CONTEC HEALTHCARE

Best Practices: Cleaning and Disinfecting Donning and Doffing for HDs

Pharmacy Training Day

Clean counts most

Before we begin…

I’d like to share a story with you.

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I asked ChatGPT “Explain Sterile Compounding to a 1st Grader

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Sterile compounding is when medicines are made in a very clean and safe environment to make sure they don't have any germs or things that could harm our bodies. It's like making special medicine potions!

It's really important because when we get sick, we sometimes need medicines that go directly into our bodies, like through a needle or into our veins. If those medicines have any germs or bad things in them, they can make us even sicker instead of helping us feel better.

By making medicines in a super clean and safe way, we make sure they are safe for us to use. It's like having a superpower to fight off any bad things that could make us more sick!

Also, sometimes people need special medicines that aren't available in stores. With sterile compounding, we can make customized medicines just for them, with the right amount and no ingredients that they might be allergic to.

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Write a Dr. Seuss Poem about Sterile Compounding

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In a sterile lab, not far away, A Pharmacist named Dr. Jay, With goggles on and gloves so fine, Made special medicines, every time.

With a whisk and a swirl, he'd mix and blend, Creating potions to help and mend. But sterile compounding was his greatest task, To keep all patients safe, that was his ask.

He followed USP 797, oh so keen, To ensure his lab was squeaky clean. He scrubbed and sanitized, without a miss, To prevent any germs or icky abyss.

He worked with care, precision, and grace, Measuring liquids at a steady pace. Each ingredient had to be just right, To create medicines shining so bright.

In his lab, there were no sneezes or coughs, Only beakers, flasks, and sterile cloths. Dr. Jay wore a gown, like a superhero cape, To shield his medicines from any escape.

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Q: USP Chapter 797 states that all critical sites must be wiped with sterile 70% IPA in the PEC to provide both chemical and mechanical actions to remove contaminants. But the Chapter does not say that you need to wipe one vial with one wipe. Is there any evidence to support wiping multiple vials with one wipe?

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One study published in the Journal of Oncology Pharmacy Practice evaluated the effectiveness of using a single sterile 70% IPA wipe to clean multiple vials. The study found that using a single wipe for up to 10 vials was effective in reducing the level of bacterial contamination to an acceptable level.

Another study published in the Journal of Pharmacy Technology evaluated the use of multiple sterile wipes versus a single sterile wipe for cleaning vials in a PEC. The study found that there was no significant difference in the level of microbial contamination between the two methods, suggesting that a single wipe can effectively clean multiple vials.

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Chatbots May 'Hallucinate' More Often Than Many Realize

When summarizing facts, ChatGPT technology makes things up about 3 percent of the time, according to research from a new start-up. A Google system's rate was 27 percent.

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Chatbots sometimes make things up. Is AI's hallucination problem fixable?

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By Catherine Thorbecke, CNN

6 minute read · Published 2:35 PM EDT, Tue August 29, 2023

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Learning Objectives

- Upon completion of this session, learners will know the best practices for daily cleaning and disinfection of PECs and SECs.
- Upon completion of this session, learners will know the best practices for Hazardous Drug (HD) decontamination of CPECs.
- Upon completion of this session, learners will know the best practices for Donning and Doffing PPE in Hazardous Compounding Environments

Today's Presentation is based on best-practices inspired by USP Chatper 797

I will cross-reference NAPRA where possible

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Cleaning and Disinfecting PECs

Pharmacies invest lots of money to build state-of-the-art cleanrooms and hire the best pharmacist.

But without robust cleaning and disinfecting, can you feel confident in the sterile drugs that were compounded in that room?

When it comes to the safety of the patient - The person cleaning your cleanroom is every bit as important as the pharmacy technician who is making the drug or the Doctors and Nurses who administer it.

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SOP

Importance of a detailed Protocol

- USP <797> and NAPRA only establishe cleaning frequencies
- Technicians are being asked to clean something they cannot see.
- So how do you or they know that the surface is clean?
- By establishing a detailed, validated and easily repeatable process to ensure consistency and compliance

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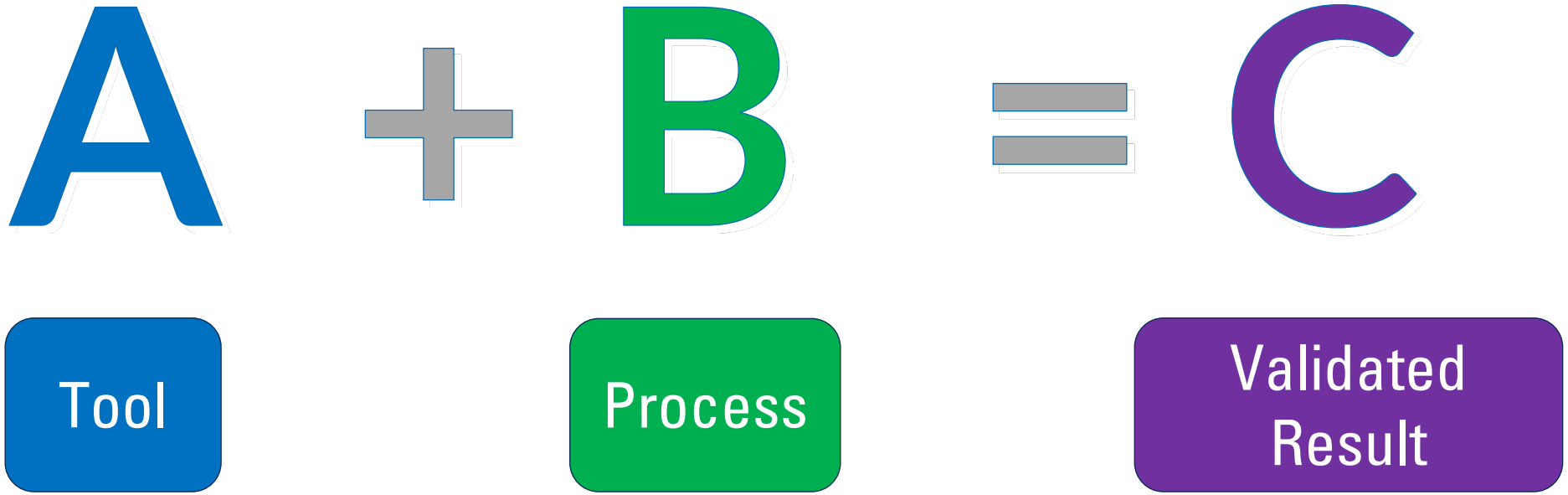

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Products used to clean and disinfect the PEC

USP Chapter 797 (2023)

- EPA Registered disinfectant
- Cleaning and disinfecting agents used within the PEC **must be sterile**
- In addition, cleaning and disinfecting supplies used in the PEC **must be sterile** (with exception of tools)
- All cleaning and disinfecting supplies (e.g., wipers, sponges, pads, and mop heads) must be low lint
- Wipers, sponges, pads, and mop heads should be disposable.
- Sterile 70% IPA

NAPRA

- Use of a germicidal disinfectant is required
- Daily use of a germicidal disinfectant should be augmented weekly (or monthly) use of a sporicidal agent
- All equipment shall be non-shedding (lint free) and preferably disposable

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Required Cleaning Frequencies for PEC

USP Chapter 797 (2023)

Daily before Compounding

Apply sterile 70% IPA to the horizontal work surface at least every 30 minutes if the compounding process takes 30 minutes or less. If the compounding process takes more than 30 minutes, compounding must not be disrupted, and the work surface of the PEC must be disinfected immediately after compounding

When surface contamination is known or suspected

NAPRA

Daily with Germicidal Disinfectant

Monthly with a Sporicidal Agent

Process to Clean and Disinfect a PEC

- Wipe Gloved Hands and Cleaning Supplies with Sterile 70% Alcohol before placing them inside of the PEC
- Clean the IV Bar, hangers, hardware and any items that live on the deck
- Clean and Disinfect your cleaning tool
- Start by cleaning the ceiling of the PEC
- Clean back wall of PEC
- Clean both side walls of PEC
- Lastly, clean the work surface of the PEC
- Allow Surfaces to remain wet for the required dwell time
- A residue removal step is required in the PEC: repeat all steps cleaning all sides of the PEC in the appropriate order with Sterile 70% Alcohol.
- Clean and disinfect your cleaning tool

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Germfree

Don’t “Break the Plane” of the PEC

Don’t break the plane – help to maintain ISO 5 quality air inside of your PEC

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Cleaning and Disinfecting the SEC

Best Practices

General Concepts for Cleaning in a Cleanroom

- Always wipe cleanest to dirtiest
- Use unidirectional overlapping strokes.
- Clean odd surfaces (thermostats, light switches, etc.) before cleaning large flat surfaces.
- Best Practice is to clean room at the end of the day – leaving room to rest.
- Cleaning Activities cannot be performed while compounding is taking place.

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Required Cleaning Frequencies for SEC

USP Chapter 797 (2023)

Daily: Floors, Counters, High Touch Surfaces, Sink

Monthly: Irregular Surfaces, Walls, Ceilings, Storage Shelves and Bins, Outside surfaces of the PEC

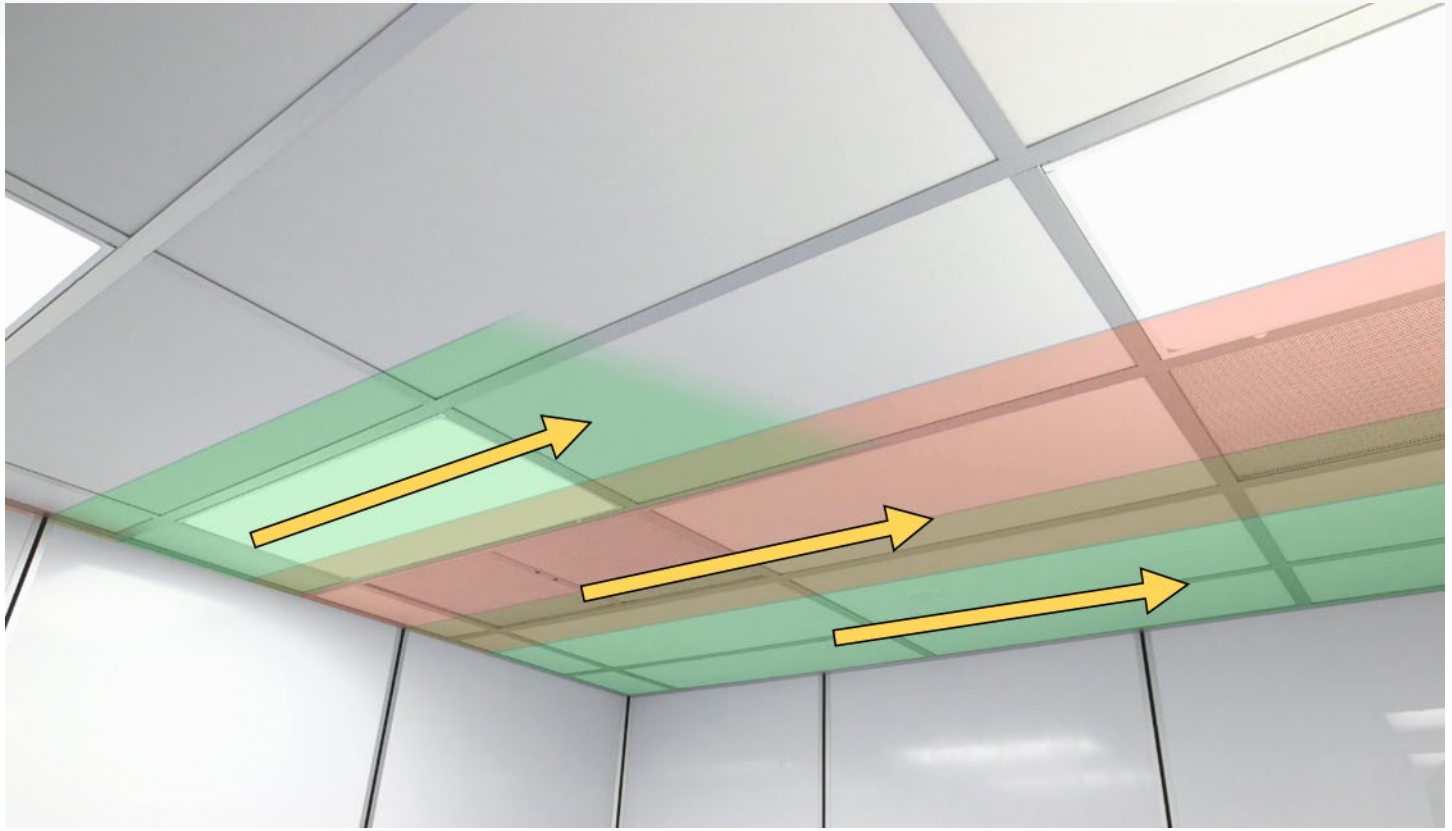
NAPRA

Daily: Floors, Counters, High Touch Surfaces,

Monthly: Irregular Surfaces, Walls, Ceilings, Storage Shelves and Bins, Outside surfaces of the LAFH

SEC - Process to Clean and Disinfect Ceiling

- Eye protection should be worn when cleaning overhead
- Starting in cleanest area of the room: clean ceiling using overlapping, unidirectional strokes.
- Start in the ISO Class 7 buffer room and clean towards the ISO Class 8 ante-room.
- Allow ceilings to remain wet for appropriate dwell time
- Allow ceiling to dry completely before compounding resumes.



SEC - Process to Clean and Disinfect Walls

- Eye protection should be worn when cleaning overhead
- Clean small items first: light switch, air return, etc
- Starting in cleanest area of the room: clean walls using overlapping, unidirectional strokes.
- Start in the ISO Class 7 buffer room and clean towards the ISO Class 8 ante-room.
- Allow walls to remain wet for appropriate dwell time: Allow walls to dry completely before compounding resumes.

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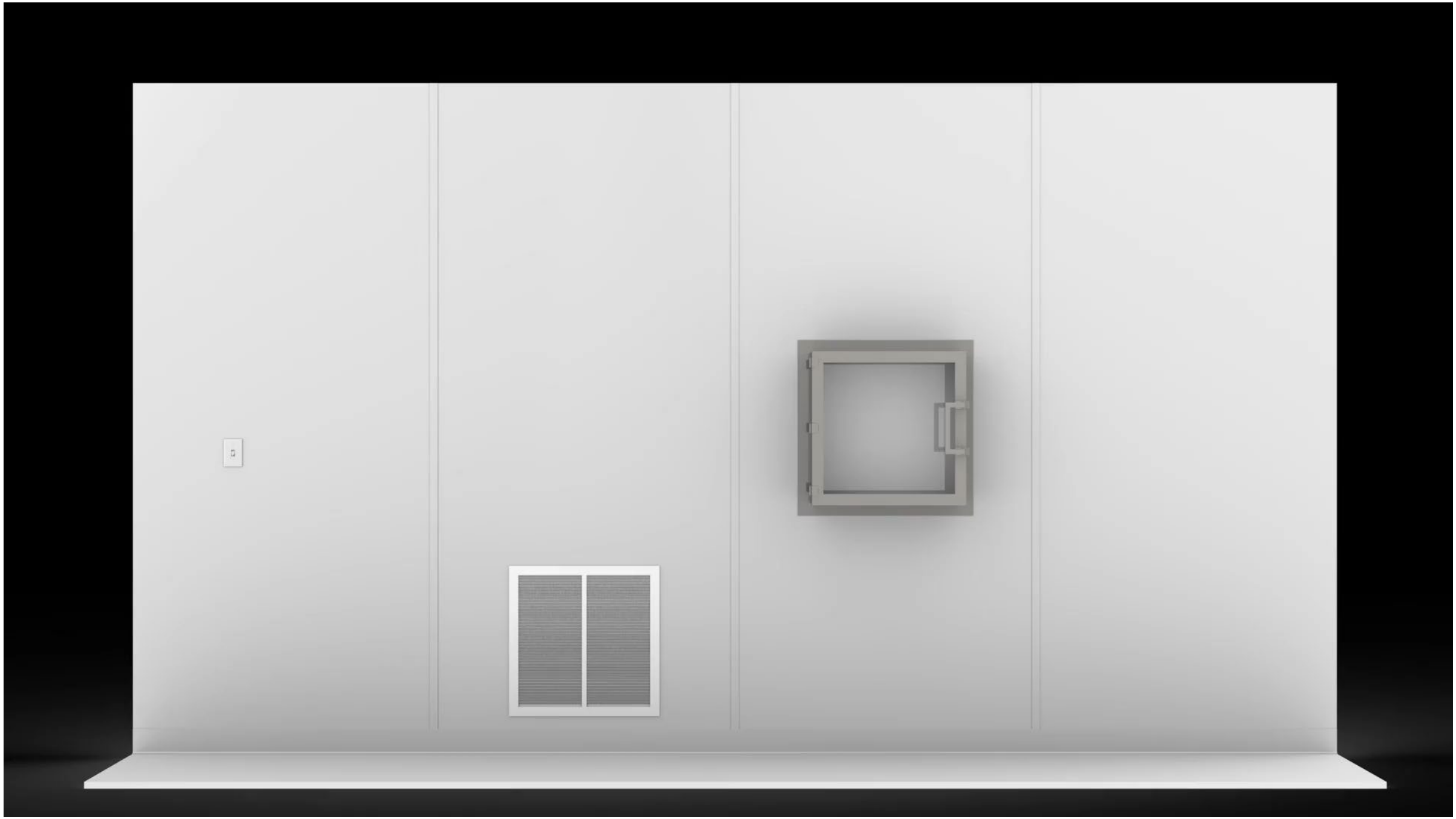
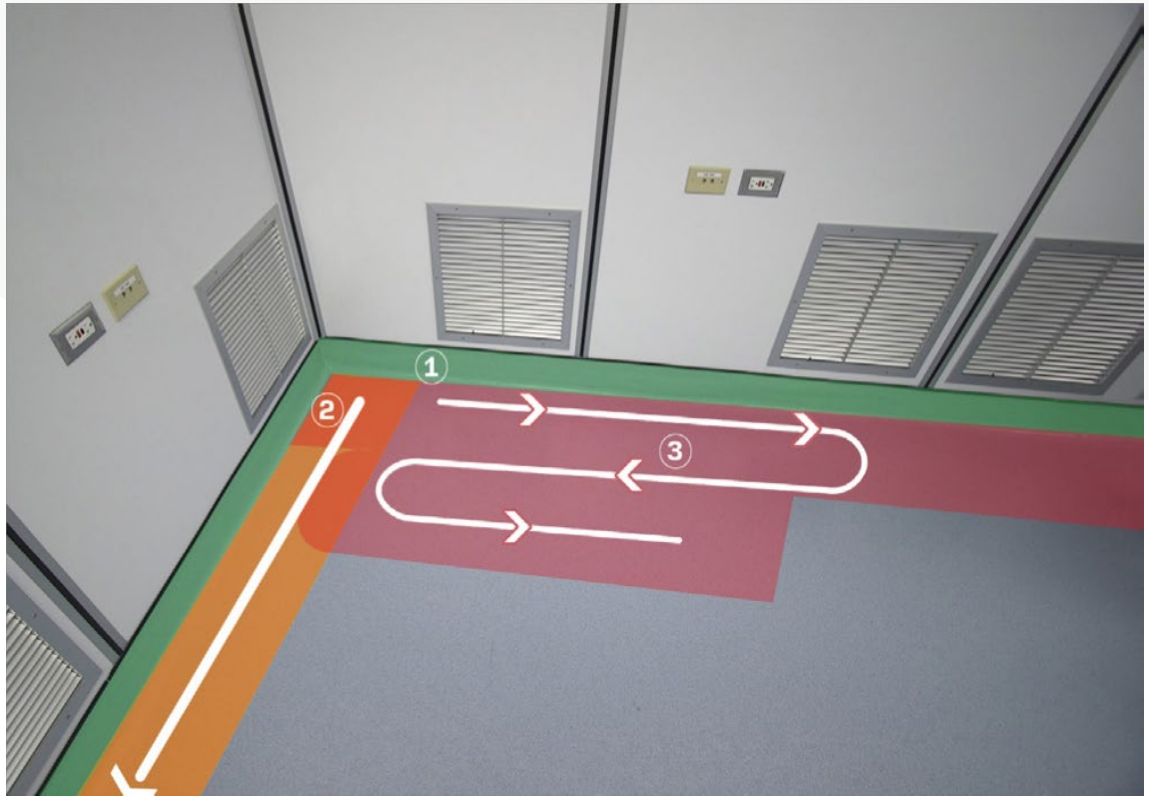


SEC - Process to Clean and Disinfect Floors

- Always begin at the corner farthest from the exit door and mop toward the door.
- Start by cleaning the horizontal section of the floor that is coved to the wall. (Fig 1)
- Make an initial mopping path along the wall, (Fig 2) and then use an “S-curve” with the ends of each stroke fully overlapping the initial path along the wall. (Fig 3)
- Clean the floor in a continuous S-motion towards the exit of the cleanroom, rotating the mophead at the end of each sideways stroke in order to keep the same leading edge of the mop moving forward from start to finish.
- Allow floors to remain wet for appropriate dwell time.
- Allow floors to dry completely before compounding begins.



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HD Dectontamination in the PEC

Decontamination vs Disinfection vs Deactivation

Disinfectant: a chemical or physical agent used on inanimate surfaces and objects to destroy fungi, viruses, and bacteria. Sporicidal disinfectants are considered a special class of disinfectants that also are effective against bacterial and fungal spores.

Decontamination: Inactivation, neutralization, or removal of HD contaminants on surfaces.

Deactivation: Render a compound inert or active.

USP <800> states: “There is no one proven method for deactivating all compounds. The ultimate goal should be complete surface decontamination

NAPRA States: Surface decontamination is the transfer of hazardous drug containment from a fixture(counter) to a disposable surface(wipe)

HD WIPE SAMPLING

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Process to Decontaminate a CPEC

(same process as cleaning)
Process will differ based on Decon Agent that you're using

- Wipe Gloved Hands and Cleaning Supplies with Sterile 70% Alcohol before placing them inside of the CPEC
- Wet a wipe with your decontamination agent, Clean the IV Bar, hangers, hardware and any items that live on the deck
- Start by decontaminating the ceiling of the CPEC
- Decontaminate back wall of CPEC
- Decontaminate both side walls of CPEC
- Lastly, Decontaminate the work surface of the CPEC
- Allow Surfaces to remain wet for the required dwell time
- Note: single-pass/double-pass? Are they using CSTDs
- Clean and disinfect your cleaning tool


Germfree

Donning and Doffing of PPE for HD Compounding

USP <800> - PPE Requirements

At the most basic level, all of the rules in <797> or NAPRA exist to protect the drug from YOU.

When compounding hazardous drugs, some **additional** rules (USP <800>) should be put in place to protect YOU from the drug

Double the PPE:

- Double Glove
- Double Gown
- Double Bootie

Hazardous Compounding Donning Sequence

The process starts the same as the process for non-hazardous compounding, this example assumes the sink is located on the clean side of the LOD.

- Enter room, put on hair net, facemask
- Put on DOUBLE shoe covers, one foot at a time across the LOD
- Perform Hand Hygiene - dry hands
- Don the IV Frock
- Don HD Chemo Gown
- Slide cuffs of HD Gown up the forearm (over the IV Frock)
- Use Alcohol Based hand rub
- Don the first pair of sterile gloves, pulling the glove cuff up over the IV frock
- Be sure to treat the sterile glove wrapper with care – you'll need it.
- Carefully, using that sterile wrapper, pull the cuff of the HD gown off your forearm, down over top of the First Sterile Glove cuff
- Don the second pair of sterile gloves, pulling the glove cuff up over the HD Gown

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Hazardous Compounding - Doffing Sequence

- Remove outer sterile gloves inside of C-PEC and place them in plastic bag inside of the C-PEC for disposal in trace hazardous waste container.
- Remove outer shoe covers – place in yellow trace waste
- Remove the chemotherapy gown slowly. First untie gown at waist. Then pull gown off at the shoulders slowly turning the gown inside out and being aware that the chemo gown is not touching IV frock underneath. Discard in yellow trace waste
- Remove the inner pair of sterile gloves by carefully peeling off the first glove without touching your skin. Place that glove in the palm of the other hand. Slide your finger underneath the cuff of the second glove and pull the glove off inside out - making a pouch containing both gloves. Discard in yellow trace waste
- Remove IV Frock and immediately perform hand hygiene with soap and water immediately after leaving the Hazardous Compounding area.

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Dispose all used materials in trace waste

Consider all PPE worn when handling HDs **to be contaminated** with, at minimum, trace quantities of HDs. PPE must be placed in an appropriate waste container and further disposed of per local, state, and federal regulations. PPE worn during compounding should be disposed of in the proper waste container before leaving the C-SEC

QUESTIONS