

Sterile Suite Orientation

Seattle Children's Inpatient Pharmacy



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Introduction

This document describes the minimum standards used when preparing compounded sterile preparations (CSP) in the sterile compounding suite. The main function of this document is to describe a prescribed sequence to minimize harm, including death, to human patients that could result from:

- microbial contamination (non-sterility)
- excessive bacterial endotoxins
- variability from the intended strength of correct ingredients
- chemical and physical contaminants, and/or use of ingredients of inappropriate quality

Proper use of the sterile compounding suite is standardized to minimize the potential for contact with non-sterile surfaces, introduction of particulate matter, and mix-ups with other products or CSPs.

Introducing Items into the Sterile Suite

Passthrough Doors and Cabinets

Transferring materials between the non-sterile pharmacy and the sterile suite is conducted through permanently built two-sided cabinets with a door on either side, to minimize the risk of introducing contaminants into the sterile compounding suite. These cabinets are also built between the anteroom and the buffer room of the sterile suite, to further maintain appropriate air quality for sterile compounding.

Key Points

- Only one of the two doors for each passthrough can be opened at a time, while the other will remain closed and not allow access into the cabinet until the first is closed and latched.
- The mechanical system allowing for one-door access to the cabinets must be preserved by carefully handling the cabinet door handles to avoid damage.
- There are five pass-through cabinets, including one larger garage pass-through for bulk items and replenishing stock:
 1. Interior Front Fill Passthrough
 2. Interior Cart Fill Passthrough
 3. Exterior Non-Hazardous Passthrough
 4. Exterior Hazardous Passthrough
 5. Garage Passthrough

Interior Front Fill Passthrough

This passthrough is located between the sterile compounding buffer room and the sterile suite anteroom. It's used for the sterile front fill and flex technicians to pass their prepared sterile medications and special dilution compounds to the anteroom pharmacists to check and finalize. The pharmacists will also return the trays used for presentation with this passthrough and pass the technicians occasional labels and medications sent in from the exterior (PO) front fill and cart fill areas. Figures 1 and 2 below depict the location and the front and inside of the front fill passthrough.

Interior Cart Fill Passthrough

This passthrough is located between the sterile compounding buffer room and the sterile suite anteroom, to the left of the front fill passthrough. It's used for the sterile cart fill technician to pass their prepared sterile medications and special dilution compounds to the anteroom pharmacists to check and finalize. The pharmacists will also return the large multi-segmented cart fill tray used for presentation on the upper shelf of the passthrough. Figure 1 below depicts the location of the cart fill passthrough in relation to the front fill passthrough.

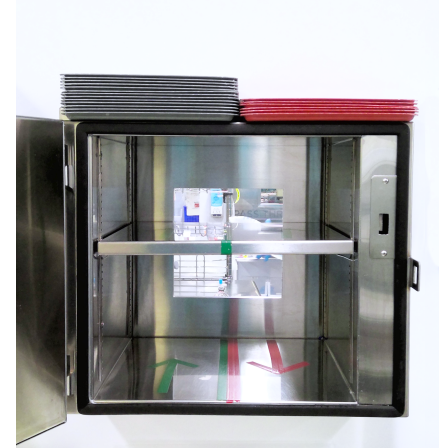
Figure 1: Interior Cart Fill and Front Fill Passthroughs Location

View of the interior cart fill passthrough (left) and front fill passthrough (right) from the pharmacist checking area in the anteroom of the sterile suite.



Figure 2: Interior Front Fill Passthrough

The front and inside of the front fill passthrough from the buffer room side, displaying the standard location of the presentation trays and the arrows within the passthrough marking the outgoing and returned tray placement.



Exterior Non-Hazardous Passthrough

This passthrough is located between the non-sterile pharmacist checking area and the sterile suite pharmacist checking area within the anteroom. It's used primarily for the anteroom pharmacists to place the finalized sterile compounded medications into the labeled cabinet bins, including:

- Scheduled
- First dose
- Redispensed
- STAT and time sensitive
- Controlled
- Next-day dialysis, infusion, or surgery center
- Surgery pharmacy special dilution prepack
- Cart fill

The labeled bins always remain either in the passthrough or within the sterile compounding suite and must not be taken out into the non-sterile area. One exception to this is the cart fills bins, which are removed to complete the cart fill but returned to the passthrough after wiping down thoroughly with sterile IPA. Individual items, refrigerated drugs, or small amounts of stock requested by the sterile suite staff may occasionally be requested and introduced into the sterile suite using this passthrough but must first be wiped with sterile IPA.

Exterior Hazardous Passthrough

This passthrough is located between the non-sterile pharmacy window and next-day medications shelf area and the sterile hazardous compounding buffer room. It's used primarily for the hazardous compounding technician and/or sterile suite pharmacists to place the finalized hazardous sterile compounded medications into the labeled cabinet bins, including:

- Scheduled
- First dose
- Redispatched
- STAT and time sensitive
- Controlled
- Cart fill

The labeled bins always remain either in the passthrough or within the sterile compounding suite and must not be taken out into the non-sterile area. Individual items, refrigerated drugs, and hazardous compounding stock items can be introduced into the sterile suite using this passthrough but must first be wiped with sterile IPA. Figure 3 below depicts exterior view of the hazardous passthrough.

Garage Passthrough

The garage is located between the non-sterile front fill area and the sterile anteroom storage area. It's used primarily to introduce:

- Non-refrigerated sterile drug stock
- IV and diluent fluid bag stock
- Non-hazardous compounding supply stock

The cart and bins within the garage always remain either in the garage passthrough or within the sterile compounding suite and must not be taken out into the non-sterile area. All items introduced onto this cart are to be first wiped down with sterile isopropyl alcohol (IPA) before closing the garage door, with will automatically initiate an air-sterilization process. Figure 4 below depicts the interior sterile suite view of the garage passthrough and dedicated cart.

Figure 3: Exterior Hazardous Passthrough

The front of the hazardous passthrough from the next-day rack area from outside of the sterile suite.

The green center bar is displayed when the door may be opened and will appear red when opened from the inside.



Figure 4: Garage Passthrough

The front of the garage passthrough from the anteroom storage area. Control panel on the right is used to open and close the garage door.

The passthrough cart may enter the sterile suite from this side.



Non-Hazardous Materials Handling



Task

Introducing items into the sterile suite anteroom.



Key Points

Prior to performing this task, material handlers will complete donning and doffing training checklist.

- Cardboard is **never** allowed into the sterile compounding room
- All items must be wiped down with sterile 70% IPA using low-lint wipers by personnel wearing gloves before it is placed into pass-through(s) and introduced to the anteroom, while ensuring the packaging integrity is not compromised.



Action

1. Receive and reconcile items from wholesaler.
2. Don disposable gloves and wipe down receiving cart with sterile 70% IPA.
3. Unpack items and place on wiped-down cart. Travel cart to anteroom garage door.
4. Wipe down supplies using sterile 70% IPA. This must be done by garage door.
5. Open pass-through garage door and place disinfected items onto garage cart.
6. Follow donning procedures for entering sterile compounding area.
7. Open garage door, remove cart, close garage door and properly restock items into clean side anteroom.
8. Wipe down with empty cart and wheels with sterile 70% IPA.
9. Obtain outgoing Kanbans.
10. Follow doffing procedures for exiting sterile compounding area.

Hazardous Materials Handling



Task

Introducing items into the sterile suite hazardous room.



Key Points

Prior to performing this task, material handlers will don a surgical mask, chemo gown, and two pairs of gloves.

- Cardboard is **never** allowed into the sterile compounding room
- All items must be wiped down with sterile 70% IPA using low-lint wipers by personnel wearing gloves before it is placed into pass-through(s) and introduced to the anteroom, while ensuring the packaging integrity is not compromised.
- Hazardous materials will be stocked into the correct areas by the scheduled hazardous pharmacy technician after they're placed in the passthrough by the materials handler. Refrigerated meds will be prioritized and placed in the hazardous fridge as soon as possible.



Action

1. Receive and reconcile items from wholesaler.
2. Don surgical mask, chemo gown, and two pairs of disposable gloves.
3. Wipe down the hazardous materials with sterile 70% IPA and place on the clean designated hazardous cart.
4. Travel the cart to the exterior hazardous passthrough and place the items inside. Display the “refrigerated medications” card to alert the hazardous technician if there items that need to be placed into the fridge as soon as possible.
5. Gather the outgoing kanbans to deliver to purchasing staff.

Inventory Management



Task

Pharmacy technicians are responsible for restocking supplies and using the Kanban system for ensuring inventory management.



Key Points

- Cardboard is **never** allowed into the sterile compounding room
- All items must be wiped down with sterile 70% IPA using low-lint wipers by personnel wearing gloves before it is placed into pass-through(s) and introduced to the anteroom, while ensuring the packaging integrity is not compromised.



Action

1. Prepare stock list and gather supplies needed.
2. Use gloves and sterile 70% IPA to wipe down cart to be used for transporting supplies to the outside of the garage.
3. Place stock onto disinfected cart. Travel cart to anteroom garage door.
4. Wipe down supplies using sterile 70% IPA. This must be done by garage door.
5. Open pass-through garage door and place disinfected items onto garage cart.
6. Follow donning procedures for entering sterile compounding area if you are putting the supplies away.
7. Open garage door, remove cart, and properly restock items.
8. Wipe down garage cart and wheels with sterile 70% IPA, return to garage, and close garage door.

Maintaining Air Quality

Pressure Readout Displays

There are three doors within the sterile compounding suite, and much like the passthrough cabinets, only one door of these can remain open at any given time to maintain appropriate air pressure and reduce contaminants from entering the sterile compounding area. The open door must be fully closed before another will open by motion switch activation. The pressure of each room withing the sterile compounding suite is monitored with the pressure readout displays, as outlined below. Figure 5 below depicts the two possible readings of the pressure displays, and the screen that displays the list of pressures for each sensor.



Task

Validate accurate pressure readouts for each sterile compounding suite area.



Key Points

- Pressure readout displays are located near ever door.
- A complete list of pressures in each sterile suite room is located near the tube station.
- The sterile suite is designed with separate doors between compounding areas to improve air quality by limiting movement between areas at the same time.



Action

1. Identify locations of each pressure readout displays located near every door.
2. Verify that the pressure is within normal range by validating the pressure readout display is green with a door and arrow icon and reads **NORMAL** before entering.
3. Escalate to the line leader pharmacist if the display is red with a universal no sign icon and reads **ALARM**, who will follow standard work for out-of-range IV room pressure.

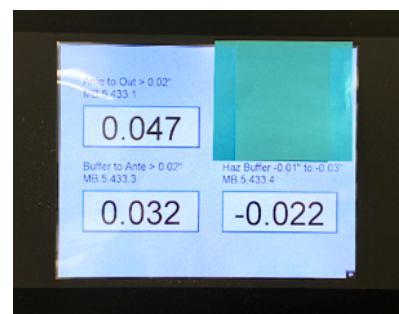
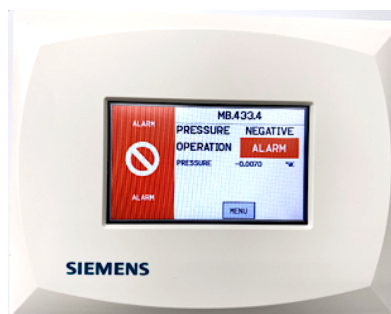


Figure 5: Pressure Readout Displays

A pressure readout display verifying the pressure is normal (left) and alerting that the pressure is out of range (center). The image to the right is the screen that displays the list of pressures for each location of the pressure sensors, located near the tube station.

Personal Hygiene



Task

Maintain proper personal hygiene to minimize risk of contamination to the environment and compounded sterile products.



Key Points

Personal hygiene is essential to maintain microbial control of the environment. Most microorganisms detected in cleanrooms are transferred from individuals. Those who may have a higher risk of contaminating the CSP and the environment must report the following conditions to the designated person:

- Rashes
- Recent tattoos
- Oozing sores
- Conjunctivitis
- Active respiratory infection

The designated person is responsible for evaluating whether these individuals should be excluded from working in compounding areas before their conditions have resolved because of the risk of contaminating the CSP and the environment.

No one wearing street clothes is permitted to enter the sterile suite.



Action

1. Remove personal outer garments and all exposed personal clothing, including long-sleeved shirts, bandanas, coats, jackets, sweaters, and vests.
2. Remove all cosmetics to avoid shedding particles.
3. Remove all hand, wrist, and other exposed jewelry that could interfere with the effectiveness of garbing or otherwise increase the risk of contamination to CSPs, including rings and piercings.
4. Cover any jewelry that cannot be removed before entering the sterile suite.
5. Store earbuds, headphones, and all personal devices outside of the sterile suite.
6. Keep nails clean and neatly trimmed to minimize particle shedding and avoid glove puncture.
7. Remove any nail polish, artificial nails, and nail extenders before entering the sterile suite.
8. Place employee badge without lanyard inside scrub pocket and covered to avoid contamination of CSPs.
9. Wipe down personal eyeglasses with provided eyeglass cleaning wipes or sterile 70% IPA.

Hand Hygiene



Task

Perform proper hand washing procedure **every time** the sterile suite is entered.



Action

1. Remove visible debris from underneath fingernails with a disposable nail cleaner under warm running water.
2. Wash hands and forearms up to the elbows with soap and water for at least 30 seconds.
3. Dry hands and forearms to the elbows with low-lint disposable towels or wipes.

Garbing



Task

Perform proper donning and doffing of garb **every time** the sterile suite is entered and exited.



Key Points

- Garb must be donned and doffed in an order that reduces the risk of contamination.
- Personnel are not to doff their garb while other staff are donning. Incoming staff have priority to don; however, if one person is doffing, the individual donning will wait.



Action

Donning

1. Peel top layer off sticky mat when visibly soiled and step on mat before entering the anteroom.
2. Wipe down eyeglasses with provided cleaning wipe, if applicable.
3. Don face mask, then beard cover if applicable.
4. Cover all hair with bouffant hair cover.
5. Approach line of demarcation and hang jacket on an available hook.
6. Don one shoe cover and step covered shoe onto the clean side of the line of demarcation.
7. Don the other shoe cover and place the second covered shoe over the line of demarcation.
8. Visually inspect garb in the mirror to ensure it is covering properly.
9. Perform hand hygiene procedure.
10. Don the low-shedding cuffed jacket hanging from the hook.
11. Open sterile glove package on approved glove cart.
12. Apply alcohol-based hand sanitizer to one hand and rub hands together using vigorous friction, covering all surfaces of the hands and fingers until hands are dry. Do not wave hands to facilitate drying.
13. Don sterile gloves and inspect for holes, punctures, or tears. Replace gloves if a defect is found.
14. Spray outside of donned gloves with sterile 70% IPA and let dry. Do not wave hands to facilitate drying process. **Alcohol-based gels and hand sanitizers cannot be used on gloves.**

Doffing

1. Doff low-shedding cuffed jacket and hang on an available hook on the interior (clean) side of the line of demarcation.
2. Cross line of demarcation, then remove and dispose of garb the order in which they were donned:
 1. Face mask
 2. Beard cover if applicable
 3. Bouffant hair cover
 4. Eye shield if applicable
 5. Shoe covers
 6. Gloves

Hazardous Personal Protective Equipment



Task

Perform proper donning and doffing of hazardous personal protective equipment (PPE) **every time** the sterile suite hazardous room is entered and exited.



Key Points

- Appropriate hazardous PPE must be worn in addition to the initial sterile suite garb.
- Hazardous PPE includes a chemo gown, a second pair of shoe covers, and a second pair of gloves approved for chemotherapy production.



Action

Donning

1. Apply second pair of shoe covers over initial garbing pair.
2. Don special respiratory protection if needed.
3. Enter hazardous room and don a chemo gown. Ensure the gown is properly fastened and tied around waist.
4. Don special eye and face protection if needed.
5. Spray gloves with sterile IPA and allow to dry.
6. Apply second pair of gloves approved for chemotherapy production.

Doffing

1. Remove second pair of gloves inside PEC and dispose of in sealable plastic hazardous bag.
2. Remove chemo gown and discard when exiting the hazardous room, unless otherwise instructed due to PPE shortages.
3. Remove outer shoe cover of one shoe and step over hazardous line of demarcation.
4. Remove outer shoe cover of the opposite shoe and step over hazardous line of demarcation.
5. Dispose of outer shoe covers in hazardous garbage bin.
6. Remove inner pair of gloves and dispose of in hazardous garbage bin, then exit the hazardous room.
7. Wash hands thoroughly and dry with non-shedding wipes.
8. Apply new gloves before returning to sterile compounding.

Cleaning the Non-Hazardous Rooms

Pharmacy Technicians

Primary Engineering Controls



Task

Pharmacy Technicians perform daily and monthly cleaning, and monthly sporicidal application to primary engineering controls (PECs) and any equipment inside using facility approved agents and procedures.



Key Points

- Cleaning, disinfecting and organizing of the following non-hazardous work surfaces should occur at minimum at the end of every shift by a trained pharmacy technician, pharmacist and/or pharmacy student with a one-step disinfectant.
- Direct and contiguous compounding areas should be cleaned with 70% sterile Isopropyl alcohol at a minimum of every 30 minutes, after spills or when the work surface is visibly soiled.
- Once monthly, in coordination with pharmacy staff and environmental services, an EPA registered sporicidal cleaning will replace the one-step disinfectant. Coordination must be completed to ensure all surfaces are cleaned within 72 hours at the same interval each month.



Supplies

- Sterile water **as necessary**
- One-step disinfectant **daily**
- Sterile 70% IPA **daily**
- One-step sporicidal agent **monthly**



Action

1. Perform hand hygiene and glove per standard operating procedure, then gather supplies.
2. Spray gloves with sterile 70% IPA and let dry.
3. Remove all items from PEC and dispose of non-reusable items.
4. Saturate non-shedding wipe with one-step disinfectant cleaner, or use a pre-saturated one-step disinfectant wipe. The wipe should be full saturated but not dripping. **Do not spray directly into the PEC or toward the HEPA filter.**
5. Clean the interior of the PEC from top to bottom and back to front in the following order:
 1. Ceiling
 2. HEPA diffuser screen
 3. Each interior side of the PEC
 4. IV bar and hooks
 5. Items housed on the deck, such as automated compounding devices (ACD)
 6. Deck of the PEC, carefully moving any items housed to clean underneath
6. Allow the one-step disinfectant to remain for the duration indicated on the product label.
7. Repeat the interior PEC cleaning with sterile 70% IPA and allow to dry for 30 seconds.
8. Dispose of gloves, then perform hand hygiene and don new gloves before compounding.
9. Document daily shift cleaning task in Simplify 797. Clean PEC deck with sterile 70% IPA at minimum every 30 minutes and when visibly soiled.

Secondary Engineering Controls



Task

Pharmacy Technicians perform daily and monthly cleaning, and monthly sporicidal application to secondary engineering controls (SECs) in the buffer room using facility approved agents and procedures.



Key Points

- Cleaning, disinfecting and organizing of the following non-hazardous work surfaces should occur at minimum at the end of every shift by a trained pharmacy technician, pharmacist and/or pharmacy student with a one-step disinfectant.
- Once monthly, in coordination with pharmacy staff and environmental services, an EPA registered sporicidal cleaning will replace the one-step disinfectant. Coordination must be completed to ensure all surfaces are cleaned within 72 hours at the same interval each month.

Secondary engineering controls include:

- Carts, counters, and work surfaces
- Pass-throughs into the anteroom
- Trays used for presentation
- High-touch areas, such as pass-through handles, Omnicell surfaces, printers, tablets, and EPIC equipment
- Shelves and storage bins **monthly**



Supplies

- One-step disinfectant **daily**
- Sterile 70% IPA **daily**
- One-step sporicidal agent **monthly**



Action

1. Perform hand hygiene and don gloves per standard operating procedure.
2. Gather necessary cleaning supplies.
3. Remove all items from carts, counters, and other surfaces to be cleaned.
4. Clean all SECs listed above daily with pre-saturated disinfectant wipes.
5. Allow the one-step disinfectant to remain on the surfaces for the duration indicated on the product label.
6. Dispose of gloves, then perform hand hygiene and don new gloves before compounding.
7. Document daily shift cleaning task in Simplify 797.

Pharmacists

Secondary Engineering Controls



Task

Pharmacists perform daily and monthly cleaning, and monthly sporicidal application to SECs in the ante room using facility approved agents and procedures.



Key Points

- Cleaning, disinfecting and organizing of the following non-hazardous work surfaces should occur at minimum at the end of every shift by a trained pharmacy technician, pharmacist and/or pharmacy student with a one-step disinfectant.
- Once monthly, in coordination with pharmacy staff and environmental services, an EPA registered sporicidal cleaning agent will replace the one-step disinfectant. Coordination must be completed to ensure all surfaces are cleaned within 72 hours at the same interval each month.

Secondary engineering controls include:

- Carts and counters
- Pass-throughs in and out of the IV room including ceiling, sides, shelves, and bins
- Devices and high-touch areas, such as pass-through handles, Omnicell surfaces, printers, tablets, and EPIC equipment



Supplies

- One-step disinfectant **daily**
- One-step sporicidal agent **monthly**
- Sterile non-shedding wipes



Action

1. Perform hand hygiene and don gloves per standard operating procedure.
2. Gather necessary cleaning supplies.
3. Remove all items from carts, counters, and other surfaces to be cleaned.
4. Clean all SECs listed above daily with pre-saturated disinfectant wipes.
5. Allow the one-step disinfectant to remain on the surfaces for the duration indicated on the product label.
6. Dispose of gloves, then perform hand hygiene and don new gloves before compounding.
7. Document daily shift cleaning task in Simplify 797.

Environmental Services

Secondary Engineering Controls



Task

Pharmacy and environmental services staff perform daily and monthly cleaning, and monthly sporicidal application to SECs in the ante room using facility approved agents and procedures.



Key Points

- Cleaning and disinfecting of the following areas are performed at a minimum of the indicated frequency by trained environmental services staff during a time when no or limited aseptic operations are in progress.
- All cleaning tools and supplies are non-shedding and dedicated to the sterile compounding room.
- Once monthly, in coordination with pharmacy staff, an EPA registered sporicidal cleaning agent will replace the one-step disinfectant. Coordination must be completed to ensure all surfaces are cleaned within 72 hours at the same interval each month.

Secondary engineering controls include:

- Garbage and recycling removal
- Floors
- Exterior of PEC
- Ceilings, lights, and filter grates **monthly**
- Trash bins interior and exterior **monthly**
- Exterior of refrigerators and large equipment **monthly**



Supplies

- One-step disinfectant **daily**
- One-step sporicidal agent **monthly**
- Sterile non-shedding wipes
- Micro Cinch mop and disposable pads
- Klean Max wall mop and disposable pads



Action: Daily

1. Perform hand hygiene and don gloves per standard operating procedure.
2. Gather necessary cleaning supplies.
3. Clean dedicated reusable cleaning tools with one-step disinfectant.
4. Transfer garbage and recycling bins to ante room at least six feet away from the compounding hoods, then remove garbage and recycling bags.
5. Clean garbing bench and sink using one-step disinfectant. Allow the one-step disinfectant to remain on the surfaces for the duration indicated on the product label.
6. Discard wipes when visibly soiled or too dry to sufficiently wet surfaces.
7. Attach a new sterile mop head and mop the entire floor surface starting from farther corner of the buffer room into the ante room towards the line of demarcation using the one-step disinfectant.
8. Clean dedicated reusable cleaning tools with one-step disinfectant.
9. Document the cleaning on a monthly log to be reviewed by pharmacy staff.



Action: Monthly

1. Perform hand hygiene and don gloves per standard operating procedure.
2. Gather necessary cleaning supplies.
3. Clean dedicated reusable cleaning tools using a sterile non-shedding wipe saturated with the sporicidal disinfectant.
4. Transfer garbage and recycling bins to ante room at least six feet away from the compounding hoods, then remove garbage and recycling bags.
5. Clean garbing bench and sink with the sporicidal disinfectant. Allow the sporicidal disinfectant to remain on the surfaces for the duration indicated on the product label.
6. Discard wipes into a sealable plastic bag when visibly soiled or too dry to sufficiently wet surfaces.
7. Attach a new sterile mop head to a reusable cleaning tool and saturate with the sporicidal disinfectant.
8. Clean the following areas while saturating the mop head with the sporicidal disinfectant as often as needed:
 - Ceilings, ceiling lights, and HEPA filter grates
 - Walls, windows, doorframes, and all mounted wall items
 - Exterior of PEC
9. Discard soiled mop head into a sealable plastic bag. Allow the sporicidal disinfectant to remain on the surfaces for the duration indicated on the product label.
10. Attach a new sterile mop head and saturate with the sporicidal disinfectant and mop the entire floor surface starting from farther corner of the buffer room into the ante room towards the line of demarcation using the one-step disinfectant.
11. Discard mop head into a sealable plastic bag and clean reusable cleaning tools with a non-shedding wipe saturated with the sporicidal disinfectant.
12. Clean all glass surfaces with a non-shedding wipe saturated in sterile IPA.
13. Document cleaning on the monthly log to be reviewed by pharmacy staff. If documentation is not completed, pharmacy staff is to contact Environmental Services to complete the cleaning as soon as possible.

Cleaning the Hazardous Room

Pharmacy Technicians

Primary Engineering Controls



Task

Pharmacy Technicians perform daily and monthly cleaning, and monthly sporicidal application to PECs and any equipment inside using facility approved agents and procedures.



Key Points

- Deactivating, decontaminating, disinfecting, and organizing of the following hazardous work surfaces should occur at minimum at the end of every shift by a trained pharmacy technician, pharmacist and/or pharmacy student with a one-step disinfectant.
- Direct and contiguous compounding areas should be cleaned with 70% sterile Isopropyl alcohol at a minimum of every 30 minutes, after spills or when the work surface is visibly soiled.
- Once monthly, the grill tray and surface under the deck will be cleaned.



Supplies

- Deactivating and decontaminating sporicidal agent: Peridox RTU
- Sterile 70% IPA
- Dedicated hazardous Easy Reach cleaning tool
- Sterile non-shedding Easy Reach tool covers
- Sterile non-shedding wipes
- Plastic sealable hazardous bags



Action: Daily

1. Perform hand hygiene and glove per standard operating procedure.
2. Apply additional hazardous room PPE, then gather supplies.
3. Spray gloves with sterile 70% IPA and let dry.
4. Saturate non-shedding wipe with Peridox and wipe the dedicated leaning tool twice. Allow the agent to remain on the surface for 3 minutes.
5. Saturate a non-shedding wipe with sterile IPA or use a pre-saturated wipe to disinfect the dedicated cleaning tool.
6. Place a cover on the cleaning tool inside of the hood and saturate with Peridox.
7. Clean the interior of the PEC from top to bottom and back to front in the following order:
 1. Ceiling
 2. HEPA diffuser screen
 3. Each interior side of the PEC
 4. IV bar and hooks
 5. Items housed on the deck, such as automated compounding devices (ACD)
 6. Deck of the PEC, carefully moving any items housed to clean underneath
8. Allow the Peridox to remain on the surfaces for three minutes
9. Re-saturate the cleaning tool cover with Peridox and repeat steps 7-8.
10. Replace the cleaning tool cover and repeat steps 6-8 with sterile IPA.
11. Dispose of outer pair of gloves, non-shedding wipes, cleaning tool covers in a disposable plastic hazardous bag and place into the hazardous garbage bin.



Action: Monthly

Cleaning Under the Grill Tray

1. Perform hand hygiene and glove per standard operating procedure.
2. Apply additional hazardous room garb, then gather supplies.
3. Spray gloves with sterile 70% IPA and let dry.
4. Lift the front view screen and hold down the alarm button to silence the sound.
5. Remove the grill tray and place on the deck.
6. Saturate a sterile non-shedding wipe with Peridox and wipe the grill using long overlapping strokes. Repeat.
7. Allow the Peridox to remain on the surface for 3 minutes.
8. Dispose of the wipe in a disposable sealable plastic hazardous bag.
9. Saturate a new wipe with sterile IPA and wipe the grill using long overlapping strokes.
10. Dispose of the wipe in the same disposable sealable plastic hazardous bag.

Cleaning Under the PEC Deck

1. Lift the deck tray.
2. Saturate a sterile non-shedding wipe with Peridox and wipe under the deck using long overlapping strokes. Repeat.
3. Allow the Peridox to remain on the surface for 3 minutes.
4. Dispose of the wipe in a disposable sealable plastic hazardous bag.
5. Saturate a new wipe with sterile IPA and wipe under the deck using long overlapping strokes.
6. Dispose of the wipe in the same disposable sealable plastic hazardous bag.

Secondary Engineering Controls



Task

Pharmacy Technicians perform daily and monthly cleaning, and monthly sporicidal application to PECs and any equipment inside using facility approved agents and procedures.



Key Points

- Deactivating, decontaminating, disinfecting, and organizing of the following hazardous work surfaces should occur at minimum at the end of every shift by a trained pharmacy technician, pharmacist and/or pharmacy student with a deactivating and decontaminating agent.
- Once monthly, in coordination with pharmacy staff and environmental services, an EPA registered deactivating and decontaminating sporicidal cleaning agent will replace the one-step deactivating and decontaminating agent. Coordination must be completed to ensure all surfaces are cleaned within 72 hours at the same time each month.

Secondary Engineering Controls include:

- Carts, counters, and work surfaces
- Passthroughs, interior and exterior
- Trays used for presentation
- High-touch areas such as handles, printers, and EPIC equipment
- Chairs and stools **monthly**
- Shelves and storage bins **monthly**



Supplies

- Deactivating and decontaminating agent: Dispatch **daily**
- Deactivating and decontaminating sporicidal agent: Peridox RTU **monthly**
- Sterile 70% IPA
- Dedicated hazardous Easy Reach cleaning tool
- Sterile non-shedding Easy Reach tool covers
- Sterile non-shedding wipes
- Plastic sealable hazardous bags



Action: Daily

1. Perform hand hygiene and glove per standard operating procedure.
2. Apply additional hazardous room PPE, then gather supplies.
3. Remove all items from counters, carts, and other surfaces.
4. Use pre-saturated Dispatch wipes to wipe down all surfaces included in the list of SEC equipment above. Allow the deactivating/decontaminating agent to remain on the surfaces for the duration indicated on the Dispatch label.
5. Repeat step 4 with pre-saturated sterile IPA wipes or a sterile non-shedding wipe saturated with sterile IPA.
6. Dispose of all soiled wipes and outer pair of gloves in a disposable sealable plastic hazardous bag.
7. Dispose of all hazardous PPE and repeat hand hygiene and garbing process prior to resuming compounding.

Environmental Services

Secondary Engineering Controls



Task

Pharmacy and environmental services staff perform daily and monthly cleaning, and monthly sporicidal application to SECs in the ante room using facility approved agents and procedures.



Key Points

- All cleaning tools and supplies are non-shedding and dedicated to the sterile compounding room. All disposable cleaning wipes and mop heads are disposed of in a sealable plastic hazard bag, then disposed of in the hazardous medication bin.
- Once monthly, in coordination with pharmacy staff, an EPA registered sporicidal cleaning agent will replace the one-step disinfectant. Coordination must be completed to ensure all surfaces are cleaned within 72 hours at the same interval each month.

Secondary engineering controls include:

- Garbage and recycling removal
- Floors
- Exterior of PEC
- Ceilings, lights, and filter grates **monthly**
- Trash bins interior and exterior **monthly**
- Exterior of refrigerators and large equipment **monthly**



Supplies

- One-step disinfectant **daily**
- One-step sporicidal agent **monthly**
- Sterile non-shedding wipes
- Micro Cinch mop and disposable pads
- Klean Max wall mop and disposable pads



Action: Daily

1. Perform hand hygiene and don gloves per standard operating procedure.
2. Apply additional hazardous PPE, then gather supplies.
3. Clean dedicated reusable cleaning tools with one-step disinfectant.
4. Empty garbage and place bags inside a secondary garbage bag to contain trace hazardous materials.
5. Place lid on black hazardous medication bin, then place bin in secondary garbage bag.
6. Attach a new sterile mop head and mop the entire floor surface starting from farther corner of the buffer room into the ante room towards the line of demarcation using the one-step disinfectant.
7. Clean dedicated reusable cleaning tools with one-step disinfectant.
8. Document the cleaning on a monthly log to be reviewed by pharmacy staff.



Action: Monthly

1. Perform hand hygiene and don gloves per standard operating procedure.
2. Apply additional hazardous PPE, then gather necessary cleaning supplies.
3. Clean dedicated reusable cleaning tools using a sterile non-shedding wipe saturated with the sporicidal disinfectant.
4. Empty garbage and place bags inside a secondary garbage bag to contain trace hazardous materials.
5. Place lid on black hazardous medication bin, then place bin in secondary garbage bag.
6. Attach a new sterile mop head to a reusable cleaning tool and saturate with the sporicidal disinfectant.
7. Clean the following areas while saturating the mop head with the sporicidal disinfectant as often as needed:
8. Ceilings, ceiling lights, and HEPA filter grates
9. Walls, windows, doorframes, and all mounted wall items
10. Exterior of PEC
11. Discard soiled mop head into a sealable plastic hazardous bag. Allow the sporicidal disinfectant to remain on the surfaces for the duration indicated on the product label.
12. Attach a new sterile mop head and saturate with the sporicidal disinfectant and mop the entire floor surface starting from farther corner of the buffer room into the ante room towards the line of demarcation using the one-step disinfectant.
13. Discard mop head into a sealable plastic hazardous bag and clean reusable cleaning tools with a non-shedding wipe saturated with the sporicidal disinfectant.
14. Document cleaning on the monthly log to be reviewed by pharmacy staff. If documentation is not completed, pharmacy staff is to contact Environmental Services to complete the cleaning as soon as possible.

Compounding Sterile Products

Aseptic Technique



Task

Adhere to strict sterile compounding guidelines for aseptic manipulation to reduce contamination of pathogens that pose risk of harm to patients.



Key Points

- All item used in the laminar hood must be wiped down with sterile 70% IPA prior to entering.
- Limit the number of items in the laminar hood to only those needed to prepare the next compound.
- Arrange all compounding items using straight-line technique towards the HEPA filter at the back of the hood and ensure no items are blocked from airflow at any point during the sterile compounding process.
- Avoid talking, coughing, and sneezing towards the laminar hood. Relace soiled mask and gloves, and re-garb as often as needed.
- Avoid touching any critical sites with your hands or the deck of the laminar hood.



Action

1. Ensure the deck of the hood is clean and sanitized prior to sterile compounding.
2. Select only the single-unit syringes, needles, alcohol swabs, drug and diluent vials and/or bags, and any additional supplies required to prepare the next compound.
3. Remove any vials or fluid bags from outer packaging.
4. Wipe down all non-paper items with 70% sterile IPA before placing them in the hood.
5. Spray sterile IPA onto gloves and evenly disperse while allowing them to dry. **Do not spray alcohol directly into the hood.**
6. Arrange supplies facing the HEPA filter at the back of the hood, and in a straight line in order of intended use. If any syringes, needles, ampoules are turned towards the outside of the hood, they can no longer be used for sterile compounding and must be disposed of.
7. Remove syringes and needles/filter straws from outer packaging while opening towards the HEPA filter and attach while holding each so they're parallel to the back of the hood. Prime syringe for easier use and place it back on the deck of the hood, pointing towards the filter.
8. Wipe the entry point of each vial or bag with one alcohol pad for each individual entry point.
9. Hold the vial flat on the deck and puncture with the needle bevel faced up, moving from a 45 to 90-degree angle as you enter. Ensure the syringe remains parallel to the HEPA filter and that airflow is never interrupted.
10. Lift and invert the vial to draw up the desired dose, then inject into the fluid bag or final syringe, if needed.
11. Cap the final product syringe from the sterile cap tray, using the those farthest from the HEPA filter first to avoid blocking airflow to the remaining caps. Apply a sterile foil seal to the medication port of the final products is a fluid bag.
12. Properly dispose of all packaging and used compounding supplies.
13. Check the final compound to ensure its free of defects or visible particulates.
14. Wipe the deck of the hood from back to front with sterile IPA when visibly soiled, and at least every 30 minutes of compounding.

Non-Hazardous Cart Fill Procedure



Task

Complete the sterile cart fill orders every two hours, according to standard production workflow.



Key Points

Cart fill medications are produced in a one-piece flow and presented in one six-segment tray.

- Piece: one dose/one label
- Cart fill tray: 6 pieces
- 2 trays in rotation for each cart fill, with more trays added as needed



Action

Technicians Preparing for the Cart Fill

1. Run EPIC report “SC Rx Sterile Non-Hazardous End Batch Report” to view the anticipated drugs needed for the next cart fill.
2. Gather any items needed from the report that are located outside of the buffer room.
3. Print the cart fill labels from EPIC for each individual cart by navigating through the following:
 1. Dispense Queue
 2. Dispense Type: Cart Fills
 3. Due Time Filter: Show All
 4. Sort By: Unit / Room / Bed
 5. Cart Name: SC MAIN STERILE NON-HAZ BATCH (1-3)
4. Clean and disinfect the laminar hood.

Technicians Preparing Cart Fill Doses

1. Tear one label from the rest to complete each dose individually.
2. Open Dispense Preparation in EPIC, scan the label QR code, then the drug and diluent you’ll be using to prepare the dose.
3. Aseptically prepare the dose within the laminar hood.
4. Use MASTERS to ensure accurate preparation, then initial the label on the Prep line and finalize the Dispense Prep on EPIC.
5. Label the finalized dose and place in the cart fill tray from top to bottom, left to right. When the tray is full with 6 finalized doses, move the tray to the bottom shelf of the cart fill passthrough.
6. Remove the returned tray from the top shelf of the passthrough once the pharmacist has checked all doses and return the stock. If a non-verbal communication card is presented with one of the doses, correct the error and place in the next cart fill tray to be presented.

Pharmacists Checking Cart Fill Doses

1. Remove the completed cart fill tray from the bottom shelf of the passthrough.
2. Use MASTERS to check each dose individually and scan the label QR code to finalize in EPIC.
3. Place the finalized doses into the exterior cart fill tray from front to back.
4. If an error is detected or Dispense Preparation has not been completed for a dose, return the item to the cart fill tray and include the appropriate non-verbal communication card.
5. Return the cart fill tray to the top shelf of the interior cart fill passthrough, then place the exterior cart fill tray with the finalized doses into the exterior non-hazardous passthrough.

Non-Hazardous Front Fill Procedure



Task

Complete the sterile front fill orders according to standard production workflow.



Key Points

Front fill medications are produced in a one-piece flow and presented on an individual tray.

- Piece: one dose/one label



Action:

Technicians Preparing Front Fill Doses

1. Clean and disinfect the laminar hood.
2. Print the front fill labels from EPIC for each individual dose by navigating through the following:
 1. Dispense Queue
 2. Dispense Type: First Doses / Redispenses
 3. Due Time Filter: Next 4 Hours
 4. Sort By: Due Times
3. Open Dispense Preparation in EPIC, scan the label QR code, then the drug and diluent you'll be using to prepare the dose.
4. Aseptically prepare the dose within the laminar hood.
5. Use MASTERS to ensure accurate preparation, then initial the label on the Prep line and finalize the Dispense Prep on EPIC.
6. Label the finalized dose and place on a front fill tray, then place into the front fill passthrough.
7. Remove the returned tray from the passthrough once the pharmacist has checked the dose and return the stock. If a non-verbal communication card is presented with one of the doses, correct the error and send the dose back through the passthrough on tray for the pharmacist to check.

Pharmacists Checking Cart Fill Doses

1. Remove the completed cart fill tray from the bottom shelf of the passthrough.
2. Use MASTERS to check each dose individually and scan the label QR code to finalize in EPIC.
3. Place the finalized doses into the exterior cart fill tray from front to back.
4. If an error is detected or Dispense Preparation has not been completed for a dose, return the item to the cart fill tray and include a non-verbal communication card with the correction required by the technician.

Hazardous Cart Fill and Front Fill Procedure



Task

Complete the sterile hazardous cart fill and front fill orders according to standard production workflow.



Key Points

Hazardous medications are produced in a one-piece flow and presented on an individual tray.

- Piece: one dose/one label
- Closed-system transfer devices are used when hazardous compounding unless incompatible with the medication. Needles are always avoided, if possible.
- Medications stored in glass ampoules are removed using a filter straw attached directly to the closed-system syringe.
- Airflow in the hazardous hood is vertical and comes from the HEPA filter above, as opposed to the non-hazardous horizontal airflow hoods. Avoid interrupting airflow by blocking from above.
- All hazardous medications dispensed in a bag will include tubing and be primed with drug for immediate use when prepared. **Ensure the roller clamp is closed prior to finalizing.**
- Tacrolimus drips, busulfan, and carboplatin desensitization doses dispensed in syringes will include attached syringe tubing primed with drug for immediate use when prepared. **Ensure the tubing is not clamped prior to finalizing.**
- All hazardous doses are wiped with sterile IPA when removed from the hood, prior to labeling and finalizing.



Action

Technicians Preparing for the Hazardous Cart Fill

1. Run EPIC report “SC Rx Sterile Hazardous End Batch Report” to view the anticipated drugs needed for the next cart fill.
2. Print the cart fill labels from EPIC individually within each cart by navigating through the following:
 1. Dispense Queue
 2. Dispense Type: Cart Fills
 3. Due Time Filter: Show All
 4. Sort By: Unit / Room / Bed
 5. Cart Name: SC MAIN STERILE HAZ BATCH (1-3)
3. Clean and disinfect the laminar hood.
4. Place an absorbent hazardous mat plastic side-down on the laminar hood deck.

Technicians Preparing Hazardous Cart Fill Doses

1. Print and prepare each dose individually.
2. Open Dispense Preparation in EPIC, scan the label QR code, then the drug and diluent you'll be using to prepare the dose.
3. Aseptically prepare the dose within the laminar hood.
4. Use MASTERS to ensure accurate preparation, then initial the label on the Prep line and finalize the Dispense Prep on EPIC.
5. Label the finalized dose and place on a yellow hazardous tray, then place the tray on the hazardous checking cart.



Action continued

Technicians Preparing Hazardous Front Fill Doses

1. Clean and disinfect the laminar hood.
2. Place an absorbent hazardous mat plastic side-down on the laminar hood deck.
3. Print the hazardous front fill labels from EPIC for each individual dose by navigating through the following:
 1. Dispense Queue
 2. Dispense Type: First Doses / Redisponses
 3. Due Time Filter: Next 4 Hours
 4. Sort By: Due Times
4. Open Dispense Preparation in EPIC, scan the label QR code, then the drug and diluent you'll be using to prepare the dose.
5. Aseptically prepare the dose within the laminar hood.
6. Use MASTERS to ensure accurate preparation, then initial the label on the Prep line and finalize the Dispense Prep on EPIC.
7. Label the finalized dose and place on yellow hazardous tray, then place onto the hazardous checking cart.

Pharmacists Checking Hazardous Doses

1. Apply additional hazardous PPE before entering the sterile suite hazardous room.
2. Use MASTERS to check each dose individually and scan the label QR code to finalize in EPIC.
3. Place the finalized doses into individual hazardous bags, and transfer to the hazardous passthrough.
4. If an error is detected or Dispense Preparation has not been completed for a dose, communicate with the hazardous pharmacy technician to correct the error.
5. Dispose of hazardous PPE in the hazardous garbage bin, then perform proper hand hygiene and apply new gloves before returning to non-hazardous sterile dose checking.