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CriticalPoint Pearls of Knowledge — January 2025

Critical Cleaning Performance Requirements in Sterile Compounding Environments

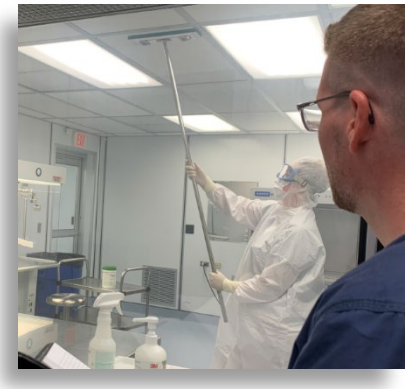
Introduction

Most pharmacy staff who have a role in the compounding area (e.g., segregated compounding areas [SCAs], cleanroom suites, and ISO Class 5 environments) are likely familiar with cleaning-related tasks. However, the primary challenge in a cleaning program often results from operational and documentative elements that aren't clearly described or consistently followed as written policy. Some pharmacies can get lost "in the weeds" describing operational tasks when a simpler approach may be more practical. Other pharmacies may implement written policies that are too generic, leaving room for interpretation by staff performing a particular duty. In this month's Pearl, we discuss cleaning and disinfection activities required in USP standards and examine details your pharmacy staff are potentially misunderstanding about cleaning and disinfection in sterile compounding environments.

Defining pharmacy work function objectives

A trained and competent pharmacy staff member may be able to recite the majority of their organization's cleaning procedures. They can list the steps and actions that pertain to specific surfaces and environments and name the appropriate cleaning agent selected by their leadership team. However, can the staff member describe the why behind some of the meticulous steps written into policy? Are they able to define cleaning-related functions and terminologies?

CriticalPoint emphasizes developing proficient pharmacy team members rather than merely defining competent team members through forms and documentation. Competency refers to an individual's knowledge, skill, and ability in a specific job function. Whereas proficiency reveals the level of skill or expertise that an individual has in a particular job function. Being competent in USP-related job functions is required but may miss the mark by reducing it to a check-the-box-type exercise for compliance.



Striving for job function proficiency is paramount to the success of the pharmacy and leads to operational compliance rather than seeking a goal for regulatory compliance. Having staff who understand the why behind every what to do the job properly is more important than performing the task itself. This understanding among staff also builds an excellent work culture where roles and functions are performed with consistency and confidence.

Practice contamination control fundamentals

We do not work in sterile environments; we perform sterile compounding. The cleanroom suite and the ISO Class 5 primary engineering control (PEC) are not sterile nor provide sterility. Pharmacies must educate their staff on contamination control awareness and practice contamination control principles every second of every day. Pharmacy staff performing cleanroom-related tasks must understand the concept of contamination control in order to limit or reduce the number of particles and microbes entering controlled compounding environments.

Contamination control is broken down into 3 overall elements:

1. Hand hygiene and garbing
2. Material handling (wiping all items that enter the controlled environment)
3. Proper conduct inside controlled environments (e.g., moving slowly, not talking while facing the PEC, not touching garb or face, resanitizing gloves, etc.)

The more stringent the policy is regarding the selection of cleaning, disinfectant, and sporicidal agents, process performance, and detailed material handling descriptions, the more effectively the environment can maintain a microbial state of control.

Understanding cleaning, disinfection, and sanitization fundamentals

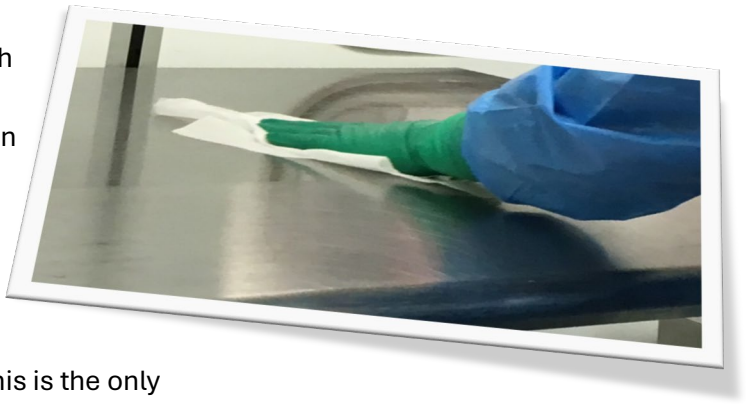
In addition to adhering to contamination control principles, pharmacies must follow a disciplined program addressing proper sanitation. This process focuses on reducing the number of disease-causing germs on cleaned surfaces to a safe level.

However, the term sanitization does not appear in USP <797> with respect to cleaning and disinfection. Nevertheless, sanitization is achievable (surfaces cleaned to a safe level), and the success or failure of this practice is revealed in the microbiological monitoring results. Successful programs address the faults in contamination control principles through the proper sanitization of target surfaces and items brought into the cleanroom suite and PECs.

The terms cleaning, disinfection, and sanitization are used interchangeably by many; however, they have distinctly different meanings and should be used carefully. Let's discuss the terms that are relevant to cleaning and sanitization of sterile compounding environments. We'll provide background and rationale for their use and propose desirable performance criteria.

- Cleaning is primarily a mechanical process (scrubbing) that is chemically enhanced by using an agent containing a surfactant or detergent. Cleaning agents remove many microbes, dirt, and both visible and invisible debris and also prepare a surface for disinfection.
  - Surfactants lower the surface tension of the agent so that the agent can penetrate dirt, wetting the surface more evenly and is, therefore, better at lifting dirt from a target surface. A detergent is one type of surfactant (called a surface-active agent).
- Disinfecting agents are chemical or physical agents used on target surfaces that aim to destroy fungi, viruses, and bacteria.

- Sporicidal agents are chemical or physical agents that destroy bacterial and fungal spores when used at a sufficient concentration for a specified contact (dwell) time. The expectation (or efficacy) of these agents is to kill all vegetative microorganisms.



- Dwell time (also called contact time and which is not defined in USP <797>), is the time the cleaning agent must remain wet on a surface in order to achieve the intended effect (killing microorganisms) specified on the product label. This is often the most often misunderstood step in the process among your staff!
  - Time and saturation rates are two important factors of "dwell" or "contact." This is the only way to achieve the formulated efficacy (effectiveness) of the selected agent.
  - Since airflow inherently has greater velocities (feet per minute or FPM) inside PECs and air changes per hour are high within the cleanroom suite, it is best to select a cleaning agent that has a dwell time as low as possible (while having good efficacy), typically 3 minutes or less.
  - Testing conducted at the CriticalPoint Center for Training and Research in 2018 has shown that it is difficult to achieve dwell times greater than 3 minutes (the actual results showed all agents dried before 3 minutes and 45 seconds) inside a PEC without reapplication, which is not desirable.
  - Do you know the dwell time of your current daily cleaning agent? It is included in the manufacturer's instructions for use provided you are using an EPA-registered one-step disinfectant cleaner.
- Per USP <797>, **cleaning and disinfection is a two-step process**. Select agents may achieve one but not the other in this process. Therefore, two select agents are required to achieve USP compliance.
- As mentioned in USP <797>, many disinfectants (that are EPA registered) are *one-step cleaning and disinfectant agents*. These agents have been specifically formulated to be effective for *both steps* without the need for a separate step.
- **EPA-registered one-step disinfectants are an allowable and strongly recommended choice** when selecting appropriate agents for cleaning and disinfecting.
  - Selecting one-step agents benefits cost (without having multiple agents), time efficiency, and consistency among staff when using one-step products.
  - Cleaning agents must be compatible with the surfaces in your facility. EPA-registered one-step disinfectant cleaners provide the information on dwell time and compatibilities.
- CriticalPoint strongly suggests the use of ready-to-use (RTU) cleaning agents. We believe the higher cost of RTU agents is outweighed by improved consistency, efficacy, and efficiency of work.
  - Note: Properly mixing agents with appropriate water selections (e.g., hard or tap water, sterile water) may be inconsistent among staff without appropriate training and documentation.
  - The training and documentation necessary to properly implement this type of cleaning policy may be an area of interest during inspections and must be process-verified to avoid potential citations.
  - USP <797> states that sterile agents MUST be used in ISO Class 5 devices. Therefore, sterile water (additional cost factor) must be used when mixing agents for use.

The burden of sterile cleaning agents

The use of sterile low-lint wipers in ISO Class 5 PECs while compounding has been a long-standing practice and requirement in USP <797>. However, navigating the USP requirement on cleaning, disinfectant, and sporicidal agents in ISO Class 5 PECs has had some initial operational challenges. Obvious concerns were almost immediately raised and addressed regarding using sterile and nonsterile cleaning agents.

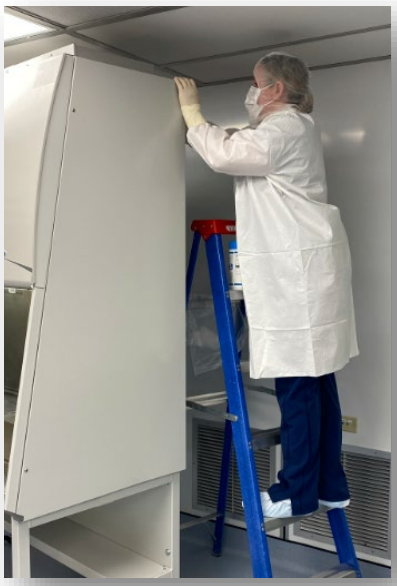
Pharmacies who choose to use sterile and nonsterile agents between differing ISO classes quickly realize that, operationally, it may be more cumbersome than it's worth. Training and education, documentation, storage, and proper labeling are all factors to consider when trying to separate cleaning agents for the intended ISO classifications.

Many pharmacies have decided to go with sterile agents for all ISO classes, streamlining the process, training, and documentation. This has also removed the previously mentioned complications. Essentially, the same processes and written procedures have been revised slightly, addressing "sterile agents" within organizational policy.

- Cleaning, disinfecting, and sporicidal agents used within the PEC must be sterile.
- USP does not address the type of cleaning agent used to clean and disinfect the exteriors of PECs, which is another factor in pharmacies choosing to use sterile agents for all surfaces and environmental ISO classes. This eliminates potential misuse of sterile and nonsterile agents regarding the interior and exterior of the PEC.
- All supplies (with the exception of tool handles and holders) must be sterile and low-lint. Tools must be cleaned and disinfected before being brought into the PEC work area.

Summary

In the context of roles and responsibility for staff, strive for operational compliance and proficiency rather than regulatory compliance and competency. Resist the singular objective of competency through forms and documentation. Ensure the pharmacy staff understands the why behind the what with organizational cleaning policy and procedures. Remember that USP <797> is minimum standard practice. Policies based on minimum standard may be too broad-based and not specific to your facility's needs for compliance.



A well-trained staff who know and understand cleaning agents, their purpose for use, and the methods required to effectively reduce disease-causing germs on cleaned surfaces to safe levels is paramount to patient safety—because proper contamination control is more consistently achieved. The benefit of having a staff-wide understanding of proper cleaning protocol is a sustained microbial state of control.

References

The United States Pharmacopeial Convention, Inc. USP <797> Pharmaceutical Compounding—Sterile Preparations. 2024.