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By Kate Douglass, MS, RN, APN,C, CRNI, and Eric S. Kastango, MBA, RPh, FASHP

Requirements and Best Practices for **Sanitizing Engineering Controls**

Poor cleaning practices are associated with microbial contamination of compounded sterile preparations (CSPs), and consequently performing appropriate daily and monthly cleaning are vital to risk prevention. Though the professional literature contains an abundance of information detailing policies and procedures (P&Ps) for cleaning sterile compounding primary and secondary engineering controls, much misunderstanding, misinterpretation, and myth continues to surround this topic. CriticalPoint's 2013 pharmacy compliance survey revealed the overall compliance with cleaning-related elements required by USP Chapter <797> to be 73%; thus, the need for improvement still exists (see **SIDEBAR**). Addressing these challenging domains—by utilizing the best available data—will ensure correct cleaning practices and dispel common cleaning myths (see **TABLE 1**).

Clarifying common terminology is the first step toward ensuring an accurate understanding of cleaning concepts. Cleaning is a mechanical process using detergent and water to remove dirt, debris, and germs, and is performed to prepare a surface for disinfection. Sanitizing is a chemical process used to decrease the number of germs on cleaned surfaces to a safe level. Disinfecting is another chemical process that destroys 100% of the harmful bacteria, viruses, and fungi on surfaces, but does not necessarily destroy their spores; sporicidal agents are those that kill microorganisms and their spores. Therefore, what is often described as a cleaning program would be more accurately defined as a sanitization program, whereby cleaning and disinfecting results in an environment that is suitable for sterile compounding and surface microbial bioburden is reduced to safe levels. Regardless of the proper use of particulate-free HEPA filtered first air, hand hygiene, garbing, disinfection of gloves, proper aseptic technique, and cleaning of surfaces, the actual environment where compounding is performed is not completely sterile; therefore, the term sanitization is more appropriate.

TABLE 1

Common Cleaning Myths

Cleaning Myth	Requirement/Best Practice
Use 70% isopropyl alcohol (IPA) only for cleaning.	Refer to Appendix II of USP <797> for a list of germicidal detergents (eg, quaternary ammonium or phenolic) in addition to sterile IPA (sIPA).
Rotate cleaning agents.	Rotation is not required or necessary. Use germicidal detergent daily. A sporicidal agent should be used monthly (or more frequently) depending on environmental sampling results.
Clean inside primary engineering controls (PECs) with sIPA daily.	Clean inside PECs daily with diluted germicidal detergent daily followed by sIPA.
Dilute designated cleaning agent with tap water.	Dilute designated cleaning agent with sterile water for use inside ISO Class 5 space and tap water elsewhere.
sIPA and/or germicidal detergents can be used to deactivate hazardous drugs (HDs).	2% sodium hypochlorite (or other agents per drug SDS [previously MSDS]) must be used to deactivate HD residues inside BSCs/CACIs before cleaning with a germicidal detergent and sIPA.

Types and Rotation of Cleaning Agents

Though United States Pharmacopeia (USP) Chapter <797> does not recommend specific germicidal detergents, it identifies the common classes of disinfectants and the corresponding properties of each (see Appendix II).[1] Another helpful resource is USP Chapter <1072> Disinfectants and Antiseptics, which suggests the daily use of a bactericidal disinfectant with weekly (or monthly) use of a sporicidal agent.[2]

The rotation of cleaning agents has been a suggested practice; however, this concept is commonly misused when applied to controlled environment sanitization programs. Chapter <1072> states that the development of microbial resistance to disinfectants is not likely, as "disinfectants are more powerful biocidal agents than antibiotics and they are applied in high concentrations against low populations of microorganisms usually not growing actively, so the selective pressure for the development of resistance is less profound."[2] Therefore, it is not valid to apply the model of antibiotic resistance to the mode of action of disinfectants.[3] Antibiotic resistance occurs when microorganisms actually alter their structure to render them resistant to the action of the antibiotic, whereas disinfectants work through a chemical action that destroys the cell membrane or other structures. As such, daily use of a germicidal detergent, with periodic use of a sporicidal agent, is recommended.

Tap Water vs Sterile Water

Cleaning must be performed with a germicidal detergent mixed with water, but USP Chapter <797> is not clear with regard to the type of water to be used. Though the chapter does not explicitly require the use of sterile water inside of primary engineering controls (PECs), it states "water-soluble solid residues are removed with sterile water (for injection or irrigation) and low-shedding wipes."[2] It stands to reason then if the Chapter instructs compounders to wipe solid residues with sterile water, then it is likely that the intention of the committee was to require the use of sterile water inside of the ISO Class 5 space. Just as the mandate for sterile gloves is made in order to ensure that compounding is begun with a known zero bioburden state on gloved hands, the use of sterile water makes similar sense.

Tap water has significantly higher amounts of both colony-forming units (CFUs) and pyrogens (see online-only **TABLE 2** at **www.pppmag.com/waterbioburden**). Though the inside of PECs is not sterile and the cleaning supplies (low-linting wipes and buckets) are not sterile, the use of sterile water dramatically reduces the level of bioburden introduced while cleaning PECs. However, tap water can be used to dilute the designated germicidal detergent used to clean the secondary engineering controls (SECs; buffer and ante-areas).

Proper Dilution and Documentation of the Germicidal Detergent and Sporicidal Agent

Follow the manufacturer's instructions to dilute the germicidal detergent. The practice of "eyeballing it" is common; however, this has resulted in solutions that are too dilute, ineffective, and have later been tied to environmental sampling action level excursions, making it clear this practice should be avoided. Some type of measuring device, such as a graduated cylinder, should be kept at the ante-room sink for measurement of cleaning solutions. To prevent the risk of splashing, the cleaning agent should be added to the desired amount of water. Though not specifically required by the Chapter, it is considered best practice to document the preparation of cleaning solutions. To ensure accurate dilution, use a solution preparation log that includes the volume of the designated agent required for commonly used volumes of water and also specifies the type of water to be used.

Where is a Germicidal Detergent Used?

The designated germicidal detergent is used in all of the following locations:

- On all surfaces inside of the PECs used at your facility: laminar air flow workbenches (LAFWs), biological safety cabinets (BSCs), compounding aseptic isolators (CAIs), compounding aseptic containment isolators (CACIs), as well as integrated vertical laminar flow workbenches
- Ceilings
- Walls/doors/handles/pass-throughs
- All surfaces of furniture
- Outside surfaces of PECs
- Floors of rooms and full height pass-throughs

Cleaning Supplies

Cleaning supplies must be dedicated to the area of use. If conventional cellulose mop heads are used, then each area must have a mop dedicated for use in that location unless the mop head is changed between areas or a specific cleaning order is accomplished and the cellulose mop head discarded. For example, the same cellulose mop head could be used to clean all of the following areas in the buffer and ante-areas only if they are cleaned in this order: ceilings, walls, floors, and then disposed. The depth and variety of cleaning supplies available today offer more flexibility and have improved dramatically from those available even 10 years ago. A popular choice is to use stainless or plastic mop handles that utilize changeable mop heads and covers. All mops should be hung on the wall; supplies for cleaning are generally kept on the clean side of the ante-area convenient to the sink. Be sure to purchase buckets that are large enough to accommodate the mop used, incorporate a wringer, and have gradations either in liters or gallons so that staff can measure exactly how much water is in the bucket.

Ergonomic issues also should be considered. Each gallon of water equals 8.34 pounds, so a bucket containing 3 gallons of water—a common amount used for cleaning floors—weighs 25 pounds. Staff should be trained in using appropriate body mechanics for lifting buckets of cleaning solution to prevent injury. Some newer ante-room designs incorporate a tap water spigot that is located near the floor to fill buckets easily. Use of a bucket cart to move the cleaning solution from area to area is also strongly encouraged.

Staff may be required to wear safety goggles when there is a risk of splashing or dripping of cleaning fluids, for example, during cleaning solution preparation or when cleaning ceilings. Buckets must be rinsed, dried, and stored in an inverted position so there is no standing water in which microbial contamination could proliferate. Low-linting wipers should be used in all controlled sterile compounding environments; these wipes can be purchased dry or prewetted with a variety of agents.

CRITICALPOINT'S 2013 <797> SURVEY

Overall Compliance with Cleaning-related Elements Required by USP Chapter <797>*

Compounding Facility Management: Cleaning and Disinfecting

Cleaning materials that are reused (mop handles, mop heads, etc) are labeled according to their location of use AND policies and procedures have been developed regarding maintenance of the reusable items so that repeated use does not increase the bioburden of the controlled environments.	45.5%
Easily cleanable horizontal work surfaces in the buffer (cleanroom), ante- or segregated compounding areas are cleaned daily and documented.	69.0%
Floors in the buffer area, ante-area, or segregated compounding area are cleaned daily with the designated cleaning agent after compounding has been completed and this activity is documented.	67.5%
Personnel who perform cleaning receive training in and successfully pass initial and ongoing competency assessments in both of these areas: 1) Hand hygiene and garbing (which includes gloved fingertip sampling) and 2) Cleaning and disinfecting.	56.9%
Sterile 70% isopropyl alcohol (sIPA) is allowed to remain in contact with surfaces to be disinfected for 10-30 seconds before compounding activities are started.	79.0%
Mops, wipers, and other cleaning equipment are non-shedding and if reusable, they are dedicated to use in the buffer area, ante-area, or segregated compounding area.	74.2%
Only trained compounding personnel clean inside of the ISO Class 5 work areas.	96.0%
Supplies, components, and other items required for compounding are removed from their outer packaging before entering the buffer area.	94.8%
The critical areas inside the ISO Class 5 environments are cleaned and disinfected at the beginning of each work shift, between batches, every 30 minutes during continuous compounding, when there are spills, and in the event of or suspicion of procedural breach.	80.5%
Trained personnel use written policies and procedures that detail cleaning agents, non-shedding wipes, mop materials, procedures for cleaning, frequency of cleaning, and documentation forms.	74.7%
Walls, ceilings, emptied shelving and supply bins are cleaned at least monthly with designated cleaning agent and documented.	74.0%
Overall Compliance with Cleaning Domain	**73.3%**

*N=1045

IPA: Sterile or Nonsterile?

Sterile 70% isopropyl alcohol (sIPA) must be used in the following situations:

- To disinfect all surfaces inside the PECs after the daily cleaning with the germicidal detergent and sterile water
- Inside the PEC at the beginning of the compounding day/shift, before starting each batch, every 30 minutes, when visibly soiled, after a spill, and whenever contamination is suspected
- To sanitize sterile gloves anytime gloved hands leave the ISO Class 5 space and after touching non-sterile items
- To wipe off items before placing them inside the ISO Class 5 area
- To disinfect any critical site before it is accessed by vigorously wiping in one direction three times and allowing the sIPA to dry before use

TABLE 3

Cleaning Primary Engineering Controls

What is the same?	What is different?
1. Complete hand hygiene and garbing appropriate to compounding area 2. Cleaning solution is germicidal detergent; sporicidal may be rotated in weekly or monthly 3. Cleaning solution prepared in container dedicated for use in ISO Class 5 areas and documented 4. All surfaces cleaned with cleaning agent diluted with sterile water 5. Use low-linting wipes and/or tools dedicated to ISO Class 5 areas 6. Disinfect all surfaces with sterile 70% IPA (sIPA) after cleaning 7. Order of cleaning with cleaning agent followed by sIPA: ■ Ceiling ■ Back ■ Sides, IV bar and hooks ■ Anything in PEC ■ Deck	**LAFW: Same** **Integrated VLF: Same except** ■ Surfaces need to be reached with mop ■ Clean/disinfect inside surface of polycarbonate resin **CAI: Same except** ■ Surfaces may need to be reached with isolator tool (preferable to open CAI if in controlled space) ■ Surfaces of ante-chamber are decontaminated and cleaned before the main chamber and in same order **BSC: If used for HD, same except** ■ Add 1st step: deactivate HD residue on all surfaces with appropriate agent followed by cleaning agent and sIPA ■ Additional surface to decontaminate/clean (inside of the sash view screen) ■ PPE/trash from decontamination discarded in black RCRA bag; rest discarded in yellow HD trace trash. **CACI: If used for HD same except** ■ Add 1st step: deactivate HD residue on all surfaces with appropriate agent followed by cleaning agent and sIPA ■ Surfaces may need to be reached with isolator tool (preferable to open CACI if in controlled space) ■ Surfaces of ante-chamber are decontaminated and cleaned before the main chamber and in same order ■ Additional surface to decontaminate/clean (inside of the sash view screen) ■ PPE/trash from decontamination discarded in black RCRA bag; rest discarded in yellow HD trace trash.

General Principles of Cleaning

While there is more than one correct way to perform cleaning, there are some guiding principles that should be employed when developing P&Ps. Begin by requiring cleaning from top to bottom, and from the cleanest to the dirtiest areas. During daily cleaning, the PECs are generally cleaned first, followed by all easily cleanable horizontal surfaces in the buffer area, ante-area or segregated compounding area, while floors are cleaned last. Clean from the farthest area moving out of the controlled environment as cleaning occurs. Wipe in one direction (rather than in circles) and overlap each row so the entire surface is completely wetted with the cleaning agent. All surfaces need to be visibly wetted, but not dripping, and the agent must be allowed to air dry. This additional wait time is critical to achieving the desired effectiveness. Staff performing cleaning must perform hand hygiene and garb as appropriate to the area being cleaned (eg, hazardous vs non-hazardous).

Material Handling Considerations

The Chapter requires that "supplies and equipment from shipping cartons shall be wiped with a suitable disinfecting agent (eg, 70% IPA) delivered from a spray bottle or other suitable delivery method. After the disinfectant is sprayed or wiped on the given surface to be disinfected, the disinfectant shall be allowed to dry, during which time the items shall not be used for compounding purposes."[1] Remember that the particles produced by corrugated cardboard can carry any microorganism; however, it has been found that corrugated cardboard is an especially suitable growth medium for mold and its spores. Though the use of 70% IPA is appropriate to wipe down supplies and drug containers brought into the cleanroom, one might also consider the use of a sporicidal agent, such as Steriplex SD, that destroys spores, bacteria, viruses, and fungi. This particular agent is non-corrosive, non-fuming, non-toxic, is not a skin irritant or sensitizer, and thus reduces the risk to staff and cleanroom furniture.

Cleaning PECs

In keeping with the general top to bottom, cleanest to dirtiest rules, the surfaces of all PECs should be cleaned in the same order: ceiling; back; sides, IV bar, and hangers; anything on the deck (automated compounding devices, sharps units, etc); and the deck itself.

When cleaning isolators, there are additional surfaces to be cleaned; again, in keeping with the general rules, the surfaces of the main chamber are cleaned in the order outlined above, followed by those same surfaces in the isolator ante-chamber. Isolators may be cleaned with the front panel open or closed. If they are cleaned with the front panel closed, then an isolator cleaning tool will be required to reach all surfaces inside.

It is perfectly acceptable to open CAIs to clean them, as it is easier to reach and properly clean all surfaces and makes cleaning more efficient. If the CAI is in a controlled space (ISO Class 7 or 8), then it is recommended that you clean the unit by opening the front cover. If your CAI resides in a segregated compounding area (non–ISO-classified area), you may still open the unit to clean it with the germicidal detergent diluted with sterile water; however, close the unit to disinfect the surfaces with sIPA. If a CAI is opened for cleaning, it must be allowed to operate for about 10 minutes before restarting compounding activities. If cleaning with a closed cover, all cleaning items (isolator cleaning tool, cleaning tool heads wetted with germicidal detergent diluted with sterile water, sIPA spray bottle, and low-linting wipes or pre-wetted wipes) must be transferred in to the isolator through the ante-chamber. Whether open or closed, clean the isolator surfaces in the same manner as other PECs, and remember to clean the front view cover of both the ante-chamber and main chamber. Most CAIs have a sliding tray in the ante-chamber that must be moved to clean underneath it with both germicidal detergent solution followed by sIPA.

Considerations for Cleaning Hazardous Drug PECs

Before cleaning BSCs and CACIs, all of the surfaces to be cleaned must be decontaminated by using an appropriate agent to deactivate the hazardous drug (HD) residue. Even though compounding is not occurring, the process of deactivating the HDs can cause the residues to volatilize; therefore, a dual chamber respirator must be worn during this decontamination process. A dual chamber respirator that traps both particles and gases is required during the decontamination step; an N-95 respirator is not sufficient as it traps only particles.

The Safety Data Sheets (SDS, formerly MSDS) for each drug provides information about the chemicals that can be used to deactivate them. Many HDs are deactivated by 2% sodium hypochlorite solution (bleach). Be aware that many household types of bleach contain 5% to 6% active chlorine, so read the label carefully before diluting the bleach with sterile water. Sodium thiosulfate 0.9% also can be used to deactivate HDs. Decontaminate all surfaces of the BSC or CACI in the same manner described above in terms of surfaces and sequence. After decontamination, follow the same steps to clean with germicidal detergent diluted with sterile water followed by sIPA.

Whether to clean CACIs and BSCs with the front cover or sash open or closed is an area of some controversy. Opening the cover or sash facilitates thorough cleaning. If the cover or sash is opened, ensure that the PEC has not been used for compounding for at least 10 minutes and that it remains on at all times. Anyone

TABLE 4

Disinfecting PECs and Daily/Monthly Cleaning of SECs

PEC Disinfection	Daily	Monthly
ISO Class 5 PEC* and work surfaces ■ Beginning of day or shift ■ Prior to each batch ■ Every 30 minutes ■ When visibly soiled ■ As spills occur ■ When contamination is suspected	Empty trash ISO Class 5 PEC** Easily cleanable horizontal surfaces in ante- and cleanrooms (including pass-through counter) **Restock daily supply cart** Floors from furthest location in cleanroom out through ante-room (including pass-through floor)	Empty trash Ceiling Walls, pass-throughs Every surface ■ Outside of PECs ■ All carts (top, bottom, wheels, etc) ■ Supply bins ■ Doors, handles, vents ISO Class 5 PEC** **Restock supply cart** Floors (same as daily) **Clean refrigerators, freezers, incubators, etc**

* Disinfect PEC with sterile 70% IPA (sIPA).
** Clean with germicidal detergent diluted with sterile water for irrigation followed by sIPA.
All other surfaces cleaned with germicidal detergent diluted with tap water. Easily cleanable horizontal. surfaces can additionally be cleaned with IPA after germicidal detergent.
Best practice recommendations indicated in red; order is best practice recommendation only.

in the immediate area must be appropriately garbed. If the CACI is housed in air quality inferior to ISO Class 8, after it is cleaned with diluted germicidal detergent, the front cover must be closed. The disinfection with sIPA should occur with the front cover closed. If the front cover/sash will remain closed during all phases of decontamination and cleaning, then wearing a dual chamber respirator is not necessary, but the use of an isolator cleaning tool is required. **TABLE 3** provides a visual snapshot summarizing the highlights of cleaning PECs.

There is a drip pan underneath the surface of the deck of both CACIs and BSCs; the decks of both of these types of equipment can and should be lifted to be cleaned at least monthly and in the event of a spill. CACIs especially operate under significant negative pressure, and lightweight paper needle covers or even low-linting wipes are sometimes sucked in beneath the deck. The wipers can significantly block airflow, so if you notice a decrease in the airflow in your CACI, check underneath the deck (see online-only **PHOTO** at **www.pppmag.com/CACI**).

Daily and Monthly Cleaning of SECs

After the PECs are cleaned, the SECs (buffer area and ante-area) are cleaned next, in keeping with the order of cleaning from the cleanest area (PECs) to the dirtiest. It is always best to empty all trash containers (be sure to empty trash at least six feet away from PECs) and restock any supply carts before starting the cleaning process, since the area must be allowed to rest for about 20 minutes at the conclusion of cleaning for all surfaces to dry.

All easily cleanable horizontal surfaces of both the buffer and ante-area must be cleaned with germicidal detergent diluted with tap water on a daily basis. These surfaces include flat solid surfaces such as the seats of stools/chairs, small three-tiered carts, pass-through counters (small pass-throughs that are not full height), tables, sinks, etc. Finally, the floors should be cleaned with the germicidal detergent solution, working from the furthest point in the buffer area (cleanroom) out into the ante-area.

Monthly cleaning includes all of the activities of daily cleaning plus additional tasks. **TABLE 4** provides an overview of the cleaning tasks and the suggested sequence of cleaning. Keeping in mind the rules of top to bottom and cleanest to dirtiest, it is not possible to perform monthly cleaning without violating one of those two rules (eg, top to bottom would require starting with the ceiling, whereas going from cleanest to dirtiest would require starting with the inside of the PECs). A general top to bottom approach to monthly cleaning is suggested; however, it is acceptable if your organization starts the monthly cleaning beginning with the PECs. What is vital is that every single surface of all furniture and supply bins is cleaned with the germicidal detergent solution. Performing the monthly cleaning properly takes time and generally more than one staff member.

To evaluate the time commitment for monthly cleaning, complete the cleaning in its entirety and record the time required in actual FTE hours, rather than just estimating. Plan the staffing accordingly. It is suggested that the activities associated with monthly cleaning occur together on one occasion each month approximately four weeks from the previous instance. If workload requirements do not permit this, it is acceptable to break monthly cleaning tasks up and accomplish them over two to three days, but the mechanism for doing so should be carefully detailed in written P&Ps. Experience has shown that it is not uncommon for elements of monthly cleaning to occur sporadically over month-long periods. For example, ceilings may be cleaned "monthly" in that they are cleaned once in each consecutive month but there may be an eight-week gap between instances where ceilings were cleaned–at the beginning of one month and the very end of the next month. Adherence to strictly controlled cleaning P&Ps will ensure monthly cleaning is completed correctly and on time.

Written P&Ps, Staff Training, and Competency Verification

Staff that perform cleaning must receive training on how to perform those activities and accompanying documentation before they are permitted to clean independently. Training must be based your organization's written P&P. A high degree of specificity is desired in a written P&P so they will serve as a road map providing step-by-step instructions. The P&P must cover the following in detail:

- What to clean (PECs and SECs, as well as other unclassified spaces, such as segregated compounding areas, general preparation or labeling areas, incubators, etc)
- When to clean (daily, monthly, when spills occur, and when microbial contamination is known or suspected [ie, when environmental sampling action levels are triggered])
- How to clean
- What to clean with (which germicidal detergent, use of sporicidal agent, sIPA, decontamination agents, sterile water/tap water, etc)
- Who should clean (which staff members are responsible)
- Training and competency requirements
- Documentation requirements

Documentation forms, whether electronic or paper-based, should be designed to capture required information and to provide visual cues to staff to guide them in their activities, especially with regard to cleaning solutions and specific areas to be cleaned (for an example of a daily/monthly cleaning log for the compounding room and a sample cleaning solution preparation log, visit: **www.pppmag.com/logsamples).**

Since staff must perform hand hygiene and the garbing appropriate to the space being cleaned (eg, hazardous or non-hazardous), successful demonstration of that competency is required, as well as successful demonstration of the activities in the cleaning competency itself. Chapter USP <797> provides sample competency forms in Appendix III (Hand Hygiene and Garbing) and Appendix V (Cleaning and Disinfection) that can be used to develop your organization's

TABLE 5

Environmental Sampling Requirements and Best Practice Suggestions

Environmental Sampling Test	Required Frequency	Suggested Best Practice Frequency
Non-Viable Particle Counts	■ At initial facility commissioning ■ Every 6 months during recertification of facility and engineering controls in compounding areas	■ As required in Chapter <797>
Volumetric Air Sampling	■ Every 6 months	■ Weekly for high risk ■ Monthly for low/medium risk
Gloved Fingertip Sampling	■ Initially during garbing x 3 ■ Every 6 months during media fills for high risk ■ Annually during media fill for low/medium risk	■ Initially during garbing x 3 ■ Weekly during media fills for high risk ■ Monthly during media fills for low/medium risk
Surface Sampling	■ Periodic	■ Weekly for high risk ■ Monthly for low/medium risk

competency verification documentation. Nevertheless, successful completion of a behavioral checklist under staged observation is not a replacement for observation in the actual work setting while cleaning is occurring.

One element of every successful program is pharmacy leadership's ability to educate compounding staff to understand, believe, and buy in to the importance of proper cleaning to maintaining a state of control so that the risk of introducing contamination into CSPs is reduced. Ongoing observation of cleaning activities is crucial because staff respects what management deems important enough to inspect. Acknowledge the positive behavior of staff that take care to perform cleaning and its accompanying documentation correctly. It is equally important to take the opportunity to provide additional instruction and remediation should observation lead to the identification of behaviors that are not desired.

Observation of cleaning and review of documentation are equally important if cleaning activities are outsourced. Whether these services are provided by a department internal to the organization (eg, hospital environmental services department) or externally to a firm that specializes in cleaning pharmacy controlled environments, there are some additional considerations relevant to the evaluation of whether to outsource cleaning activities. PECs may only be cleaned by properly trained pharmacy compounding staff, and cleaning of PECs cannot be outsourced. If all or some of the daily or monthly cleaning activities are outsourced, these staff must still be trained in the same manner in which you would train pharmacy staff. They must also successfully complete the Hand Hygiene and Garbing and Cleaning and Disinfection competencies. The outsourced cleaning staff does not need to complete the gloved fingertip samples (three consecutive samples of zero CFUs for both hands), since they are not performing any activity inside of the PECs. They do, however, need to complete didactic training, testing, and competency verification before performing cleaning.

An additional concern when non-pharmacy staff perform cleaning inside the pharmacy is potential access to drugs in supply bins inside the non-hazardous and hazardous buffer areas, and so a pharmacist employee should supervise these staff members. Even if these items are sequestered in a locked stainless steel cage, it is still strongly recommended that these staff be routinely observed for compliance with written P&Ps.

Verifying Cleaning Adequacy

An environmental sampling program is designed to provide feedback about whether the PECs and SECs, cleaning and disinfection procedures, and employee work practices work together to result in a suitable environment for sterile compounding. Sampling should be frequent enough to facilitate the early detection of contamination and its sources, which may include personnel, work surfaces, supplies, equipment, and failure of engineering controls. Chapter <797> utilizes several approaches to assess and evaluate microbial and particulate burden, including:

- Particle counts (non-viable)
- Volumetric air sampling (viable)
- Surface sampling (viable)
- Gloved fingertip sampling (viable)

USP Chapter <797> ties viable and non-viable testing to certain conditions as a minimum standard of practice. Moreover, the frequencies of environmental sampling required in the Chapter may not provide sufficient data for meaningful trending; likewise, they may not provide the timely feedback required to facilitate the early detection of a condition that could adversely affect the CSPs made in the facility. **TABLE 5** briefly summarizes the frequency of environmental sampling metrics required by the chapter, as well as suggested best practice frequencies.

Summary

Joining engineering controls and compounding work practices, the design and implementation of a comprehensive sanitization program for sterile compounding environments is one of the three key components of a robust environmental quality management program; the goal of this program is to ensure that a state of control is achieved and maintained. Proper cleaning and disinfection must occur regularly as one way to ensure the environment is suitable for the preparation of sterile medications. The effectiveness of these three components is evaluated by ongoing environmental sampling (see online-only **FIGURE 1** at **www.pppmag.com/stateofcontrol**). ■

References

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3. Sutton S. Disinfectant Rotation – A Microbiologist's View. Controlled Environments. July 2005. http://www.cemag.us/articles/2005/07/disinfectant-rotation-microbiologists-view#.UgE7BZLVB8F Accessed August 9, 2013.

A sample daily/monthly cleaning log for controlled environments is available at: www.pppmag.com/cecleaninglog

Kate Douglass, MS, RN, APN,C, CRNI, is vice president of CriticalPoint, a health care training and development company. She is one of the 2013 USP <797> Compliance Study co-directors. Kate has personally supervised the design, engineering, and build of several pharmacy compounding facilities that met or exceeded USP requirements and is one of the faculty of CriticalPoint's Sterile Compounding Boot Camp.

Eric S. Kastango, MBA, RPh, FASHP, is the president, CEO, and owner of Clinical IQ LLC, a provider of customized process and educational strategies for the pharmaceutical, medical device, and health care industries. A member of the USP's Compounding Expert Committee from 2005 to 2012, Eric now serves as an Expert Consultant on the USP Council of Experts.