MOVEMENT OF SUPPLIES AND EQUIPMENT INTO AND THROUGH THE PHARMACY CONTROLLED AREA PROCEDURE

Summary of Changes

	NEW	Previous
BC Cancer	NEW	

1. Introduction

1.1. Focus

To delineate appropriate procedures for movement of sterile compounding supplies and equipment through the controlled area and into the PEC/C-PECs while maintaining cleanliness of the rooms and minimizing introduction of microbial contamination.

1.2. Health Organization Site Applicability

BC Cancer Regional Cancer Centre Pharmacies

1.3. Practice Level

Pharmacy Professional Practice Leaders

- Provide necessary decontaminating, cleaning and disinfecting agents
- Provide training on when and how to use the various agents available

Pharmacy Personnel

- Follow decontaminating, cleaning and disinfection procedures at all times when moving supplies and equipment through the controlled area and into the PEC/C-PECs

Controlled Area and Equipment Certification Personnel

- Follow cleaning and disinfection procedures at all times when moving supplies and equipment through the controlled area and into the PEC/C-PECs

Facility Housekeeping, Maintenance and Stores Personnel

- Follow cleaning and disinfection procedures at all times when moving supplies and equipment through the controlled area

1.4. Definitions

Containment Primary Engineering Control: A device that provides an ISO Class 5 environment for the exposure of critical sites during aseptic compounding and that is designed to minimize airborne contamination of hazardous products, to protect workers and the environment from exposure to hazardous drugs. The airflow is unidirectional (laminar flow), and the first air (air exiting the high-efficiency particulate air filter) is free from airborne particulates.

Controlled area: An area or space where the only activities taking place are those related to the compounding of sterile preparations. The controlled area is designed to minimize the introduction, generation and retention of particulate and microbial contamination.

Decontaminate: The transfer of a hazardous drug from a fixed surface (e.g., counter, bag of solution) to a disposable surface (e.g., wipe, cloth). The wipe is then contained and discarded as hazardous waste.

Demarcation line: A line (real or virtual) that separates the clean and dirty sides of the anteroom.

Disinfectant: A disinfecting agent, typically of a chemical nature, that can destroy microorganisms or other pathogens, but not necessarily bacterial or fungal spores. Refers to substances applied to inanimate objects.

Dwell time: the amount of time that a sanitizer or disinfectant must be in contact with the surface, and remain wet, in order to achieve the product's advertised kill rate.

Germicidal: A substance that has the ability to kill microorganisms.

Germicidal Disinfectant Detergent: An agent that helps to remove dirt and oil but also contains compounds which kill microorganisms.

Hazardous Drug: A drug that exhibits at least one 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

OR the drug:

1. has a structure and toxicity profile that mimics an existing drug previously determined hazardous by the above criteria
2. is or contains a living organism with the potential to cause infections in humans
3. has insufficient information to properly evaluate the characteristics of the drug but the drug is primarily used to treat cancer

Personal Protective Equipment: all garb and accessories such as masks, gloves, gowns, respirators, goggles, face shields, and others that protect both the sterile preparation and the personnel. It enables compliance with the expected specifications of a controlled environment and protect personnel from exposure to physical or chemical risks.

Primary Engineering Control: a device that provides an ISO Class 5 environment for the protection of critical sites when sterile preparations are being compounded. The air flows horizontally toward the worker or vertically towards the work surface.

Sporicidal: An agent that destroys bacterial and fungal spores when used in sufficient concentration for a specified dwell time. It is expected to kill all vegetative microorganisms.

Sterile Isopropyl alcohol: Isopropyl alcohol that is sterilized from spores using gamma-irradiation; hence sterile isopropyl alcohol is used in controlled areas.

1.5. Abbreviations and Acronyms

C-PEC: Containment Primary Engineering Control (e.g. biological safety cabinet)
CSP: Compounded Sterile Preparation
HD: Hazardous Drug
ISO: International Organization for Standardization
PEC: Primary Engineering Control (e.g., horizontal laminar airflow workbench)
PPE: Personal Protective Equipment
sIPA: Sterile Isopropyl Alcohol

1.6. Need to Know

Approximately 60% of packaging is contaminated with bacteria and 40% with bacterial spores. A standardized procedure for moving supplies and equipment through the controlled area contributes to a cleaner and safer environment for compounding sterile preparations.

Items introduced into the controlled area must be limited to those essential to sterile compounding. Exception: if a C-PEC is required to aid in protection of personnel during compounding or manipulation of a non-sterile hazardous drug.

When packaging integrity will not be compromised, supplies brought into in the controlled area must be disinfected by wiping (not spraying) using a sporicidal agent

prior to being used or stored. When packaging integrity will be compromised, supplies brought into the controlled area must be placed into zip lock bags prior to storage. Immediately before supplies are brought into the clean room and again before being placed into the PEC/C-PEC (if applicable), they must be (re-)disinfected by wiping (not spraying) using sterile 70% isopropyl alcohol.

Before any furniture or equipment is used in the controlled area, it must be disinfected by wiping (not spraying) using a germicidal disinfectant detergent or a sporicidal agent. Immediately before furniture and equipment are brought into the clean room and again before being placed into the PEC/C-PEC (if applicable), they must be re-disinfected by wiping (not spraying) using sterile 70% isopropyl alcohol.

Personnel must wear at least 1 pair of gloves when disinfecting items. Disinfecting items must not compromise package integrity when applicable.

When a germicidal disinfectant detergent or sporicidal agent is used, the packaging must remain wet for the minimum dwell time specified by the manufacturer. When sterile 70% isopropyl alcohol is used, it must be allowed to dry.

The wiping procedure must not render the label or other pertinent information unreadable. The wipes must be changed regularly so the items remain wet for the required minimum dwell time.

Cardboard has been found to harbour bacterial and mould spores. No shipping cartons or cardboard are permitted in the controlled area.

Exceptions:

- Drug vials may remain in their manufacturer-supplied boxes for transport to, and storage in, the controlled area (e.g., HD storage room [hazardous drugs] and set-up/staging room [non-hazardous drugs]).
    - Boxes may be required by the manufacturer in the event that the drug will be returned to the manufacturer for credit.
    - Boxes provide an additional level of hazardous drug spill protection by limiting the spread of a hazardous drug spill.
- If a damaged hazardous drug shipping container needs to be opened to retrieve undamaged items, this must be done in a C-PEC.

Preferred sporicidals appear in **bold font** in the applicable sections below.

1.7. Equipment and Supplies

- Chemotherapy gloves
- Personal protective equipment and scrubs when working in the controlled area and PEC/C-PEC
- Germicidal disinfectant detergent
- Sporicidal agent
- Sterile 70% isopropyl alcohol

2. Procedure

2.1. Steps

Introducing supplies and equipment into the controlled area

Before any supply or equipment is introduced into the controlled area, it must first be removed from its shipping container.

Items received in manufacturer-supplied cardboard boxes must be removed from their cardboard boxes and placed into sealed zip lock bags before being transferred into the controlled area (e.g., alcohol swabs, needles).

Exceptions:

- Drug vials may remain in their manufacturer-supplied boxes for transport to, and storage in, the controlled area (e.g., HD storage room [hazardous drugs] and set-up/staging room [non-hazardous drugs]).
- If a damaged hazardous drug shipping container needs to be opened to retrieve undamaged items, this must be done inside a C-PEC.

Items may be placed in bins to facilitate their transfer into the controlled area. These bins must be appropriately decontaminated and then disinfected prior to each use using a decontaminating agent and then a sporicidal. For example:

- 0.5% accelerated hydrogen peroxide or CaviCide followed by CaviWipes Bleach (plastic bins)
  OR
- 0.5% accelerated hydrogen peroxide followed by Peridox (plastic or stainless steel bins)
  OR
- Peridox (as a decontaminating agent) followed by Peridox (as a sporicidal) (plastic or stainless steel bins)

When using a cart pass-through, all surfaces of the carts must be decontaminated using 0.5% accelerated hydrogen peroxide (or CaviCide or Peridox), and then disinfected using Peridox daily.

Note:

- Bleach is not recommended for use on stainless steel surfaces as it will corrode them. If used on stainless steel surfaces, bleach must be neutralized using sodium thiosulphate or removed using a germicidal disinfectant detergent.
- When Peridox is used as the decontaminating agent and the sporicidal, it must be applied twice.
- Peridox reacts with CaviCide and may discolor stainless steel surfaces.

Carts used to transfer items from the receiving area into the controlled area must be dedicated to this purpose and not be used interchangeably with carts used to transfer items from the set-up/staging room into the clean room.

Drug vials:

- Hazardous and non-hazardous drug vials may remain in their manufacturer-supplied boxes for storage in the HD storage room or set-up/staging room.
- Hazardous and non-hazardous drug vials being stored in the Hazardous Drug Storage Room must be removed from any plastic bags they have been shipped in, prior to storage.
- Non-hazardous drug vials being stored outside of the Hazardous Drug Storage Room (e.g., the set-up/staging room) must be placed into sealed zip lock bags before transfer into the controlled area. The zip lock bags must be disinfected using a sporicidal prior to storage. These vials may be removed from the zip lock bag if they are being stored in bins within a refrigerator.

Supplies, equipment and furniture that will be used or stored in the controlled area:

- Disinfecting items with paper-type packaging may compromise the sterility of the item (e.g., needles, syringes with paper backing, alcohol swabs).
    - Remove these items from their manufacturer-supplied boxes outside of the controlled area and place in a sealable plastic bag prior to transferring into the controlled area.
    - Items removed from a cardboard box that are contained in a sealed plastic bag may remain in the plastic bag when transferring the items

into the controlled area. The outer surface of the sealed plastic bag must be disinfected using a sporicidal agent.

- Items that are not contained in paper-type packaging must be individually disinfected using a sporicidal.

  Exception:

  - Intravenous solution bags packaged in multipacks (e.g., 100 mL solution bags) may remain in the plastic packaging until placed into set-up trays or bins for compounding. The plastic packaging must be disinfected using a sporicidal prior to storing in the controlled area.
- Clean and disinfect furniture or equipment using a germicidal disinfectant detergent or a sporicidal agent prior to use in the controlled area.

Removing drug vials from their manufacturer-supplied boxes (Peridox)

- **During tray set-up:**
  - Remove vials from their manufacturer-supplied boxes.
  - Decontaminate and disinfect the vials using a wipe moistened with a sporicidal before placing the vials in the tray. Note that when the vial contains a hazardous drug, the sporicidal should be one that has been shown to also decontaminate surfaces (e.g., Peridox).
    - Do NOT use the same wipe to disinfect multiple hazardous drugs.
    - The same wipe may be used to disinfect multiple vials of the SAME hazardous drug.
    - The same wipe may be used to disinfect multiple vials of non-hazardous drugs.
  - Dispose of the used wipe in a sealable zip lock bag and then into an appropriate waste container.

Sporicidal Odor Limiting and Containment Strategies:

When using a sporicidal, it is recommended to use odor limiting and odor containment strategies. Odor limiting and containment strategies may include:

- placing the moistened wipes for use into a sealable container (e.g., canister with a spring-loaded lid, zip lock bag).
- discarding used moistened wipes into a sealable container (e.g., zip lock bag);

    - During use, unsealed zip lock bags can be folded in half for easier repeated access.
- wearing a N95 or elastomeric half or full face mask respirator with an appropriate filter cartridge.

Introducing supplies and equipment into the clean room:

Where packaging allows, compounding equipment and supplies shall be disinfected using sterile 70% isopropyl alcohol just before being transferred to the clean side of the anteroom or into the pass-through leading into the clean room.

Furniture (e.g., chairs) or equipment (e.g., certification, cleaning equipment) shall be disinfected using sterile 70% isopropyl alcohol just before being transferred to the clean side of the anteroom.

Products and supplies intended for patient-specific or batch compounding shall be individually organized on trays or in bins to avoid errors or mix-ups upon transferring into the clean room. Intravenous solution bags shall be removed from their plastic packaging upon placement into the set-up tray or bin.

Compounding supplies shall be individually disinfected using 70% sIPA and placed into a disinfected tray or bin just before being transferred to the clean side of the anteroom or into the pass-through leading into the clean room.

When using a cart pass-through, the trays and bins must be placed onto carts that are decontaminated and disinfected daily.

When transferring trays and bins through the anteroom using carts, one cart must be dedicated to the set-up/staging area and not move past the demarcation line in the anteroom. Another cart must be dedicated to the clean side of the demarcation line in the anteroom and the clean room.

Trays and bins used to transfer HD compounding supplies and drugs into the clean room must be decontaminated after each use by wiping with a decontaminating agent or using the dishwasher.

Trays, bins and carts used for transferring compounding supplies into the hazardous clean room shall be kept separate and not be used interchangeably with trays, bins and carts used for transferring compounding supplies into the non-hazardous clean room.

Carts used to transfer items from the set-up/staging room onto the clean side of the anteroom or into the clean room shall be kept separate and not be used interchangeably with those used to transfer items from the receiving area into the controlled area.

Introducing supplies and equipment into the PEC/C-PEC:

- All items (e.g., compounding supplies, certification equipment) and gloved hands must be disinfected using 70% sIPA prior to placement inside the PEC or C-PEC.
    - Items that have protected or disinfectable critical sites (e.g., ChemoLock™ Bag Spikes, chemotherapy dispensing pins) may be removed from their protective over-wrap upon placement inside the PEC/C-PEC and placed directly onto the work surface, but not on the front grill.
    - Items that have critical sites that are not protected or disinfectable (e.g., needles, syringes) must not be removed from their protective over-wrap until immediately prior to use.
- The paper-side of each item must be lightly disinfected using 70% sIPA to remove any gross particulate prior to placement inside the PEC/C-PEC.
- Once items necessary for compounding have been placed into the PEC/C-PEC, gloves must be disinfected again using 70% sIPA prior to placing gloved hands into the PEC/C-PEC for compounding.

3. Related Documents and References

3.1. Related Documents

BC Cancer Pharmacy Practice Standards for Hazardous Drugs Manual

3.2. References

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