparation of hazardous drugs.

Standard:

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.\(^{15}\)
A warning sign must clearly identify the hazard and state that access to the cleanroom is controlled and limited to authorized personnel only.

The sign should contain wording such as:

**CAUTION CHEMOTHERAPY**

(OR hazardous drugs)

Authorized Personnel Only

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**B.2.2 Hazardous Drug Anteroom**

Hazardous drug anterooms act as a transition space between hazardous drug cleanrooms and other areas in the pharmacy. They help to maintain the ISO classification and pressure differential in the cleanrooms. Anterooms may be used for storage of supplies and drug and for staging of components as long as these activities do not interfere with maintaining the ISO classification.

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

Some anterooms are so small that the door leading from other areas in the pharmacy into the anteroom acts as the demarcation line.

**Standard:**

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.

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**B.2.3 Other Rooms in the Controlled Work Area**

Within the controlled work area, some facilities physical design may include a separate HD storage room as well as a supply storage and set-up room. These rooms may maintain an ISO Class 8 environment.

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**B.3 Equipment**

**B.3.1 Biological Safety Cabinets**

A Biological Safety Cabinet (BSC) is a ventilated containment cabinet that may aid in the:

- protection of the operator
- protection of the sterile admixture
- protection of the environment

It is imperative that workers are told and understand that the BSC does not prevent the generation of hazardous drug contamination within the cabinet and that the effectiveness of containing HD contamination within the cabinet depends on the operator's use and proper technique.

**Standard:**

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

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

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

B.3.1.1 Class I BSC

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

Standard:

Class I BSCs are used when there is a need for containment, but not aseptic product protection and therefore must not be used for sterile hazardous drug preparation. 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. A BSC is not required when handling (e.g., counting or repackaging) final dosage forms of non-sterile hazardous drugs that do not produce particles, aerosols, or gases.

B.3.1.2 Class II BSC

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

- A front access opening with inward airflow
- HEPA-filtered, vertical unidirectional airflow within the work area
- HEPA-filtered air exhausted back into the room, back over the work surface, or out through a facility exhaust system

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

Standard:

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

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

Standard:

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

B.3.1.2.a Class II Type B1 BSC

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

The major route for "used" air (60-70%), which may be contaminated with hazardous drug particles, to exit the work surface of the BSC is via the rear exhaust grill. This “contaminated” air is HEPA-filtered below the work surface and trenched to remove drug particles and is then expelled from the top of the BSC through a second HEPA filter into an outside duct away from any air intake locations. This prevents recirculation into the room.
A portion (30-40%) of potentially contaminated air is drawn through the front intake grill. It combines with air that flows in from the room. This combined air is HEPA filtered below the work surface and then recycled through a second HEPA filter before it re-circulates to the work surface.

The combined air that flows from the room and from the BSC interior into the front intake grill produces a protective "air curtain" that prevents particles from entering or leaving via the BSC's front opening. Penetration of this curtain by the arms of the operator, although unavoidable, decreases optimal function of the protective "air curtain". 25,28

Due to the potential for HD contamination of the cabinet during the hazardous drug preparation process, it is preferable to choose a BSC that does not re-circulate air to the work surface (e.g., Class II B2). 26

Airflow in a Class II Type B1 Biological Safety Cabinet (BSC) 29

B.3.1.2.b Class II Type B2 BSC

A Class II Type B2 cabinet is a total exhaust cabinet. All potentially contaminated air from the BSC's work area is expelled directly to the facility's external exhaust system. Filtered air is not re-circulated to the work area inside the cabinet or into the room. Room air enters through the top of the cabinet and passes through a HEPA filter before it flows vertically towards the work surface. Just before the air meets the work surface, the now potentially contaminated air splits and is drawn towards the front and rear exhaust grills. Simultaneously, room air enters through the front opening and is pulled down through the front grill. The HEPA filtered air that flows vertically to the work surface along with air that is drawn in from the room through the front intake grill produces a protective "air curtain" that prevents particles from entering or leaving via the BSC's front opening. Penetration of this curtain by the arms of the operator, although unavoidable, decreases optimal function of the protective "air curtain". 25,28 100% of this air is filtered then drawn out to an exhaust vent and HEPA filtered a second time before exhausting to the facility's external exhaust system.

Airflow in a Class II Type B2 Biological Safety Cabinet (BSC) 29
B.3.1.3 HEPA Filter

A HEPA filter is a High Efficiency Particulate Air filter that traps approximately 99.9% of particulate matter 0.3 microns in size or greater to provide ultra clean air.\textsuperscript{25,30} Airborne contamination control is achieved in the controlled work area and biological safety cabinets through the use of HEPA filters. HEPA filters are effective at trapping particulates but do not capture volatile drugs or vapours.\textsuperscript{30}

**Standard:**

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.\textsuperscript{13}

HEPA-filtered air is not considered sterile; however, the presence of micro-organisms in the filtered air stream is very unlikely. Contamination of a sterile product is most likely due to the introduction of foreign material (e.g., bacteria, particles) from supplies placed into the BSC and/or from the hands or arms of the operator. In addition to compromising the sterility of the drug, particulate matter may act as a carrier for hazardous drug particles or aerosols.\textsuperscript{25}

B.3.1.4 Airflow

**Standard:**

**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.**\textsuperscript{26}

HEPA filtered air flows through the work zone from the top of the cabinet towards the work surface. As it descends the air 'splits' with some air being drawn through the front intake grill and some through the rear exhaust grill.\textsuperscript{31}

The top to bottom flow of HEPA-filtered air in a BSC has a number of functions:\textsuperscript{25}

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

**Standard:**

Manipulations must be performed at least six inches in from the front opening of the cabinet,\textsuperscript{12} behind the air ‘split’.\textsuperscript{31} Contaminated air must be able to escape via the rear grill, not via the front opening.\textsuperscript{27}

In order for the BSC to help protect the operator, paths of airflow must remain clear.\textsuperscript{32}

It is important to avoid:\textsuperscript{25,30}

- overloading the BSC\textsuperscript{19}
- crowding the BSC work space\textsuperscript{24}
- rapid movements inside, or near the front opening of the BSC\textsuperscript{19}
- unnecessary movements in and out of the front opening
- activities that disturb or block the airflow inside the BSC

**Note:**

- In horizontal laminar airflow hoods, clean air flows from back to front, sweeping particles and organisms away from the drug but directly towards the operator.
- **Standard:** Horizontal laminar airflow hoods must not be used for the preparation of hazardous drugs\textsuperscript{14}
B.3.1.5 Ultraviolet Lights

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

Standard:

The ultraviolet light may cause eye damage and must not be turned on when personnel are working in or near the BSC, or in the cleanroom.\(^ {30,33} \)

B.3.1.6 Viewing Window

Standard:

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.\(^ {30,33} \)

Each individual owner’s manual should be consulted for recommended BSC viewing window height (normally eight to ten inches) – cabinets should not be operated with the window in any other position.

- If the viewing window height is above the manufacturer’s recommended level, it could cause intake air velocity to drop too low for proper personnel protection
- If the viewing window height is below the manufacturer’s recommended level, it could cause intake air velocity to increase and allow unfiltered air to cross onto the work surface and contaminate the product

B.3.1.7 Location

Standard:

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.\(^ {26} \)

B.3.1.8 Monitoring

Standard:

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.\(^ {12,14} \) It must be equipped with a continuous monitoring device to allow confirmation of adequate airflow and cabinet performance.\(^ {13} \)

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

Some Class II Type B BSCs must have a remote or plant air exhaust system for proper operation. These systems are internally interlocked so that the internal blower will not start unless the exhaust flow is within 10% of the required airflow. Should the airflow fall below the 10% limit during operation, the cabinet initiates an audible alarm and visual error messages, de-energizing the internal blower.\(^ {34} \)
Standard:

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.33

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.19

Note:

➢ Most BSCs are wired to the facility’s back-up generator, so a long term power shutdown would only occur when the unit is unplugged, or as the result of a catastrophic event

B.3.1.9 Testing and Certifying Biological Safety Cabinets

Biological safety cabinets are essential components of the overall contamination control strategy for aseptic compounding. As such, it is imperative that they perform as designed.26

Standard:

Testing and certifying the biological safety cabinet must be completed by a qualified person (e.g., a person who has been accredited by the National Sanitation Foundation [NSF] to perform testing of biological safety cabinets) when installed.35 Certification procedures used must meet the requirements of the NSF Standard 49- Biosafety Cab inetry: Design, Construction, Performance, and Field Certification (current version)15,35 The BSC must be re-certified every six months15 and when the cabinet is altered or repaired or the HEPA filter is changed.15,33,35 Testing and certifying the biological safety cabinet must occur during dynamic operating conditions.15

Prior to servicing a biological safety cabinet, service technicians or maintenance workers must be informed that the BSC may be contaminated with hazardous drugs.4 Appropriate personal protective equipment must be worn when testing, certifying or servicing the BSC.4,15

After field certification, the BSC must have certification information posted on the front of the cabinet housing in a readily visible location.15,35

B.3.1.10 Replacing HEPA Filters

HEPA filters will require replacement when they become loaded to the extent that sufficient airflow can no longer be maintained or if they are overtly contaminated by a breach in technique that causes hazardous drug to be introduced onto the clean side of the supply HEPA filter.28

Standard:

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

Before replacement of a HEPA filter contaminated with hazardous drug occurs, the NSF technician and the pharmacy department should arrange a mutually acceptable procedure and time for replacing and subsequently disposing of a contaminated HEPA filter.28

Standard:

Appropriate personal protective equipment must be worn when replacing HEPA filters and the contaminated filters must be handled and disposed of as hazardous waste.18,24
B.3.1.11 Turning off a Biological Safety Cabinet

Standard:
If it is necessary to turn off a BSC for testing and certifying or for maintenance, the entire inner cabinet must be decontaminated first.\footnote{12}
The owner is responsible for decontaminating the BSC prior to shutting it down for repair or servicing. Once the BSC is decontaminated, the internal blower and the external exhaust fan may be turned off.

Standard:
If the internal blower and external exhaust fan of a BSC are both turned off, the work-access opening and the HEPA exhaust area must be covered with impermeable plastic and sealed with tape to prevent any remaining hazardous drug contamination from inadvertently escaping from the BSC until maintenance work begins. The BSC must be sealed with plastic whenever it is moved or left inoperative for a period of time.\footnote{31}

Refer to BCCA Pharmacy Directives – Module 1 – Appendix 2 – Number VI-60: Biological Safety Cabinets – Selection and Maintenance
Refer to BCCA Pharmacy Directives – Module 1 – Appendix 2 – Number VI-20: Biological Safety Cabinet (BSC) Decontamination
Refer to Checklists - Module 1 - Appendix 1: Decontamination of the Biological Safety Cabinet

B.3.1.12 Cleaning Biological Safety Cabinets

Standard:
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 day\footnote{26} using an aqueous antibacterial agent (e.g., chlorhexidine 0.05\%, \textit{CaviWipe}\textsuperscript{TM}) followed by \textit{sterile} 70\% alcohol.\footnote{26}

Prior to cleaning a BSC, proper hand hygiene procedures must be followed and full personal protective equipment (PPE) must be donned.\footnote{15}

See Personal Protective Equipment (PPE) and Cleanroom Garb in Section C.2
See Hand Washing in Section C.3

B.3.1.12a Cleaning All Interior Biological Safety Cabinet Surfaces

Standard:
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\%, \textit{CaviWipe}\textsuperscript{TM}) followed by \textit{sterile} 70\% alcohol.\footnote{26} 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 minutes\footnote{19} afterwards.
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)

**Note:**

- Do not use 70% alcohol on the viewing window if it is made of plastic (e.g., Plexiglas) as this may cause permanent fogging. A low-lint towel moistened with sterile water for irrigation may be used following an aqueous antibacterial agent to remove residue or streaking.

**Standard:**

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 shields 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 cabinet must wear an N95 or better respirator in addition to all other PPE if the viewing window is raised.

When the viewing window is raised, the protective airflow into the cabinet is interrupted, so there is a chance that HD particles may be expelled during cleaning. The presence of others in the room while the BSC is being cleaned with the viewing window raised may increase the number of particles available to be drawn into and contaminate the interior of the BSC. To ensure others are aware, a sign on the outside of the door to the cleanroom must be hung indicating “DO NOT ENTER – Cleaning/Decontaminating the BSC”.

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

**B.3.1.12b Cleaning the Work Surface of the BSC**

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

**Standard:**

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

- 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.
B.3.1.13 Decontaminating Biological Safety Cabinets

Decontamination is the physical removal of hazardous drug from a non-disposable surface to a disposable surface or the chemical inactivation of hazardous drug from a surface.\textsuperscript{24} The BCCA recommends physical removal because there is no known single non-toxic product available that will deactivate all hazardous drugs. Physical removal is achieved by wiping non-disposable surfaces with disposable towels moistened with aqueous alkaline detergent solution. This is followed by wiping with water to remove the soap residue and then sterile 70% alcohol to disinfect the surfaces. Alcohol alone will not deactivate or remove hazardous drug from a surface and may result in the spreading of HD contamination.\textsuperscript{24}

Routine decontamination of the BSC is necessary to maintain an environment as free from contamination as possible and to reduce the potential health risks associated with exposure of healthcare workers preparing and handling hazardous drug(s).

Standard:

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.\textsuperscript{19}

Prior to decontaminating the BSC, proper hand hygiene procedures must be followed and full personal protective equipment (PPE) must be donned.\textsuperscript{15}

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 shields\textsuperscript{4} to prevent splashing into the eyes.

See Personal Protective Equipment (PPE) and Cleanroom Garb in Section C.2
See Hand Washing in Section C.3
Refer to BCCA Pharmacy Directives – Module 1 – Appendix 2 – Number VI-30: Personal Protective Equipment (PPE)

Standard:

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 cabinet\textsuperscript{26} must wear an N95 or better respirator in addition to all other PPE when the viewing window has been raised.

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

Removable parts of the BSC are decontaminated within the cabinet and shall not be removed. When cleaning the trough underneath the work surface in a biological safety cabinet, personnel must have a firm hold of all cleaning materials so that they are not drawn up into the airflow causing damage to the HEPA filters.

Standard:

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.\textsuperscript{18}

Refer to Checklists – Module 1 – Appendix 1: Decontamination of the Biological Safety Cabinet
Refer to BCCA Pharmacy Directives – Module 1 – Appendix 2 – Number VI-20: Biological Safety Cabinet (BSC) Decontamination
B.3.2 Communication System

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

**Standard:**

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.  

B.3.3 Carts

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

If carts are used, one cart should be reserved for the “dirty” area of the anteroom. A second cart, dedicated to the ‘clean’ area of the anteroom may enter the cleanroom.

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

In facilities where the anteroom is too small to hold two carts, a cart may pass over the demarcation line in the anteroom into the cleanroom only after all surfaces have been cleaned and disinfected. In such instances, the cart must remain closer to the door leading from the cleanroom into the anteroom, not the biological safety cabinet.

Section C

C.1 General Protective Guidelines

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

**Standard:**

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.

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

**Standard:**

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.

It is important to recognize that exposure requires direct contact with the drug particles, vapours or droplets. This is why most of the protective measures involve maintaining some form of barrier between the worker and the hazardous drug.
Contact with hazardous drugs including drug contamination on vial surfaces, receipt of broken vials, compounding and administration of hazardous drugs, handling hazardous drug waste, and disposing of contaminated materials may cause contamination of the work environment, which may lead to exposure of workers.

The possible routes of HD exposure to avoid are:\textsuperscript{13,25}

- Direct skin contact or puncture\textsuperscript{28}
- Inhalation of HD powders, sprayed droplets (aerosols\textsuperscript{28,38}) or vapours
- Swallowing (ingestion) of HD powders or aerosols
- Oral exposure from surface contact (hand to mouth)\textsuperscript{28}

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

- Withdrawing devices including needles from HD vials
- Transferring HD from one container to another
- Recapping HD needles (unsafely)
- Breaking open glass HD ampoules

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

- Expelling air from a syringe used for HD into the BSC environment, contaminating the air
- Expelling any solution from a syringe into a HD waste container
- Removing administration lines from infusion bags containing HD
- Priming intravenous administration lines with HD solution
- Placing gloved hands in or around the mouth or eyes
- Eating, drinking, chewing gum, or applying cosmetics in or near areas where hazardous drugs are handled, received, stored, or administered

Despite all precautions, there may be occasions when drugs penetrate a protective barrier. This could include an accidental skin puncture or when a drug container breaks. It is important to follow established procedures for dealing with accidental HD contact and for cleaning up HD spills. Staff should locate and be familiar with these procedures before they are needed to help prevent panic when such an event occurs.\textsuperscript{25}

See Personnel Hygiene in the Cleanroom and BSC in Section E.1.1
See Accidental Exposure to Hazardous Drugs Section H.2
Refer to Checklists – Module 1 – Appendix 1: Personnel Contamination
Refer to BCCA Systemic Therapy Policy V-30: Hazardous Drug Spill Management

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

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

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

- Workers’ exposure to hazardous drugs by providing a physical barrier to extraneous drug particles on surfaces or those generated during the compounding process
- Particulate burden within the cleanroom
- Spread of HD contamination to areas outside the HD work environment

Standard:

Personal protective equipment and cleanroom garb must be provided to minimize or prevent healthcare workers exposure to hazardous drugs.\textsuperscript{13} All personnel entering the controlled work areas must follow appropriate hand hygiene and garbing procedures.\textsuperscript{15}
Refer to Checklists – Module 1 – Appendix 1: Donning of Personal Protective Equipment to Enter a Chemotherapy Cleanroom

C.2.1 Scrubs

The recommended use of scrub uniforms made of low-lint cotton or cotton/polyester material reduces the bioburden in the cleanroom environment and helps to limit the spread of HD contamination. Street clothes should be replaced with fresh scrubs daily when the work assignment will take place in the controlled work area.

Standard:

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

Wearing scrubs outside the facility should be discouraged. Scrubs should be isolated when laundered if contamination is suspected.

C.2.2 Footwear

Standard:

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

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.”

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

Standard:

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.

C.2.3 Shoe Covers

Shoe covers help to minimize the spread of particulate contamination from footwear worn into the controlled work area. Shoe covers also help to minimize the spread of HD particulate contamination from inside the HD cleanroom to areas outside. The floor in hazardous drug cleanrooms has been shown to be contaminated with hazardous drug.

Standard:

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

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. 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.

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

C.2.4 Hair Covers

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

Standard:

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

The hair cover (and beard cover if necessary) must be donned on the dirty side of the demarcation line in the anteroom. 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.

Hair and beard covers must be removed on the dirty side of the demarcation line in the anteroom. In facilities that have incorporated a gowning room in the controlled work area, the hair cover is not removed in the anteroom. The hair cover is removed on the dirty side of the demarcation line in the gowning room.

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

C.2.5 Surgical Masks

Surgical masks do not provide respiratory protection against hazardous drug aerosols; however, they do protect the cleanroom environment from possible contamination by personnel.

Standard:

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

Masks worn in the hazardous drug cleanroom should be removed on the dirty side of the demarcation line in the anteroom.

Standard:

Masks must be disposed of in hazardous waste containers. Masks must not be saved for reuse.
C.2.6 Respirators

A respirator is a personal protective device worn on the face that covers at least the nose and mouth. It is used to reduce the wearer’s risk of inhaling hazardous airborne particles, gases and/or vapours. An N95 respirator is one type of disposable particulate respirator. These respirators only protect against inhalation of particles – not gases or vapours.41

Standard:

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.18,19,27

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.17

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.17

Respirators worn in the controlled work area may be removed on the clean side of the demarcation line in the anteroom if being replaced with a surgical mask (for re-entry into the cleanroom). Alternately, remove respirators on the dirty side of the anteroom (when not re-entering the cleanroom).

Standard:

Once removed, disposable respirators must be discarded into HD waste containers14, not saved for reuse.26

A NIOSH-approved Powered Air Purifying Respirator (PAPR) equipped with a HEPA filter may also be used. The PAPR does not require fit testing. The PAPR may be selected for use if the N95 or P100 respirator does not fit, if the employee has facial hair or a facial shape that interferes with mask-to-face seal, or if the N95 or P100 respirators are unavailable. These non-disposable respirators must be cleaned according to the manufacturer’s recommendations to ensure continued operator protection during future use.

C.2.7 Chemotherapy Gowns

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

Standard:

To decrease particulate levels in the preparation area and to decrease the risk of direct skin contact with hazardous drugs, workers must wear non-linting, impermeable, disposable chemotherapy gowns with long sleeves and tight-fitting cuffs, a closed front, and tied around the waist.14 Chemotherapy gowns must be worn for all activities that may result in the worker’s direct exposure to hazardous drugs.14

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.13
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.\textsuperscript{12}

The isolation / new chemotherapy gown is removed on the clean side of the demarcation line in the gowning room and hung up for later use or placed in a laundry bin (isolation gown) or disposed of (chemotherapy gown).

Personnel leaving the cleanroom to exit the anteroom directly into the general pharmacy (no gowning room in the controlled work area) do not need to don an isolation gown or a new chemotherapy gown.

Chemotherapy gowns worn during hazardous drug compounding are disposed of at the end of each work shift or immediately in the event of any suspected hazardous drug contamination.

Standard:

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.\textsuperscript{26}

Used chemotherapy gowns must be discarded into hazardous waste containers.\textsuperscript{14}

\textbf{C.2.8 Isolation Gowns}

Isolation gowns may be worn to decrease particulate levels in the controlled work area when protection from hazardous drug exposure is not a concern.

Standard:

Isolation or chemotherapy gowns must be worn by all personnel working in the controlled work areas.\textsuperscript{14}

Isolation gowns must be low-shedding with long sleeves and tight fitting cuffs, a closed front, and tied around the waist.\textsuperscript{12}

Isolation gowns may be removed on the clean side of the demarcation line in the anteroom and hung up for later use, disposed of, or placed into a laundry bin. In facilities that have incorporated a gowning room in the controlled work area, isolation gowns are removed on the clean side of the demarcation line in the gowning room, not in the anteroom. Isolation gowns should be worn for a maximum of one day. Lab coats should not be worn in the controlled work area in place of isolation gowns.

\textbf{C.2.9 Chemotherapy Gloves}

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

Tiny holes or thinning of the gloves may occur during use. Gloves should be handled gently to avoid tearing or stressing the material.\textsuperscript{25} Tweezers could be used to avoid activities which may tear or stress gloves, such as removing vial closures and handling adhesive surfaces of labels or seals.

Standard:

Chemotherapy gloves worn when mixing hazardous drugs in the biological safety cabinet must be sterile\textsuperscript{12} and be long enough to cover the cuff of the chemotherapy gown.\textsuperscript{4} 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.\textsuperscript{26} Alcohol must not be sprayed onto gloves to remove powder.\textsuperscript{12}
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 (Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Gloves). 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.

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

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).

Chemotherapy gloves must be disposed of in hazardous waste containers.

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

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

Standard:
Latex-free ‘chemotherapy-approved’ gloves must be made available to staff.
C.2.10 Eye Protection

Eye protection is not necessary when working in a BSC with the viewing window at the manufacturer's recommended operating level.

Standard:

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.¹⁸,¹⁹

Eye shields or safety goggles may be washed with aqueous alkaline detergent solution and water for re-use. If hazardous drug contamination is suspected, they must be discarded in a hazardous waste container.

Contact lenses may absorb aerosolized drug and pose an extra potential hazard in the event of a splash of any hazardous solution into the eye. If possible, glasses should be worn for vision correction while preparing hazardous drug sterile preparations.₃¹

When glasses are worn for vision correction, safety goggles with side shields must be worn over them while cleaning or decontaminating a BSC with the viewing window raised and during HD spill cleanup outside the BSC.

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

<table>
<thead>
<tr>
<th>Personal Protective Equipment and Cleanroom Garb (Summary)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Before entering the Controlled Work Area (CWA)</strong></td>
</tr>
<tr>
<td>To enter the anteroom:</td>
</tr>
<tr>
<td>On the dirty side of the demarcation line in the anteroom</td>
</tr>
<tr>
<td>Scrubs / low-lint clothing</td>
</tr>
<tr>
<td>Clean shoes</td>
</tr>
<tr>
<td>Remove: jewellery, cosmetics, nail polish and other nail applications, etc.</td>
</tr>
<tr>
<td>See Section E.1.1 for a more complete list</td>
</tr>
<tr>
<td>To work in the anteroom or enter the cleanroom:</td>
</tr>
<tr>
<td>On the clean side of the demarcation line</td>
</tr>
<tr>
<td>Hair cover</td>
</tr>
<tr>
<td>Beard cover (if applicable)</td>
</tr>
<tr>
<td>Surgical mask (or respirator depending on the activities being performed in the cleanroom)</td>
</tr>
<tr>
<td>To enter the cleanroom:</td>
</tr>
<tr>
<td>Safety goggles- depending on the activities being performed in the cleanroom</td>
</tr>
<tr>
<td>Gown- chemotherapy gown if working in the BSC; isolation gown or chemotherapy gown if not working in the BSC</td>
</tr>
<tr>
<td>Perform appropriate hand hygiene prior to donning inner pair of chemotherapy gloves</td>
</tr>
<tr>
<td>Gloves- two pairs of sterile chemotherapy gloves if working in the BSC; 2 pairs of non-sterile chemotherapy gloves if not working in the BSC; ensure gloves long enough to cover the cuff of the chemotherapy gown</td>
</tr>
<tr>
<td>Shoe covers- don a second (outer) pair of shoe covers prior to entering the cleanroom</td>
</tr>
</tbody>
</table>

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1. BCCA PHARMACY PRACTICE STANDARDS FOR HAZARDOUS DRUGS © February 2017
Standard:

Removing a respirator (e.g., after cleaning or decontaminating the BSC) and replacing with a surgical mask must not occur in the cleanroom. This activity may occur on the clean side of the demarcation line in the anteroom.

Table 2: Summary of Process for Donning Personal Protective Equipment and Cleanroom Garb (For controlled work area with other rooms in addition to anteroom and cleanroom)

<table>
<thead>
<tr>
<th>Personal Protective Equipment and Cleanroom Garb (Summary)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Before entering the Controlled Work Area (CWA)</strong></td>
</tr>
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<td><strong>On the dirty side of the demarcation line in the gowning room</strong></td>
</tr>
<tr>
<td>Scrubs / low-lint clothing</td>
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<tr>
<td>Clean shoes</td>
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<tr>
<td>Remove: jewellery, cosmetics, nail polish and other nail applications, etc.</td>
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</tbody>
</table>
C.3 Hand Hygiene

Standard:

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 performed\(^{14}\) to remove possible drug contamination.

C.3.1 Hand Hygiene Agents

Hand hygiene agents chosen for use by non-compounding personnel, such as plain soap and water, should be designed to remove visible soil and hazardous drug contamination.\(^{44}\) Plain soap has limited, if any, antimicrobial activity.\(^{45}\)

Hand hygiene agents chosen for use by compounding personnel should be antimicrobial soaps containing detergent and an antimicrobial agent (e.g., chlorhexidine, iodine compounds) designed to rapidly kill the majority of transient skin flora.

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

C.3.1.1 Alcohol-Based Hand Rub

Alcohol-Based Hand Rubs (ABHR) remove micro-organisms more effectively, require less time to use, and irritate skin less often than hand washing with soap and water or other antiseptic agents.\(^{46}\) Alcohols are preferred as a hand rub because of their effectiveness, immediate activity, excellent spreading on the surfaces of hands and quick evaporation.

The efficacy of the alcohol-based hand rub depends on the quality of the product, the amount of product used (one to two full pumps of product onto one palm)\(^{47}\), the time spent rubbing (the volume should be such that 15 seconds of rubbing is required for drying)\(^{47}\) and the hand surface rubbed. Alcohol-based hand rubs should not be used with water, as water will dilute the alcohol and reduce its effectiveness.

Standard:

Alcohol-based hand rubs used to disinfect hands before compounding parenteral hazardous drugs must have a minimum alcohol concentration of 70%, and be used in conjunction with plain or an antimicrobial soap. (See table in Section C.3.2.1)\(^{47}\)

C.3.2 Hand Washing After Handling Hazardous Drugs

Standard:

Personnel handling hazardous drugs must wash their hands with soap and water immediately after removal of chemotherapy gloves\(^{14}\).

Notes:

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

C.3.2.1 Compounding personnel

Standard:

Personnel compounding sterile hazardous drug preparations must perform hand hygiene before donning two pairs of sterile chemotherapy gloves.\(^{12}\) Prior to performing hand hygiene, all jewellery including bracelets, rings and watches must be removed to prevent material from being trapped around or underneath them.\(^{12}\) Hands must be dried with a clean, low lint towel.\(^ {26}\)
Table 3: Hand Hygiene for Sterile Compounding Personnel

<table>
<thead>
<tr>
<th>Step</th>
<th>Plain Soap &amp; Alcohol-Based Hand Rub (ABHR)</th>
<th>Antimicrobial Soap</th>
<th>Antimicrobial Soap &amp; Alcohol-Based Hand Rub (ABHR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 1</td>
<td>Under running water, use a disposable nail pick to remove debris from underneath fingernails&lt;sup&gt;15&lt;/sup&gt;</td>
<td>Under running water, use a disposable nail pick to remove debris from underneath fingernails&lt;sup&gt;15&lt;/sup&gt;</td>
<td>Under running water, use a disposable nail pick to remove debris from underneath fingernails&lt;sup&gt;15&lt;/sup&gt;</td>
</tr>
<tr>
<td>Step 2</td>
<td>Wash hands and arms to elbows with plain soap and water for 30&lt;sup&gt;15&lt;/sup&gt;-60&lt;sup&gt;48&lt;/sup&gt; seconds</td>
<td>Wash hands and arms to elbows for 2 to 3 minutes&lt;sup&gt;49-53&lt;/sup&gt; with antimicrobial soap (e.g., 4% chlorhexidine, povidone-iodine)</td>
<td>Wash hands and arms to elbows for 30&lt;sup&gt;15&lt;/sup&gt;-60&lt;sup&gt;46&lt;/sup&gt; seconds with antimicrobial soap (e.g., 4% chlorhexidine, povidone-iodine)</td>
</tr>
<tr>
<td>Step 3</td>
<td>Rinse with water</td>
<td>Rinse with water</td>
<td>Rinse with water</td>
</tr>
<tr>
<td>Step 4</td>
<td>Dry hands and forearms with low-lint towel; allow hands and arms to completely dry</td>
<td>Dry hands and forearms with low-lint towel; allow hands and arms to completely dry</td>
<td>Dry hands and forearms with low-lint towel; allow hands and arms to completely dry</td>
</tr>
<tr>
<td>Step 5</td>
<td>Use the towel to turn off the water taps (if applicable)</td>
<td>Use the towel to turn off the water taps (if applicable)</td>
<td>Use the towel to turn off the water taps (if applicable)</td>
</tr>
<tr>
<td>Step 6</td>
<td>Discard the towel</td>
<td>Discard the towel</td>
<td>Discard the towel</td>
</tr>
<tr>
<td>Step 7</td>
<td>Dispense a minimum of 2 full pumps of ABHR onto one palm</td>
<td>Don inner pair of sterile chemotherapy gloves</td>
<td>Dispense a minimum of 2 full pumps of ABHR onto one palm</td>
</tr>
<tr>
<td>Step 8</td>
<td>Immerse fingertips of the opposite hand into the ABHR for several seconds</td>
<td></td>
<td>Immerse fingertips of the opposite hand into the ABHR for several seconds</td>
</tr>
<tr>
<td>Step 9</td>
<td>Cover the hand and forearm of the opposite hand with ABHR for a minimum of 15 seconds (until fully evaporated)</td>
<td></td>
<td>Cover the hand and forearm of the opposite hand with ABHR for a minimum of 15 seconds (until fully evaporated)</td>
</tr>
<tr>
<td>Step 10</td>
<td>Repeat with other hand and forearm allowing the ABHR to fully evaporate</td>
<td></td>
<td>Repeat with other hand and forearm allowing the ABHR to fully evaporate</td>
</tr>
<tr>
<td>Step 11</td>
<td>Don inner pair of sterile chemotherapy gloves</td>
<td>Don inner pair of sterile chemotherapy gloves</td>
<td>Don inner pair of sterile chemotherapy gloves</td>
</tr>
</tbody>
</table>

C.3.2.2 Non-compounding personnel

Non-compounding personnel working in the clean room may perform hand hygiene by applying ABHR to hands prior to donning chemotherapy gloves in place of washing hands with soap and water.

C.3.3 Nails and Nail Polish

Long nails are difficult to clean, can pierce gloves and harbour more micro-organisms than short nails. Healthcare workers who wear artificial nails are more likely to harbour gram-negative pathogens on their fingertips than those who have natural nails both before and after performing hand hygiene. Freshly applied nail polish does not increase the number of bacteria removed from skin under nails, but chipped nail polish may support the growth of large numbers of organisms on fingernails.<sup>44</sup>
Standard:
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.15

**C.4 Safety Stations**
The first 10 to 15 seconds after exposure to a hazardous substance are critical. Delaying treatment, even for a few seconds, may cause serious injury. Emergency showers and eyewash stations provide on-the-spot decontamination. They allow workers to flush away hazardous substances that can cause injury.54

Standard:
Eyewash stations and emergency showers must be easily accessible and clearly identified by signs which indicate their location and provide clear directions for their use.16

The sign should be in the form of a symbol that does not require workers to have language skills to understand it.54

Standard:
Personnel that are required to use emergency eyewash and shower facilities must be adequately trained in their location and proper use.16

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”

See Accidental Exposure to Hazardous Drugs in Section H.2

**C.4.1 Eyewash Stations**
Eye wash stations are designed to immediately flush contaminants out of the eyes after exposure. Tap water is not recommended for flushing the eyes as pressure damage can occur.54
C.4.1.1 Sink Mounted

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

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

C.4.1.2 Hand Held Portable

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

Standard:

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

C.4.2 Emergency Showers

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

Standard:

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

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

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

C.4.3 Safety Stations Maintenance

Standard:

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

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

Hand held portable eyewash equipment must be inspected and maintained according to the manufacturer’s instructions.\(^{54}\)

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

Section D

D.1 Supplies

D.1.1 Wipes/Towels

Pre-moistened antibacterial wipes/towels (e.g., CaviWipes™) may be used to physically remove HD particles from the work surface of the BSC, and the outside surfaces of gloves, products, and devices prior to removal from the BSC. Other wipes are commercially available however consideration when choosing these products is recommended due to the possibility of chemical interaction with approved solutions already in use.

Soap-free, low lint towels and gauze are available to be moistened with sterile 70% alcohol, aqueous antibacterial solution or aqueous alkaline detergent solution.

D.1.2 Preparation Pad / Sterile Drape

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

- introduction of particulates into the work area\(^{59}\)
- uneven work surface may cause HD spills\(^{59}\)
- increased difficulty of HD spill detection\(^{59}\)
- additional HD contaminated material for disposal\(^{59}\)
- compromises the containment properties of the biological safety cabinet\(^{21}\)

D.1.3 Alcohol Swabs and Solutions

Standard:

Single use, individually packaged sterile 70% isopropyl alcohol swabs must be used to disinfect a critical site prior to accessing.\(^{26}\) Gauze pads or other particle-generating material moistened with alcohol must not be used to disinfect critical sites of containers prior to accessing.\(^{26}\)

See Disinfecting Critical Sites in Section E.2.3

Sterile 70% alcohol is used for disinfecting devices and supplies prior to placement into the biological safety cabinet and for disinfecting surfaces of the BSC following decontamination or cleaning.\(^{26}\) Bottles of sterile 70% isopropyl alcohol and/or pre-moistened wipes should be readily available in cleanrooms.\(^{18,26}\) Disinfecting agents used in the cleanroom should be applied through the use of wipes moistened with an appropriate solution, not delivered by a spray bottle to avoid dispersing particulate and spreading HD residue, and to minimize the risk of inhaling the disinfectant.

Alcohol does not kill bacterial spores.\(^{26}\) Non-sterile alcohol may harbour resistant microbial spores. Opened bottles of non-sterile 70% alcohol (isopropyl or ethyl) should be discarded at day end to minimize the potential for microbial contamination.

Standard:

Partially emptied containers of alcohol must not be topped up.\(^{18}\)
D.1.4 Aqueous Cleaning/Decontaminating Agents

Cleaning agents should be low residue and low-foaming with antibacterial and/or virucidal activity (e.g., chlorhexidine 0.05% solution, CaviWipes™) and be compatible with stainless steel. Decontaminating agents should be low residue and low-foaming aqueous detergent solutions with an alkaline pH of 8-9 and be compatible with stainless steel.

When selecting cleaning or decontaminating agents, careful consideration should be given to compatibilities, effectiveness, and inappropriate or toxic residues. Diluted solutions should be prepared and stored according to the manufacturer's directions and kept in previously cleaned containers. Agents used for decontamination and cleaning in the cleanroom should be applied through the use of wipes moistened with an appropriate solution, not delivered by a spray bottle to avoid dispersing particulate and spreading HD residue, and to minimize risk of inhaling the agent. Solution should be applied to the towel or gauze in such a manner as to avoid contaminating the bulk solution. Partly emptied containers should not be topped up.

D.2 Devices

Standard:

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

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

Standard:

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

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

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

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

The following section contains information illustrating a number of devices currently being used by pharmacies in British Columbia that are preparing hazardous drugs. It would be impractical to describe every device currently being used. The devices available for compounding chemotherapy are numerous and are constantly changing.
D.2.1 Syringes

Syringes are made of either glass or plastic. Disposable plastic syringes are frequently used in compounding sterile preparations because they are inexpensive, durable and are in contact with substances only for a short time, which minimizes the potential for incompatibility with the plastic itself.\textsuperscript{32}

A luer-lock disposable syringe is 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.\textsuperscript{13} Over tightening luer-lock connections could cause cracking or breaking of the device(s).

**Standard:**

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.\textsuperscript{12} This minimizes the risk of the plunger accidentally separating from the syringe barrel.

There are three main parts of a syringe:

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

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

See Critical Sites in Section E.2.1

**Standard:**

A syringe must not be used more than five times for a single compounding procedure (e.g., reconstitution).\textsuperscript{27}

Syringes that have been used to withdraw and inject HD should not be re-used. Studies show HD contamination infiltrates onto the plungers of syringes after a single preparation.\textsuperscript{60} There is a risk of contaminating the operator’s gloves if the plunger is accidentally touched.

D.2.2 Syringe Tip Caps

A luer-lock syringe tip cap is used to protect the syringe tip/hub from contamination during storage or transport.\textsuperscript{13} It also prevents HD solution from being accidentally ejected since the plunger cannot be pushed in or withdrawn when a luer-lock tip cap is in place.\textsuperscript{25} A multi-function tip cap may be used on a chemotherapy dispensing pin if the original intermittent stopper cap is discarded.

**Standard:**

Care must be taken to avoid touch-contaminating the end of the multi-function tip cap that will be luer-locked to either the syringe or the chemotherapy dispensing pin (critical site).\textsuperscript{26}

Tip caps may be packaged in multiples where each row of caps is sterile until the paper backing is peeled away. The paper should be peeled away at an angle to expose only one tip cap at a time. Tip caps packaged in a tray are single function with only one connection end (critical site).
In some cases, tip caps and syringes without luer-locks are used. For example, some hazardous pediatric medications must be dispensed in a slip tip syringe. Therefore, a slip tip syringe cap must be used. The dose should be appropriately packaged to ensure the plunger is not manipulated during transport causing HD solution to be accidentally ejected.

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

### D.2.3 Needles

**Standard:**

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

There are three main parts of a needle:

1. hub
2. shaft
3. bevel

**Standard:**

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

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

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

**Standard:**

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

### D.2.4 Needle Caps

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

**Standard:**

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

### D.2.5 Needle Cap Holders

A needle cap holder is a device used to securely house the cap of the needle. It also helps to protect from needle stick injuries by enabling the worker to recap the needle without having to hold the needle cap. It allows for a one-handed recapping of the needle.
D.2.6 Seals

A seal should be affixed to infusion solution bag ports and HD vials that have been accessed during drug preparation. The presence of a seal indicates that the port of the infusion solution bag and/or HD vial has been accessed. Leakage from a poorly punctured entry may not be contained by the foil seal. Vials and infusion solution bags that have foil seals affixed should be handled carefully. The seal self-destructs upon attempted removal and cannot be effectively reapplied providing tamper evident security. They are available in a variety of sizes and colors.62

D.2.7 Filters

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

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

Standard:

Solutions prepared for parenteral administration must be filtered when there is a possibility that glass particles27 or particulate matter (e.g., core from a vial stopper) may be present and the solution is filterable.

Refer to Checklists – Module 1 – Appendix 1: Checking for Particulate in Vials, Syringes, and Final Products in the Biological Safety Cabinet
Refer to Checklists – Module 1 – Appendix 1: Filtering Particulate from Solution in Vials and Syringes
Refer to Checklists – Module 1 – Appendix 1: Filtering Particulate from Solution in Vials and Syringes Using PhaSeal™
Refer to BCCA Pharmacy Directives – Module 1 – Appendix 2 – Number III-50-04 Management of Particulate During Sterile Preparation

D.2.7.1 Filter Needles

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

Standard:

The same filter needle must not be used for both withdrawing and expelling solution.25,32

D.2.7.2 Filter Discs

A hydrophilic filter disc is used for filtering withdrawn solution (e.g., from one syringe to another).

Standard:

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

Filter discs with slip tip connections are not recommended for use with hazardous drugs as accidental detachment can occur.
D.2.8 Filter Venting Devices

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

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

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

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

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

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

**Standard:**

Negative pressure technique must not be used for hazardous drug reconstitution or withdrawal if filter venting devices\(^{18}\) or closed system drug transfer devices\(^{4,18}\) are available.

Care must be taken if negative pressure technique is used. Build-up of positive pressure within the vial will cause back spray of solution when the needle is removed. Excess negative pressure will result in spillage from the bevel of the needle when it is removed from the vial.\(^{24}\)

**Exception:**

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

Refer to Checklists – Module 1 - Appendix 1: Reconstitution of a Hazardous Drug Using Negative Pressure Technique

Refer to Checklists – Module 4 - Appendix 1: Preparation of Parenteral Hazardous Drugs for Latex Allergy Patients

Refer to BCCA Pharmacy Directives – Module 4 – Appendix 2 – Number VI-70: Guidelines for Preparation of Parenteral Hazardous Drugs for Latex Allergy Patients

**D.2.8.1 Chemotherapy Dispensing Pins**

The KENDALL CHEMOBLOC® and the BRAUN CHEMO DISPENSING PIN® are examples of hydrophobic venting devices that have a spike for entry into the vial allowing for reconstitution and multiple withdrawals of the drug with only one puncture. Equalization of pressure during use enables the reconstitution and withdrawal of solution from a vial to be performed with less risk of exposure to aerosolized hazardous drugs than with a needle and syringe alone.
Chemotherapy dispensing pins should not be used for viscous drugs that could plug the filter before the total dose is withdrawn.

**Standard:**

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

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

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

- The luer-lock end of a chemotherapy dispensing pin inserted into a HD vial (with or without drug inside) must be sealed with either a cap or an attached syringe
- When the original intermittent stopper cap or tip cap is removed, place it (connecting end up) on an alcohol swab outside the immediate working area so it does not become contaminated
- If the chemotherapy dispensing pin becomes plugged, carefully remove it from the vial stopper and discard into the HD sharps container. Re-disinfect the vial stopper and insert a new chemotherapy dispensing pin

**Note:**

- **Standard:** Chemotherapy dispensing pins must be inspected for cracks prior to use. A cracked chemotherapy dispensing pin must be replaced prior to manipulation of HD solution
- **Standard:** Chemotherapy dispensing pins must be disposed of in a HD sharps waste container if removed from a HD vial
- **Standard:** A new chemotherapy dispensing pin must be used for each vial. Spraying of the solution or touch contamination can occur upon removal of the pin

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

Refer to Checklists – Module 1 – Appendix 1: Withdrawal from a Hazardous Drug Vial Using a Chemotherapy Dispensing Pin

**D.2.8.2 Chemotherapy Vents**

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

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

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

If the filter in a chemotherapy vent becomes wet, equalization of pressure inside the vial may not occur. A wet filter may cause the chemotherapy vent to become plugged.
Standard:
A new chemotherapy vent must be inserted prior to removal of a plugged chemotherapy vent. Multiple punctures of a HD vial stopper that has a chemotherapy vent inserted may be necessary.

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

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

Refer to Checklists – Module 1 – Appendix 1: Reconstitution of a Hazardous Drug Using a CHEMO-VENT®
Refer to Checklists – Module 1 – Appendix 1: Withdrawal from a Hazardous Drug Vial Using a CHEMO-VENT®

D.2.9 Syringe Fluid Dispensing Connectors/Syringe Tip Connectors

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

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

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

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

Refer to Checklists – Module 1 – Appendix 1: Withdrawal from a Solution / Diluent Bag Using a Dispensing Pin / Universal Spike

D.2.11 Solution/Intravenous Administration Sets

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

Refer to Checklists – Module 1 – Appendix 1: Priming Solution / Administration Sets inside the Biological Safety Cabinet

D.2.12 Buretrols

A buretrol is used to transfer large volumes of solution either from one container to another container or from a container to a patient via gravity. The 150mL volumetric fill chamber is a control tube that allows for exact measuring of solutions to be transferred from one intravenous admixture bag to a second container without the use of syringes. Above the volumetric fill chamber is a spike for insertion, a clamp, and an air valve.
A releasable clamp sits on the tubing just below the fill chamber. An administration port that accepts a solution set spike is distal to the releasable clamp. When the releasable clamp is open, solution may flow from the volumetric fill chamber into the solution set.

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

D.2.13 Winged Infusion Sets

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

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

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

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

D.2.14 Closed System Drug Transfer Devices

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

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

Standard:

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

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

The ChemoLock™ system is a needlefree, membrane-to-membrane closed system which mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug or vapor concentrations outside the system. It has a “click to lock” technology. The system snaps together with an audible click to ensure a safe and secure connection.
The ChemoLock™ is a two-piece system (ChemoLock™ Injector and Port). The female luer end of the Injector is compatible with all ISO syringes and tubing sets, while the male end will only connect to the ChemoLock™ Port. The Port accepts only the ChemoLock™ Injector. The ChemoLock™ Port is the access point on all Vial Spikes, Bag Spikes and Administration Sets (e.g., primary lines). The Injector is a stand-alone for use on syringes or administration sets (e.g., secondary lines).

During the four month transition period wherein the six regional cancer centres will be switching from PhaSeal™ to ChemoLock™, information about both closed systems will be included in this standards manual.

D.2.14.1 PhaSeal™ Vial Assembly Fixture

The PhaSeal™ Vial Assembly Fixture is a mechanical device that is used inside the biological safety cabinet for consistent and simple attachment of a PhaSeal™ Protector to a drug vial.

D.2.14.2 PhaSeal™ Protector

The PhaSeal™ Protector is a pressure equalization device with a sharp metal cannula that pierces the vial stopper and permanently attaches to a hazardous drug vial during preparation of hazardous drugs. The Protector provides closed pressure equalization through a sealed expansion chamber and dry connections via the double membrane technology. This ensures that there is neither overpressure nor a vacuum when air or fluid is injected into or aspirated from the vial.

Refer to Checklists - Module 1 - Appendix 1: Attaching a PhaSeal™ Protector to a Hazardous Drug Vial Using a Vial Assembly Fixture

D.2.14.3 PhaSeal™ Injector Luer Lock

The PhaSeal™ Injector Luer Lock ensures a closed drug transfer by means of double elastomeric membranes. The Injector Luer Lock is attached to a standard luer lock syringe or an administration line port. There is a sharp metal cannula that is engaged using a twisting motion causing the cannula to pierce the membrane, resulting in fluid transfer through a leak-proof connection for the preparation and administration of drugs.

D.2.14.4 PhaSeal™ Infusion Adaptor

The PhaSeal™ Infusion Adapter spikes into the administration port of an infusion bag. It has a built-in PhaSeal™ Connector to facilitate a dry, leak-proof connection for addition of drug into an infusion solution bag. The distal end (blue) of the adapter is used by nurses to spike the appropriate administration set into the adaptor via a dry, leak-proof connection.

D.2.14.5 PhaSeal™ Connector Luer Lock

The PhaSeal™ Connector Luer Lock attaches to the access port on an INFUSOR™ for addition of hazardous drug during preparation or onto a port on an intravenous line for administration of hazardous drugs. The Connector Luer Lock attaches to an Injector Luer Lock to provide a dry, leak-proof connection for safe drug transfer via injection or infusion.
D.2.14.6 PhaSeal™ Secondary Set with Drip Chamber

The PhaSeal™ Secondary set with drip chamber has a built-in PhaSeal™ Connector to facilitate a dry, leak-proof connection for addition of drug into an infusion solution bag and safe administration of hazardous drugs.

Refer to Checklists - Module 1 - Appendix 1: Reconstitution of a Hazardous Drug Using PhaSeal™
Refer to Checklists - Module 1 - Appendix 1: Withdrawal from One Hazardous Drug Vial Using PhaSeal™
Refer to Checklists - Module 1 - Appendix 1: Withdrawal from More than One Hazardous Drug Vial Using PhaSeal™

D.2.14.7 ChemoLock™ Vial Spike

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

The Port on the ChemoLock™ Vial Spikes has been tested to and is approved for up to 10 activations.

D.2.14.8 ChemoLock™ Injector

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

The priming volume of the ChemoLock™ Injector is 0.3 mL. The ChemoLock™ Injector has been tested to and is approved for up to 10 activations.

D.2.14.9 ChemoLock™ Bag Spike

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

The Port on the ChemoLock™ Bag Spike has been tested to and is approved for up to 10 activations.

D.2.14.10 ChemoLock™ Port

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

The priming volume of the Port is 0.1 mL. The Port has been tested to and is approved for up to 10 activations.

D.2.14.11 ChemoLock™ Syringe Transfer Set with MicroClave and ChemoLock™ Port

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

The Port on the ChemoLock™ Syringe Transfer Set has been tested to and is approved for up to 10 activations.
D.2.14.12 ChemoLock™ Syringe Transfer Set with Double ChemoLock™ Ports

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

The Ports on the ChemoLock™ Syringe Transfer Set have been tested to and are approved for up to 10 activations.

D.2.14.13 ChemoLock™ Secondary Set with Drip Chamber

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

D.3 Containers

D.3.1 Ampoules

An ampoule is a small glass container sealed to preserve the sterility of an injectable solution. Ampoules can be used to package drugs that may not be chemically compatible with plastic containers or rubber closures. The upper portion of the ampoule (head) is ‘snapped’ off creating an open-system.27 Drug in an open system container is vulnerable to microbial contamination. Environmental hazardous drug aerosol/vapour contamination is a risk when working with open system containers containing hazardous drug.

Standard:

The length of time between opening an ampoule and transferring the solution into a closed-system (e.g., syringe) must be minimized.12

Gather and assemble the syringe and needle or filter device prior to opening the ampoule to minimize the length of time the drug is exposed.

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

Standard:

The neck of the ampoule must be wiped to disinfect using a sterile 70% alcohol swab before breaking and must not be touch-contaminated after being disinfected.26

A new sterile alcohol swab may be wrapped around the neck of the glass ampoule before breaking it to protect the fingers from sharp edges. An ampoule breaker may be used in place of a new sterile alcohol swab. An ampoule breaker used to break off the upper portion of an ampoule containing a hazardous drug should be dedicated for this purpose and not be used on ampoules containing non-hazardous drug. A non-disposable ampoule breaker must be cleaned with soap and water after every use.25

Standard:

Glass particles in solutions must be filtered prior to administration83 unless the manufacturer indicates the solution cannot be filtered. Solution must not be withdrawn and injected using the same filtration equipment.12

If a filter device (e.g., needle or disc) was used to withdraw a hazardous drug solution into a syringe, the filter device must be changed to a regular needle for injection into a solution container.
Drug solutions that are oily or too viscous to be filtered should be drawn up using a 20 gauge or smaller needle bore, leaving behind a residual volume of solution in the ampoule. This residual volume should contain any glass particulate that was produced when the ampoule was broken. The residual volume from an ampoule containing hazardous drug should be withdrawn. The syringe must be tip capped and then discarded in a hazardous drug waste container.

**Standard:**

*All parts of an opened ampoule must be discarded into a sharps container.*

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

Refer to BCCA Pharmacy Directives – Module 1 – Appendix 2 – Number III-50-04 Management of Particulate During Sterile Preparation

**D.3.2 Vials**

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

**Standard:**

*Removal of a flip top cap from a hazardous drug vial must be performed carefully inside the BSC to ‘contain’ and avoid spreading HD contamination to areas outside of the BSC.*

Studies show HD surface contamination exists on commercially available vials of hazardous drugs as delivered from the manufacturer.

**Standard:**

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

The product stability may be determined by referring to the BCCA Chemotherapy Preparation and Stability Chart.

Refer to Checklists – Module 1 – Appendix 1: Preventing Core Formation

Refer to BCCA Pharmacy Directives – Module 1 – Appendix 2 – Number III-40-03: Vials as Delivered to Facility

Refer to the BCCA Chemotherapy Preparation and Stability Chart in the Cancer Drug Manual, Appendix 8 at [http://www.bccancer.bc.ca/health-professionals/professional-resources/cancer-drug-manual](http://www.bccancer.bc.ca/health-professionals/professional-resources/cancer-drug-manual)

**D.3.3 Polyvinyl Chloride (PVC) Bags**

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

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

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

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

**Standard:**

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

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

**D.3.5 Empty Sterile Infusion Bags**

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

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

**Standard:**

Infusion bags used for hazardous drug solution waste must be disposed of as hazardous drug waste. Refer to Checklists - Module 1 - Appendix 1: Preventing Core Formation

Refer to Checklists – Module 1 – Appendix 1: Injection of Drug(s) into an IV Solution Bag

**D.3.6 Evacuated Containers**

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

Evacuated containers may be used when:

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

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

**D.4 Ambulatory Drug Delivery Infusion Devices**

Elastomeric infusion devices are non-electric disposable ambulatory drug infusion devices. The use of a programmable ambulatory pump (e.g., Computerized Ambulatory Drug Delivery [CADD®], Ambulatory Infusion Manager [AIM®]) may occur with some clinical trials or in circumstances when an elastomeric infusion device is not deemed appropriate. Other fixed-rate infusion devices may be used, provided that they are able to administer the ordered dose over the ordered infusion duration.
D.4.1 Elastomeric Infusion Devices

Based on the recommendations of the Institute for Safe Medication Practice (ISMP) Canada, the BC Cancer Agency has revised all treatments with 5-fluorouracil continuous infusions to minimize the potential for medication errors. The use of elastomeric infusion devices is one of several recommendations made by the ISMP to increase patient safety.\(^9\) The BCCA has chosen to implement this recommendation and has switched to elastomeric infusion devices for ambulatory delivery of continuous 5-fluorouracil infusions. The BCCA has selected Baxter’s elastomeric INFUSORs™ for ambulatory chemotherapy delivery because they are readily available and their performance standards meet the needs of the agency.

Baxter elastomeric INFUSORs™ consist of an elastomeric reservoir (balloon) inside a hard plastic outer casing (cover) with attached infusion delivery tubing.

D.4.1.1 Medication Delivery via INFUSOR™

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

D.4.1.2 INFUSOR™ Flow Rates

Elastomeric INFUSORs™ are available with flow rates ranging from 0.5 to 500 mL per hour and running times from thirty minutes to twelve days. Reservoir volumes usually range from 50 to 500 mL. Chemotherapy medication is delivered using devices with fixed flow rates ranging from 0.5 to 5 mL per hour.

To ensure the most accurate flow rate, Baxter INFUSORs™ should be filled to their labelled ‘nominal volume’.\(^9\) A reduction in fill volume (i.e., less than 81%) may result in an increased flow rate and therefore is not recommended. The potential increase in flow rate resulting from a reduction in fill volume is indicated below:\(^9\)

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

- LV2 and LV5 INFUSORs™ have a nominal volume of 240 mL, so should be filled with at least 81% x 240 mL = 194 mL for the most accurate flow rate
- SV2 INFUSORs™ have a nominal volume of 96 mL, so should be filled with at least 81% x 96 mL = 78 mL for the most accurate flow rate

Note that nominal volume is not the same as maximum volume capacity. Maximum and nominal values for each INFUSOR™ size can be found in the INFUSOR’s™ package insert. See section D.4.1.3 for a summary table indicating maximum and nominal volumes for several Baxter elastomeric INFUSORs™.

Standard:

The correct size of elastomeric INFUSOR™ with the correct infusion rate must be selected when preparing hazardous drug medication.37

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

Fluid viscosity is strongly affected by temperature and somewhat affected by drug concentration.94 INFUSORs™ are designed to operate at the labelled flow rate when the diluent is D5W. Substituting a less viscous diluent such as normal saline may increase the flow rate by approximately 10%.92

Pressure gradient may be affected by vertical displacement of the device relative to the infusion site (e.g., patient), initial filling volume (e.g., under/overfilling), storage conditions (e.g., refrigeration/freezing), and variations in barometric pressure.94

Standard:

To decrease the risk of accidental exposure to hazardous drug, the delivery tubing of the INFUSOR™ must be primed with hazardous drug-free solution.13,92

D.4.1.3 INFUSOR™ Volume Capacities and Fixed Flow Rates

There are two INFUSOR™ design shapes available from Baxter – tubular and rounded (baby bottle shape). Both designs are available in different maximum volume capacities and fixed flow rates. Some examples of the two shapes of INFUSORs™ are:92

<table>
<thead>
<tr>
<th>Baxter’s Description</th>
<th>Shape</th>
<th>Color Code</th>
<th>Fixed Flow Rate</th>
<th>Maximum Volume</th>
<th>Nominal Volume</th>
<th>Residual Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>Two-Day INFUSOR™</td>
<td>Tubular</td>
<td>Black</td>
<td>2 mL/hr</td>
<td>105 mL</td>
<td>96 mL</td>
<td>2.5 mL</td>
</tr>
<tr>
<td>INFUSOR™ SV2</td>
<td>Baby bottle</td>
<td>Yellow</td>
<td>2 mL/hr</td>
<td>130 mL</td>
<td>96 mL</td>
<td>1 mL</td>
</tr>
<tr>
<td>INFUSOR™ LV1.5</td>
<td>Baby bottle</td>
<td>Pink</td>
<td>1.5 mL/hr</td>
<td>300 mL</td>
<td>252 mL</td>
<td>3 mL</td>
</tr>
<tr>
<td>INFUSOR™ LV2</td>
<td>Baby bottle</td>
<td>Yellow</td>
<td>2 mL/hr</td>
<td>300 mL</td>
<td>240 mL</td>
<td>3 mL</td>
</tr>
<tr>
<td>INFUSOR™ LV5</td>
<td>Baby bottle</td>
<td>Maroon</td>
<td>5 mL/hr</td>
<td>300 mL</td>
<td>240 mL</td>
<td>3 mL</td>
</tr>
</tbody>
</table>

‘SV’ = small volume; ‘LV’ = large volume. The number following indicates the fixed flow rate of that device.90

D.4.1.4 Hazardous Drug Medication Infusion Device Labels

Standard:

The intended infusion rate must be stated in millilitres per hour (mL/hour) on the medication label when hazardous drug is administrated via an infusion device.90

Refer to Checklists – Module 1 – Appendix 1: Elastomeric INFUSOR™ Preparation
Refer to Checklists – Module 1 – Appendix 1: Elastomeric INFUSOR™ Preparation Using PhaSeal™

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

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

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


Standard:

To decrease the risk of exposure to hazardous drug, the tubing of a CADD® medication cassette reservoir must be primed with hazardous drug-free solution.\(^{13}\)

Note:

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

Section E

E.1 Operational Standards for Sterile Hazardous Drug Preparation

Standard:

Hazardous drugs shall be prepared only under conditions that protect the healthcare workers and other personnel in the preparation and storage areas.\(^{26}\)

Operational standards must be adhered to when preparing sterile HD admixtures.\(^{12}\)

E.1.1 Personnel Hygiene in the Controlled Work Area

- Standard: Eating, drinking, smoking, chewing gum, or storing food in the controlled work area is strictly prohibited\(^{15,15}\)
- Standard: 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 admixtures\(^{15,26}\)
- Standard: Personnel must remove:
  - jewellery, studs, and other accessories from fingers, wrists, forearms, face including nose, tongue and ears, and neck\(^{12,15}\)
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

nail polish and other nail applications (nail extensions, synthetic nail-lengthening products), natural nails must be kept neat and trimmed

personal outer garments (e.g., bandanas, coats, hats, jackets, scarves, sweaters, vests) because they shed flakes and particles

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

- Standard: Personnel must wear scrubs or clean, low-lint clothing to enter the controlled work area
- Standard: Hair covers (covering hair and ears completely) and beard covers (as applicable), must be worn by all personnel working in the controlled work area
- Standard: Hair covers and beard covers (as applicable) must be donned on the dirty side of the demarcation line in the anteroom
  Or
- Standard: Hair covers and beard covers (as applicable), must be donned on the dirty side of the demarcation line in the gowning room
- Standard: 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 anteroom
- Standard: 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 PPE if the viewing window is raised
- Standard: 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 side
  Or
- Standard: 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 side
- Standard: A second (outer) pair of shoe covers must be donned on the clean side of the anteroom before stepping inside the hazardous drug cleanroom
- Standard: A chemotherapy or isolation gown must be donned on the clean side of the demarcation line in the anteroom (depending on the work being performed)
  Or
- Standard: 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)
- Standard: 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)
- Standard: Hand hygiene must be performed and gloves donned on the clean side of the demarcation line in the anteroom
  Or
- Standard: Hand hygiene must be performed and gloves donned on the clean side of the demarcation line in the gowning room
- Standard: 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
- Standard: 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
- Standard: 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.

- Standard: 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.
- Standard: 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.
- Standard: Lab coats and isolation gowns must not be worn in place of chemotherapy gowns when protection from HD exposure is required because they permit the permeation of hazardous drug and can hold spilled hazardous drug against the skin, thereby increasing exposure.
- Standard: Two pairs of disposable chemotherapy gloves must be worn at all times by all personnel when hazardous drug exposure is possible (e.g., when handling hazardous drug vials, when mixing hazardous drug in the BSC). Both pairs of chemotherapy gloves must be inspected for visible defects. Gloves that have visible defects must not be worn.
- Standard: Gloves must be powder-free because powder can contaminate the work area and can absorb and retain hazardous drug.
- Standard: 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.
- Standard: 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.

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

Refer to Checklists – Module 1 – Appendix 1: Donning of Personal Protective Equipment to Enter a Chemotherapy Cleanroom

Refer to Checklists – Module 1 – Appendix 1: Exiting the Chemotherapy Cleanroom to Wash Hands Every 30 Minutes during Hazardous Drug Compounding

E.1.3 Biological Safety Cabinet

- Standard: The UV light may cause eye damage and must not be turned on when personnel are working in the cleanroom.
- Standard: 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.
Standard: The viewing window must be kept at the manufacturer’s recommended level during HD preparation\textsuperscript{30,33}

Standard: Rapid arm movements that could disrupt the air curtain must be minimized\textsuperscript{30,33}

Standard: The front air intake grill and the rear air exhaust route must not be blocked\textsuperscript{30,33}

Materials required for the preparation should be placed as far in from the front grill as practical, without blocking the rear grill\textsuperscript{30}

The front grill must not be blocked at any time during the compounding process

Standard: Manipulations must be performed at least six inches in from the front opening and side walls of the BSC\textsuperscript{12}

Standard: The work surface of the BSC must be cleaned and disinfected between each preparation using aqueous antibacterial solution (e.g., CaviWipe) followed by sterile 70% alcohol\textsuperscript{12}

Standard: Following hazardous drug compounding, the BSC must purge for at least five minutes\textsuperscript{33} 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\textsuperscript{TM}) followed by sterile 70% alcohol:\textsuperscript{26}

- after preparations within the BSC are completed for the day\textsuperscript{12}
- prior to compounding ‘latex-free’ preparations\textsuperscript{12}
- prior to compounding sterile HD preparations in a BSC once it has been used to compound non-sterile HD preparations\textsuperscript{12}
- prior to resuming compounding in a BSC that is turned off between aseptic processes for any reason (e.g., power interruption, maintenance)\textsuperscript{12}

Refer to Checklists – Module 1 – Appendix 1: Cleaning Interior Biological Safety Cabinet Surfaces

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

Refer to BCCA Pharmacy Directives – Module 1 – Appendix 2 - Number VI-20: Biological Safety Cabinet (BSC) Decontamination

\textbf{E.1.4 General Procedures}

- Chair height should be adjusted so that the operator’s shoulders are level with the bottom of the front viewing window when seated. This provides face and eye protection while positioning the operator to compound within a biological safety cabinet\textsuperscript{27}

- Only materials required to aseptically prepare a single dose for one patient should be placed into the BSC at one time\textsuperscript{95} This creates a less crowded work space and improves patient safety by minimizing the chance that the wrong drug is selected and injected into the final container (e.g., diluent bag) which could then possibly go undetected during the final product check

- Standard: Unnecessary items must not be taken into the BSC since airflow is disrupted in an overcrowded BSC\textsuperscript{36}

- Standard: HD vials must be wiped with low-lint towels or gauze moistened with \textbf{sterile} 70% alcohol to disinfect and physically remove HD contamination prior to placement inside the BSC\textsuperscript{26}

- Standard: 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 \textbf{sterile} 70% alcohol\textsuperscript{26}

- Whenever possible without compromising critical sites, outer wrappings should be removed from sterile supplies before placing the supplies inside the BSC\textsuperscript{26}
➢ Standard: Best practice standards for aseptic technique in vertical airflow must be adhered to when preparing sterile hazardous drug admixtures.  
➢ Standard: 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; supplies are stored to the side of the critical area in a ‘storage zone’  
➢ Excess supplies should not be brought into the BSC  
➢ Standard: To decrease particle generation inside the BSC, paper coverings must be peeled away from needle hubs (critical sites) rather than pushing them through. Tweezers may be used to handle sticky surfaces of foil seals and to remove multiple or sharp vial caps to protect gloves from tearing and potential contamination.
➢ Standard: Critical sites must be protected as soon as possible after being exposed and must not be touch contaminated.
➢ Standard: Infusion solution bag ports and vial stoppers must be disinfected with sterile 70% alcohol prior to accessing.
➢ Standard: A new sterile alcohol swab must be used to disinfect each critical site.
➢ Standard: When reconstituting, the drug must be completely dissolved before withdrawing a dose or storing for future use.
➢ Standard: Syringes must not be overfilled with hazardous drug. In most cases, syringes should not be more than three-quarters (75%) full, although some preparations require accurate volume measurements that necessitate the use of a smaller volume syringe.

➢ Standard: Each syringe barrel must be marked with a line indicating the volume of solution withdrawn and the name of the solution using a thin-tipped permanent marker. The line indicating the volume withdrawn into the syringe must be marked when the solution is in the syringe. Solution volumes that equal numbers marked on the syringe barrel by the manufacturer must also be marked with a line, not by circling the number at the calibrated volume.

➢ To modify the required volume in a syringe which has been out of the BSC, standard aseptic practice requires that the HD first be transferred from the original syringe to a new syringe using a transfer device. The syringe plunger has been exposed to a non-ISO Class 5 environment and cannot be disinfected.
➢ Standard: Negative pressure technique must not be used for hazardous drug reconstitution or withdrawal if filter venting devices or closed system drug transfer devices are available.
➢ Standard: A puncture-proof sharps container must be used for disposal of all sharp objects including needles, chemotherapy dispensing pins, and chemotherapy vents.
➢ Standard: All non-sharp waste generated during compounding of hazardous drugs must be placed inside a HD waste container (e.g., zip lock bag or sharps container) in the BSC for later removal and disposal.

Refer to Checklists – Module 1 – Appendix 1: Placement of Drugs and Supplies into the Biological Safety Cabinet
Refer to Checklists – Module 1 – Appendix 1: Decontamination of the Biological Safety Cabinet

E.1.5 Removing Products from the BSC
➢ Standard: 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.
➢ Accessed infusion solution bag ports should be covered with a foil seal.
Standard: 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)."15

Studies have shown that outer chemotherapy gloves may be contaminated with HD after compounding."14

Standard: Outer chemotherapy gloves worn when compounding hazardous drugs must be removed, discarded within the 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.12

Standard: 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.12

Standard: The final preparation must be labelled immediately after it is removed from the BSC with the patient specific and required warning labels.96

To remove a vial of HD that will be saved for reuse from the BSC:

- Standard: the vial stopper must be wiped with a sterile 70% alcohol swab26 to remove possible HD residue (if there is not a chemotherapy dispensing pin or CSDTD inserted) and should be covered with a foil seal.
- Standard: the puncture date and time or beyond use date and time must be written directly on the vial with a thin-tipped permanent marker.12
- Standard: the vial must be cleaned with a new towel moistened with an aqueous antibacterial agent (e.g., CaviWipe™).12
- Standard: 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.25

Standard: 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.4

Refer to Checklists – Module 1 – Appendix 1: Removal of the Product and Supplies for Final Product Check Outside of the Biological Safety Cabinet

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

E.1.6 Warning Labels

- Standard: All hazardous drugs and hazardous drug preparations must be easily identifiable by personnel involved in their handling.13
- Standard: The container of hazardous drug must be appropriately labelled indicating the contents are hazardous in nature.13

E.1.7 Exiting the Cleanroom

- Standard: PPE must be appropriately removed upon exiting the controlled work area.13,14
  - Standard: Removal of chemotherapy gowns for storage or disposal must be done with care to avoid spreading HD contamination to other non-contaminated garments.14
  - Standard: Outer gloves must be discarded in a hazardous waste container (inside or outside of the BSC) prior to exiting the cleanroom – outer gloves must NOT be worn outside the cleanroom once compounding hazardous drugs in the BSC has occurred.12
✓ Standard: 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{14}
✓ Standard: Mask and hair cover(s) must not be removed inside the cleanroom\textsuperscript{15}
✓ Standard: Mask, hair cover(s) and inner gloves must be discarded in a hazardous waste container\textsuperscript{14}
✓ Standard: Hands must be washed immediately with soap and water every time gloves are removed\textsuperscript{14}
✓ Standard: A buttoned lab coat (or isolation gown) must be donned over scrubs upon exiting the anteroom\textsuperscript{25,27}

Refer to Checklists – Module 1 – Appendix 1: Removal of Personal Protective Equipment after Working in a Biological Safety Cabinet
Refer to Checklists – Module 1 – Appendix 1: Removal of Personal Protective Equipment When Exiting the Chemotherapy Cleanroom

E.2 Aseptic/Protective Routines

E.2.1 Critical Sites

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

Standard:

Critical sites must be protected as much as possible and must not be touch-contaminated.\textsuperscript{26} Protection of critical sites by precluding physical contact and airborne contamination must be given the highest priority in aseptic compounding practice.\textsuperscript{26}

E.2.2 First Air

First air is unobstructed HEPA filtered air that washes over components (solution containers, syringes, gloves, etc.) in the work area of the BSC. Air that flows downstream from the HEPA filter may become contaminated with particles dislodged from components and PPE (e.g., chemotherapy gown sleeves and gloves) that are placed in the first air.\textsuperscript{26}

Standard:

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{15,26}
E.2.3 Disinfecting Critical Sites

Standard:
The stopper on a vial or the port on an infusion solution bag must be disinfected using a sterile 70% alcohol swab just prior to penetration. At least 10 seconds must be allowed for the alcohol to dry (act) before manipulations begin.\footnote{26} Wiping a critical site with a sterile alcohol swab is necessary for disinfection and the physical removal of particulates.

Standard:
The correct technique to disinfect a critical site is to make several firm strokes in the same direction over the rubber closure.\footnote{12} A new sterile swab must be used to disinfect each new surface.\footnote{12} 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.\footnote{26}

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\footnote{26} to remove possible HD residue.

E.2.4 Coring

When piercing infusion bag ports and vial stoppers with needles, it is important to avoid coring.\footnote{12} Coring occurs when the bevel tip and the bevel heel do not penetrate the port or stopper at the same point\footnote{32} causing particles of the port or stopper to end up in the diluent/HD solution.

Standard:
Each vial and final product must be checked for particulate (e.g., coring) after each puncture of a vial stopper or infusion solution bag port.\footnote{15}

Vials, syringes, and final products are checked for particulate by rotating upside down and right side up, while visually inspecting the contents.
E.2.5 Capping Needles Safely

Standard:

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.

If recapping a needle is required, a one-handed ‘scoop’ method or a needle cap holder should be used.

Standard:

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

Refer to Checklists – Module 1 – Appendix 1: Capping Needles Safely

In the event of a needle stick injury, see Accidental Exposure to Hazardous Drugs: Accidental Injection/Skin Puncture in Section H.2.4

E.3 Safe Handling Aseptic Techniques

E.3.1 Transfer of Hazardous Drug Solution from a Syringe

Standard:

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

Excess drug may be injected back into the original drug vial, an empty sterile vial, or an empty infusion bag. Another option is to transfer the calculated hazardous drug volume to a fresh syringe via a syringe fluid dispensing connector. The excess drug may be left in the original syringe, capped with a luer-lock tip cap and discarded into the HD waste container or labelled for future use.

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

Standard:

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

E.3.2 Removal of Bubbles/Air from a Syringe

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

Standard:

Bubbles and air must be removed carefully in a manner that prevents the release of HD solution and minimizes the production of HD aerosols in the BSC.

Refer to Checklists – Module 1 – Appendix 1: Removal of Bubbles / Air from a Syringe
E.3.3 Attaching and Priming Solution / Administration Sets

Standard:

Priming any intravenous administration set with hazardous drug solution in an uncontrolled environment must be avoided.\(^{13}\)

Best practice is to attach and prime the appropriate intravenous administration set to the final container in the BSC before adding drug.\(^{4}\)

Standard:

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

Refer to Checklists – Module 1 – Appendix 1: Priming Solution / Administration Sets inside the Biological Safety Cabinet
Refer to BCCA Pharmacy Directives – Module 1 – Appendix 2 – Number III-50-01: Priming Lines Standards

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

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

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

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

Refer to Checklists – Module 1 – Appendix 1: Withdrawal of Solution from an IV Solution Bag

Section F

F.1 Clean Up and Waste Disposal

F.1.1 Biological Safety Cabinet Waste Cleanup

Standard:

The entire aseptic preparation area must be kept clean so that aseptically prepared products remain as free from potential microbial and hazardous drug contamination as possible.\(^{14,26}\)

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

Waste generated throughout the cleaning or decontamination procedures should be collected in suitable zip lock bags that are sealed and cleaned with a new towel moistened with an aqueous antibacterial agent (e.g., CaviWipe™) inside the BSC, just prior to removal.\(^{14}\)

To facilitate overall cleanliness in the vicinity of the BSC, the stainless steel trolley(s), countertops and other surrounding surfaces should be cleaned regularly.

Refer to Checklists – Module 1 – Appendix 1: Cleaning Interior Biological Safety Cabinet Surfaces
Refer to Checklists – Module 1 – Appendix 1: Decontamination of the Biological Safety Cabinet
Refer to Checklists – Module 1 – Appendix 1: Clean Up and Waste Disposal in the Biological Safety Cabinet
F.1.2 Hazardous Waste Disposal

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

All disposable items that may have come in contact with hazardous drugs during receipt, storage, preparation or administration must be treated as hazardous waste including PPE.13 Hazardous waste must be disposed of separately from general waste in hazardous waste containers with lids.12 The hazardous waste container must be distinctly different from other types of waste containers12 (e.g., bright yellow or red coloring with hazardous warning labels).

All disposable non-sharp HD waste must be disposed of in 4 mil thick plastic bags which are placed inside a rigid HD waste container or carton so that all waste is essentially ‘double-bagged’.12 The HD waste containers should be leak proof, have a lid that seals securely and be labelled with an appropriate hazardous warning label. HD container lids should be closed except when placing contaminated materials into the containers to reduce the risk of HD aerosols/vapours being released into the environment.27

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

All sharps used for the preparation and administration of hazardous drug admixtures must be placed into a puncture-proof hazardous drug sharps container for disposal12 without being crushed or clipped.27,59 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.12 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.12

When no more than three-quarters full, the container or carton should be securely closed with the lid sealed.

Standard:
Two pairs of chemotherapy gloves must be worn while handling hazardous waste.4

While awaiting removal from the facility for disposal, hazardous waste must be stored in a secure area in securely sealed and properly labelled containers.27

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

Standard:
Hazardous waste must be transported and disposed of according to Federal and Provincial regulations after leaving the facility.14
Section G

G.1 Safe Handling of Oral, Topical and Pre-Packaged Hazardous Drug Dosage Forms

Standard:

All drugs listed on the facility’s hazardous drug list must be handled according to the facility’s hazardous drug safe handling guidelines. 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.

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

G.1.1 Oral Preparations

- Standard: 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.
- Standard: All activities likely to result in particle generation, for example, weighing or mixing powder, crushing tablets/capsules, or filling capsules, must be performed in an externally vented, minimum Class I biological safety cabinet in a negative pressure room (with at least 12 APH) to minimize the risk of spreading HD contaminated particulate throughout the rest of the pharmacy.
- Standard: Counting of non-coated tablets or capsules that have visual evidence of HD powder residue on them or compounding HD oral solutions must be performed using containment strategies such as preparation inside an externally vented, minimum Class I biological safety cabinet to reduce the risk of HD exposure.
- Standard: Dedicated ‘chemotherapy’ counting trays and spatulas must be used to count loose HD tablets and capsules.
- “Chemotherapy” dedicated counting tray(s), spatula(s) and countertops should be cleaned after each use with aqueous alkaline detergent solution. The towel used must be disposed of in HD waste.
- Standard: Hands must be washed with soap and water immediately after removing chemotherapy gloves.
- Standard: Gloves worn when handling hazardous drugs must be discarded in HD waste.
- Standard: Automated counting machines must not be used to count hazardous drug tablets and capsules.

G.1.2 Topical Preparations

- Standard: Two pairs of chemotherapy gloves must be worn when handling hazardous drug topical preparations that have been removed from the original packaging.
- Standard: Compounding hazardous topical products, especially activities likely to result in particle generation, must be performed in an externally vented minimum Class I biological safety cabinet.
G.1.3 Pre-filled Syringes

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

Standard:

All interior surfaces of a 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

Standard:

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. These locations include hazardous drug preparation, dispensing, storage and receiving areas.

H.1.1 Recommended Spill Kit Contents

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

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

PPE

1. Disposable moisture-resistant long-sleeved gown with elastic cuffs and tie(s) in back
2. Two pair of chemotherapy-approved gloves
3. Disposable safety eye goggles or face shield
4. Shoe covers
5. Hair bonnet
6. N95 (e.g. 3M 1870 NIOSH respirator) or better disposable respirator

Supplies

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

Documents

1. Laminated copy of BCCA Provincial HD Spill Control Directive
2. Laminated copy of applicable Site Directives
Standard:

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

Training and competency assessments should be documented.

Refer to Checklists – Module 1 – Appendix 1: Hazardous Drug Spill Control in Pharmacy – Clean-up of a Spill within a Biological Safety Cabinet

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

Refer to BCCA Pharmacy Directives – Module 1 – Appendix 2 – Number VI-10: Hazardous Drug Spill Control in Pharmacy

Refer to the BCCA Pharmacy CON Educator’s Hazardous Drug Spill Control in Pharmacy In-service at http://learn.phsa.ca/bcca/hdspills/player.html

H.2 Accidental Exposure to Hazardous Drugs

Standard:

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

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

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

Refer to BCCA Systemic Therapy Policy: V-20: Employee Health: Management of Risks Related to Hazardous Drugs

H.2.1 Inhalation

Exposure through inhalation is greatest when particles of aerosolized or vaporized hazardous drug are released into the environment while injecting into a vial or infusion solution bag, and when expelling air from a hazardous drug-filled syringe. Studies have shown that some hazardous drugs tested may evaporate from solid to gaseous forms under normal working conditions. Safe handling techniques and the proper use of a Class II Type B BSC will reduce possible inhalation exposure. Respirators are necessary to minimize inhalation exposure to HD aerosols when cleaning and decontaminating the BSC with the viewing window open and when cleaning up a hazardous drug spill.

H.2.2 Ingestion

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

Standard:

Personnel must not take food, gum, drinks, cigarettes or personal medication into an area where hazardous drugs are handled (e.g., received, stored, prepared, administered and disposed).
In the event that inhalation or ingestion occurs, no management or treatment is required unless unusual symptoms occur.
1. Monitor for possible symptoms
2. Report any unusual symptoms to your professional practice leader/department manager and your family physician

**H.2.3 Absorption/Skin Contact**

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

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

**In the event of accidental skin contact:**
1. Immediately remove gloves and/or contaminated clothing
2. Cleanse the affected skin immediately with soap and warm running water – use shower if appropriate
3. Rinse again with warm running water for at least fifteen minutes
4. Notify supervisor
5. Call the Provincial Workplace Health Call Centre reporting line at 1-866-922-9464

**In the event of accidental eye contact:**
1. CALL FOR HELP
2. Remove gloves
3. Immediately proceed to the eyewash station and flush open eyes with copious amounts of water for at least fifteen minutes (or use bottled eyewash solution)
4. Hold eye(s) open with thumb and finger and look directly into the water stream – move eye(s) around to wash all around
5. Do NOT rub eye(s)
6. Do NOT use tap water as pressure damage may occur\(^{18,54}\)
7. Notify supervisor and report immediately to a physician
8. Note which hazardous drug was involved and the quantity of drug that the eye(s) were exposed to
9. Call the Provincial Workplace Health Call Centre reporting line at 1-866-922-9464

**H.2.4 Accidental Injection/Skin Puncture**

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

**See Capping Needles Safely in Section E.2.5**

In the event of accidental injection/skin puncture:
1. Remove gloves
2. Rinse the area with warm running water and allow the wound to bleed freely to flush out any drug. Do **not** squeeze the puncture area\(^{13}\)
3. Wash the area thoroughly with soap and water and rinse with warm running water for at least fifteen minutes
4. The HD and approximately how much was injected should be noted
5. The supervisor must be informed of an accidental injection/skin puncture immediately
6. The Occupational Health Nurse must be contacted as soon as possible
7. Call the Provincial Workplace Health Call Centre reporting line at 1-866-922-9464

Refer to Checklists – Module 1 – Appendix 1: Personnel Contamination
Section I

I.1 Receipt and Unpacking

The results of several studies show that surface contamination exists on commercially supplied vials of hazardous drugs supplied by manufacturers to pharmacies.9,86,87,98-100

Standard:

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

Safe handling procedures must be followed to avoid breakage of hazardous drug containers, to minimize exposure to hazardous drugs, and to contain spills that occur when receiving and unpacking hazardous drugs within the pharmacy.12

I.1.1 Receipt

- Shipping cartons, including re-packaged totes/cartons from the facility’s stores/distribution departments that contain HD deliveries to the pharmacy department from suppliers or vendors should have hazard warning labels on the outside packaging to identify the hazardous nature of the contents

- When hazardous drugs are received by the pharmacy department in totes/cartons without hazard warning labels, the sender (e.g., suppliers, vendors or the facility’s stores/distribution department) should be notified and encouraged to utilize warning labels to identify the hazardous nature of the contents

- Standard: Two pairs of chemotherapy gloves must be worn when packing and unpacking boxes containing hazardous drugs12

- Standard: The outside of cartons must be examined for possible damage prior to opening14

I.1.2 Receipt of a Damaged Shipment

Standard:

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

Damaged cartons, totes, and/or packages containing hazardous drugs that are received must NOT be opened and the receiver must don full PPE including a respirator and safety goggles to handle the package101 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 goggles101 and follow procedures outlined in the BCCA Directive VI-10 Hazardous Spill Control in Pharmacy.

The supplier should be notified after proper containment of a damaged carton, tote, or package or any damaged contents. It is not advisable to return damaged hazardous drug vials to the supplier but should instead be disposed of appropriately.18

Refer to BCCA Pharmacy Directive – Module 1- Appendix 2 – Number III-40-14; Problems with Medication Shipments

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Standard:

HD spill kits with written procedures for use must be located in all areas where hazardous drugs are received.\textsuperscript{4,27}

Refer to BCCA Pharmacy Directives – Module 1 – Appendix 2 – Number VI -10: Hazardous Drug Spill Control in Pharmacy

1.2 Storage

- Standard: Containers, shelves and bins used for HD storage must be properly labelled with hazard warning labels identifying the drugs that require special handling\textsuperscript{13}
- Standard: Barriers and other design features on bins and shelves must be present to contain accidental leakage and reduce the chance of drugs falling to the floor\textsuperscript{12}
- Standard: Hazardous drugs must be stored in a manner that prevents spillage or breakage if the container falls\textsuperscript{14}
- Standard: 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\textsuperscript{14} Many hazardous drugs have sufficient vapour pressures that allow volatilization at room temperature\textsuperscript{12}
- Refrigerated antineoplastic hazardous drugs should be stored in a dedicated refrigerator in a negative pressure room with at least 12 air changes per hour\textsuperscript{14}
- Standard: Refrigerator temperatures must maintain a cold temperature range of 2°C to 8°C\textsuperscript{15}
- Standard: To prevent errors from occurring, medication that can be easily mistaken for another (sounds alike, looks alike, similar labelling) must be separated in all areas of the pharmacy\textsuperscript{12}
- Hazardous drugs should be stored at or below eye-level
- Standard: Access to areas where hazardous drugs are stored must be limited to authorized personnel\textsuperscript{12}
- Standard: Hazardous drugs spill kits with written procedures for use must be readily available in areas where hazardous drugs are stored.\textsuperscript{13}

1.3 Packaging and Transportation

Standard:

Hazardous drugs must be packaged and transported in a manner which minimizes the risk of HD exposure due to a spill or breakage during transit.\textsuperscript{14}

Hazardous drugs should be packaged in a sealed, leak-proof container with HD warning labels on the outside.\textsuperscript{12}

Some considerations when determining hazardous drug packaging for transport include:

- package hazardous drugs separately from non-hazardous drugs
- protect from light where required
- protect from breakage during transit
- contain any leakage if contents break or rupture
- use child-proof packaging for tablet containers (if appropriate e.g., patient-specific take home medications)
- label appropriately with auxiliary instructions
- use methods for cooling drugs which require refrigeration (cold packs, dry ice)
Reusable packaging should be designated for HD transport only\textsuperscript{18} and must be decontaminated and re-used as per site-specific policies. Disposable HD packaging materials should be discarded as hazardous waste.

Site specific procedures for transporting hazardous drugs should be developed and maintained. Pharmacy staff involved in transporting hazardous drugs must be properly trained to adhere to site specific HD transport procedures. The method of transporting hazardous drugs must not produce stress on the contents or packaging.

**Standard:**

\textbf{Pneumatic tubes or other mechanical transport systems that produce stress on the contents must not be used for hazardous drug transport.}\textsuperscript{14}

Non-pharmacy personnel transporting hazardous drugs should be aware of HD spill procedures. Spill kits should either accompany hazardous drug packages during transport or be easily accessible.\textsuperscript{14}


37. BCCA Division of Pharmacy. BCCA Best Practice Safe Handling Standards. 2008.


89. Cole S. Baxter Healthcare - Information regarding the plastic protective over wrap pouch used on VIAFLEX plastic containers manufactured by Baxter Corporation. 2008 Feb. 8;E-mail received Feb. 8, 2008.

90. BCCA Division of Pharmacy. BCCA Systemic Therapy Update - Elastomeric Infusors. 2008 June;2(11).


