



EDUCATIONAL RESOURCES

 COMPOUNDING PHARMACY

# Optimizing Cleanroom Practices: Cleaning and Disinfecting PECs and SECs

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# Tour of the new ACHC cleanroom



# Learning Objectives

- Explain USP <797> and <800> requirements for material handling, including wiping items prior to introduction into the SEC or PEC.
- Apply USP-compliant cleaning and disinfection practices to cleanroom surfaces such as floors, walls, and ceilings. (SECs)
- Demonstrate proper procedures for cleaning and disinfecting Primary Engineering Controls (PECs) in alignment with USP standards.
- Differentiate required cleaning frequencies, tools, disinfectants, and sporicidal agents as outlined in USP <797> and <800>.

# Material Handling

# Introducing items into the SEC

- Before any item is introduced into the clean side of anteroom(s), placed into pass-through chamber(s), or brought into the SCA, providing that packaging integrity will not be compromised, it must be wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% IPA using low-lint wipers by personnel wearing gloves.
- If an EPA-registered disinfectant or sporicidal disinfectant is used, the agent must be allowed to dwell for the minimum contact time specified by the manufacturer.
- If sterile 70% IPA is used, it must be allowed to dry. The wiping procedure should not compromise the packaging integrity or render the product label unreadable.



**Best Practice is to use a Sporicidal Agent**

# Introducing items to the PEC

- Just before any item is introduced into the PEC, it must be wiped with sterile 70% IPA using sterile low-lint wipers and allowed to dry before use
- When sterile items are received in sealed containers designed to keep them sterile until opening, the sterile items may be removed from the covering as the supplies are introduced into the ISO Class 5 PEC without the need to wipe the individual sterile supply items with sterile 70% IPA.
- The wiping procedure must not render the label unreadable.

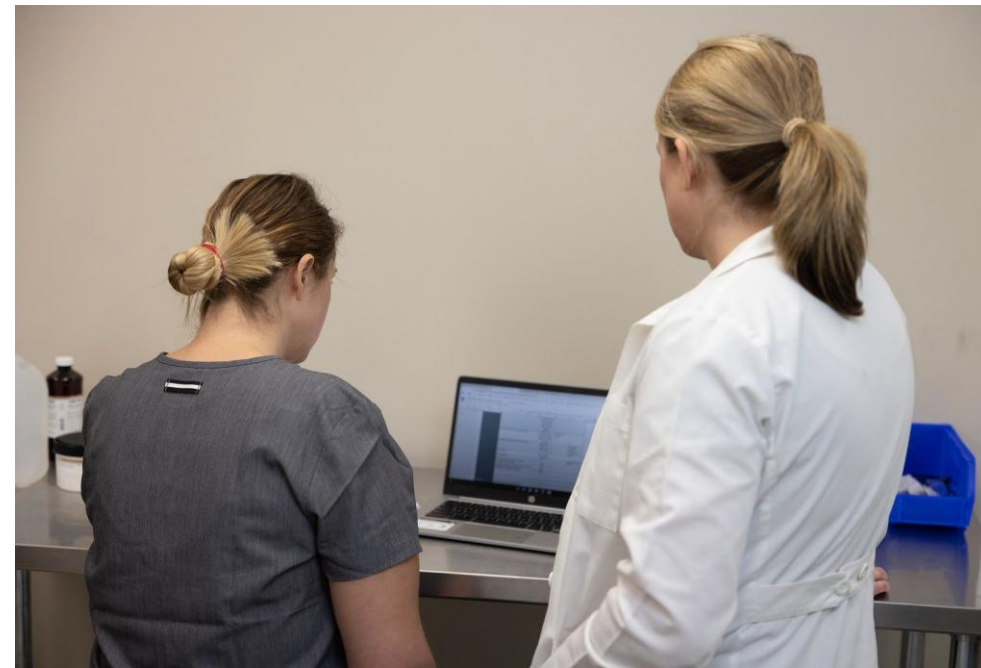


# Cleaning the PEC

# SOP

## Importance of a detailed Protocol

- USP <797> establishes cleaning frequencies – not cleaning methods or best practices.
- Technicians are being 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
- Training and observing staff to ensure compliance



# Products used for Daily Cleaning of PECs

- 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



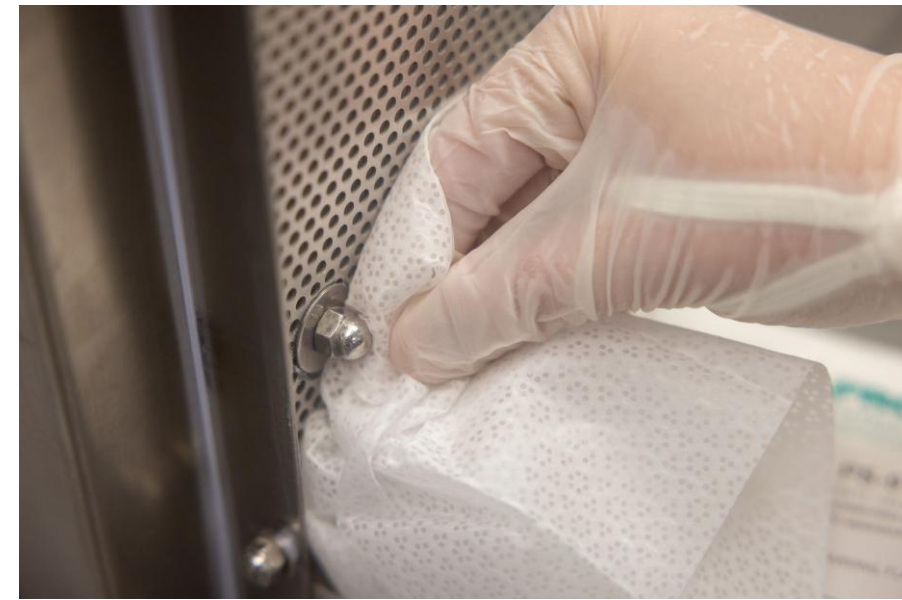
# Required Cleaning and Disinfecting Frequency in the PEC

- The entire PEC (all interior surfaces) must be cleaned and disinfected daily.
- On days when compounding occurs
- When surface contamination is known or expected
- 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



# 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





# Applying Sporocidal Agents in the PEC

This is required by USP Chapter 797

# Required Frequency for Sporidical Application in the PEC

Category 1 & 2 = Monthly

Category 3 = Weekly



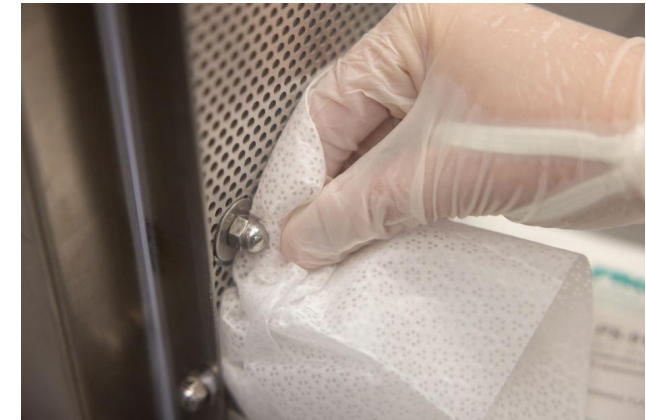
# Products used for Sporidical Application in PECs and CPECs

- EPA Registered Sporidical disinfectant
- Sporidical 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% Alcohol



# Process to apply Sporidical Agent in PEC/CPEC

- Wipe Gloved Hands and Cleaning Supplies with Sterile 70% Alcohol before placing them inside of the CPEC
- 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 CPEC
- Clean back wall of CPEC
- Clean both side walls of CPEC
- Lastly, clean the work surface of the CPEC
- Two passes may be required\*
- Allow Surfaces to remain wet for the required dwell time
- A residue removal step is required in the CPEC: repeat all steps cleaning all sides of the PEC in the appropriate order with Sterile 70% Alcohol.
- Clean and disinfect your cleaning tool





# Cleaning the SEC

# The “Why”

The people who clean and maintain the SEC are just as important to ensuring patient safety as the pharmacist who compounds the CSP or the nurse who administers it.



# SOP

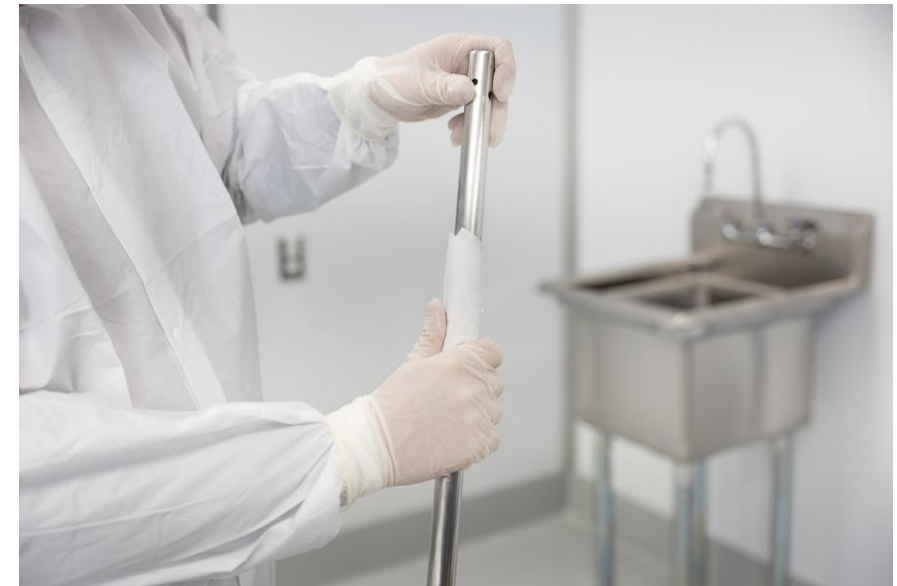
## Importance of a detailed Protocol

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# Agents and Supplies for Cleaning, Disinfecting, and Sporidicidal Disinfectants

- In classified areas outside of the PEC, sterile cleaning and disinfecting agents should be used.
- When diluting concentrated cleaning and disinfecting agents for use outside of the PEC, sterile water should be used.
- All cleaning and disinfecting supplies (e.g., wipers, sponges, pads, and mop heads) with the exception of tool handles and holders must be low lint.
- Reusable cleaning tools must be made of cleanable materials and must be cleaned and disinfected before and after each use.

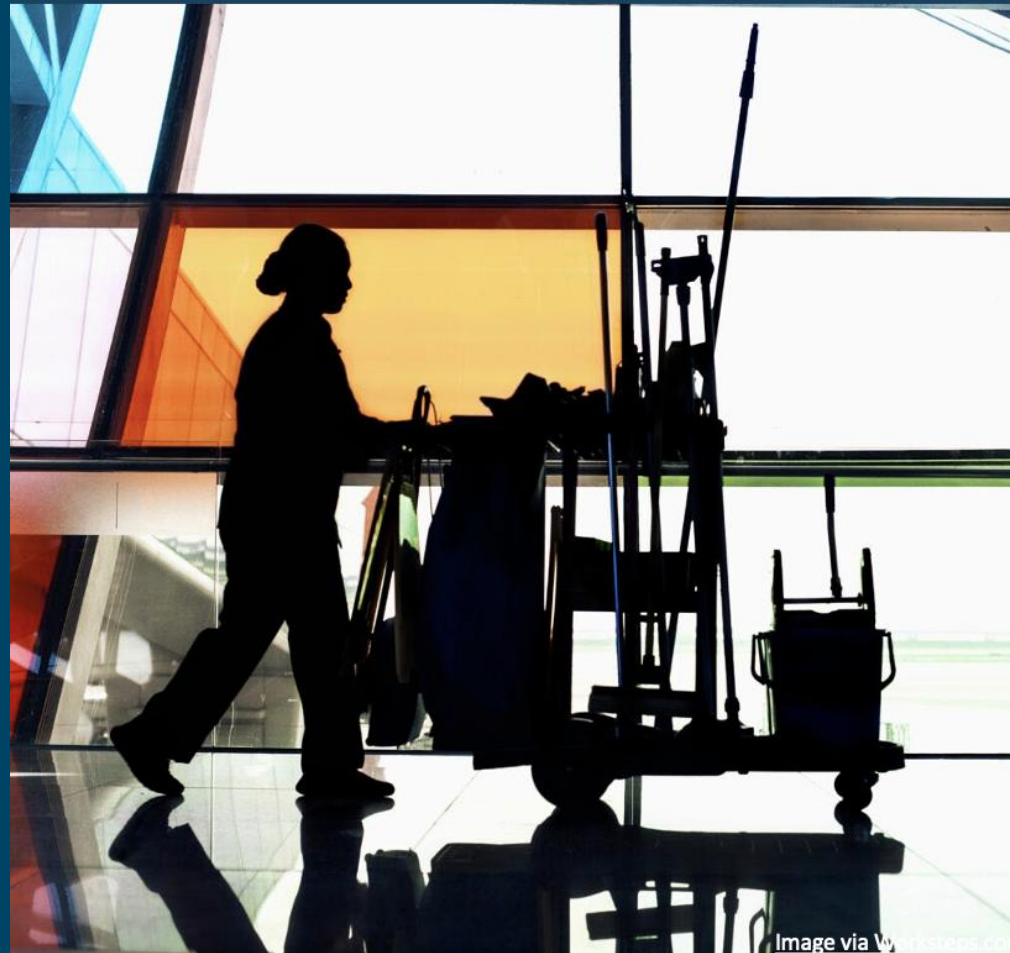


# Agents and Supplies for Cleaning, Disinfecting, and Sporicidal Disinfectants

- Wipers, sponges, pads, and mop heads should be disposable. If disposable cleaning supplies are used, they must be discarded after each cleaning activity.
- Reusable cleaning tools must be dedicated for use in the classified areas or SCA and must not be removed from these areas except for disposal.
- They must be discarded as determined based on the condition of the tools.



# Do not bring cleaning supplies from outside into your Cleanroom



# Required Cleaning Frequencies

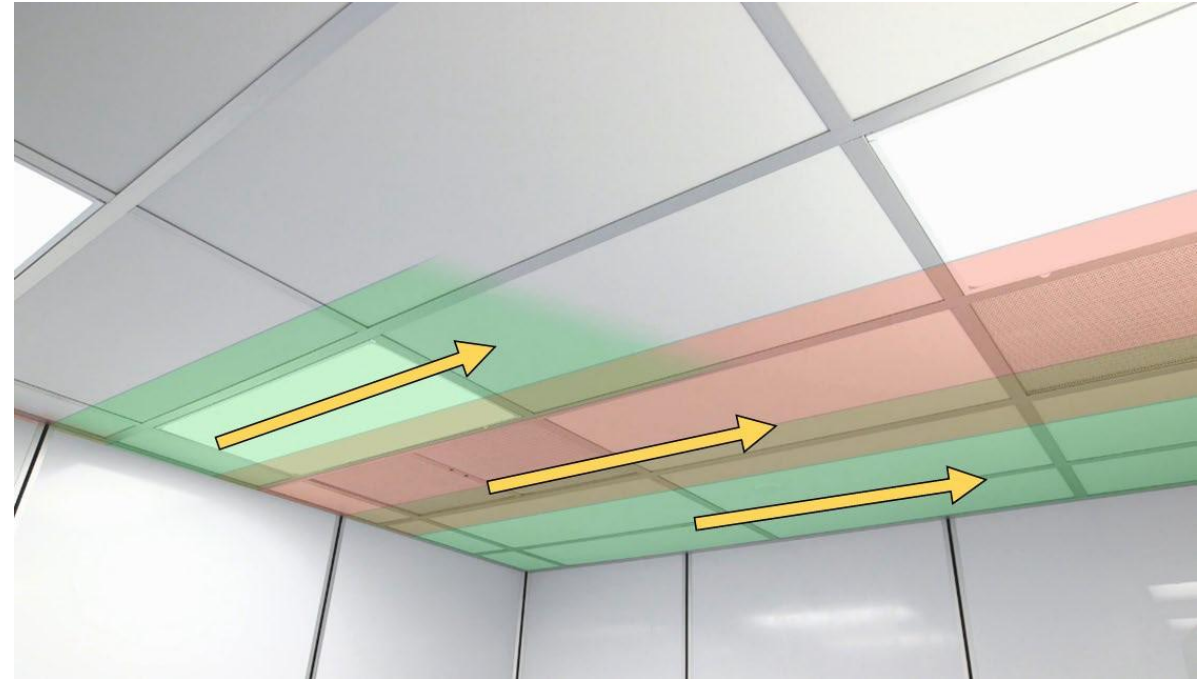
**Table 10. Minimum Frequency for Cleaning and Disinfecting Surfaces and Applying Sporidical Disinfectants in Classified Areas and in the SCA<sup>a</sup>**

Site	Cleaning	Disinfecting <sup>b</sup>	Applying Sporidical Disinfectant
Pass-through chambers	<ul style="list-style-type: none"> <li>Daily on days when compounding occurs</li> </ul>	<ul style="list-style-type: none"> <li>Daily on days when compounding occurs</li> </ul>	<ul style="list-style-type: none"> <li>Monthly for entities compounding Category 1 and/or Category 2 CSPs</li> <li>Weekly for entities compounding Category 3 CSPs</li> </ul>
Work surface(s) outside the PEC	<ul style="list-style-type: none"> <li>Daily on days when compounding occurs</li> </ul>	<ul style="list-style-type: none"> <li>Daily on days when compounding occurs</li> </ul>	
Floor(s)	<ul style="list-style-type: none"> <li>Daily on days when compounding occurs</li> </ul>	<ul style="list-style-type: none"> <li>Daily on days when compounding occurs</li> </ul>	
Wall(s), door(s), and door frame(s)	<ul style="list-style-type: none"> <li>Monthly</li> </ul>	<ul style="list-style-type: none"> <li>Monthly</li> </ul>	<ul style="list-style-type: none"> <li>Monthly</li> </ul>
Ceiling(s) <sup>c</sup>			
Storage shelving and bin(s)			
Equipment outside the PEC(s)			

Source USP 797

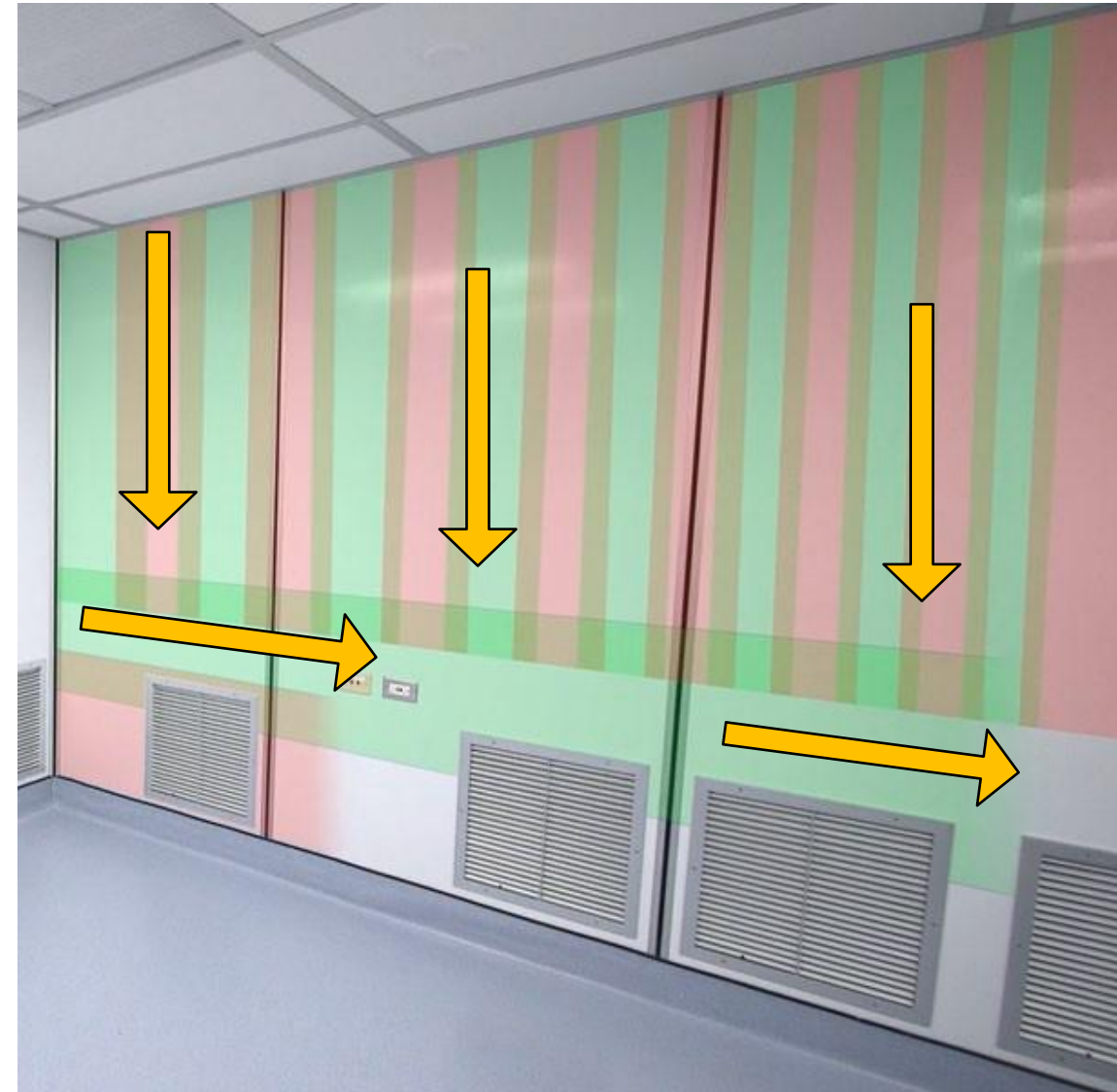
# Process to Clean and Disinfect Ceilings

- 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.
- Ensure ceilings to remain wet for appropriate dwell time
- Allow ceiling to dry completely before compounding resumes.



# Process to Clean and Disinfect Walls

- Eye protection should be worn when cleaning over your shoulders
- 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.
- Ensure walls to remain wet for appropriate dwell time
- Allow walls to dry completely before compounding resumes.





# Process to Clean and Disinfect Walls – Special Considerations

Do not let mop touch the coved section where the wall meets the floor



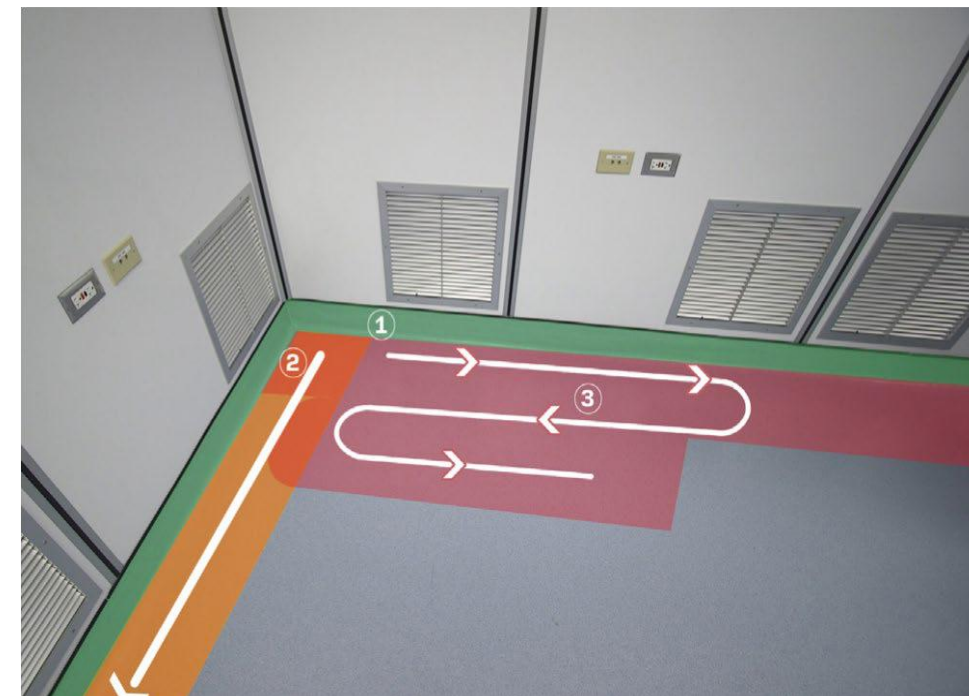
# Process to Clean and Disinfect Walls – Special Considerations

- Clean the air returns by hand!



# 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 covered 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.
- Ensure floors to remain wet for appropriate dwell time.
- Allow floors to dry completely before compounding begins





# Process to Clean and Floors – Special Considerations

- Clean that edge of the coved section by hand, it's part of the wall, not the floor



# Be careful to NEVER Break the Plane of the PEC while cleaning



# Room Work: High-Touch Surfaces



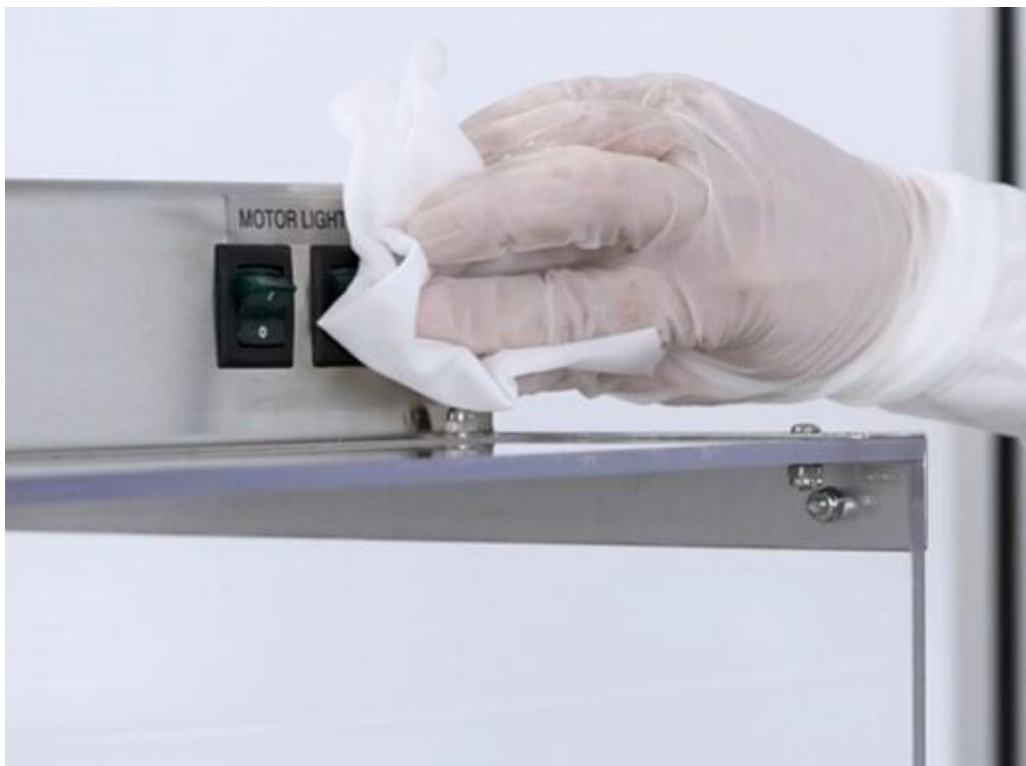
# During Monthly Cleaning – don't forget the outside of the PEC

- If your PEC is on Casters, move it away from the wall for cleaning
- If your PEC/CPEC is fixed, install it with enough distance to the wall for cleaning access



# During Monthly Cleaning

Pay particular attention to any controls and the power cord



# During Monthly Cleaning

Don't forget the Casters.... Casters never lie!



# Water Sources in the Cleanroom

- Surfaces of the sink(s) must be cleaned and disinfected each day of use, and a sporicidal disinfectant must be applied at least monthly
- The order of hand washing and garbing depends on the placement of the sink



That seems like a lot!

I don't have the time.....

My way is quicker

If you don't have time to do it right, when will you have time to do it over?



**John Wooden**



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# Thank you

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