Sterile Hazardous Mixing:
Come over to the safe side!

About Me

- Attended Red Deer College, took the first PEBC exam and became registered.
- Worked for Shoppers, Safeway and Costco before coming to Alberta Health Services.
- Certified in Chemotherapy and IVs for 13 years. Aspetic Lead in hazardous compounding.
- Worked Rural; patient specific preparations. Worked Urban; batching preparations and TPN.
- Busy mom to two boys. Find me travelling, outdoors or planning my move to Paris.

Disclaimer:

Presenter Personal Disclosure

Presenter's Name: *Lauren Adduono*

- I have no current or past relationships with commercial entities.
- I have received a speaker's fee from PTSA for this learning activity.

Objectives:

1. Introduction to Hazardous Sterile Compounding – Clearly define the differences between Sterile Compounding and Hazardous Sterile Compounding; Understand basic rules and regulations technicians are required to follow while sterile compounding hazardous mediations.

2. Handling Hazardous Medications and Preparations - Understand the safety measures that are taken to feel confident and comfortable handling these medications.

3. Closed Device System – Understand the system and all devices; defining each devices purpose with a general idea of how to use these together as a system, and how they keep staff and patients safe.

Safety

- PPE + Cleaning
- Preparations
- Devices
- Embedded Worksheets

Gowns

1. Gowns

All staff entering the controlled areas follow hand hygiene directives and don PPE in the same manner. A disposable "chemo" gown, tested by the manufacturer for resistance to permeability by hazardous drugs, must be worn over an inner, lint-free, non-shedding gown. Chemo gowns are also worn when unpacking damaged hazardous drug shipments or cleaning up a hazardous drug spill. The gown must have a closed front, long sleeves and fitted cuffs. Lint-free gowns reduce the particulate level of the work area and low permeability material resists the penetration of drug particles and spills. Worn gowns are not to be worn outside the clean room. Gowns are discarded and replaced at the earliest of the manufacturer's time limit for permeation of the gown or after 2-3 hours of continuous compounding activity or after each removal or after contamination of the gown has occurred.

Worn/used chemo gowns are always discarded immediately in hazardous waste containers.

Gloves

2. Gloves

Disposable sterile and non-sterile gloves are worn for the handling of cytotoxic drugs and cytotoxic-contaminated materials. Both sterile and non-sterile gloves must meet American Society for Testing and Materials (ASTM) D-6978-05 standards for handling chemotherapy and should be powder free. Two sets of non-sterile gloves are required for receiving and unpacking hazardous drugs and managing spills outside of the controlled areas. Two sets of sterile gloves are required for cleaning and disinfecting controlled areas and BSCs, compounding hazardous drug preparations, and managing spills inside controlled areas and BSCs. Sterile gloves used for compounding hazardous drug preparations are worn in such a manner that produces a tight fit and exposes no skin. To achieve maximum protection, the inner gloves are pulled over the cuffs of the inner gown and the outer gloves are worn over the cuffs of the outer gown. Outer sterile gloves are put on inside the clean room and are wiped with gauze moistened with sterile 70% isopropyl alcohol just prior to beginning work in the BSC. If gloved hands are removed from the BSC, they are wiped with gauze moistened with sterile 70% isopropyl alcohol before leaving the BSC and again upon re-entering the BSC. When finished working in the BSC, the outer gloves are removed and placed in the hazardous waste bag inside the BSC. Both pairs of sterile gloves should be changed at least every 30 minutes during continuous sterile compounding and changed immediately if torn, punctured or contaminated. Some glove manufacturers include the warning “DO NOT USE WITH CARMUSTINE AND THIOTEPA” on their packaging because they are harsh cytotoxic drugs and may have permeation times of less than 30 minutes. As an extra precaution when preparing carmustine and thiotepa, both sets of gloves are to be changed immediately before and after the preparation is complete.

Goggles/Safety Glasses

3. Goggles/Safety Glasses

Goggles/safety glasses with a face shield are worn when cleaning up cytotoxic spills and when unpacking suspected damaged drug shipments, decontaminating and deactivating the BSC when the viewing window is raised. Goggles/safety glasses and face shields that are not contaminated are wiped down with germicidal wipes regularly and rinsed with water after using and dried with a disposable towel. If they have been contaminated, discard in cytotoxic waste container. Contact lenses may be worn if working in a BSC.

Masks/Respirator

4. Masks

Surgical masks must be worn by all personnel in the clean room and must be changed after 3.5 hours of continuous compounding, after each removal or if contamination has occurred/is suspected. Surgical masks do not provide protection against breathing aerosols.
A chemical cartridge respirator with a pre-filter is worn when cleaning up cytotoxic/hazardous drug spills, when decontaminating and deactivating the BSC when the viewing window is raised and when unpacking damaged (or suspected damaged) cytotoxic/hazardous drug shipments. Chemical cartridge respirators must be fit-tested. Cartridges are to be replaced when it becomes difficult to breathe comfortably and/or if the cartridge filter appears dirty or physically damaged. For more information about cleaning, storage and replacement of

Hair Covers

5. Hair and Beard Covers

Disposable head and facial hair coverings (where necessary) are worn by personnel in the clean room to prevent hair and skin particles from contaminating the BSC and clean room air. Personnel have been found to be the major source of particulate load in a sterile preparation area. Hair covers are put on before gowning and hand washing.

Shoe Covers

6. Shoe Covers

Shoe covers are worn to minimize the potential for particulate contamination and to prevent the contamination of shoes and subsequent spread of contamination to other areas of the pharmacy. Two pairs of disposable shoe covers are to be worn on the clean side of the line of demarcation in the anteroom and in the clean room.

PPE
Donning

PPE Donning activities to be performed on the ***DIRTY SIDE*** of Ante Area Prior to crossing the Line of Demarcation (LOD)	
Head Cover/Bouffant	• Ensure all hair is tucked in • Fully cover ears • Hijab covers are available from CPSM
Beard Cover	• If applicable
Surgical Mask **OR** **Respirator**	• Surgical mask – from bridge of nose to below chin; pleats down • Worn anytime the BSC window is **down** • Obtain respirator "kit" and don mask with cartridges affixed, then goggles, then face shield • Worn anytime the BSC window is **up**
Shoe Covers	• Don two shoe covers on one foot and step over line of demarcation. • Don two shoe covers on the other foot and s demarcation (both feet now on the floor on c
PPE Donning activities to be performed on the *CLEAN* After crossing the Line of Demarcation (	
Perform Aseptic Hand Wash	• Soap and water wash, followed by: • Alcohol-based (Avagard) Handwash Metho ○ OR Alternate Scrub Method ○ If applicable, see Scrub Method with
Inner Gown	• Don non-shedding inner gown • Note: if outer gowns are stored in ante area moisture/permeability resistant gown to take
Enter the clean room	

PPE Donning activities to be performed ***INSIDE THE CLEAN ROOM***	
Sterile Gloves	• Open one pair of sterile gloves • Alcohol-based (Avagard) hand rub • Don inner gloves aseptically, ensuring gloves are pulled over the cuffs of the **inner** gown • Open the second (outer) pair of sterile gloves; do not don yet
Disposable Chemo Gown	• Don gown (long sleeves with fitted cuffs) • Must be back-closing (no open front) and tied up to minimize billowing of gown
Sterile Gloves	• Don outer gloves, ensuring gloves are pulled over the cuffs of the **outer** gown • Clean gloves with sterile 70% IPA
Glove Changes	• Both pairs of sterile gloves must be changed every 30 minutes or when torn, punctured or contaminated • Glove change is performed in the clean room • Outer gloves are removed inside the BSC • After removing inner gloves, one pump of Avagard is applied to hands prior to donning two new pairs • Note: New gloves may be donned by **either** pulling up the chemo gown sleeves carefully and safely (no contamination), **OR**, by removing the chemo gown prior to donning
Respirator to Surgical Mask Transition in the Clean Room	• Remove outer pair of gloves inside the BSC • In doffing area, remove face shield, goggles and half face piece mask • Place reusable equipment into designated bin to await cleaning • Don alternate type of mask/face protection (surgical mask) • Remove inner gloves • One pump of Avagard • Don two new pairs of gloves as per glove change process

PPE
Doffing

DOFFING: ***Discard all disposable PPE into hazardous waste container***

PPE Doffing activities to be performed *INSIDE THE CLEAN ROOM*	
Remove Outer Pair Of Sterile Gloves	• Remove inside the BSC and place into hazardous waste
Proceed to the Doffing Area	• Inside the clean room • Small area in the shape of a semi-circle delineated with a line on the floor • Includes the door to exit the clean room and enter the ante room
Remove Outer Shoe Covers	• Remove one outer shoe cover at a time while stepping into the designated doffing area
Inside Doffing Area	• Remove and dispose of outer gown • Remove and dispose of inner gloves
Exit the Clean Room	
PPE Doffing activities to be performed on the *CLEAN SIDE* of the Ante Area	
Surgical Mask **OR** **Respirator**	• IF wearing a respirator, remove face shield, goggles and half face respirator mask by touching ONLY the back of the head straps of each piece of equipment, and set aside for cleaning • IF wearing a surgical mask do not remove it yet • Remove and dispose of inner gown, or if reusable, place into laundry containment bag or hang for re-use (maximum one shift)
	• Wash hands with soap and water
PPE Doffing activities to be performed on the *DIRTY SIDE* of the Ante Area	
Remove and Dispose	• Remove inner shoe covers while stepping over the line of demarcation onto the dirty side • Surgical mask • Beard cover (if applicable) • Head cover/bouffant
Wash hands and forearms thoroughly with regular soap and water prior to beginning any tasks in the uncontrolled area(s).	

BSC Cleaning & Disinfecting

BSCs must be decontaminated twice daily and deactivated a minimum of once weekly. Whenever the viewing window is raised from its regular working position, the intake air velocity drops too low to ensure personal protection. Because of this, anytime the viewing window is raised such as during deactivation, sterile compounding must cease in the entire cleanroom. Only personnel involved in the immediate procedure occurring within that BSC shall be in the clean room at that time and they must be wearing a chemical cartridge respirator. The use of the Clipper Mop to perform decontamination processes in the BSCs allows for the viewing window to remain in its regular working position. This has increased efficiency in the clean room because the work in the room can continue rather than cease. Clipper Mop training resources are found on the CCA Pharmacy Share Point site:

A. Daily Decontamination

The BSC shall be cleaned and disinfected twice daily - in the morning and at the end of the compounding day. The floor of the BSC should be cleaned in between each preparation and when spillage occurs. Whenever a surface is cleaned, it is first wiped with an AHS approved germicidal such as Accel PREVention, followed by a disinfecting wipe of 70% sterile isopropyl alcohol. Alcohol is never used alone because studies have shown that alcohol, when not preceded by a germicidal wipe, can result in spreading around the chemical contamination rather than removing it. If sterile compounding does not occur daily, BSC decontamination needs to occur only on the days that sterile compounding occurs, but must occur a minimum of once per week. At the completion of any BSC decontamination, disposable protective apparel is discarded according to designated doffing procedures and discarded as hazardous waste. New PPE is donned prior to starting sterile compounding.

B. Weekly Deactivation and Sporicidal

The BSC shall undergo a thorough deactivation on a weekly basis with sterile water and an AHS approved deactivating agent such as Peridox RTU followed by 70% sterile isopropyl alcohol. Chemical contaminants are difficult to remove. Deactivation renders them inert which minimizes the potential for chemical cross contamination of sterile products. There is no single deactivation agent that is effective against all cytotoxic drugs, so work has been done to ensure that AHS approved deactivating agents have proven results on many cytotoxic drugs. In addition to weekly deactivation, it is recommended that deactivation also occurs before and after the hood is certified, serviced or moved, whenever it has been turned off (i.e., power outage) and immediately after a large spill. All primary engineering controls also require a weekly clean with an agent that exhibits sporicidal activity. Peridox RTU is a Health Canada approved sporicidal agent and therefore the weekly deactivation also takes care of the sporicidal cleaning requirement. The surface wipe with sterile water is required weekly in order to remove the build-up of cleaning agents which present as a “film” on BSC surfaces and viewing windows.

Preparations

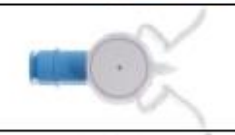
Two Categories:

1. Closed System

2. Open System

Devices- Closed System

Closed System Devices

Product Description	Image
Spinning Lock *Priming Volume : 0.34 mL*	
Locking Universal Vented Vial Access Device *Priming Volume : 0.18 mL*	
Closed Vial Spike *Priming Volume : 0.18 mL*	
13mm Vented Vial Spike with Tritan, *Priming Volume : 0.32 mL*	
13mm Closed Vial Spike	Image not yet available
Closed System Bag Spike *Priming Volume : 0.43 mL*	
Bag Spike *Priming Volume : 0.1 mL*	
Port Adapter *Priming Volume : 0.1 mL*	
Syringe Transfer Set Port *Priming Volume : 0.21 mL*	
Cap for	Image not yet available
5 pack Caps for	Image not yet available
30" Non-DEHP Admin Set w/ 20 Drop Port Drip Chamber, Spiros, Hanger with Purple Cap *Priming Volume : 3.4 mL*	

When do I use a Spinning Lock on a syringe?

1. All Chemotherapy/Hazardous drugs
2. Diluent syringes *AFTER diluent has been drawn* when using the (closed) Vial Spike on the drug vial

Exceptions:
IT injections
IV doses < 1mL *(lose too much in spinning Lock)*
Diluent syringes for reconstituted drug when the vial is ***not*** using a Lock Closed Vial Spike
Diluent syringes for Baxter infusor pumps
Trial Specific Procedures

Not needed for: Non-NIOSH listed drugs

Product Information

CL2000S	Spinning Lock Priming Volume: 0.34 mL	

How to use:

1. Attach the Spinning Lock to the syringe.
2. Turn the Spinning Lock until you hear a click
3. Turn the Spinning Lock clockwise and counter clockwise to confirm that it is attached properly

Spinning Lock

When do I use Closed System *Vented* Vial Spike?

1. All liquid Chemotherapy/Hazardous drugs that have standard sized stoppers (CL-70).
2. All liquid Chemotherapy/Hazardous drugs that are not viscous and have the smaller 13mm vial stoppers (CL-72).

Exceptions: IT injections
Drugs that are not compatible with the vent or spike of the vented Vial Spike
Trial Specific Procedures

Not needed for: Non-NIOSH listed drugs

Product Information:

CL-70	Locking Universal Vented Vial Access Device Priming Volume: 0.18 mL	

For vials with standard sized stoppers

CL-72	13mm Vented Vial Spike with Tritan, Priming Volume: 0.32 mL	

For vials with smaller sized stoppers (ie. 1 mL vinorelbine)

Drug withdrawal

Vented Vial Spike

When do I use Reconstitute *Closed* Vial Spike?

1. All Chemotherapy/Hazardous drugs that require reconstitution.

Exceptions: IT injections
Vials that are not compatible with the spike of the
[redacted] Closed Vial Spike
Trial Specific Procedures

Not needed for: Non-NIOSH listed drugs

Product Information

CL-80	[redacted] Closed Vial Spike Priming Volume: 0.18 mL	
CL- 82	13mm Closed Vial Spike	Image not yet available

13 mm

Closed System
Reconstitute

Bag Spike

Product Information

CL-10	Closed System Bag Spike Priming Volume: 0.43 mL	

Draw up diluent using Bag Spike (CH-10)

Cap syringe with Spinning Lock and get the diluent volume checked

Reconstituting using the Closed Vial Spike

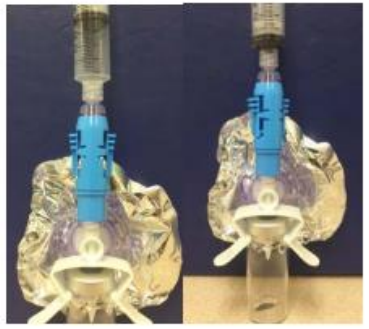
- The balloon cover on vial spike must be removed for ALL reconstitution volumes.
- A Spinning Lock will be required for diluent syringe(s) as only a Spinning Lock can attach to a Vial spike.
- DO NOT add Spinning Lock prior to drawing up diluent as adding the volume from the Spinning Lock may over-dilute the drug concentration
- Drug volume can be lost into the balloon and, once in the balloon, be extremely difficult to retrieve, to avoid this :
    - Make sure that the vial is always in the upright position when reconstituting, not slanted.
    - NEVER push back a large volume (air or liquid) into the vial when the vial is inverted and the spike is immersed in liquid.

Draw up diluent using Bag Spike (CH-10)

Cap syringe with Spinning Lock and get the diluent volume checked

Add diluent to the drug vial

While leaving the spinning Lock attached to the closed vial spike, pull air into the diluent syringe and push into vial to ensure all diluent is flushed out of the closed vial spike and into the vial



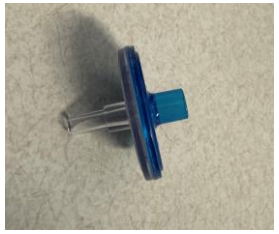
Pull air into the diluent syringe to relieve any positive pressure in the vial/balloon and disconnect the spinning Lock closed vial spike

Syringe Final Product

(closed)

Injecting into IV bag

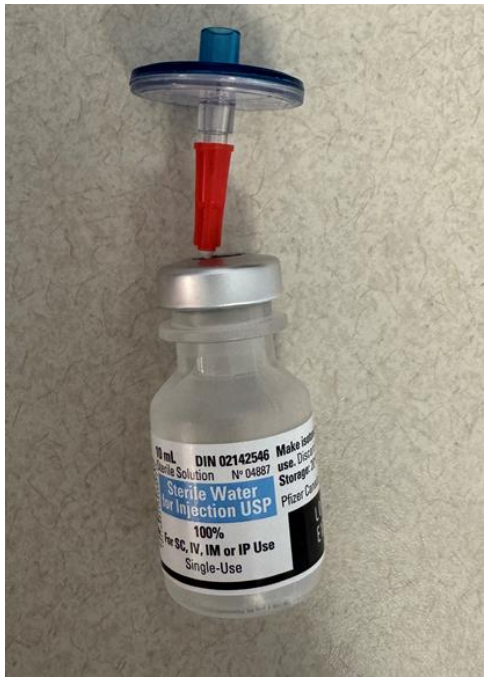
Admin Set



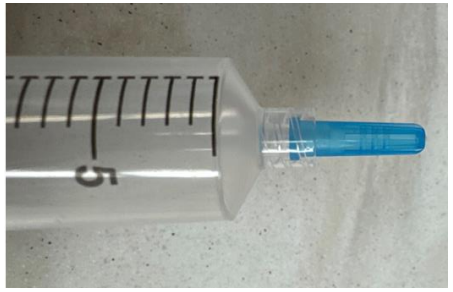
0.22 Micron Filter

Micron Filter with 18 G blunt fill needle

Vented Vial with filter



Volume drawn from vial in Open System



Syringe final product with cap.

Dose added to final product preparation via WHITE PORT

Devices- Open System

Embedded Worksheets

IntraVenous
cyclophosphamide
20 mg/mL
DIN:02241799
02241800

Mfg: _____

*Alt. DIN/Mfg: _____

Initials Tech:____ Initials ACC:____

Dose #	Admin details				Set up initials		
	Date	Time	Location	Tech initials	Room temp drugs pulled	Fridge drugs pulled	Supplies pulled
1			[SKIP in Epic]				
2			[SKIP in Epic]				

Preparation Notes

LATEX ALLERGY sticker *(if needed)*

NAPRA Vial Expiry = 6 hours RT

Auxiliary Label(s):
- CYTOTOXIC MATERIAL HANDLE PROPERLY

Final Product Expiry:
in NS infusion (conc 0.24 to 20 mg/mL): 30 hrs RT or 7 days F
in D5W infusion (conc 0.24 to 20 mg/mL): 24 hrs RT or 36 hrs F

Special Supplies: None

Preparation Instructions:
- Clear, colorless solution
- Venting: Use closed system
- Final preparation: Clear, colorless solution in an IV bag

Additional Information:
- May be an irritant
- Avoid the use of utensils, needles or parts of infusion pumps made of aluminum

LABEL DOSE #1

DOSE #1

● Assembly Check Initials:	Drug lot # (or RECON lot #) & NAPRA vial expiry
● Prep Initials:	
● Dose Check Initials:	Volume in each syringe
● Final Product Check Initials:	
● Patient Order Complete Initials:	Prep Date & Time

Chemotherapy Preparation Worksheet: cyclophosphamide IV

● ASSEMBLY CHECK (Technician) ●

Order readiness from physician order
1. [Epic: scan patient (dispense) label to open dispense prep and check order is ready to prepare]
2. [SKIP in Epic] Prep date / time on final product label is appropriate for admin date / time on physician order
3. [SKIP in Epic] Order is not on hold

Match Physician Order to Worksheet and Labels
4. Match Physician order to worksheet, worksheet label and final product label:
   - Patient Name and ID #
   - Drug Name
   - Dose and Route
   - Physician, Location, Dose # or Day #
   - If applicable, IV solution type/volume and admin duration for pumps

Check Allergies, Special Supplies and Dose Volume
5. Check whether patient has latex allergy and if so, ensure sticker has been added to worksheet
6. Any special supplies (shown on "Special Supplies" area) required for this order are present
7. Perform a dose volume check using a calculator

Match drugs & supplies to worksheet & worksheet label
8. Quantity of drug vials (expiry date) – if drug not already in BSC
9. Match drug DIN to worksheet.
10. Type & size of solution bag, volume & expiry as applicable (If drug volume too large for bag follow site specific procedures)
11. Check # of final product labels required & that they all match the worksheet label
12. **Follow assembly check instructions on RECON sheet** (if applicable)
13. **Initial worksheet for assembly check [Epic: AND 'save work']**

● PREPARATION (Technician) ●

1. Match drug, concentration & DIN on vial to worksheet [EPIC: AND scan patient (dispense) label and THEN barcode labels on BOTH drug and diluent and match to worksheet]
2. Confirm Assembly Check is signed off
3. Check that product & special supplies are included & are free of defects & verify manufacturer expiry on all
4. Determine NAPRA expiry & record on vial AND worksheet (or confirm expiry if previously punctured vial used)
5. [EPIC: initial worksheet for preparation] Record Drug Lot # (or RECON Lot #) & initial worksheet for preparation.
6. Mental estimation for dose converted to volume of drug needed
7. Follow any prep notes & draw up drug into syringe(s)
8. Call for dose check [EPIC: AND select 'mid-prep review']

● MID-PREP DOSE CHECK IN PERSON (Authorized Chemotherapy Checker (ACC) & Technician) ●

1. *Tech* - bring drug syringes & vials to window
2. [Epic: **ACC** - open mid- prep review for order name and patient name]
3. **ACC** – verbalize drug name (and concentration if applicable) and volumes in syringe(s)
4. **ACC** - match drug name & volume to final product label & record each volume of syringe on worksheet
5. *Tech* - verbalize DIN from drug vial & **ACC** match DIN to worksheet
6. *Tech* - verbalize NAPRA expiry from drug vial & **ACC** match NAPRA expiry to worksheet
7. *Tech* - bring solution bag to window, if applicable
8. **ACC** – if applicable, verbalize solution bag type & volume, match to final product label & verify expiry of solution bag
9. **ACC** - verify special supplies & drug prep info (see prep notes)
10. **ACC** - [Epic: record prep time on worksheet & expiries on worksheet label and final product label] record prep time on worksheet & final product labels
11. **ACC** - verify worksheet label & final product label match
12. **ACC** - give final product label to tech
13. **ACC** - initial worksheet for dose check & confirm Preparation Tech is signed off [Epic: AND approve or reject mid-prep check]

● PREPARATION cont'd (Technician) ●

1. Confirm Dose Check is signed off by ACC [Epic: AND in dispense prep: check patient name and age, drug and concentration to select correct preparation THEN check status is 'ready to resume prep']
2. Prepare product
3. Wipe port (if applicable), hands, product, & rotate final product
4. Label the final product
5. Verify drug on vial one final time and discard or place vial to the side for later use
6. [Epic: Finalize in dispense prep]

● FINAL PRODUCT CHECK (ACC) ●

Match Physician Order to Worksheet and Labels
1. [Epic: Open dispense check and scan the final product label to access the physician order]
2. [Epic: Match final product label to worksheet and worksheet label] Match Physician order to worksheet, worksheet label and final product label:
   - Patient Name and ID #
   - Drug Name
   - Dose (verify drug volume with a calculator), Route and Correct IV solution type and volume
   - Physician, Location, Dose # or Day #
   - Correct volume of syringe recorded on worksheet

Final Inspection
3. Reasonableness check [Epic: review patient storyboard in 'order history'] Review the physician order (for cancer drugs supplied) to confirm:
   - Drugs are not listed as patient allergy (or noted as OK by triage pharmacist),
   - BSA or weight noted for dosing calculation
4. Affix auxiliary labels shown under preparation notes
5. Verify date & time of preparation and product expiry are appropriate for administration date and time.
6. Inspection for particulates, color, seal integrity
7. **Initial final product label for release**
8. **Initial worksheet for**

Embedded Worksheets- Reconstitution

Preparation Notes:
- Venting: Use closed system
- Shake vigorously
- Clear colorless solution

Additional Information:
- May be an irritant
- Avoid the use of utensils, needles or parts of infusion pumps made of aluminum
- Temperature fluctuations can lead to the melting of cyclophosphamide. Do NOT use vials containing melted substance (the powder becomes a clear or viscous yellow liquid)

cyclophosphamide 1000 mg
IntraVenous

DIN:

Vial Conc: 20 mg/mL Total: 1000 mg = 50 mL

Vial Stability: NAPRA Expiry = 6 hours RT

Diluent: Normal Saline (NS)
RECON. Instructions: Add 50 mL NS
*** Alternate MFG Diluent: _____**

● ASSEMBLY CHECK (Technician) ●

Match drug vial to RECONsheet
1. Drug name, vial size, DIN # (record DIN if different brand & review product monograph)*
2. Drug lot#, drug expiry
3. RECON Lot #, Qty of vials reconstituted

Match diluent to RECONsheet
1. Diluent name, volume
2. Diluent lot #, diluent expiry

Initial RECONsheet for assembly check

● PREPARATION (Technician) ●
1. Match drug & DIN# on vial to RECONsheet
2. Record NAPRA expiry on RECONsheet & vials
3. Draw up diluent & call for check

● FINAL RECON CHECK (Tech & ACC*) ●
1. Tech - bring drug, diluent (bag & syringe(s)) to window
2. ACC* - verbalize drug name from vial at window & verbalize diluent name & volume in syringe(s)
3. ACC* - match drug name, diluent & volume & mfg expiry date to RECONsheet
4. Tech - verbalize DIN#, RECON Lot # & NAPRA vial expiry date
5. ACC* - match verbalized info from Tech in #4 to RECONsheet, confirming NAPRA vial expiry
6. **ACC* - initial RECONsheet for Final Check**
7. Tech - reconstitute drug
8. **Tech - initial RECONsheet for preparation**

	Drug			Reconstituted Vial Info			Diluent		Final Product		
Date	Drug Lot #	Drug Expiry	Drug DIN* (if different from brand)	RECON Lot # **	Qty	NAPRA Expiry (date & time) **6 hrs RT**	Diluent Lot #	Diluent Expiry	● **Assembly Check** Tech initials	● **Prep** Tech initials	● **Final RECON** ACC* initials

* **Note:** if printed worksheet DIN & vial DIN, do NOT match because of brand change, a second person (**ACC***) must confirm correct drug & initial beside the written DIN & diluent information.

** Assigned Lot # is: number for the month followed by a number for the mg followed by a dash & consecutive numbers starting with 001. E.g., Gemcitabine 200 mg for Feb: 022-001. Each month, a new CIVA RECONsheet is started.

Central IV Admixture (CIVA) RECONsheet

Receiving & Unpacking Hazardous Medications

REFERENCE DOCUMENT

To determine any precautions required by pharmacy personnel when receiving/unpacking hazardous medications for sterile compounding.

Principles for receiving and/or unpacking **undamaged** hazardous medications for sterile compounding include:

- Two pairs of ASTM International–approved gloves must be worn at all times
- The receiving/unpacking location must be a low traffic area separate from the hazardous storage area, and outside of controlled areas (clean room and anteroom), to limit the introduction of dust and particles into the controlled areas.
- A spill kit with chemical cartridge respirator must always be in the immediate vicinity.
- A container, box or outside bag containing a shipment of hazardous materials is considered not chemically contaminated (so may be returned to the supplier if needed).
- Packaging materials inside delivery containers must be discarded in regular waste containers.
- Manufacturer's individual packaging that has been in direct contact with vials containing hazardous products is considered chemically contaminated and must be discarded in a hazardous waste container. Note: This does not need to occur upon receipt; vials may remain in manufacturer's individual packaging until time of use.
- A C-PEC used for sterile compounding must not be utilized for unpacking damaged hazardous medication shipments.

Principles to be followed for receiving and/or unpacking **damaged** hazardous medications for sterile compounding (I.e. A spill may have occurred inside the container) include:

- Follow PPE requirements as outlined in the AHS PPE Guide.
- All packaging materials must be considered chemically contaminated and must be discarded in a hazardous waste container.
- Follow one of the two steps below:
    1. When a C-PEC for compounding of non-sterile hazardous medications is available:
        a) Remove inner container from outer box.
        b) Place in impervious container.
        c) Transport to C-PEC
        d) Place a plastic-backed preparation mat on the work surface of the C-PEC.
        e) Open the package and remove any usable items.
        f) Wipe the outside of these items with both germicidal and then non-sterile isopropyl alcohol.
        g) Remove the items from the C-PEC to be transported to the appropriate storage location.
        h) Dispose of hazardous waste along with the mat and cleaning disposables.
        i) Deactivate, decontaminate and clean the C-PEC.
    2. When a C-PEC for compounding of non-sterile hazardous medications is not available:
        a) Place any remaining damaged item(s) in an impervious container.
        b) Label the impervious container as hazardous.
        c) Contact the supplier for instructions on returning the damaged items.
        d) If the supplier declines the return, dispose of as hazardous waste.

References

Cancer Care Alberta Pharmacy – Hazardous Products Training Manual AB, Canada: Alberta Health Services; 2020 Apr 1 [updated 2023 June]; [cited 2025-June-10].

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Thank you

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