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RATIONALE
To increase awareness among Pharmacy staff about possible health risks posed by working with hazardous drugs and to provide them with measures for protecting their health.

DIRECTIVE:
All BCCA Pharmacy staff will read the three page summary of worker/employer recommendations which accompanies the US National Institute of Occupational Safety and Health NIOSH Alert “Preventing occupational exposures to antineoplastic and other hazardous drugs in health care settings”.

DEFINITIONS
NIOSH - National Institution for Occupational Safety and Health
PSHWG – Pharmacy Safe Handling Working Group (reports to P4C)
Pharmacy PPL – Pharmacy Professional Practice Leader
P4C – Provincial Pharmacy Professional Practice Council

PROCEDURES
1. The Pharmacy PPL or delegate will provide a copy of the three page summary of the NIOSH Alert to all pharmacy staff members.
2. The summary will be accompanied by the “BCCA statement to accompany NIOSH Alert summary” (Appendix 1) to relate the American NIOSH Alert to work in BCCA centres.
3. Questions arising from this information should be directed to the Pharmacy PPL.
# APPENDIX I

**BCCA STATEMENT TO ACCOMPANY NIOSH ALERT SUMMARY OF WORKER/EMPLOYER RECOMMENDATIONS**

The purpose of the NIOSH Alert is to increase awareness among health care workers and employers about possible health risks posed by working with hazardous drugs, and to provide them with measures for protecting their health. This three-page document summarizes the full NIOSH Alert, which makes recommendations based on published literature and case studies. The Alert was developed by a committee of individuals in the United States, representing a broad range of disciplines working with hazardous drugs. This alert applies to all workers who handle hazardous drugs.

Current BCCA safe handling policies and procedures remain in force. The full contents of the NIOSH Alert are being reviewed by the BCCA Pharmacy Safe Handling Working Group. Some details may not apply specifically to pharmacy practice in Canada. Any recommendations resulting from the review will be forwarded to the Provincial Pharmacy Professional Practice Council for approval and implementation.

If you have any questions arising from this summary, please direct them to your Pharmacy Professional Practice Leader.

Additional resources may be found in:

- WorkSafe BC regulations [WCB Part 6 Substance specific requirements - cytotoxic drugs](#)
- BCCA policies and procedures
- [NIOSH Alert](#)
RATIONALE
The results of several European and American studies show surface contamination exists on commercially available vials of chemotherapy as delivered from manufacturers. Given the increasingly global nature of the pharmaceutical supply chain, it is assumed that vials delivered to Canadian hospital pharmacies are also contaminated.

DIRECTIVE
Exposure control steps should begin when cytotoxic and hazardous drugs enter the facility.

PROCEDURES
Persons involved in drug distribution, receiving and inventory control should:
1. be informed of the existence of surface contamination on chemotherapy and hazardous drug vials
2. wear gloves when handling chemotherapy and hazardous drug vials
3. quarantine packages with visual signs of damage, and open in a biological safety cabinet (BSC) using personal protective equipment (eg, gown, gloves, etc)
4. wash their hands after handling chemotherapy and hazardous drug vials (NB, gloves are not a substitute for hand washing)
5. dispose of potentially contaminated materials (eg, gloves) as hazardous waste

Employers are encouraged to:
1. make sure the storage area has sufficient general exhaust ventilation to dilute and remove any airborne contaminants
2. depending on the physical nature and quantity of the stored drugs, consider installing a dedicated emergency exhaust fan that is large enough to quickly purge airborne contaminants from the storage room in the event of a spill and prevent contamination in adjacent areas
3. purchase products which are verified to be free of external contamination

REFERENCES


Provincial Pharmacy Directive

III-40-14: Problems with Medication Shipments to Pharmacy

Effective Date: May 21, 2013
Approved By: Provincial Pharmacy Professional Practice Council

Review Date: Revision Date:
Page 1 of 2

RATIONALE

The medication supply chain must be maintained at all times during transport. Standard procedures must be in place to identify and resolve problems with shipments received in error, damaged or outside of allowable storage conditions.

DIRECTIVE

Pharmacy will follow standard procedures for handling shipments that have been:

1. Received outside recommended temperature range
2. Received in error (shipping or ordering)
3. Received damaged or broken

Pharmacy will quarantine any of these shipments

PROCEDURE

Pharmacy purchaser/receiver:

- Upon receipt of any shipment, examine to determine if product was maintained at recommended temperature range or not maintained under optimal storage conditions, damaged in transport and/or if there have been any shipping/ordering errors
- Identify products that have been improperly stored, damaged or received in error and isolate them from all other products

1. Received outside recommended temperature range or was not maintained under optimal storage conditions
   - Inform PPL or delegate
   - Document details of improper storage
   - Contact Manufacturer/vendor to find out if product can be used. If not, request credit and/or replacement of product
   - Destroy on site or return product to Manufacturer/vendor
   - If product is to be destroyed, document wastage as appropriate

2. Received damaged or broken
   - Hazardous Drugs (HD) received damaged, please refer to policy VI-10 (Hazardous Drug Spill Control in Pharmacy) on how to handle
     - Inform PPL
     - Document details of damaged shipment
     - Contact Manufacturer/Vendor, provide details and request credit and/or replacement of product(s)
     - Destroy on site
For all non-hazardous shipments

- Inform PPL
- Document details of damaged shipment
- Contact Manufacturer/Vendor, provide details and request credit and/or replacement of product(s)
- Destroy on site or return damaged product(s) only if reasonable to do so

3. Received in error (shipping or ordering)

- Due to shipping error, contact Manufacturer/Vendor and arrange for product to be sent back at no cost to BCCA
- Due to ordering error:
  - Inform PPL or delegate of order error
  - Determine if pharmacy stocks and it is feasible to keep on hand or transfer stock to another BCCA site to avoid restocking fee
  - If not stocked, return product for credit and incur possible restocking fee

REFERENCES


III-50-01: Priming Lines Standards

Effective Date: Oct. 29, 2003

Approved by: Provincial Pharmacy Professional Practice Council

Review Date: Revision Date:

PRIMING LINES: MEETING CYTOTOXIC AND INFECTION CONTROL STANDARDS

Background and Purpose

The 4 Cancer Centres prepare and administer cytotoxic and non-cytotoxic drugs to cancer patients. How the centres achieve this is not consistent. It is recognized that each centre can operationalize procedures to be centre specific, as long as cytotoxic safe handling and infection control standards are met.

Guiding Principles

1. All items that are considered cytotoxic must be prepared by pharmacy in a Class II type B biological safety cabinet.
2. Tubing attachment points, which will be exposed to handlers, will be primed with drug-free solution to decrease cytotoxic exposure.
3. All items that are to be infused by continuous infusion (> 24 hours) must be prepared aseptically by pharmacy in an appropriate preparation cabinet to minimize risk of bacterial contamination.
4. All items originally prepared by Pharmacy must be returned to Pharmacy for manipulation if required.

Examples

1. Minibags/large volume infusion (LVI) bags containing cytotoxic drugs:
   a) If the administration port is not compromised by pharmacy and the membrane is intact, it is deemed safe for nursing to attach tubing to this port.
      (1) When the bag is a secondary line, the attached tubing is backwashed by the main line. Examples: Cyclophosphamide 900 mg in 100mL D5W or Vinorelbine 40 mg in 50mL D5W.
      (2) When the bag is the primary line, then the tubing is primed with neutral solution and attached to the bag by nursing before administration to the patient. Examples: Paclitaxel 300 mg in 500 mL D5W or Docetaxel 100 mg in 250 mL D5W
   b) If the administration port is compromised by pharmacy, then the tubing is primed with neutral solution and attached to the bag by pharmacy in a biological safety cabinet. Example: Cisplatin with Mannitol when manufactured using the administration port.
2. Ambulatory devices containing cytotoxic drugs: All tubing exposed to handlers will be primed with drug-free solution. Examples: 50 mL and 100 mL Pharmacia Cassettes containing Fluorouracil used with CADD pumps.
3. Ambulatory devices alarming or failing during treatment:
   a) Site Specific Nursing/Physician services will determine if patients need to report to hospital for assessment and physician follow up. If treatment is interrupted, it will not be restarted until the NEXT full Ambulatory Care Chemotherapy Unit/Pharmacy working day.
   b) If the medication reservoir (cassette, minibag etc) requires manipulation, this will be done by Pharmacy in the appropriate preparation cabinet.
### III-50-01: Priming Lines Standards

<table>
<thead>
<tr>
<th>Nature of Infusion</th>
<th>Tubing Primed By</th>
<th>Priming Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minibag/LVI bags (Intermittent Infusion), port intact</td>
<td>Nurse</td>
<td>Administration port membrane of Minibag/LVI bags is intact and thus is drug-free. Nursing will prime tubing with neutral solution and attach it to administration port. Or: Tubing is attached and then backwashed by main IV line by nursing.</td>
</tr>
<tr>
<td>Minibag/LVI bags (Intermittent Infusion), port not intact</td>
<td>Pharmacy technician in BSC</td>
<td>If pharmacy manipulates the administration port, pharmacy will prime tubing with neutral solution and attached to bag in biological safety cabinet.</td>
</tr>
<tr>
<td>Baxter Infusor</td>
<td>Pharmacy technician in BSC</td>
<td>When preparing Baxter Infusor in BSC, Pharmacy will push in neutral solution (D5W) first to prime the infusion tubing before adding chemotherapy agents.</td>
</tr>
<tr>
<td>CADD 50 mL/100 mL Cassettes</td>
<td>Pharmacy technician in BSC</td>
<td>When preparing CADD Cassettes in BSC, Pharmacy will prepare the CADD Cassette with chemotherapy agents. Then, separately prime the CADD extension tubing with neutral solution before attaching it to the filled cassette. The extension tubing will be primed by pushing D5W into the tubing using a 5-mL syringe.</td>
</tr>
<tr>
<td>CADD adaptor, empty viaflex bag port intact</td>
<td>Nurse</td>
<td>Administration port membrane of Minibag/LVI bags is intact and thus is drug-free. Nursing will prime CADD adaptor with extension tubing with neutral solution and attach it to administration port.</td>
</tr>
<tr>
<td>CADD adaptor, empty viaflex bag, port not intact</td>
<td>Pharmacy technician in BSC</td>
<td>IF pharmacy manipulates the administration port, pharmacy will prime CADD adaptor with extension tubing with neutral solution and attached to bag in biological safety cabinet.</td>
</tr>
<tr>
<td>AIM pump, empty viaflex bag, port intact</td>
<td>Nurse</td>
<td>Administration port membrane of Minibag/LVI bags is intact and thus is drug-free. Nursing will prime tubing with neutral solution and attach it to administration port.</td>
</tr>
<tr>
<td>AIM pump, empty viaflex bag, port not intact</td>
<td>Pharmacy technician in BSC</td>
<td>IF pharmacy manipulates the administration port, pharmacy will prime tubing with neutral solution and attached to bag in biological safety cabinet.</td>
</tr>
</tbody>
</table>

### REFERENCE

RATIONALE

Particulate found in sterile preparations can be a risk to patient safety if it is present in the final product during administration. One potential source of particulate is from coring. Coring can occur during the preparation of parenteral products when the bevel tip and bevel heel of a needle do not penetrate an infusion bag port or vial stopper at the same point, causing particles from the port or stopper to be pushed into the vial or bag.¹

DIRECTIVE

To ensure the highest quality of compounded sterile product, the pharmacy assistant or technician will use standardized procedures to inspect for evidence of particulate or foreign matter and determine the actions to follow.

PROCEDURES

1. Each vial and final product (e.g., infusion bag, Infusor®, syringe) will be checked for particulate after each puncture of a vial stopper or infusion bag port. Vials, syringes, and final products should be thoroughly checked for any particulate by rotating upside down and right side up, while visually inspecting the contents.

2. If particulate is found in a vial or syringe, the BCCA Drug Filtering Chart will be reviewed to identify whether the drug can be filtered.
   a. If the drug cannot be filtered, the vial or syringe will be wasted and a new vial or syringe will be prepared.
   b. If the drug can be filtered, then the vial or syringe will be filtered according to the instructions in Module 1 - Checklists of the BCCA Pharmacy Practice Standards for Hazardous Drugs Manual.

3. If particulate is found in the prepared infusion bag or Infusor®, the PPO or Protocol will be consulted to determine if it is standard practice to use a 0.22 micron in-line filter to administer the preparation.
   a. If use of an in-line filter for administration of the preparation is standard practice, it may be dispensed.
   b. If it is not standard practice to use an in-line filter with the preparation, consult the BCCA Drug Filtering Chart. If the drug can be filtered, consideration may be given to dispensing the preparation along with in-line filter tubing. Pharmacy will communicate with nursing re: the need to use an in-line filter.
   c. If the drug cannot be filtered the preparation must be discarded and remixed. After two unsuccessful attempts (particulate found twice) remix the preparation without a Closed System Drug Transfer Device.

4. Document the occurrence of a particulate in the Sterile Solutions Coring and Particle record.

DEFINITIONS

Coring: Cores form when pieces (particulate) of vial stopper or infusion injection port break off and are deposited into sterile parenteral solution. Coring may be influenced by (i) vial stopper, (ii) needle/spike design and (iii) technique.

REFERENCES

RATIONALE

The labeled drug volume may not be equivalent to the actual drug volume that can be withdrawn from a drug vial. Overfill may occur where there is more drug volume available than the labeled volume. Underfill may occur where there is less drug volume available than the labeled volume. Under or over fill can occur whether a drug requires reconstitution or comes as a ready-to-use liquid from the manufacturer. A consistent procedure is required to ensure the correct dosage is prepared.

DIRECTIVE

The correct volume of drug will always be used when a drug is prepared.

PROCEDURE

1. If necessary reconstitute the drug vial according to the manufacturer’s directions and information in the BCCA Chemotherapy Preparation and Stability Chart. If no reconstitution is required, drug vials are ready for removal of the correct dose.

2. Withdraw the calculated volume for a dose from the vial.
   a. If the total labeled drug volume of the vial cannot be withdrawn (i.e. Underfill), a new vial will be accessed to obtain the correct calculated volume.
   b. If there is significant overfill in the vial and less than the expected number of vials is required to provide the dose, the correct calculated volume will be used for the dose.

REFERENCES

RATIONALE
To minimize the exposure of staff and patients to hazardous drugs, spills must be managed appropriately, according to established policies and procedures.

DIRECTIVE
New employees will be advised of this spill directive and will be required to demonstrate competence in spill control. Training and competency assessment will be documented. Hazardous drug spill control re-familiarization for all employees will be done and documented annually by completing the BCCA Hazardous Spills Pharmacy In-Service on the PHSA LearningHub.

Spill size will determine who is authorized to conduct the cleanup and decontamination and how the cleanup is managed. Refer to details below. This directive applies to Pharmacy areas and staff. Pharmacy staff are not expected to supervise or participate in the clean-up of spills outside of Pharmacy areas.

Spill kit stations will be located in all areas where exposures may occur. These areas should include but are not limited to hazardous drug mixing area, hazardous drug dispensing area, hazardous drug storage area, and hazardous drug receiving area.

PROCEDURES
SPILL KIT CONTENTS
Spill kits bought from a commercial source should be carefully reviewed to ensure they contain all items required under this directive. The contents of the kit should be, wherever possible, latex free.

Spill kits will 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 PHSA 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 (refer to VI-30 Personal Protective Equipment Directive)
2. Two pair of chemotherapy gloves (refer to VI-30 Personal Protective Equipment Directive)
3. Disposable safety goggles or face shield
4. Shoe covers
5. Hair bonnet
6. N95 (e.g. 3M 1870 NIOSH mask) or better disposable respirator mask (note: fit testing of all potential users must be done annually)
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. Disinfecting agent(s) for biohazardous drugs (Select agent(s) from table in Appendix 1)
7. Warning sign and plastic “caution” tape (to quarantine spill area)
8. 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

Personnel Contamination
In the case of any spill, if there is, or potentially is, personnel contamination, either from the spilling or the clean-up of the spill, the following procedures must be followed:
1. Immediately remove contaminated PPE or clothing and discard or label for laundry according to Site Directive.
2. Immediately cleanse the affected skin with soap and water. Use shower if appropriate.
3. In the case of eye exposure, gently flush affected eye(s) at an eyewash fountain or with water or isotonic eyewash solution designated for that purpose for 15 minutes. Hold your eye(s) open with your thumb and finger and look directly into the water stream. Do not rub your eye(s).
4. Seek First Aid or medical attention if required (Inform supervisor if leaving the department).
5. The employee will
   o Contact the Workplace Health Call Centre at 1-866-922-9464 to report the potential HD exposure and/or personal injury
   o Complete a PSLS Safety Event form if a patient or a patient’s medication was involved in the HD spill
   o Complete a PSLS Hazard Event form if there was no patient involvement
   o Inform family doctor or general practitioner of the exposure
6. The department manager will
   o Receive an email from Workplace Health and will document the exposure in the employee’s exposure record

HD Spill Control
This directive is arranged into three categories of spills:
I. spills within a biological safety cabinet (BSC).
II. spills outside of a BSC that may reasonably be contained and cleaned within the Centre’s capacity.
III. spills outside of a BSC that are of a size or extent large enough to be beyond a Centre’s capacity to contain and clean.
I. Clean-up of spills within a BSC

1. Cease all compounding activity
2. Inform supervisor that a spill has occurred.
3. If personnel contamination has occurred, follow Personnel Contamination Procedure. This procedure takes precedence over clean-up of the spill itself.
4. Restrict movement of personnel near the BSC to optimize proper airflow of the BSC and minimize the risk of air spillage, i.e. moving air out the front of the BSC and into the room.
5. If outer gloves have been contaminated by the spill, remove them immediately, within the BSC, and deposit them in the garbage container within the BSC. Remove arms from the BSC and don a new pair of outer gloves before proceeding further.
6. Obtain spill kit.
7. Use contents of spill kit, as appropriate, to clean the spill within the BSC. Liquids should be blotted with absorbent material (gauze pads, spill-control pads, pillows, etc.) Solids should be wiped with wetted absorbent material in such a way as to limit their spread.
8. Any broken glass fragments should be picked up using a scoop (never the hands) and placed in a sharps container. The container should then go into a HD disposal bag, along with all other contaminated waste.
9. If a biohazardous drug is spilled, specific disinfecting agents that are effective for the spilled biohazardous drug (See Appendix 1) must be applied for the required contact time to disinfect the contaminated surfaces prior to continuing with the following decontamination steps.
10. The spill area should be decontaminated by cleaning three times using a basic (i.e. pH 8-9) detergent solution followed by water (Detergent-Water-Detergent-Water-Detergent-Water).
11. In the event of a HD spill directly onto a HEPA filter, the BSC should be left running and labelled - DO NOT USE- until the filter can be changed and disposed of properly by trained personnel wearing appropriate PPE.
12. All clean-up materials should be in sealed containers prior to removal from the BSC and ultimately contained in a rigid closed container labelled as HD waste. PPE used during the clean-up should at the completion of the job be contained in the same manner. Containers should be disposed of in an appropriate manner in accordance with all applicable federal, provincial and municipal regulations.
13. Spills within a BSC necessitate decontamination of all interior BSC surfaces after completion of the spill clean-up as outlined in the BCCA Pharmacy Directive VI-20; Biological Safety Cabinet (BSC) Decontamination.
14. Following decontamination, aseptic conditions should be re-established by disinfecting surfaces with alcohol and then purging circulating air by allowing the BSC fan/blower to run for thirty minutes.
15. The employee will
   - Contact the Workplace Health Call Centre at 1-866-922-9464 to report the potential HD exposure and/or personal injury.
   - Complete a PSLS Safety Event form if a patient or a patient's medication was involved in the HD spill.
   - Complete a PSLS Hazard Event form if there was no patient involvement
   - Inform family doctor or general practitioner of the exposure.
16. The department manager will
   - Receive an email from Workplace Health and will document the exposure in the employee’s exposure record.
17. All used items from the Spill Kit should be replaced immediately following the clean-up.
II. Clean-up of spills outside of a BSC that may reasonably be contained and cleaned within the Centre's capacity

1. Isolate the area and alert all individuals in the area of the spill to prevent spread of the spill.
2. Reasonably restrict the number of personnel involved in the clean-up. Never work alone.
3. Inform supervisor that a spill has occurred.
4. If personnel contamination has occurred, or potentially has occurred, follow Personnel Contamination Procedure. This procedure takes precedence over clean-up of the spill itself.
5. Obtain spill kit.
6. Don PPE, as appropriate to the spill.
7. Limit spread of the spill through use of absorbent sheets or spill control pads. If a powder is involved, damp cloths or towels should be used.
8. Avoid aerosol generation and dispersal of powder or liquid spilled.
9. Use contents of spill kit, as appropriate, to clean the spill. Liquids should be blotted with absorbent material (gauze pads, spill-control pads, pillows, etc.); solids should be wiped with wetted absorbent material in such a way as to limit their spread.
10. Any broken glass fragments should be picked up using a scoop (never the hands) and placed in a sharps container. The container should then go into an HD disposal bag, along with all other contaminated waste.
11. If a biohazardous drug is spilled, specific disinfecting agents that are effective for the spilled biohazardous drug (See Appendix 1) must be applied for the required contact time to disinfect the contaminated surfaces prior to continuing with the following decontamination steps.
12. The spill area should be decontaminated by cleaning three times using a basic (i.e. pH 8-9) detergent solution three times followed by water (Detergent-Water-Detergent-Water-Detergent-Water).
13. This process should be done by Pharmacy or Housekeeping staff as has been delineated in site-specific Housekeeping contracts – refer to Site Directive.
14. All clean-up materials should be placed in sealed containers and ultimately contained in a rigid closed container labelled as HD waste. PPE used during the clean-up should at the completion of the job be disposed of in the same manner. Dispose of all spill cleanup materials in an HD waste container in accordance with all applicable federal, provincial and municipal regulations.
15. The employee will
   a. Contact the Workplace Health Call Centre at 1-866-922-9464 to report the potential HD exposure and/or personal injury.
   b. Complete a PSSL Safety Event form if a patient or a patient's medication was involved in the HD spill.
   c. Complete a PSSL Hazard Event form if there was no patient involvement
   d. Inform family doctor or general practitioner of the exposure.
16. The department manager will
   a. Receive an email from Workplace Health and will document the exposure in the employee’s exposure record.
17. All used items from the Spill Kit should be replaced immediately following the clean-up.
III. Clean-up of spills outside of a BSC that are of a size or extent large enough to be beyond a Centre’s capacity to contain and clean

1. Alert all individuals in the area of the spill to prevent spread of the spill and then isolate the area to prevent personnel exposure to the HD.
2. Avoid aerosol generation and dispersal of powder or liquid spilled.
3. Inform supervisor that a spill has occurred.
4. If personnel contamination has occurred, or potentially has occurred, follow Personnel Contamination Procedure.
5. Upon confirming that size of the spill is beyond the Centre’s capacity to contain and clean, the supervisor will call for the external Hazardous Material (HazMat) Response Team according to the Site Directive e.g. Code Brown.
6. Remain available to the HazMat team to provide details about the HD spilled, the quantity spilled and the circumstances and extent of contamination.
7. The employee(s) involved in the spill will
   - Contact the Workplace Health Call Centre at 1-866-922-9464 to report the potential HD exposure and/or personal injury.
   - Complete a PSL Safety Event form if a patient or a patient’s medication was involved in the HD spill.
   - Complete a PSLS Hazard Event form if there was no patient involvement
   - Inform family doctor or general practitioner of the exposure.
8. The department manager will
   - Receive an email from Workplace Health and will document the exposure in the employee’s exposure record.
9. All items used from the Spill Kit should be replaced immediately following the clean-up.

DEFINITIONS

Biohazardous Drug: A drug containing living organisms with potential to cause infections in humans. Biohazardous drugs are considered hazardous drugs and will be included on the NIOSH HD List or BCCA HD List Addendum. Note: Biohazardous drugs may include gene therapy, biologicals and/or biohazards.

Chemotherapy Gloves: Such gloves must meet the ASTM standard D 6978-05 or an equivalent standard (as required by the USA FDA). Usually they are 0.1 mm or more in thickness (more than the 0.08 mm minimum allowed for examination gloves) as outlined in BCCA Pharmacy Directive VI-30: Personal Protective Equipment.

Decontamination: The removal or inactivation of hazardous drug from a surface, through chemical inactivation, or removal from a non-disposable surface to a disposable surface (e.g. gauze) by use of a cleaning agent. See also BCCA Pharmacy Directive VI-20; Biological Safety Cabinet (BSC) Decontamination.

Disinfect/Disinfection: The destruction and removal of disease-causing pathogens/microorganisms from surfaces or inanimate objects through the application and removal of a disinfecting agent.¹

Disinfecting Agent: Agent capable of destroying (inactivating) disease-causing pathogens/microorganisms when applied to surfaces or inanimate objects.
VI-10: Hazardous Drug Spill Control in Pharmacy

**Effective Date:** June 14, 2006
**Approved by:** Provincial Pharmacy Professional Practice Council

**Review Date:**
Revision Date: Jan 2010, March 2010, Sep 2012, April 2013, September 2013, January 7, 2015

**Hazardous Drug (HD):** Drug that exhibits one or more of the following characteristics in humans and/or animals: carcinogenicity, teratogenicity or other developmental toxicity, reproductive toxicity, organ toxicity at low doses, genotoxicity and structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the five previous criteria. If there is no information found and the drug is primarily used as an antineoplastic agent, it will be deemed as hazardous. If a drug contains living organisms with potential to cause infections in humans it will be considered a hazardous drug and will be designated a biohazardous drug on the NIOSH HD List or BCCA HD List Addendum. Note: Hazardous drugs have been referred to as “cytotoxic, antineoplastic, hazardous, and/or chemotherapy”.

**HEPA filter:** High Efficiency Particulate Air filters found in most Biological Safety Cabinets that trap approximately 99.9% of particulate matter 0.3 micron size or greater to provide ultra clean air.

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

**PPE:** Personal Protective Equipment- Items such as gloves, gowns, respirators, goggles, face shields, and others that protect individual workers from hazardous physical or chemical exposures outlined in BCCA Pharmacy Directive VI-30: Personal Protective Equipment.

**Respirator:** A type of PPE that prevents harmful materials from entering the respiratory system, usually by filtering hazardous agents from workplace air, and meeting NIOSH and OSHA standards for use with hazardous drugs as outlined in BCCA Pharmacy Directive VI-30: Personal Protective Equipment.

**Spill:** Any unintentional, uncontained dispersal of a compound.

**Spill kit station:** Designated location where supplies and personal protective equipment (PPE) are stored in preparation for cleaning up a spill. Each station should be clearly identified with a label that includes the words “Hazardous Drug Spill Kit”. If kits are stored within a cupboard, the outermost door of the cupboard must be labelled.
VI-10: Hazardous Drug Spill Control in Pharmacy

Effective Date: June 14, 2006

Approved by: Provincial Pharmacy Professional Practice Council

Review Date:

Revision Date: Jan 2010, March 2010, Sep 2012, April 2013, September 2013, January 7, 2015

REFERENCES

1. ASCO 2004 “Criteria for Facilities and Personnel for the Administration of Parenteral Systemic Antineoplastic Therapy” [JCO 2004; 22(22)]
4. CSHP 1997 Guidelines for the Handling and Disposal of Hazardous Pharmaceuticals (Including Cytotoxic Drugs)
5. DHHS/CDC 2004 NIOSH Alert: Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings
6. OSHA (www.osha.gov) Laws and Regulations > Standards > Part 1910 (Occupational Safety and Health Standards)
7. PHSA EWS Portal Toolkit document "If you get something in your eyes"
8. WorkSafe BC Regulations, Part 6: Substance specific requirements: Cytotoxic drugs
13. PCS product label (on file)
14. Email from NCIC; Jean Powers; March 2013 (on file)
15. NCIC. Reolysin Trials; NCIC Frequently Asked Questions (FAQ); 2012 September 2012
Appendix 1

Biohazardous Drugs - Surface Disinfection Table

<table>
<thead>
<tr>
<th>Biohazardous Drug</th>
<th>Recommended Disinfecting Agent</th>
<th>Alternative Recommended Disinfecting Agent</th>
<th>Contact time (surfaces must be wet)</th>
<th>Other instructions</th>
<th>BSC Purge Time</th>
</tr>
</thead>
</table>
| Reovirus Serotype 3- Dearing Strain (Reolysin®) | 800ppm* Javex Bleach$^{11}$ | Surface Safe$^{8,15}$ | 30 seconds | 1. Follow disinfection with neutralizing agent**
2. Wipe surfaces with sterile water for irrigation to remove residue | 15 minutes |
| Bacillus Calmette-Guerin (BCG) | Cavicide® Solution$^{12}$ | | 3 minutes | Follow disinfection by wiping surfaces with 70% alcohol | 15 minutes |

*800ppm Javex Bleach (1/75)$^{11} = 7$ mL regular strength (5-7%) bleach qs’d to 500 mL Sterile Water for Irrigation

**Neutralizing agent - 1% Sodium Thiosulfate Solution = 316 mL sodium thiosulfate (1.58%) solution qs’d to 500 mL with Sterile Water for Irrigation
RATIONALE

Hazardous drugs for topical and parenteral administration are prepared in a Biological Safety Cabinet (BSC). Studies have shown that this environment becomes contaminated with the hazardous drug during preparation of the product. Routine decontamination of the BSC is necessary to maintain a contaminant-free environment and to reduce the potential health risks associated with exposure of hazardous drug(s) to health care workers preparing and handling the product.

DIRECTIVE

New employees will be advised of this decontamination directive and actively trained in the process. Such training will be documented. Decontamination will be done on a regular basis at least once weekly, and following a drug spill (see Pharmacy Directive VI-10 Hazardous Drug Spill control in Pharmacy), maintenance and testing, voluntary interruption of the BSC or relocation of the cabinet. The decontamination process will be documented each time it is completed.

DEFINITIONS

Decontamination – The removal or inactivation of hazardous drug from a surface, through chemical inactivation, or removal from a non-disposable surface to a disposable surface (e.g. gauze) by use of a cleaning agent.

Personal Protective Equipment (PPE) – items such as gloves, gowns, respirators, goggles, face shields, and others that protect individual workers from hazardous physical or chemical exposures outlined in BCCA Provincial Pharmacy Directive VI-30: Personal Protective Equipment.

Hazardous Drug (HD): Drug that exhibits one or more of the following characteristics in humans and/or animals: carcinogenicity, teratogenicity or other developmental toxicity, reproductive toxicity, organ toxicity at low doses, genotoxicity and structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the five previous criteria. If there is no information found and the drug is primarily used as an antineoplastic agent, it will be deemed as hazardous. If a drug contains living organisms with potential to cause infections in humans it will be considered a hazardous drug and will be designated a biohazardous drug on the NIOSH HD List or BCCA HD List Addendum. Note: Hazardous drugs have been referred to as “cytotoxic, antineoplastic, hazardous, and/or chemotherapy”.

PROCEDURES

To protect others from potential exposure to hazardous drugs, only personnel participating in the decontamination process shall be present in the chemotherapy preparation room or in the area of the biological safety cabinet (BSC).

Supplies

Personal Protective Equipment (PPE) and apparel worn for the procedure includes, but is not limited to the following:

- Disposable gown made of polyethylene-coated polypropylene material (non-linting, non-absorbent), with closed front, long sleeves and elastic or knit closed cuffs.
- Two pairs of chemotherapy gloves (see BCCA Chemotherapy Glove Policy) resistant to possible contaminant and chemically stable to inactivating or cleaning agent. Ensure first pair of gloves is covered by cuff of gown, and second pair of gloves covers over cuff of gown, to prevent skin exposure.
Eye protection, in the form of safety glasses with side shields or full face shield.

National Institute for Occupational Safety and Health (NIOSH) approved respirator (e.g. N95), appropriately fit tested for operator.

Eye protection and NIOSH approved respirator for decontamination, if not disposable, must be cleaned and maintained according to manufacturer's recommendation to ensure continued operator protection for future use.

Disposable hair bonnet

Materials required for procedure include the following:

- Detergent with pH 8-9
- Hot water (60°C)
- Sterile water for irrigation (SWI)
- Gauze or absorbent towels
- 70% isopropyl alcohol (IPA)
- Disposable plastic or reusable metal containers for detergent, water and IPA (e.g. plastic chemo waste bucket for detergent and water, plastic dispensing bottle for IPA)
- Sealable plastic bag (for waste generated in BSC)
- Plastic backed disposable liner

Process

1. Gather supplies and PPE.
2. Prepare sufficient aqueous detergent solution in a disposable plastic or reusable metal container (e.g. 5mL detergent diluted in 250mL SWI).
3. Transfer sufficient SWI (e.g. 250 - 500mL) to a disposable plastic container, or washable metal container. If possible, purchase SWI in a single use quantity.
4. Transfer sufficient IPA (e.g. 100 – 250mL) to a disposable plastic container, or washable metal container.
5. Place aqueous detergent solution, SWI and IPA containers on a plastic backed disposable liner outside of the BSC when not in use.
6. Scrub, glove, gown and don PPE as per standard aseptic and safe handling standards.
7. Ensure cabinet remains in operational mode with internal blower on.
8. Leave removable parts of the BSC, which are considered contaminated, in the BSC during the decontamination process.
9. Open the hinged or sliding viewing window and secure in full open position.
10. Hang sealable plastic bag on hook in the BSC to deposit contaminated waste. All contaminated waste generated throughout the procedure shall be collected in a sealable plastic bag in the BSC.
11. Using aqueous detergent solution, dampen a clean low lint cloth on work surface tray of BSC. A single piece of cloth will be used only once then discarded (i.e. no “double-dipping” of gauze if using an open bucket or bowl).
12. Working from top to bottom, and back to front (i.e. from cleaner area to more contaminated area), clean all inside surfaces of the cabinet with aqueous detergent solution (i.e. ceiling grill, back wall, fixtures, side walls, and work surface). Press gently on ceiling grill, to prevent wetting or damaging HEPA filter. To decontaminate lower portion of BSC, lift work surface tray and place against back wall, or have a second appropriately gowned personnel hold tray against wall. Wipe the under surface of tray and both sides of the front grill. Wipe the exposed drain spillage trough area twice, as this is the most heavily contaminated area. Ensure a firm hold on cleaning material to prevent suction into airflow.

13. Rinse with SWI to remove detergent residue.

14. Pour (do not spray) IPA onto gauze or absorbent cloth and use to wipe all surfaces.

15. Pull viewing window down and clean both sides with detergent, SWI and IPA to remove any touch contamination.

16. Wipe outer area of BSC with detergent and SWI to remove any drip or touch contamination.

17. Purge BSC for 30 minutes prior to aseptic operation.

18. Dispose all PPE, supplies and sealed contaminated waste from BSC in appropriate chemotherapy waste containers after completion of the procedure.


REFERENCES

1. DHHS/CDC 2004 NIOSH Alert: Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings


7. Sterile Manufacturing Service Biological Safety Cabinet (BSC) Type B2 - Decontamination: Policy no. 4.7.10. Vancouver Island Health Authority (South Island); 2003.


**RATIONALE**

Pharmacy staff handles Hazardous Drugs (HDs) while receiving, storing, preparing and disposing of oral, parenteral and topical dosage forms when involved in the delivery of cancer care. The work environment may become contaminated with HDs when they are handled. The wearing of Personal Protective Equipment (PPE) will minimize pharmacy workers’ exposure to HDs by providing a physical barrier to extraneous drug particles on surfaces or those generated during the compounding process. Appropriately worn and used PPE also minimizes the particulate burden within the sterile preparation area and reduces the spread of HD contamination into areas outside the work environment.

**DIRECTIVE**

Protective equipment and clothing must be provided and used to minimize or prevent unnecessary exposure to hazardous drugs. Criteria must be provided to staff for the selection and appropriate use of PPE. New employees will be advised of this PPE directive and will be required to demonstrate competence in the appropriate use of PPE. Training and competency assessment will be documented. All employees will review this directive as part of their annual training requirements.

**Criteria for Selection of PPE Worn to Protect from HD Contamination and Minimize Particulate**

PPE will not be assumed to be suitable for use with HDs simply because it is advertised this way by the manufacturer. Suitability must be confirmed by checking that it meets approved criteria.

**Chemotherapy Gloves**

Required Properties:\(^2^4\)

- passes permeation testing with nine chemotherapy agents as required by the American Society for Testing and Materials (ASTM) Standard 6978-05 (*Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Gloves*)\(^5\)
- made of latex, nitrile, neoprene or polyurethane (latex-free is preferable due to increasing incidence of latex allergies)
  - Gloves made of material other than latex, nitrile, neoprene or polyurethane may be used if documentation of approved testing for impermeability to chemotherapy can be provided\(^6\)
- powder-free
- sufficient length to cover gown cuff, when worn in conjunction with a chemotherapy gown

Divided into two classifications:

- **Sterile Chemotherapy Gloves** are sterile gloves (usually surgeons gloves) that meet the above criteria
- **Non-Sterile Chemotherapy Gloves** are non-sterile gloves (usually examination gloves) that meet the above criteria
Chemotherapy Gowns

Required properties:
- non-linting
- closed-front, covers from shoulders to knees and fastens/ties in the back
- long sleeves with tight-fitting cuffs
- disposable
- made of material that is sufficiently impermeable to hazardous drugs

Examples of Sufficiently Impermeable Materials
- specific constructions of polypropylene including:
  - polypropylene/molten polyethylene backing
  - spunbonded polypropylene polyethylene coating
  - Spunbond/Melt blown/spunbond nonwoven in one or multiple layers
  - Spunbond/Melt blown/spunbond nonwoven with polyethylene film
  - ethylene/vinyl acetate copolymer laminated with Tyvek
- any material or combination of materials that the manufacturer can show has been tested to be impermeable or slightly permeable to chemotherapy drugs. Permeability testing should be done using both water-based and non-water-based drugs as differences in penetration have been shown to occur.

Examples of Materials that are NOT Sufficiently Impermeable
- single layer polypropylene spunbond nonwoven
- polypropylene polyethylene copolymer spunbond alone

Respirator Masks

Definitions and Required properties:
A NIOSH-approved respirator mask is suitable for use with HDs. Respirator masks used for HDs must be N95 or better to protect against airborne particles. The number 95 refers to the percentage of particles that are filtered. The letter refers to protection against oils: N is not resistant to oil, R is somewhat resistant, and P is strongly resistant (oil proof). Respirators for HDs can be N, R or P. Examples of suitable filters include N95, N99, N100, R95, R99, R100, P95, P99 and P100.

There are three kinds of NIOSH-approved respirators available:
- Disposable or filtering face piece respirator with built in filters
- Reusable or elastomeric respirator mask with filter attachments
- Powered Air Purifying Respirator (PAPR) masks

When the operator breathes while wearing a disposable and elastomeric respirator, air is drawn in through the filter. PAPRs contain battery operated motor blowers that deliver air to a filter and then to the face piece for the operator to breath. PAPRs suitable for use with HD’s should contain NIOSH high efficiency (HE) filters which are comparable to the 100 level filters listed above.
Protective Eyewear

Required Properties:
- safety goggles with side shields or transparent full face splash shield
- may be disposable or reusable
- fit comfortably so they don’t fall off during use
- reusable protective eyewear must be compatible with the cleaning agent

Criteria for Selection of PPE Worn to Minimize Particulate

Surgical masks, hair, beard and shoe covers are worn to minimize the particulate burden in the sterile preparation room rather than for protection against HD exposure. Shoe covers are worn to avoid the spread of HD contamination to areas outside of the immediate HD sterile preparation area or HD spill site.

Shoe Covers

Required properties:
- sizes available to fit over all shoes
- non-slip bottoms
- low-lint material

Surgical Masks

Required properties:
- fit over nose and mouth and cover the chin
- affix around ears for a firm fit (elastic) or tie in two places (the back of the head and the back of the neck)
- low-lint material

Hair and Beard Covers

Required properties:
- disposable or washable
- low-lint material
- fit firmly (e.g. elastic)
- fit so that hair/beard is completely contained/covered (may require 2 covers)

PROCEDURES:

Appropriate PPE must be worn for all activities where HD exposure is possible. The “Required Personal Protective Equipment by Activity” table on the following pages outlines the PPE required for different situations when handling HDs.
## General Procedures for all PPE

- inspect for deformities such as rips, tears or missing ties prior to use
- all used disposable PPE must be discarded in HD waste containers
- non-disposable PPE may be cleaned with aqueous alkaline detergent solution and water for re-use
- wash hands after removing or disposing of PPE
- any staff entering the sterile preparation room must don the following PPE:
  - two pairs of chemotherapy gloves
  - chemotherapy gown
  - hair/beard cover(s)
  - shoe covers
  - surgical mask or a respirator mask, depending on activity (see Required Personal Protective Equipment by Activity table on page 6)

## Chemotherapy Glove Procedures

1. Two pairs of chemotherapy gloves must be worn for all activities that may result in exposure to HD.
2. Both pairs of chemotherapy gloves worn when compounding inside the BSC must be sterile.\(^\text{10}\)
3. For procedures performed outside of the BSC, two pairs of sterile or non-sterile chemotherapy gloves must be worn for all activities that may result in exposure to HD.
4. All glove types must be changed every thirty minutes or when torn, punctured or in the event of suspected contamination.
   
   Note: Gloves should be changed more often when handling drugs such as carmustine or thiotepa when specified by the glove manufacturer that ASTM 6978-05 testing showed faster glove permeation by these agents
5. Hands must be washed prior to donning gloves and immediately upon removal.

## Chemotherapy Gowns Procedures

1. Regularly dispose of chemotherapy gowns at the end of each work shift.
2. Immediately dispose of chemotherapy gowns in the event of any suspected HD contamination.
3. Removal of chemotherapy gowns for storage or disposal should be done with care to avoid the possible spread of HD contamination to other non-contaminated garments.
4. Chemotherapy gowns should be removed for storage or disposal while still in the HD work area. They should not be worn into the general pharmacy working areas to prevent spread of HD contamination from one area to another.
5. Gowns may be temporarily stored in the HD work area for reuse during the same shift.
Respirator Procedures

1. Respirator masks must be worn when cleaning or decontaminating the BSC and when disinfecting the BSC following biohazardous drug preparation if the viewing window is raised, cleaning up a HD spill outside the BSC, or cleaning inside a refrigerator used for storing HD liquids or HD parenteral dosage forms.
2. Staff must perform a seal test after donning a respirator mask.
3. All staff must be fit-tested prior to initial use of disposable or filtering face piece respirators and retested at least once a year, and when there is a change in the respirator face piece, or when a user’s physical condition changes affecting the fit if they are using filtering face piece respirator masks.
4. Elastomeric and PAPR masks do not require fit-testing.
5. Once removed, disposable respirator masks must be immediately discarded into HD waste containers, not saved for reuse.
6. Clean reusable PAPR respirators according to the manufacturer’s directions.
7. Clean reusable portion of elastomeric masks according to the manufacturer’s directions. Discard disposable filter portion into HD waste disposal bin.

Protective Eyewear Procedures

1. Safety goggles or face shield must be worn whenever there is a risk of splashing, for example cleaning, disinfecting or decontaminating a BSC with the viewing window raised, when cleaning up a hazardous drug spill outside the BSC, or when cleaning the inside a refrigerator used for storing HD liquids or HD parenteral dosage forms.
2. Reusable safety goggles or face shield may be washed with aqueous alkaline detergent solution and water for re-use. If HD contamination is suspected, they must be discarded in a hazardous waste container.
3. If possible, glasses should be worn for vision correction while preparing hazardous drug IV admixtures. When glasses are worn for vision correction, safety goggles or face shield must be worn over prescription eye glasses when there is a risk of splashing.

Required Personal Protective Equipment by Activity

See the table on the following pages for PPE by activity.
## VI-30: Personal Protective Equipment (PPE)

**Effective Date:** March 17, 2010  
**Approved by:** Provincial Pharmacy Professional Practice Council

**Review Date:**  
**Revision Date:** July 31, 2013

### Required Personal Protective Equipment by Activity

**Activities that require the same PPE regardless of location**

<table>
<thead>
<tr>
<th>Activity</th>
<th>Chemo Gloves</th>
<th>Chemo Gown</th>
<th>Hair/Beard Cover</th>
<th>Respirator Mask</th>
<th>Surgical Mask</th>
<th>Safety goggles</th>
<th>Shoe Covers</th>
</tr>
</thead>
<tbody>
<tr>
<td>HD Spill cleanup/receiving HD shipments that appear to be damaged</td>
<td>Yes(^3,4,8-11)</td>
<td>Yes(^3,4,8,9,11)</td>
<td>Yes(^4,8,9,11)</td>
<td>Yes(^4,8,9,11)</td>
<td>No(^3,4)</td>
<td>Yes(^3,4,8,9,11)</td>
<td>Yes(^4,8,9,11)</td>
</tr>
<tr>
<td>Cleaning inside refrigerators used for storing HD liquids or HD parenteral dosage forms</td>
<td>Yes(^3)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes(^3)</td>
<td>No</td>
<td>Yes(^3)</td>
<td>Yes Walk in</td>
</tr>
</tbody>
</table>

**Activities performed in the sterile preparation room inside the BSC**

<table>
<thead>
<tr>
<th>Activity</th>
<th>Chemo Gloves</th>
<th>Chemo Gown</th>
<th>Hair/Beard Cover</th>
<th>Respirator Mask</th>
<th>Surgical Mask</th>
<th>Safety goggles</th>
<th>Shoe Covers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decontaminating/cleaning/disinfecting inside BSC with the viewing window raised</td>
<td>Yes(^4,8,9,11)</td>
<td>Yes(^4,8,9,11)</td>
<td>Yes(^4,8-11)</td>
<td>Yes(^4,8,9,11)</td>
<td>No</td>
<td>Yes(^4,8,9,11)</td>
<td>Yes(^4,8-11)</td>
</tr>
<tr>
<td>Cleaning inside the BSC without raising the viewing window</td>
<td>Yes(^4,8,9)</td>
<td>Yes(^4,8)</td>
<td>Yes(^8-10)</td>
<td>No</td>
<td>Yes(^8-10)</td>
<td>No</td>
<td>Yes(^4,8-10)</td>
</tr>
<tr>
<td>Compounding</td>
<td>Yes(^3,4,8-11)</td>
<td>Yes(^3,4,8-11)</td>
<td>Yes(^4,8-11)</td>
<td>No*</td>
<td>Yes(^8-11)</td>
<td>No*</td>
<td>Yes(^4,8-11)</td>
</tr>
<tr>
<td>Preparing non-sterile doses (oral, topical)</td>
<td>Yes(^4,8-10)</td>
<td>Yes(^4,8-10)</td>
<td>Yes(^9,10)</td>
<td>No*</td>
<td>Yes(^9,10)</td>
<td>No*</td>
<td>Yes(^4,9,10)</td>
</tr>
</tbody>
</table>

*The viewing window must remain at the manufacturer’s recommended level, therefore no respirator mask or eye/face protection is required.*

**Activities performed in the sterile preparation room outside the BSC**

<table>
<thead>
<tr>
<th>Activity</th>
<th>Chemo Gloves</th>
<th>Chemo Gown</th>
<th>Hair/Beard Cover</th>
<th>Respirator Mask</th>
<th>Surgical Mask</th>
<th>Safety goggles</th>
<th>Shoe Covers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Handling and labeling HDs that have been manufactured in the BSC</td>
<td>Yes(^4,8,10)</td>
<td>Yes(^3,8,10)</td>
<td>Yes(^8,10)</td>
<td>No</td>
<td>Yes(^8,10)</td>
<td>No</td>
<td>Yes(^4,8,10)</td>
</tr>
<tr>
<td>Cleaning shelves and counter/ desk tops where HDs are received and/or stored</td>
<td>Yes(^3,8,9)</td>
<td>Yes(^8,9)</td>
<td>Yes(^8-10)</td>
<td>No</td>
<td>Yes(^8-10)</td>
<td>Yes(^8)</td>
<td>Yes(^4,8,10)</td>
</tr>
<tr>
<td>Moving inventory, housekeeping, or any activity not listed above</td>
<td>Yes(^4,8,10)</td>
<td>Yes(^3,8,10)</td>
<td>Yes(^8,10)</td>
<td>No</td>
<td>Yes(^8,10)</td>
<td>No</td>
<td>Yes(^4,8,10)</td>
</tr>
<tr>
<td>Bundling HD waste for removal from pharmacy</td>
<td>Yes(^4,8,10)</td>
<td>Yes(^4,8)</td>
<td>Yes(^8,10)</td>
<td>No</td>
<td>Yes(^8,10)</td>
<td>No</td>
<td>Yes(^4,8,10)</td>
</tr>
</tbody>
</table>
### VI-30: Personal Protective Equipment (PPE)

**Effective Date:** March 17, 2010  
**Approved by:** Provincial Pharmacy Professional Practice Council  
**Review Date:**  
**Revision Date:** July 31, 2013

#### Required Personal Protective Equipment by Activity

**Activities performed outside of the sterile preparation room/area**

<table>
<thead>
<tr>
<th>Activity</th>
<th>Chemo Gloves</th>
<th>Chemo Gown</th>
<th>Hair/Beard Cover</th>
<th>Respirator Mask</th>
<th>Surgical Mask</th>
<th>Safety goggles</th>
<th>Shoe Covers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Handling and labelling HDs that have been manufactured in the BSC</td>
<td>Yes(^4,10)</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Cleaning shelves, counters and desk surfaces where HDs are received and/or stored</td>
<td>Yes(^4)</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Unpacking intact shipments of HD inventory (NOT damaged)</td>
<td>Yes(^3,4,9-11)</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Transporting vials and potentially contaminated dosage forms to pharmacy work areas</td>
<td>Yes(^3,4,9,10)</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Bundling HD waste for removal from pharmacy</td>
<td>Yes(^4,10)</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Handling loose oral dosage forms of HD tablets or capsules (e.g. counting or placing in blister packs)</td>
<td>Yes(^4,11,12)</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Handling HD oral dosage forms that are provided in a primary dispensing container</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Handling packages of pre-filled syringes containing HD provided by the manufacturer (e.g., LHRH)</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

*Primary dispensing containers include: intravenous solution bags, elastomeric infusors, syringes, vials, ampoules, ointment jars, sealable poly bags, blister cards, manufacturer supplied packaging, or prescription vials*
DEFINITIONS

Biohazardous drug - A drug containing living organisms with potential to cause infections in humans. Biohazardous drugs are considered hazardous drugs and will be included on the NIOSH HD List or BCCA HD List Addendum. Note: Biohazardous drugs may include gene therapy, biologicals, and/or biohazards.

Biological Safety Cabinet (BSC) - A ventilated cabinet having an open front with inward airflow for personnel protection, HEPA-filtered downward airflow for product protection, and HEPA-filtered exhaust air for environmental protection.

Hazardous Drug (HD): Drug that exhibits one or more of the following characteristics in humans and/or animals: carcinogenicity, teratogenicity or other developmental toxicity, reproductive toxicity, organ toxicity at low doses, genotoxicity and structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the five previous criteria. If there is no information found and the drug is primarily used as an antineoplastic agent, it will be deemed as hazardous. If a drug contains living organisms with potential to cause infections in humans it will be considered a hazardous drug and will be designated a biohazardous drug on the NIOSH HD List or BCCA HD List Addendum. Note: Hazardous drugs have been referred to as “cytotoxic, antineoplastic, hazardous, and/or chemotherapy”.

Personal Protective Equipment (PPE) – Items such as gloves, gowns, respirators, goggles, face shields, and others that protect individual workers from hazardous physical or chemical exposures.
REFERENCES


RATIONALE

Occupational exposure to certain drugs may be hazardous to the health of healthcare workers who handle them. Hazardous drugs (HD) have the potential for causing cancer, developmental, reproductive and genetic toxicity, or harm to organs based on studies in animals and/or humans. HDs must be identified in the workplace and workers who handle them must utilize safe handling practices to minimize exposure to these agents.\(^1,2\)

Some hazardous drugs may pose less risk for 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 HD safe handling precautions may increase the worker’s risk of direct exposure.\(^1\)

DIRECTIVE

All HD dosage forms must be handled appropriately to avoid personal contact (i.e. skin, eyes, and mouth), the release of powdered, liquefied or aerosolized drug into the air, and cross contamination with other drugs.

PROCEDURES

Hazardous Drug Spill Control

Spill cleanup of all hazardous drug dosage forms must be handled according to the procedures described in the BCCA Pharmacy Directive VI-10: Hazardous Drug Spill Control in Pharmacy.

Sterile Hazardous Drug Preparation

Follow the procedures in the BCCA Pharmacy Practice Standards for Hazardous Drugs Manual – Module 1-Section E for the safe preparation of sterile hazardous drugs and disposal of potentially contaminated supplies and PPE.

Sterile Biohazardous Drugs

The following additions/exceptions to procedures found in BCCA Pharmacy Practice Standards for Hazardous Drugs Manual Module 1-Section E apply when handling sterile biohazardous drugs:

1. A sign incorporating the universal biohazard symbol must be posted on:
   - the biohazardous drug storage bins/shelves,
   - the outside of the fridge where biohazardous drugs are stored, and
   - at the entrance to the room where biohazardous drugs are prepared.\(^3\)

2. All surfaces, inside the BSC or outside the BSC (e.g., countertop where the BCG was prepared) must be disinfected after biohazardous drug preparation is finished using an effective disinfecting agent - for the required surface contact time (see Appendix 1).

3. The BSC must purge for 15 minutes after disinfecting, before preparing a different drug.
Provincial Pharmacy Directive

VI-40: Safe Handling and Preparation of Hazardous Drug Dosage Forms

<table>
<thead>
<tr>
<th>Effective Date: March 17, 2010</th>
<th>Approved By: Provincial Pharmacy Professional Practice Council</th>
</tr>
</thead>
</table>

4. Chemotherapy gloves and gown must be removed and disposed of into biohazardous (cytotoxic, hazardous) waste, hands washed, and then **new PPE donned before the preparation of a different drug in the BSC**.

5. Dispensed biohazardous drugs must be labelled as 'BIOHAZARDOUS'.

**Note:**
- Preparation of drugs in other BSCs in the same sterile preparation room may take place while biohazardous drugs are being prepared.
- Pharmacy personnel that must be present in the sterile preparation room during the cleaning (disinfecting) process must wear an N95 or better respirator mask in addition to all other PPE, while the BSC viewing window is raised.

**Bacillus Calmette-Guerin (BCG)** is on the NIOSH Hazardous Drug List and meets the BCCA definition of a biohazardous drug. Additional considerations for BCG:

- BCG preparation should be done using aseptic techniques. ⁴
- To avoid cross-contamination, parenteral drugs should not be prepared in areas where BCG has been prepared. A separate area for the preparation of BCG suspension is recommended. ⁴
- All equipment, supplies, and receptacles in contact with BCG should be handled and disposed of as biohazardous. ⁴
- If preparation cannot be performed in a containment device, then respiratory protection, gloves and a gown should be worn to avoid inhalation or contact with BCG organisms ⁴. (BCCA safe handling standards require an N95 or better respirator mask, two pairs of chemotherapy gloves and a chemotherapy gown be worn)
- Beyond use date of one hour must be assigned to sterile preparations (e.g., BCG) prepared outside of an ISO Class 5 environment (BSC). ⁵

**Unit Dose Pre-filled Hazardous Drug Syringes**

1. Boxes of unit dose HD injections in pre-filled syringes from the manufacturer (e.g., LHRH agonist hormonal agents) may be handled without donning chemotherapy gloves or gowns.

2. All dispensed unit dose pre-filled HD syringes must be labelled as 'HAZARDOUS' indicating that HD safe practices must be followed while handling the drug. ⁴, ⁶

**Non-Sterile Hazardous Drug Preparation**

**Oral Hazardous Drugs**

1. HD tablets and capsules packaged in unit dose pre-packaged blister strips or sachets from the manufacturer may be handled without donning chemotherapy gloves or gowns.

2. Two pairs of chemotherapy gloves must be worn when handling loose (removing from manufacturer’s packaging) hazardous drug tablets and capsules and when pouring a HD oral solution or suspension.

3. Loose HD tablets, capsules and oral solutions or suspensions must be counted, poured and re-packaged in a designated area of the pharmacy dispensary.
4. Hygiene conditions similar to those described for the preparation of sterile HDs also apply to the preparation of non-sterile HDs; no eating, drinking or smoking is permitted.\textsuperscript{6}

5. A dedicated “HD” counting tray and spatula must be used to count and re-package loose HD tablets and capsules.\textsuperscript{6,7}

6. “HD” dedicated counting tray(s), spatula(s) should be cleaned after each use with alkaline aqueous detergent solution.\textsuperscript{6-8} The gauze/wipe used must be disposed of as HD waste.

7. Breaking or crushing of hazardous drug tablets or opening of HD capsules, and counting (re-packaging) of tablets/capsules that have HD powder residue contamination must be performed in a Biological Safety Cabinet, while wearing full Personal Protective Equipment (PPE).\textsuperscript{1,6,7}

8. Preparation of HD oral suspension or solution from crushed tablets, opened capsules or IV solution must be performed in a Biological Safety Cabinet (BSC), while wearing full PPE.\textsuperscript{4,8}

9. All dispensed oral HDs must be labelled as ‘HAZARDOUS’ indicating that HD safe practices must be followed while handling the drug.\textsuperscript{4,6}

10. If a BSC is used for both sterile and non-sterile HD preparations all interior surfaces must be cleaned after non-sterile HD preparations and then purged for 15 minutes prior to use for preparation of HD parenteral products.\textsuperscript{8} The surfaces of the BSC should be cleaned with an aqueous antibacterial solution followed by 70% alcohol.

11. Automated counting and packaging machines should not be used to count or package hazardous drug tablets and capsules.\textsuperscript{4,7}

12. Hands should be washed thoroughly after removing chemotherapy gloves.

**Topical Hazardous Drugs**

1. Topical HD in the original manufacturer’s packaging may be handled without donning chemotherapy gloves or gowns.

2. Two pairs of chemotherapy gloves must be worn when handling topical hazardous drug preparations that are removed from the manufacturer’s packaging.

3. Compounding topical HD products must be performed in a BSC, while wearing full PPE.

4. All dispensed topical HDs must be labelled as ‘HAZARDOUS’ indicating that HD safe practices must be followed while handling the drug.\textsuperscript{4,6}

5. If a BSC is used for both sterile and non-sterile HD preparations all interior surfaces must be cleaned after non-sterile HD preparations and then purged for 15 minutes prior to use for preparation of HD parenteral products.\textsuperscript{3} The surfaces of the BSC should be cleaned with an aqueous antibacterial solution followed by 70% alcohol.

6. Hands should be washed thoroughly after removing chemotherapy gloves.
DEFINITIONS

Alkaline Aqueous Detergent Solutions: Cleaning solutions that are low residue, low-foaming, aqueous detergents with a pH of 8-9 (e.g., Dawn, Ivory, Joy dishwashing detergent products; see product MSDS to confirm solution pH).

Aqueous Antibacterial Solutions: Cleaning solutions that are low residue, non-foaming aqueous antibacterial and/or virucidal solutions compatible with stainless steel. (e.g., Chlorhexidine solution)

Biohazardous drug: A drug containing living organisms with potential to cause infections in humans. Biohazardous drugs are considered hazardous drugs and will be included on the NIOSH HD List or BCCA HD List Addendum. Note: may include drugs identified elsewhere as gene therapy, biologicals and/or biohazards.

Biological Safety Cabinet (BSC): a ventilated cabinet having an open front with inward airflow for personnel protection, HEPA-filtered downward airflow for product protection, and HEPA-filtered exhaust air for environmental protection.


Disinfect: The destruction and removal of disease-causing pathogens/microorganisms from surfaces or inanimate objects through the application and removal of a disinfecting agent.

Disinfecting Agent: An agent capable of destroying (inactivating) disease-causing pathogens/microorganisms when applied to surfaces or inanimate objects.

Hazardous Drug: Drug that exhibits one or more of the following characteristics in humans and/or animals: carcinogenicity, teratogenicity or other developmental toxicity, reproductive toxicity, organ toxicity at low doses, genotoxicity and structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the five previous criteria. If there is no information found and the drug is primarily used as an antineoplastic agent, it will be deemed as hazardous. If a drug contains living organisms with potential to cause infections in humans it will be considered a hazardous drug and will be designated a biohazardous drug on the NIOSH HD List or BCCA HD List Addendum. Note: Hazardous drugs have been referred to as “cytotoxic, antineoplastic, hazardous, and/or chemotherapy”.

Personal Protective Equipment (PPE): Protective equipment and clothing worn to prevent exposure of the skin or eyes to a hazardous drug and to prevent inhalation of powders or aerosols outlined in BCCA Pharmacy Directive VI-30: Personal Protective Equipment.

Purge: Allowing the blower/fan to run with the BSC ‘empty’ for a specified length of time while no work is being performed allowing the flow of air to remove (HEPA filtering) particles/contaminants that may be present in the work area.
REFERENCES


11. Jean Powers NCIC O. Confirmation that PCS 1000 is Effective as a disinfectant vs. Reolysin. 2013 February.


## Biohazardous Drugs - Surface Disinfection Table

<table>
<thead>
<tr>
<th>Biohazardous Drug</th>
<th>Recommended Disinfecting Agent</th>
<th>Alternative Recommended Disinfecting Agent</th>
<th>Contact time (surfaces must be wet)</th>
<th>Other instructions</th>
<th>BSC Purge Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reovirus Serotype 3-Dearing Strain (Reolysin&lt;sup&gt;®&lt;/sup&gt;)</td>
<td>800ppm* Javex Bleach&lt;sup&gt;9&lt;/sup&gt;</td>
<td>Surface Safe&lt;sup&gt;®&lt;/sup&gt;&lt;sup&gt;10&lt;/sup&gt;</td>
<td>30 seconds</td>
<td>1. Follow disinfection with neutralizing agent**</td>
<td>15 minutes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2. Wipe surfaces with sterile water for irrigation to remove residue</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>15 minutes</td>
<td></td>
</tr>
<tr>
<td>Bacillus Calmette-Guerin (BCG)</td>
<td>Cavicide&lt;sup&gt;®&lt;/sup&gt; Solution&lt;sup&gt;13&lt;/sup&gt;</td>
<td></td>
<td>3 minutes</td>
<td>Follow disinfection by wiping surfaces with 70% alcohol</td>
<td>15 minutes</td>
</tr>
</tbody>
</table>

*800ppm Javex Bleach (1/75)<sup>9</sup> = 7 mL regular strength (5-7%) bleach qs’d to 500 mL Sterile Water for Irrigation

**Neutralizing agent - 1% Sodium Thiosulfate Solution = 316 mL sodium thiosulfate (1.58%) solution qs’d to 500 mL with Sterile Water for Irrigation
RATIONALE

Biological Safety Cabinets (BSCs) are ventilated containment cabinets that aid in the protection of the operator, the product and the work environment. All preparation of parenteral hazardous drugs must be performed inside a BSC by trained personnel. An appropriate BSC must be selected, operations must be performed according to best practice standards and BSCs must be properly maintained.

DIRECTIVE

The following are guidelines for the selection of a BSC for use in manipulating hazardous drugs, and for regular maintenance programs and processes for verifying that the BSC is performing to the manufacturer’s specifications. BSC best practice operating requirements and procedures to follow in the event of a malfunction or power interruption will also be outlined.

CLASSIFICATION

Class I BSCs provide personnel and environmental protection only. They do not protect the product from microbial and/or particulate contamination and are not suitable for chemotherapy preparation.

Class II BSCs are classified according to the venting of exhaust air. Air that passes over the work surface is filtered through a High Efficiency Particulate Air (HEPA) filter. The filtered air is then exhausted externally, recycled to the work surface in the BSC, or directed into the room surrounding the BSC.

- Type A cabinets may recycle HEPA filtered air into the room or the air may be exhausted outside to the facility's external exhaust system.
- Type B cabinets do not exhaust HEPA filtered air back into the room environment, however HEPA filtered air may be re-cycled to the work surface in the BSC.
  - Type B1 BSCs exhaust 60-70% of HEPA filtered air externally (airflows from the cabinet to an external exhaust system) and recycles 30-40% of HEPA air back over the work surface.
  - Type B2 BSCs exhaust 100% of HEPA filtered air externally via an external exhaust system.

Class III BSCs provide the highest level of personnel, product and environmental protection. They provide a gas/air tight enclosure with a completely sealed viewing window. Work is performed in attached heavy duty long-sleeved gloves. The viewing window may be opened for cabinet cleaning or decontamination. Filtered room air enters the work area. Used air is double HEPA filtered or passed through a HEPA filter and an air incinerator before exhausting to the facility’s external exhaust system.
Several resources have evaluated the classification of BSC’s used in the handling and manipulation of hazardous drugs, and provide the following recommendations:

<table>
<thead>
<tr>
<th>BSC Type</th>
<th>Meets WorkSafe BC Std</th>
<th>Meets CAPhO Std</th>
<th>Meets NIOSH Std</th>
<th>Meets ASHP Std</th>
<th>Meets ISOPP Std</th>
<th>% exhausted</th>
<th>% recycled</th>
<th>Exhausts filtered air to room environment/BSC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class II Type A1</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Varies</td>
<td>Yes/Yes</td>
<td></td>
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<tr>
<td>Class II Type A2</td>
<td>No</td>
<td>No</td>
<td>*Yes</td>
<td>No</td>
<td>No</td>
<td>30-70%</td>
<td>30-70%</td>
<td>Yes/Yes</td>
</tr>
<tr>
<td>Class II Type B1</td>
<td>Yes</td>
<td>Yes</td>
<td>*Yes</td>
<td>*Yes</td>
<td>Yes</td>
<td>60-70%</td>
<td>30-40%</td>
<td>No/Yes</td>
</tr>
<tr>
<td>Class II Type B2</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>100%</td>
<td>0%</td>
<td>No</td>
</tr>
<tr>
<td>Class III</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>100%</td>
<td>0%</td>
<td>No</td>
</tr>
</tbody>
</table>

*Yes – If used under certain circumstances such as manipulation of non-volatile HD and in combination with closed system drug transfer devices. Not the preferred BSC for most HDs.

Selection of BSC:

1. Provincial WorkSafe BC legislation requires that “all mixing, preparation and priming of administration sets with a cytotoxic drug must be performed in one centralized area in a specially designated Class II Type B biological safety cabinet that (a) is exhausted to the outside atmosphere in a manner that prevents recirculation into any work area, (b) 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 (c) is equipped with a continuous monitoring device to permit confirmation of adequate airflow and cabinet performance”.4

2. Where feasible, a 100% exhaust cabinet is preferred due to the increasingly complex nature of the chemotherapy preparations, the potential for vaporization and the possible aerosolization of hazardous drug products. Feasibility would be dependent on the ability to provide a location that supports the operating specifications of these cabinets and the economic impact of replacing existing cabinets.

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

4. To minimize the impact of the failure of the BSC exhaust system, WorkSafe BC requires that each BSC be installed with independent ducting and external exhaust fan.23

5. Each facility purchasing a new BSC should ensure it is equipped with the following items, required for worker comfort and safety:
   - IV Hanger
   - Seismic Restraint System
   - Foot Stool
   - Hydraulic Lift
   - Arm/Wrist rest
6. Each facility purchasing a new BSC should ensure it is equipped with the following items, required for worker comfort and safety:
   - IV Hanger
   - Seismic Restraint System
   - Foot Stool
   - Hydraulic Lift
   - Arm/Wrist rest

**BSC Operating Requirements:**

1. The viewing window must be placed at the manufacturer’s recommended height to protect the upper body and face from any splashes or aerosols produced inside the BSC during HD preparation. The owner’s manual should be consulted for recommended BSC window height (normally eight to ten inches or 15-20 centimetres). The BSC should not be operated with the window in any other position, except during cleaning and decontamination.

2. The Biological Safety Cabinet must be operated continuously with the blower turned on 24 hours a day, 7 days a week unless it is being serviced.\(^{13}\)

3. The BSC must be equipped with continuous monitoring devices to allow confirmation of adequate airflow and cabinet performance.\(^{15}\)

4. Prior to BSC certification testing or maintenance the entire inner cabinet of the BSC must be decontaminated with an alkaline aqueous detergent solution, followed with sterile water and 70% alcohol. After decontaminating, if the internal blower and the external exhaust fan are turned off the work-access opening of the BSC and the HEPA exhaust area must be covered with impermeable plastic and sealed with tape to prevent any HD contamination from escaping. The BSC must be sealed with plastic whenever it is moved or left inoperative for any period of time.\(^{21,6}\)

**BSC Maintenance:**

1. **Selection of a Qualified BSC Certification Technician**
   - Must be accredited by National Sanitation Foundation (NSF) International
   - Must follow current NSF/ American National Standard Institute (ANSI) 49 Standards
   - Must be aware of HD exposure risks
2. Summary of Physical Tests

BSC Certification Tests by a qualified certification technician

**Required Tests (to ensure proper safety) – must be performed twice a year, every 6 months**

*According to NSF/ANSI 49:*

- HEPA Filter, Housing and Frame Leak Test
- Down flow Velocity Profile
- Airflow Smoke Patterns
- Exhaust Air CFM/Access Opening Inflow Velocity
- Site Installation Tests
  - Exhaust system performance
  - Alarm Functions
  - Blower Interlock Test
- Particle Count Test

*According to USP Standard 797, not NSF*

- BSC to meet ISO Class 5 specifications
- Rooms housing BSC to meet ISO Class 7 specifications

**Other Tests (for worker comfort and safety) – if applicable, must be performed at least annually**

- Noise Level Test
- Vibration Test
- Grounding Continuity Test
- Electrical Leakage Test
- Lighting Intensity
- Motor Voltage
- Ultraviolet Lamp Test
- Duplex Polarity Test
- Ground Fault Circuit Interrupter Test

Routine Tests performed by the BSC Operator

**Monitoring of Display Gauges/Alarms:**

- Airflow gauge readings
  - Large fluctuations in readout numbers can be indicative of a malfunctioning cabinet and should be evaluated immediately.
- Airflow alarms
  - BSCs are designed with preset airflow alarms programmed to sound if airflows change and are outside of normal operating range. Constant alarming can be indicative of a malfunctioning cabinet and should be evaluated immediately.
Paper Catch/Pre-filter:
  - Visual check performed to see that airflow is not blocked by objects in the paper catch.

Routine Tests Performed by Facility Maintenance
  - The fan belts on the external exhaust fan should be replaced on a regular basis.

3. Frequency of Testing

Certification
  - According to recommendations from ASHP and NIOSH, BSCs involved in the manipulation of hazardous drugs must be certified twice a year, every 6 months.
  - BSCs should also be certified prior to use after the following events:5,9,10
    - Initial Installation
    - Change of the HEPA filter
    - Moving of the BSC
    - Any repair or maintenance that could affect the seal of the HEPA filter
  - Recertification scheduling is the responsibility of the Facility Pharmacy Manager or a designate.
  - All testing of BSCs must be recorded when performed and records must be retained for review.
  - A BSC that meets the test criteria should have the following information visibly posted on the cabinet:5
    - Date of certification
    - Date cabinet should be recertified
    - Number of the certifiers report
    - Name, address, and telephone number of the certifying company
    - Signature of qualified person who performed the field certification tests

Routine
  - Operators should monitor and record airflow gauge readings daily to ensure adequate cabinet operation.
  - The paper catch should be checked, cleaned and documented on a weekly basis."6

Facility Maintenance
  - Fan belts on the external exhaust fan(s) should be replaced regularly by facility maintenance service at least every 4-6 months.
  - Pharmacy should be contacted prior to replacement so that BSC shutdown may occur with minimal service interruption.

4. BSC Malfunction or Power Interruption

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 outage, the safety of the product (if possible), the personnel and the environment will be maintained. The procedures should be posted on or near the BSC. (see Appendix 1)
DEFINITIONS

Aerosolization: The suspension of fine droplets or particles that are homogenously dispersed in air.

Biological Safety Cabinet (BSC): A ventilated cabinet having an open front with inward airflow for personnel protection, HEPA-filtered downward airflow for product protection, and HEPA-filtered exhaust air for environmental protection.

Closed System Drug Transfer Device: A drug transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug or vapour concentrations outside the system.14

Decontamination: The removal or inactivation of hazardous drug from a surface, through chemical inactivation, or removal from a non-disposable surface to a disposable surface (e.g. gauze) by use of a cleaning agent. See also BCCA Provincial Pharmacy Directive VI-20; Biological Safety Cabinet (BSC) Decontamination.

Hazardous Drug (HD): Drug that exhibits one or more of the following characteristics in humans and/or animals: carcinogenicity, teratogenicity or other developmental toxicity, reproductive toxicity, organ toxicity at low doses, genotoxicity, and structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the five previous criteria.14 If there is no information found and the drug is primarily used as an antineoplastic agent, it will be deemed as hazardous. If a drug contains living organisms with potential to cause infections in humans it will be considered a hazardous drug and will be designated a biohazardous drug on the NIOSH HD List or BCCA HD List Addendum. Note: Hazardous drugs have been referred to as "cytotoxic, antineoplastic, hazardous, and/or chemotherapy".

ISO Classification: Classification of air cleanliness was the first ISO 14644 International Standard prepared by ISO (International Organization for Standardization) Technical Committee 209 (ISO/TC 209). ISO 14644-1 covers the classification of air cleanliness in clean rooms and associated controlled environments. Classification in accordance with this standard is specified and accomplished exclusively in terms of concentration of airborne particles.

ISO Class 5: an environment with not more than 3250 particles 0.5 um and larger size measured per m$^3$ of air. (biological safety cabinet)

ISO Class 7: an environment with not more than 352,000 particles 0.5 um and larger size measured per m$^3$ of air. (clean room)

Paper Catch/Pre-filter: A permanent paper catch is installed behind the rear divider panel of the work zone. This area forms the return air path to the motor/blower. If the airflow is blocked, it could seriously affect the performance of the BSC.

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

3. CSA Standard Z316.3-M87, Biological Containment Cabinets: Installation and Field Testing.
4. WorkSafe BC OHS Regulation, Part 6: Substance specific requirements: Cytotoxic Drugs and OHS Regulation, Part 30 Section 30.12: Biological Safety Cabinets
23. WorkSafe BC OHS Regulation, Part 6: Substance specific requirements: Cytotoxic Drugs and OHS Regulation, Part 6 Section 6.53: Drug preparation and administration
25. Email from Luci Powers - power_enterprises@hotmail.com. Dated April 9, 2008 on file.
Appendix 1

Suggested Regional procedures for BSC Malfunction or Power Interruption

RATIONALE
To ensure that there is proper personnel/environmental protection, and minimal loss of preparation time in the event of Biological Safety Cabinet (BSC) malfunction or unplanned shutdown.

DIRECTIVE
In the event of a BSC malfunction or power interruption, appropriate procedures must be followed to ensure the safety of the BSC operator, other staff nearby, and to minimize the disruption to the HD preparation workload if possible.

PROCEDURES
The BSC is malfunctioning when:

1. BSC is alarming or the airflow gauges are showing readings that are outside of the manufacturers recommended levels.
2. The internal and/or external blower/fan turns off or works intermittently.
3. The power shuts off for more than 30 seconds.25

Post the following information on or near the BSC:

- Indicators of BSC malfunction/power interruption:
  - The internal and/or external blower/fan turns off or works intermittently (alarms)
  - The power shuts off for more than 30 seconds.25
- The manufacturers recommended readings for BSC airflow gauges
- The contact information for the maintenance department that maintains the BSC
- The contact information for the company that services the BSC
- The name of an alternate site for mixing chemotherapy in the event of a BSC malfunction – a contact person and local should be included

Everyone present in a sterile preparation room/area housing a BSC used to prepare HD’s must wear appropriate PPE when the power shuts off or the internal and/or external fans turn off – 2 pairs of gloves, gown, N95 or better respirator mask, shoe covers, hair/beard cover. Personnel involved in sealing the BSC, and those involved with repairing and/or evaluating the service interruption must also wear safety goggles in addition to the other PPE.
Immediate Response to Unexpected BSC Malfunction/Shut Down

1. The BSC operator must stop HD preparation immediately. Needles (if used) must be carefully removed from vials if reconstitution or withdrawal was in progress. Needles must be safely capped, and all exposed critical sites must be covered with caps/seals and placed on the work surface of the BSC.

2. If there is a second cabinet in the room being used, the other operator should stop mixing. There may be increased activity in the room which could disrupt airflow in the functioning cabinet (BSC or Laminar Flow Hood).

3. The operator must remove their hands from the cabinet leaving everything in the malfunctioning BSC.

4. The glass window of the BSC must be pulled down as far as it will go. (if possible)

5. The BSC operator must remove the outer pair of gloves and dispose of them in HD waste.

6. Other pharmacy workers in the room/area and the pharmacy supervisor must be informed that there is a problem with the BSC.

7. The maintenance department must be contacted— to respond urgently.

8. The chemotherapy administration area supervisor must be informed that there may be an unscheduled delay in HD preparation. There must be continuous updates provided to the chemo administration area supervisor.

9. If the BSC is going to continue to be out of service:
   a. Document the service interruption on the “BSC Maintenance Record” sheet
   b. Discard all used needles and syringes.
   c. Consult with the site supervisor to consider need for destruction of accessed vials *Remember to record wastage*

DO NOT TURN OFF THE BSC BLOWER and/or POWER UNLESS ABSOLUTELY NECESSARY!

Power Shut Down/Power Interruption

1. If the BSC fan and the external fan are both turned off for any reason, and cannot be turned on (safely), the front opening of the BSC and front HEPA filter access must be sealed with impermeable plastic until the fans can be turned on. Once the front of the BSC is sealed, personnel working in the area do not need to wear a N95 mask.

2. If the BSC has been sitting idle with the fans off for more than five minutes, once the power is back on, the BSC must be allowed to purge for 5 minutes. Cleaning and disinfection of the interior surfaces must be performed before HD drug preparation resumes.

3. Some sites may still have BSCs that share a common exhaust fan. The usual scenario is two BSCs and one exhaust fan. When one of the BSCs malfunctions/shuts down but the second BSC is operating within usual parameters it is all right to use the second BSC. It is not possible to turn off the external fan, so not possible to seal the malfunctioning BSC. In this situation it is recommended that personnel wear a N95 mask or better.
Alternative Arrangements for HD IV Preparation

If after evaluation, the maintenance engineers cannot solve the problem quickly, and some work will be required on the BSC:

Arrangements must be made to prepare chemotherapy elsewhere (another site, or another BSC).

1. When another site is going to be utilized to prepare HD in the interim, a pharmacy technician and pharmacist must gather all necessary supplies, hazardous drugs, and patient specific orders and move to the other site.

2. Communication must be arranged between the original pharmacy and the interim preparation site.

3. Communication must be arranged between the chemo administration area supervisor and the interim preparation site.

BSC Repairs or Maintenance

1. Before turning the BSC off for maintenance, repairs or servicing, it must be decontaminated

2. See the BCCA pharmacy BSC Decontamination directive VI-20.

3. After maintenance or servicing, the BSC must be decontaminated a second time

4. The BSC must purge again for 30 minutes before preparation of IV HD’s can resume.
### Appendix 2

**Suggested BSC Quality Assurance Logs**

Pharmacy Department Name

Identify BSC – BSC #1 __________

1. **Documentation of BSC Decontamination:**
   
   *Performed Weekly*

<table>
<thead>
<tr>
<th>Date</th>
<th>Duties</th>
<th>Initials</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BSC Decontamination, Check/Clean Paper Catch</td>
<td></td>
</tr>
<tr>
<td></td>
<td>BSC Decontamination, Check/Clean Paper Catch</td>
<td></td>
</tr>
<tr>
<td></td>
<td>BSC Decontamination, Check/Clean Paper Catch</td>
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<tr>
<td></td>
<td>BSC Decontamination, Check/Clean Paper Catch</td>
<td></td>
</tr>
</tbody>
</table>

2. **Documentation of BSC Airflow Gauge Values**

   *Record Daily – Notify pharmacy supervisor when values are out of manufacturer’s recommended range*

<table>
<thead>
<tr>
<th>Date</th>
<th>Downflow (FPM)</th>
<th>Exhaust (CFM)</th>
<th>Initials</th>
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Normal values (range) for Downflow-
Normal values (range) for Exhaust-

(as provided by manufacturer – BSC specific)
(as provided by manufacturer – BSC specific)
RATIONALE
Exposure to natural rubber latex (latex) can pose a health concern to patients with a latex allergy. Reactions to latex can range from mild to life-threatening. To reduce this risk, patients with latex allergy should avoid contact with medical devices and parenteral drug products containing latex.

DIRECTIVE
Patients will be classified by their oncologist as per the regional directive with either a latex sensitivity or as latex allergic (requiring full latex precautions). Patients with a latex sensitivity require no special precautions with respect to their chemotherapy preparation. Patients with a latex allergy require the following special precautions with respect to their parenteral chemotherapy preparation.

PROCEDURES

Full Latex Precautions
1. Patient Identification
   - Patients that have been identified as latex allergic must have this information entered onto their Allergy Status in the pharmacy computer system.

2. Assessment of Medications and Medical Supplies
   - Medications and manufacturing supplies used to prepare parenteral products will need to be assessed for latex content before being used by consulting the centralized list of latex-free products or by contacting the manufacturer (see appendix I).
   - When the latex content is not known, an item is assumed to contain latex until proven otherwise.
   - All parenteral medications manufactured in pharmacy will be prepared using full latex precaution procedures of the regional centre. The final compounded products will be clearly identified with an auxiliary label indicating “Latex free product-Use Latex precautions”.

Aseptic Preparation
1. Special Supplies
   - Latex-free tubing, syringes, and chemotherapy gloves
   - Low-lint-towels and a bottle of 70% alcohol (avoid using a spray bottle; the nozzle may contain latex)
   - Low-lint-towels and a bottle of aqueous antibacterial solution (e.g., 0.05% chlorhexidine solution or Wet Ones®)

2. Determining Latex Content
   - The technician/assistant setting up medications and supplies for the first treatment of a protocol using latex precautions will need to determine the latex content of medications and supplies. Note: latex content will need to be determined here if there is a brand change.
   - The rubber stopper in vials may be made from natural rubber latex or synthetic rubber. If it is made from synthetic rubber, then preparation may proceed as usual.
   - For vials with natural rubber latex stoppers or vials with stoppers of unknown composition, use a new vial for each dose and limit vial access to a maximum of two punctures. This minimizes patient exposure to any latex particles which may have transferred to the needle.
3. Preparing the biological safety cabinet
   • The fan/blower must be turned on and all unnecessary equipment and items containing latex be removed from the biological safety cabinet.
   • The inside surfaces of the biological safety cabinet must be cleaned and disinfected according to standard procedures while wearing full PPE including two pairs of latex-free chemotherapy gloves.
   • The biological safety cabinet must be allowed to purge for at least 15 minutes after cleaning.
   • The placement of supplies and compounding of preparations (for non-latex allergic patients) in the same biological safety cabinet is not permitted until the latex-free preparations have been completed and removed from the biological safety cabinet.

4. Withdrawing drugs
   a. PhaSeal™
      ➢ Withdraw the calculated volume of drug according to the process outlined in the BCCA Pharmacy Practice Standards for Hazardous Drug manual Module 1 Checklists – Withdrawal from One Hazardous Drug Vial Using PhaSeal™
         o If more than one syringe is required to withdraw a dose from one vial, use a PhaSeal™ ‘Connector/Injector Port Saver’ as described in the “Reconstituting drugs-PhaSeal™” section below or use a new vial for each volume of drug withdrawn
   b. Chemotherapy vent
      ➢ Insert a chemotherapy vent into the vial stopper
         ▪ Using the smallest gauge needle possible, withdraw a single dose into a syringe
         ▪ Change the needle before adding drug to an IV solution bag
         ▪ If dispensing the drug in a syringe, remove the needle and cap the syringe tip with a latex-free luer lock syringe tip cap
         ▪ Discard the vial after the single dose is removed or use remainder of drug for non-latex allergic patient(s)

5. Reconstituting drugs
   a. PhaSeal™
      ➢ Refer to the BCCA Pharmacy Practice Standards for Hazardous Drug manual Module 1 Checklists – Reconstitution of a Hazardous Drug Using PhaSeal™
         ▪ To maintain a maximum of two pokes into the vial stopper when reconstituting drug in a vial using PhaSeal™, a PhaSeal ‘Connector/Injector Port Saver’ must be used
            o To create a Connector/Injector Port Saver:
               • Attach a Connector Luer Lock to an Injector Luer Lock
               • Using a push-turn-push motion, attach the Injector Luer Lock to the Protector on the vial
               The Connector/Injector Port Saver must remain attached to the vial Protector for the duration of drug preparation for latex allergic patients
b. Negative pressure technique (Note: negative pressure technique not recommended for hazardous drugs).
   - Using the smallest gauge needle possible, add diluent to the vial using negative pressure technique
   - Carefully remove the needle from the vial stopper
   - Gently agitate the vial until drug is completely dissolved and no particles are visible
   - Using a new needle with the smallest gauge possible, withdraw the appropriate dose into a syringe
     - Puncture the vial stopper in a different area than the diluent needle punctured
   - Change the needle before adding the drug to an IV solution bag
   - If dispensing the drug in a syringe, remove the needle and cap the syringe tip with a latex-free luer lock syringe tip cap
   - Discard the vial after the single dose is removed or use remainder of drug for non-latex allergic patient(s)

6. Preparing dose for final product check
   - Ready supplies and the final product for the final product check as per the BCCA Pharmacy Practice Standards for Hazardous Drug manual Module 1 Checklists

7. Labelling and packaging of doses
   - Dispense in a sealed latex-free zip lock bag
   - Apply a “Latex free product-Use Latex precautions” auxiliary label to the final container and the transport bag in addition to the patient-specific and standard auxiliary labels

DEFINITIONS

Latex sensitivity - is a “non-allergic” irritant contact dermatitis, characterized by redness, cracking, scaling, and vesicle formation on exposed areas. With repeated exposure to natural rubber latex, sensitization may be increased and may progress to a systemic allergic reaction.

Latex allergy - there are two types:

a. Allergic contact dermatitis is a type IV, delayed hypersensitivity to chemicals added to latex during processing, and is characterized by an initial acute eczematous dermatitis often with vesicle formation. Typical presentation occurs 48-96 hours after exposure and skin may subsequently become dry, cracked and thickened.

b. Allergic immunoglobulin E (IgE)-mediated systemic reaction is a type I immediate hypersensitivity with symptoms that may include urticaria, flushing, edema, rhinoconjunctivitis, asthma, and anaphylaxis. Life threatening allergic reactions has most often been associated with mucosal, inhalation or parenteral exposure to latex proteins.
VI-70: Guidelines for Preparation of Parenteral Hazardous Drugs for Latex Allergy Patients

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<td>Review Date:</td>
<td>Revision Date: Dec 2010, Jan 2011, March 2011, May 2014</td>
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</table>

REFERENCES:

1. BCCA - Vancouver Centre. Preparation of Chemotherapy for Latex Allergy Patients. 1998
5. Vancouver Hospital and Health Sciences Centre. Pharmaceutical Sciences Policy and Procedure. Latex Allergic Patients. May 17, 2004
APPENDIX I:

Creating and Maintaining a Centralized list of Latex-Free Products

1. Creating a centralized list of latex-free medical supplies
   - Pharmacy staff (e.g. purchasing technician/assistant) will call the manufacturer to determine latex content of medical supplies used to prepare medication (e.g., chemo pins, filters, syringes, non-PVC bags, zipper storage bags), if not indicated on the packaging material.
   - Information will be forwarded to the Pharmacy Systems Application Technician/Assistant to be recorded and tabulated in a centralized list (see Table 1) and be available to pharmacy staff involved in preparing the medication and inform nursing staff preparing support medication.
   - Lot numbers will need to be recorded only when the latex content of a medical supply changes between lot numbers. Information will need to be obtained from the manufacturer by the pharmacy staff as needed and recorded in the centralized list by the Pharmacy Systems Application Technician/Assistant.
   - This chart is located on H:\Pharm-prov\Latex Allergies as a reference for all centers.

<table>
<thead>
<tr>
<th>Medical Supplies</th>
<th>Manufacturing Company</th>
<th>Latex Free (Yes/No)</th>
<th>Lot Number, if applicable</th>
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2. Creating a centralized list of latex-free medications
   - Pharmacy staff (e.g. purchasing Technician/Assistant) will call the manufacturer to determine latex content of medication, by asking whether there is latex in the vial stopper.
   - Information will be forwarded to the Pharmacy Systems Application Technician/Assistant to be recorded and tabulated in a centralized list (see Table 2) and be available to pharmacy staff involved in preparing the medication at that regional centre and inform nursing staff preparing support medication.
   - Lot numbers will need to be recorded only when the latex content of a medication changes between lot numbers. Information will need to be obtained from the manufacturer and recorded in the centralized list.
   - This chart is located on H:\Pharm-prov\Latex Allergies as a reference for all centers.

<table>
<thead>
<tr>
<th>Drug name and strength</th>
<th>Manufacturing Company</th>
<th>Latex free (Yes/No)</th>
<th>Lot Number, if applicable</th>
<th>Date</th>
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</thead>
<tbody>
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</table>

3. Maintaining a centralized list of latex-free products
   - According to manufacturers, latex content does not change between lot numbers of products. If any changes occur, communication from the manufacturer, in the form of a “Dear Healthcare Professional” letter, will be faxed or emailed to all dispensing pharmacies indicating the lot numbers affected.
   - Pharmacy staff (e.g. purchasing technicians/assistants) will be responsible for forwarding this information to the Pharmacy Systems Application Technician/Assistant who will update the centralized list of latex-free products at that point specifying the date and the lot numbers affected.
   - If new products or strengths of medications become available, pharmacy staff will call the manufacturer to determine latex content and will forward that information to the Pharmacy Systems Application Technician/Assistant to update the centralized list and record the date of activity.
   - The Provincial Pharmacy Systems Application Technician/Assistant will be responsible for updating the centralized list of latex-free products when a new drug has been added to the Benefit List and annually by contacting the manufacturers to determine if there is any new information regarding latex status.
RATIONALE

Occupational exposure to certain drugs may be hazardous to the health of healthcare workers who handle them. Hazardous drugs (HD) have the potential for causing cancer, developmental, reproductive and genetic toxicity, or harm to organs based on studies in animals and/or humans. HD must be identified in the workplace so that workers who handle them can utilize safe handling practices to minimize exposure to these agents.

DIRECTIVE

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 US National Institute for Occupational Safety and Health (NIOSH) List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings. For new oncology drugs approved for use between updates of the NIOSH List, they will be evaluated by the Provincial Drug Information and added to the BCCA HD List if deemed hazardous. For drugs not covered by the BCCA HD list, the NIOSH List should be consulted.

The BCCA HD list is posted in each BCCA Regional Cancer Centre Pharmacy. Staff who handles HD must utilize safe handling practices to minimize exposure to these agents.

BCCA HD EVALUATION CRITERIA

A Hazardous Drug (HD) is a drug exhibiting one or more of the following characteristics in animals or humans.

1. Carcinogenicity
2. Teratogenicity or other developmental toxicity
3. Reproductive toxicity
4. Organ toxicity at low doses
5. Genotoxicity
6. Structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the above criteria. (In general, this means agents which share at least structural similarity (e.g., platinums, taxanes), with or without similar toxicity profiles.)

In addition, if information about these characteristics is not available for a given drug, but the drug is primarily used as an antineoplastic agent, it will be considered a hazardous drug (HD) and added to the BCCA HD List.

A drug containing a living organism with the potential to cause infections in humans will be considered a hazardous drug with the designation of biohazardous drug, and will be included on the BCCA HD List.

PROCEDURES

1. The BCCA HD List must be posted in all areas where HD’s are received, stored and prepared.
2. A Provincial Pharmacy Drug Information pharmacist is responsible for using the BCCA HD Evaluation Criteria to evaluate “new” oncology drugs that are approved for use, between published NIOSH HD list updates. The “new” HD will be added to the BCCA HD List.
3. Biohazardous drugs will be identified on the BCCA HD List with an asterisk ‘*’.

4. The BCCA Clinical Trials pharmacists are responsible for using the BCCA HD Evaluation Criteria to evaluate “new” oncology drugs that are used in clinical trials. This information will be included in the BCCA Parenteral Drug Therapy Manual (PDTM) monograph developed by the Clinical Trials pharmacists (see Systemic Therapy Policy III-90)

5. Policies for the safe and aseptic handling of HD must be followed when receiving, storing, preparing, administering, and disposing of HD. Standards for the safe and aseptic handling of HD can be found in the BC Cancer Agency Pharmacy Practice Standards for Hazardous Drugs Manual

6. Procedures for the safe handling of hazardous drug dosage forms (including biohazardous drugs) are found in the BCCA Pharmacy Directive VI-40: Safe Handling and Preparation of HD Dosage Forms

DEFINITIONS

Antineoplastic drug: A chemotherapeutic agent that controls or kills cancer cells.

Biohazardous Drug: A drug containing living organisms with potential to cause infections in humans. Biohazardous drugs are considered hazardous drugs and will be included on the BCCA HD List. Note: Biohazardous drugs may include gene therapy, biologicals, and/or biohazards.

Hazardous Drug (HD): Drug that exhibits one or more of the following characteristics in humans and/or animals: carcinogenicity, teratogenicity or other developmental toxicity, reproductive toxicity, organ toxicity at low doses, genotoxicity and structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the five previous criteria. If there is no information found and the drug is primarily used as an antineoplastic agent, it will be deemed as hazardous. If a drug contains living organisms with potential to cause infections in humans it will be considered a hazardous drug and will be designated a biohazardous drug on the BCCA HD List. Note: Hazardous drugs have been referred to as “cytotoxic, antineoplastic, hazardous, and/or chemotherapy”.

REFERENCES

4. WorkSafe BC OHS Regulation, Part 6: Substance specific requirements: Cytotoxic Drugs
Appendix I - NIOSH Hazardous Drug List

For the complete and current NIOSH List, refer to CDC – NIOSH Numbered Publications.

Appendix II – BC Cancer Agency: Hazardous Drug List

For current list, see Cancer Drug Manual.

Appendix III – Guiding Principles for the Hazardous Drug Evaluation of BCCA Drugs (see following)

Appendix IV – BC Cancer Agency: Hazardous Drug Evaluation Form (see following)

Appendix III

Guiding Principles in Assessing Hazardous Drugs

BCCA will create and maintain a Hazardous Drug list for drugs available at BCCA for the treatment of cancer and/or supportive therapy as per the BCCA Benefit Drug List or via Compassionate Access Program (CAP).

1. BCCA will adopt the currently posted NIOSH List such that a drug included in the NIOSH List will be deemed hazardous by BCCA.

2. A drug has been reviewed by NIOSH if it is in one or more of the following documents:
   a. NIOSH Lists, including the lists of deleted drugs
   b. Lists of drugs fitting or not fitting NIOSH Criteria
   c. NIOSH Draft Proposed Additions and Deletions
   d. NIOSH Peer Response

3. A drug that has been reviewed by NIOSH but does not appear in the most current NIOSH List is considered deemed to be non-hazardous.

4. BCCA assumes that NIOSH considers a drug at low risk for occupational exposure if the drug is available in the U.S. before September 2004 but has not been deemed hazardous in subsequent NIOSH evaluations.

5. A drug not reviewed by NIOSH will be evaluated by BCCA using criteria adapted from NIOSH guidelines.
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<th>DRUG SPECIFIC INFORMATION</th>
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<td>GENERIC NAME</td>
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<tr>
<td>BRAND NAME(s)</td>
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<tr>
<td>On NIOSH List?</td>
<td>YES</td>
<td>NO</td>
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<tr>
<th>HAZARDOUS CHARACTERISTICS (*From the NIOSH 2010 definition)</th>
<th>YES or NO</th>
<th>DETAILS</th>
<th>RefWorks CITATION #</th>
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<tbody>
<tr>
<td>1. *CARCINOGENICITY</td>
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<td>2. *TERATOGENICITY / DEVELOPMENTAL TOXICITY</td>
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<td>(2a. FDA PREGNANCY CATEGORY)</td>
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<tr>
<td>3. *REPRODUCTIVE TOXICITY</td>
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<td>4. *ORGAN TOXICITY (LOW DOSES)</td>
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<td>5. *GENOTOXICITY</td>
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<td>6. *NEW DRUGS THAT MIMIC STRUCTURE &amp; TOXICITY OF EXISTING DRUGS DEEMED HAZARDOUS BY CRITERIA ABOVE</td>
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<tr>
<td>7. NO INFORMATION AVAILABLE; HOWEVER DRUG IS PRIMARILY USED AS AN ANTIINEOPLASTIC AGENT.</td>
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<tr>
<td>8. A DRUG CONTAINING LIVING ORGANISMS WITH POTENTIAL TO CAUSE INFECTIONS IN HUMANS.</td>
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<tr>
<th>BIOHAZARDOUS DRUG?</th>
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Add to BCCA HD List? | YES | NO | Reason: |
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Rationale

Standard procedures for the safe packaging, labelling, and transport of Hazardous Drugs (HD) must be followed to ensure the safety of patients, visitors, and facility staff.\textsuperscript{1}

**Directive**

All HD transported from BCCA pharmacies must be done so in a manner which minimizes the risk of exposure to HD should a spill or breakage occur during transport.\textsuperscript{1,3}

**A. General Procedures**

HD must be packaged, labelled, and transported in a manner that maintains protection of the product, personnel, and the surrounding environment.\textsuperscript{1,3} The transport of HD is complex and includes:

- Shipment of HD from the manufacturer to the distributor.
- Shipment of HD from the distributor to the Cancer Centres.
- Internal movement of HD through the Cancer Centres to Pharmacy.
- Movement of HD within Pharmacy and to patient care areas.
- HD dispensed from Pharmacy to patients to take home.
- HD dispensed from Pharmacy to be mailed or couriered to the patient. (Subsequent internal movement of the package from Pharmacy through the Cancer Centre to the mail room).
- HD compounded in the Chemotherapy Sterile Preparation Room transported to treatment areas for administration to patient.
- Shipment of HD to other facilities.

The method of transport must not produce stress on the contents or packaging; the use of pneumatic tube systems must be avoided.\textsuperscript{1,3,6}

All HD preparations and products must be transported directly to their destination with no detours in order to minimize the number of areas within the facility which could be contaminated should a spill occur.\textsuperscript{3}

All HD must be received by a staff member who is responsible for ensuring that the HDs remain inside their protective packaging until required for use.

For HD sent through the mail, refer to Canada Post guidelines for shipping (ABCs of Mailing - Personal: Section 3.2.1).\textsuperscript{7} Products that BCCA pharmacies are shipping which are listed as Dangerous Goods in the Transport of Dangerous Goods Act are unlikely to meet the minimum quantity requirements to qualify for designation as dangerous goods. For more information see Transport of Dangerous Goods Regulations.

**Personnel**

All BCCA pharmacy personnel involved in the transport of HD products must receive appropriate instruction and training prior to transporting HD.\textsuperscript{1,3,8} Personnel must be aware of:

- Distinct identifying labels indicating the presence of hazardous or cytotoxic drugs.
- Procedures required for handling damaged containers of HD and spill control (see BCCA Provincial Pharmacy directive VI-10: HD Spill Control in Pharmacy, and BCCA Provincial Systemic Policy V-30: Hazardous Drug Spill Management).
- The location of Spill Kits within the areas of the facility through which they are transporting HD.
B. HAZARDOUS DRUG PACKAGING AND LABELING

1) HD Standard Packaging Requirements:
All HD must be dispensed or stored in a suitable primary dispensing container such as: intravenous solution bags, elastomeric infusors, syringes, vials, ampoules, ointment jars, sealable poly bags, blister cards, manufacturer supplied packaging, or prescription vials.

Packaging surrounding the primary container may consist of “inner” and “outer” containers dependent upon the route of transport and the final destination of the HD. See Appendix 1: Inner and Outer Containers Required For The Transport of HD for details.

- **inner** containers must be sealed, leak-proof and see-through; typically a “zippered” or heat-sealed bag
- **outer** containers must be suitable to enclose the HD product and robust enough to withstand normal conditions of transport and handling:
  - **Type A** – a hard-shell plastic box with a secure lid
  - **Type B** – moulded foam or corrugated cardboard
  - **Type C** – padded envelope

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

Any non-disposable outer containers must be dedicated for the transportation of HD only and must be decontaminated prior to re-use. All other packaging material must be disposed of as HD waste.

Re-usable cold packs, used for refrigeration during transport, must be separated from direct contact with HD by placing in a re-sealable “zippered” bag (i.e. an inner container). The “zippered” bag must be disposed of as HD waste.

Additional packaging requirements:
- Latex–free materials should be employed for the primary, inner, and outer containers whenever possible due to the increasing number of latex allergies observed in patients and health care workers.
- All compounded HD parenteral syringes must be dispensed with either a luer locking tip cap or a closed system drug transfer device except in special circumstances where luer lock syringes are not recommended, such as pediatric doses or as specified in some clinical trials.
- Any medication to be taken home (i.e. NOT administered in a treatment area within a BCCA facility) must NOT be placed inside the same inner container as the compounded HD parenteral admixtures which are administered within the facility; for example:
  - Corticosteroids
  - Oral leucovorin
  - Oral HD medication
• Any non-HD medication that is to be administered in a treatment area within a BCCA facility, and handled as per non-HD medication standards must NOT be placed inside the same inner container as the compounded HD parenteral admixtures which are administered within the facility; for example
  o Corticosteroids
  o Oral leucovorin
  o Oral HD medication

• Any stock inventory of HD requiring repackaging for transport within or outside the facility (e.g. outside sale, shipment to another facility, etc) must be repackaged with a suitable inner and outer container and left in its original, primary packaging whenever possible.

2) HD Standard Labelling Requirements:
In addition to mandatory prescription labelling requirements on the primary container, all containers (primary, inner, and outer) used in the dispensing and transport of HDs must be clearly identified with distinctive warning labels. Example:

Auxiliary labelling may be placed on packaging when deemed appropriate; for example:
  o Keep Refrigerated
  o Protect From Light

All compounded HD parenteral admixtures transported from Pharmacy through public areas of a facility (i.e. non-treatment areas) will require HD Spill Control information to be affixed to all outer containers; for example:

IN THE EVENT OF A SPILL OR BREAKAGE:
• Isolate area and prevent anyone from going near the spill area.
• Inform supervisor that a Hazardous Drug spill has occurred.
• Stay with the spill until help arrives.

Any repackaged stock inventory of HD will require both the inner and outer containers to be relabelled with all appropriate warning and auxiliary labels.
DEFINITIONS

Compounded HD Parenteral Admixtures: Hazardous drugs that are prepared by pharmacy in a biological safety cabinet (BSC) for parenteral administration.

Facility: A treatment centre, hospital, or research centre with buildings which are physically attached to one another by means of connecting doors, hallways or tunnels.

Hazardous Drug (HD): Drug that exhibits one or more of the following characteristics in humans and/or animals: carcinogenicity, teratogenicity or other developmental toxicity, reproductive toxicity, organ toxicity at low doses, genotoxicity and structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the five previous criteria.\(^7\) If there is no information found and the drug is primarily used as an antineoplastic agent, it will be deemed as hazardous. If a drug contains living organisms with potential to cause infections in humans it will be considered a hazardous drug and will be designated a biohazardous drug on the NIOSH HD List or BCCA HD List Addendum. Note: Hazardous drugs have been referred to as “cytotoxic, antineoplastic, hazardous, and/or chemotherapy”.\(^10\)

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

Stock Inventory of HD's: HDs that remain in their original primary packaging as received from manufacturers, vendors and other facilities.

Transportation of HD: The movement of any HD within or outside the facility.

Treatment areas: Any areas within a facility where patients are administered systemic or radiation therapy, including but not limited to the Ambulatory Care Unit, the Ambulatory Chemotherapy Care Unit, Inpatient wards, Medical Daycare, and Radiation Therapy Support. These areas may also include reception areas, waiting rooms, and connecting corridors depending upon the physical layout of each Cancer Centre.
### VI-100: Transportation of Hazardous Drugs

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<td>Provincial Pharmacy Professional Practice Council</td>
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<tr>
<td>Revision Date:</td>
<td>October 15, 2014</td>
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</table>

### REFERENCES

1. Canadian Association for Pharmacy in Oncology (CAPhO). Standards of Practice for Oncology Pharmacy in Canada. 2nd ed.; November 2009.


7. Canada Post: ABCs of Mailing-Personal. Available at: https://www.canadapost.ca/tools/pg/manual/PGabcmail-e.asp


## Appendix I

### Inner and Outer Containers Required For the Transport of HD

<table>
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<th>PROCEDURE</th>
<th>INNER CONTAINER REQUIRED</th>
<th>TYPE OF OUTER CONTAINER REQUIRED</th>
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<tbody>
<tr>
<td><strong>1) Compounded HD Parenteral Admixtures</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transport through public areas of a facility (non-treatment areas)</td>
<td>Yes</td>
<td>Type A or B</td>
</tr>
<tr>
<td>Transport within a treatment area or pharmacy department</td>
<td>Yes</td>
<td>None</td>
</tr>
<tr>
<td>Transport to another facility</td>
<td>Yes</td>
<td>Type A or B</td>
</tr>
<tr>
<td>Dispensed to outpatients</td>
<td>Yes</td>
<td>None</td>
</tr>
<tr>
<td><strong>2) Solid, Liquid, Topical, &amp; Injectable HD Dosage Forms</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Solid oral HD dosage forms (loose &amp; blister-pack) dispensed to outpatients &amp; inpatients</td>
<td>No</td>
<td>None</td>
</tr>
<tr>
<td>Solid oral HD dosage forms (loose tablets &amp; capsules) transported via mail’ or courier</td>
<td>Yes</td>
<td>Type B or C</td>
</tr>
<tr>
<td>Blister-packaged solid oral HD dosage forms transported via mail’ or courier</td>
<td>Yes</td>
<td>Type B or C</td>
</tr>
<tr>
<td>Liquid oral HD dosage forms dispensed to outpatients &amp; inpatients</td>
<td>Yes</td>
<td>None</td>
</tr>
<tr>
<td>Liquid oral HD dosage forms transported via mail’ or courier</td>
<td>Yes</td>
<td>Type B</td>
</tr>
<tr>
<td>Topical HD dosage forms dispensed to outpatients &amp; inpatients</td>
<td>Yes</td>
<td>None</td>
</tr>
<tr>
<td>Topical HD dosage forms transported via mail’ or courier</td>
<td>Yes</td>
<td>Type B</td>
</tr>
<tr>
<td>Injectable HD dosage forms (e.g. vials) dispensed to outpatients and inpatients</td>
<td>Yes</td>
<td>None</td>
</tr>
<tr>
<td>Injectable HD dosage forms (e.g. vials) transported via mail’ or courier</td>
<td>Yes</td>
<td>Type B</td>
</tr>
<tr>
<td>Commercially supplied pre-filled syringes dispensed to outpatients and inpatients</td>
<td>No</td>
<td>None</td>
</tr>
<tr>
<td>Commercially supplied pre-filled syringes transported via mail’ or courier</td>
<td>No</td>
<td>MAIL: Type B (only) COURIER: Type B or C</td>
</tr>
<tr>
<td><strong>3) Stock Inventory of Hazardous Drugs</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transport within pharmacy department to storage area</td>
<td>Yes†</td>
<td>None</td>
</tr>
<tr>
<td>Movement of small quantities within the pharmacy department for dispensing or restocking</td>
<td>No</td>
<td>None</td>
</tr>
<tr>
<td>Transport through public areas of a facility</td>
<td>Yes†</td>
<td>Type A or B†</td>
</tr>
<tr>
<td>Outside sales</td>
<td>Yes</td>
<td>Type A or B</td>
</tr>
</tbody>
</table>

† Container may be original packaging from supplier

Type A = hard-shell plastic box with secure lid
Type B = moulded foam or corrugated cardboard box
Type C = padded envelope