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Best Practices for **Cleanroom Cleaning Documentation**

Effective cleaning and disinfection of controlled sterile compounding environments is one of the cornerstones to achieving and maintaining a state of microbial control in buffer, ante, and segregated compounding areas. However, these practices have not always been universally well understood, adopted, or effectively documented. While this article focuses on the documentation aspects of cleaning and disinfection, the reader is encouraged to review the material presented in *Requirements and Best Practices for Sanitizing Engineering Controls* (*PP&P*, September 2013), which provides a comprehensive review of the following information that is beyond the scope of this article:

- Essential definitions
- Types of cleaning and disinfection agents
- Types of water to use and methods of dilution
- Cleaning supplies
- General principles of cleaning
- Specific activities to occur more frequently than on a daily and monthly basis
- Considerations for cleaning hazardous drug compounding areas
- Written policies and procedures, staff training and competency verification
- Verification of the adequacy of the cleaning program

Influence of USP <797>

Documentation of cleaning and disinfection of sterile compounding areas must be consistent and capture enough discrete detail to provide a high assurance that activities are occurring as defined in the facility's policies and procedures (P&Ps), but not so much as to be cumbersome. This begs the questions of: How little is too little? How much is too much? And, just what is required? To address these questions, presented here are recommendations for best practices that also integrate USP Chapter <797> requirements.[1] However, it must be noted that Chapter <797> does not represent best practice; rather, it defines minimum practice requirements.

It is also worth mentioning that more and more state boards of pharmacy are using Chapter <797> to promulgate their own sterile compounding regulations. Some states are able to adopt USP Chapters by reference and therefore require exactly what <797> says, albeit this is somewhat influenced by any variability in which a state interprets the standard. Other states are not able to adopt USP chapters by reference and instead essentially cut and paste the chapter requirements into their regulation and add their own state-specific modifications as they go. Therefore, it is paramount that each pharmacy performing sterile compounding understands and follows its state pharmacy regulations.

Characteristics of Good Documentation Forms

Documentation can be accomplished by using either paper forms or web-based quality management systems. The current trend in health care documentation is leaning toward the utilization of electronic systems, which not only capture discrete data, but also have the advantage of sending alerts when a task has not been completed or documented. These systems also are able to perform reporting and trending based on activity and outcomes. Either method is acceptable as long as the data is captured in a timely and accurate manner. Whether electronic or paper, well-designed forms should represent the following characteristics:

- Be 100% consistent with written P&Ps
- Provide visual cues to staff, especially in multistep processes
- Capture the detail and discrete data required by regulations
- Be intuitive and easy to use
- Allow trending of important outcomes

Determine Responsibility

Documentation is best performed by those who actually complete the cleaning activities, immediately after the solution preparation or cleaning and disinfection tasks are completed. To ensure documentation is complete, correct, and timely, paper forms and logs should be routinely, but informally, reviewed by those supervising sterile compounding. In addition, the sterile compounding pharmacy manager (or designee) should formally sign off on each form; depending on the form format, sign-offs can be conducted weekly or monthly. If a manager in the course of reviewing cleaning documentation notices instances of incomplete or incorrect documentation, follow up actions with those staff members should be documented. This can be accomplished as easily as documenting the follow up actions on the back of the log form.

Documentation Demonstrates Execution

Regardless of where cleaning documentation is kept, it must be within easy access for those who need to document their activity.

Image courtesy of CriticalPoint, LLC

Establish Documentation Retention Policies

Each pharmacy should have a record retention policy, as many state and federal agencies have regulations that specify how long hospitals, community pharmacies, and other health care providers must keep certain documents. However, keep in mind that compliance with minimum record retention requirements may often be inadequate to protect an organization in the event of contractual, accreditation, or legal issues that can and do surface beyond the common two to three year period required by many state boards of pharmacy. Hospitals are required by state

law to keep records such as compounding batch logs and other patient-specific information for a minimum of seven years. Furthermore, many states require hospitals to retain medical records for seven years from the date of discharge for an adult patient. Pediatric patients' records must be kept for seven years from the date the patient is discharged or until the patient reaches the age of majority, whichever is longer.[2]

Paper-based cleaning documentation logs are often kept in a ringed binder in the main pharmacy where it is readily accessible to staff, managers, and auditors. Regardless of where the information is kept, though, it must be within easy access for those who need to document their activity. It also must be readily retrievable for any authorized individuals who wish to review it. Examples of authorized persons who can and do request this information include representatives of:

- State Boards of Pharmacy
- Accreditation Organizations
- Food and Drug Administration
- State Departments of Health
- Centers for Medicare and Medicaid Services
- Organizational Quality/Compliance Personnel

Any of these individuals is likely to scrutinize cleaning documentation for the level of detail, quality, and completeness. They also will review the written procedures to determine if they reflect current regulations and best practices, and then they will compare the documentation with the procedure—evaluating it for consistency with policy. Some inspectors may ask to access your electronic quality management documentation, so be prepared to set up access with viewing-only permissions and to assist them in navigating the system. They may also request printouts of the information for their inspection reports.

Documenting Cleaning Solution Preparation

Before daily or monthly cleaning activities are performed, cleaning solutions must be prepared according to manufacturer instructions or references. Though the body text of <797> does not directly mention a requirement to document cleaning solution preparation, Appendix V—Sample Form for Assessing Cleaning and Disinfection Procedures[3]—does include an item indicating the facility "documents disinfectant solution preparation." Certainly, it is at least a best practice to document the preparation of cleaning solutions, but it has been this author's experience that unless the commonly-used amounts of water and cleaning solutions are specified and documented, these agents may not be mixed properly. Regardless of whether cleaning duties are performed internally by pharmacy compounding staff, or if the daily and monthly cleaning activities that occur outside the primary engineering controls (PECs) are under the purview of the hospital's environmental services staff or outsourced to companies that provide specialized cleaning services, the pharmacy remains responsible for ensuring the process occurs as required. There have been instances where, upon investigation by

Sample Cleaning Solution Preparation Logs

FIGURES 1 and **2** below represent samples of solution preparation logs that can be customized to your own pharmacy operation. These types of forms will help reduce the likelihood that cleaning solutions will be mixed incorrectly and make documentation fast and easy.

FIGURE 1

Month: ______________________ Year: ________ Page ___ of ___

Cleaning Agent and Dilution Guidelines*		
Water**	Germicidal Detergent Lysol® IC™ (Example only) *Dilution: 15 mL(1/2 ounce) to 3.75 liters(1 gallon)*	Sporicidal & HD Decontamination Agent*** Clorox® Household Bleach (Example only) *(Dilution: 60 mL bleach/1 gallon of water + 60 mL distilled white vinegar results in 800 ppm free chlorine)*
½ Gallon (1893 mL)	7.5 mL	30 mL bleach / 30 mL white vinegar
1 Gallon (3785 mL)	15 mL	60 mL bleach / 60 mL white vinegar
3 Gallons (11,355 mL)	45 mL	180 mL bleach / 180 mL white vinegar

* *Dilution instructions do not apply to any agent other than Lysol IC and household bleach with vinegar*
** *Use USP Purified Water such as Sterile Water for Irrigation (SWFIrrig) to dilute agent if cleaning inside of PECs*
***Allow the bleach/vinegar solution to remain on the surface at least 30 seconds.

Day of Month	Amt water used to dilute agent in gallons/bucket	Type of Water used to Dilute Cleaning Agent	Type of Agent Used	Amount Agent in Bucket	# buckets prepared	Initials of Person Preparing	Date prepared and signed
		☐Tap ☐ SWFIrrig	☐Lysol IC ☐ Bleach/Vinegar				
		☐Tap ☐ SWFIrrig	☐Lysol IC ☐ Bleach/Vinegar				
		☐Tap ☐ SWFIrrig	☐Lysol IC ☐ Bleach/Vinegar				
		☐Tap ☐ SWFIrrig	☐Lysol IC ☐ Bleach/Vinegar				
		☐Tap ☐ SWFIrrig	☐Lysol IC ☐ Bleach/Vinegar				

FIGURE 2

Month: ______________________ Year: ________ Page ___ of ___

Cleaning Agent and Dilution Guidelines*		
Water**	Germicidal Detergent Lysol® IC™ (Example only) *Dilution: 15 mL(1/2 ounce) to 3.75 liters(1 gallon)*	Sporicidal and HD Decontamination Agent PeridoxRTU *Product is ready to use* *Allow to remain on surface 3 minutes before sIPA*
½ Gallon (1893 mL)	7.5 mL	N/A
1 Gallon (3785 mL)	15 mL	N/A
3 Gallons (11,355 mL)	45 mL	N/A

* *Dilution instructions do not apply to any agent other than Lysol IC*
** *Use USP Purified Water such as Sterile Water for Irrigation to dilute agent if cleaning inside of PECs*
Key: *N/A = not applicable Tap= tap water SW= sterile water for irrigation sIPA= sterile 70% isopropyl alcohol*

Day of Month	Amt water used to dilute agent in gallons/bucket	Type of Water used to Dilute Cleaning Agent	Type of Agent Used	Amount Agent in Bucket	# buckets prepared	Initials of Person Preparing	Date prepared and signed
	☐N/A or	☐Tap ☐ SW ☐N/A	☐Lysol IC ☐ PeridoxRTU				
	☐N/A or	☐Tap ☐ SW ☐N/A	☐Lysol IC ☐ PeridoxRTU				
	☐N/A or	☐Tap ☐ SW ☐N/A	☐Lysol IC ☐ PeridoxRTU				
	☐N/A or	☐Tap ☐ SW ☐N/A	☐Lysol IC ☐ PeridoxRTU				
	☐N/A or	☐Tap ☐ SW ☐N/A	☐Lysol IC ☐ PeridoxRTU				
	☐N/A or	☐Tap ☐ SW ☐N/A	☐Lysol IC ☐ PeridoxRTU				
	☐N/A or	☐Tap ☐ SW ☐N/A	☐Lysol IC ☐ PeridoxRTU				

FOR PDF VERSIONS OF THESE LOG FORMS, AS WELL AS FORMS FOR:

- **Daily/Monthly Cleaning Log for SECs**
- **Daily/Monthly Cleaning Log for Controlled Environments & Adjacent Areas**

please visit www.pppmag.com/cleanroomcleaningdocs

SIDEBAR

Cleaning and Disinfection of Buffer, Ante, and Segregated Compounding Areas

Chapter <797> Requirements	Suggested Elements of Performance for Good Cleaning Documentation
Minimum disinfection frequency for the inside of PECs with sterile 70% isopropyl alcohol (sIPA): • Beginning of each work shift • Before each batch is started • Every 30 minutes during continuous compounding • After spills • When surface contamination is suspected	These elements should be accounted for in written P&Ps. Ongoing and frequent (daily) observation of sterile compounding staff should verify these practices. These practices are also verified during each operator's aseptic compounding competency and media fill testing.
Daily cleaning of ante, buffer, and segregated compounding areas: • Inside surfaces of ISO Class 5 • Counters and easily cleanable work surfaces • Floors	• Document types of agents and water used (see **TABLE 1** for agents) • Specific daily activities to be documented: ▸ Cleaning solution preparation ▸ Empty trash ▸ Easily cleanable horizontal surfaces ▸ High touch surfaces such as telephones, intercoms, door handles, keyboards, computer equipment ▸ Floors (including floor of pass-through if applicable)
Monthly cleaning of ante, buffer, and segregated compounding areas: • All daily activities • Ceiling • Walls • Storage shelving	Document completion of following monthly activities: • Ceilings • Walls and all surfaces of pass-throughs • All surfaces of furniture and trash bins, outside of PECs • All surfaces of any storage containers

TABLE 1

Summary of Suggested Agents by Area

Non Hazardous Compounding Areas

PECs	Buffer, Ante, and SCA
• Germicidal detergent diluted with sterile water followed by • Sterile 70% IPA	• Germicidal detergent diluted with tap water

Weekly or monthly substitution of a sporicidal agent for the germicidal detergent is best practice.

Hazardous Drug Compounding Areas

PECs	Buffer Area
• Agent to deactivate HDs such as 2% sodium hypochlorite, Surface Safe, or PeridoxRTU followed by • Germicidal detergent diluted with sterile water followed by • Sterile 70% IPA	• Weekly deactivation of HD drug residues on high touch areas and the floor is recommended • Germicidal detergent diluted with tap water

Weekly or monthly substitution of a sporicidal agent for the germicidal detergent is best practice; however, if PeridoxRTU is used as a deactivation agent following the manufacturer's instructions, then that agent also satisfies requirements for both germicidal detergent and sporicidal agent.

going to "the Gemba,"[4] it was discovered that environmental sampling excursions were caused simply by the incorrect preparation of cleaning solutions; as specific dilutions were neither used nor was the process documented.

USP Chapter <797> requires the use of a germicidal detergent to perform cleaning. The use of a sporicidal agent substituted for the germicidal detergent on a regular basis, such as weekly or monthly, is strongly recommended in USP <1072>–Disinfectants and Antiseptics,[5] though it is not required by <797>. Also not explicitly required by <797> is the best practice of diluting the germicidal detergent or sporicidal agent that will be used to clean the surfaces inside the PECs with sterile water, while reserving tap water for use in the ISO Class 7 and 8 areas outside of the PECs. USP <797> states that surfaces inside of the PECs "shall be cleaned by removing loose material and residue from spills; for example, water-soluble solid residues are removed with sterile water (for injection or irrigation) and low-shedding wipes."[6] It stands to reason then, that if sterile water is best used to remove residues inside the PEC, then cleaning solutions used inside the PEC also should be diluted with sterile water.

Given these requirements and best practices, strong consideration should be given to the development of and documentation on a Cleaning Solution Preparation Log. Assuming graduated containers for water and cleaning solution measurements are available to staff, forms such as the examples in **FIGURES 1** and **2** help reduce the likelihood that cleaning solutions will be mixed incorrectly and make documentation fast and easy.

Documenting Daily and Monthly Cleaning Activities

There are many activities associated with daily and monthly cleaning of the nonhazardous buffer room, hazardous buffer room, and anteroom, which, taken together, are referred to as secondary engineering controls (SECs). Striking a balance between too much and too little detail can be challenging, so cleaning documentation forms need to clearly document:

- Dates cleaning occurred
- Specific areas cleaned (eg, buffer room, anteroom, hazardous buffer room, segregated compounding area)
- Type of cleaning (daily, monthly, weekly)
- Agents used in each area including what they are diluted with, if applicable (refer to **TABLE 1** and example documentation forms provided)
- Detail activities in each area:
  - If there are multiple PECs in a buffer area, number them or name them so documentation can occur for each PEC separately
  - Break down general areas to be cleaned, but written P&Ps must bear additional detail
- Initials of the person/s who performed cleaning (initials must tie back to a signature log that bears the person's initials, printed name, and signature)

Regardless of what the form looks like or how it is documented (paper or electronic), a person reviewing completed daily and monthly cleaning forms is looking to have these questions answered:

- Who performed the cleaning?
- When did they clean?
- What area did they clean?
- What items are cleaned within each area (the form can have categories with additional detail in the written procedures)?
- In what general order did they clean those items?
- What agent or agents did they use to clean the items?
- In what order did they use the agents?

Clearing Up Common Misconceptions

USP <797> states that PECs "shall be cleaned and disinfected frequently including at the beginning of each work shift, before each batch preparation is started, every

Outsourcing Considerations

As an aside, <797> also states: "Trained compounding personnel are responsible for developing, implementing, and practicing the procedures for cleaning and disinfecting the DCAs (direct compounding areas) written in the SOPs."[6] Thus, if you are considering outsourcing your cleaning services, be aware that only trained compounding personnel may clean and disinfect the surfaces inside of the PECs.

30 minutes during continuous compounding periods of individual CSPs, when there are spills, and when surface contamination is known or suspected from procedural breaches."[7] The way this statement is written has caused some confusion in the pharmacy world.

1. IPA is not a cleaning agent: This author believes that the expert committee's intention was to require the use of a sterile disinfectant, such as sterile isopropyl alcohol (sIPA) to be used at these specified intervals. However, isopropyl alcohol is not a cleaning agent, it is a disinfecting agent. Disinfecting agents are only effective after a surface has been prepared for disinfection by first being cleaned. Cleaning is both a chemical and physical process that removes dirt and other debris and prepares a surface for disinfecting.

2. Inside surfaces of PECs used for non-hazardous compounding must be cleaned daily with germicidal detergent: Daily cleaning of all the surfaces inside of the PECs as well as easily cleanable horizontal surfaces and floors of the buffer and anterooms must be performed using a germicidal disinfectant. After all of the surfaces inside the PECs (used for non-hazardous compounding) are cleaned with germicidal detergent solution, those same surfaces should be disinfected with sIPA. The daily cleaning of non-hazardous PECs is a two-step process (germicidal detergent followed by sterile IPA) compared to the one-step process of cleaning the non-hazardous buffer, ante, and segregated compounding areas (with germicidal detergent).

3. Documentation of the application of sIPA is not required every 30 minutes: Some have taken this statement literally and are looking for documentation of sIPA application to the compounding deck every 30 minutes. In reality, it occurs much more often. To document this activity would require the compounder to remove their hands from the ISO Class 5 surface and pick up a pen, document, resanitize hands, and re-enter the DCA. This would actually be at odds with the best practice of organizing work so that hands do not leave the ISO Class 5 area during compounding. In order to verify that this activity is occurring, both frequent disinfection of the deck as well as frequent disinfection of gloved hands should be specifically incorporated into both written P&Ps, as well as verified through daily observation and during aseptic technique competency.

Conclusion

There are many correct ways to document cleaning activity. This article has reviewed overall cleaning documentation requirements and best practices, and highlighted some common challenges and misunderstandings with regard to documentation. The forms available for download are but a few examples of acceptable documentation. They are free for your own use, but you must first customize them so they are consistent with your specific primary and secondary engineering controls, cleaning agents, types of water used, and your written P&Ps. Cleaning and disinfection of cleanroom environments is a critical cog in the wheel of microbial control. Careful, detailed, and complete documentation not only demonstrates compliance during inspections, but provides detail to be reviewed in the event of unexpected microbial findings. ■

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