

Establishing Sound Practices for Cleaning Your Cleanroom: Cleaning Products and Procedures for <797> Compliance

By Kate Douglass



AS HOSPITAL PHARMACIES CONTINUE TO ALTER THEIR PHYSICAL PLANTS TO meet USP Chapter <797> requirements, routine and consistent cleaning protocols can be implemented immediately with relatively minimal cost. In many cases, the routine cleaning of the compounding environment and the proper garbing of staff represent major changes in practice, but also present the potential for immediate risk reduction. Furthermore, these changes can be made at a lower cost than structural changes and without the delays inherent in the budget-approval process.

Why Clean?

Even if a cleanroom's primary and secondary engineering controls are sufficient and if strict garbing, hand-washing, and particulate-control measures are put in place, consistent and effective cleaning procedures are still required to continually minimize the overall bioburden present in the facility. Since bacteria do not fly, particles serve as transport vehicles for viable contamination, so care must be taken to reduce sources of particulate matter. Products should be unpacked and wiped down with 2% bleach or another designated agent prior to being taken into the cleanroom. No more than a day's worth of products should be stored in the cleanroom.

Who Cleans?

In most home infusion and other standalone pharmacy operations, the pharmacy staff cleans both the controlled environment and the area where drugs are stored. In hospital settings, the environmental services department may have this responsibility. The hospital's operating-room director is generally an excellent resource as you develop your cleaning protocol. Some hospital pharmacies elect to integrate the environmental-services department into weekly and monthly cleaning procedures, but perform daily cleaning themselves. Regardless of who performs the cleaning, they must be carefully trained once the cleaning protocol is established and educated in proper garbing and hand-washing. Routine observation of individuals performing cleaning and inspection of the controlled environment are recommended.

Cleaning and Sanitizing Agents

There are many choices in cleaning agents, and their expense and actions vary greatly. Though isopropyl alcohol is widely used to clean ISO Class 5 compounding surfaces, 3% hydrogen peroxide and 2% sodium hypochlorite (bleach) solutions are also effective as sanitizing agents.¹ Recent data from the CDC states that a sodium hypochlorite solution of 500 ppm is effective against almost all surface bioburden. It is suggested that the solution be made at 1000 ppm to allow for degradation if diluted with sterile water and used as a hand disinfectant. Though a significant body of literature supports bleach's power as a dis-

infectant and sterilant, bleach does not have the detergent action necessary for soil removal.² The development of resistant microflora can be prevented by rotating cleaning agents.³ An economic method would be to use a 2%-bleach solution six days a week and a detergent-based, hard-surface disinfectant one day a week, alternating the day of the week to include weekly and monthly cleanings. Bleach costs between \$0.95 and \$1.20 per 96-ounce container, while hard-surface disinfectants cost \$20 to \$35 per gallon.

Cleaning should generally occur from the cleanest area to the dirtiest— from an ISO Class 6 or 7 cleanroom to the ISO Class 8 anteroom.

Preparation of Cleaning Solutions

It is imperative that the cleaning-agent manufacturer's instructions be followed with regard to storage, handling, and dilution. The right dilution is critical to the solution's effectiveness, as insufficient dilution can cause damage to floors, sinks, and other surface areas. Some cleaning agents are highly caustic and over time, even when diluted, can cause pitting of stainless steel, especially if it is not cleanroom grade. Make glass or plastic graduated cylinders available at the sink where solutions are mixed and thoroughly rinse them after use. Material safety data sheets (MSDS) are readily available from solution manufacturers and must be available on site.

Solutions must be diluted and mixed immediately prior to use, and documentation of their preparation is strongly recommended. Add the concentrated cleaning agent to pre-measured water and mix gently. Buckets, if used, should be graduated in gallon or liter increments. Sterile water for irrigation is used with the appropriate cleaning agent in any ISO Class 5 area, including workbench or hood surfaces, walls or other surfaces of the area, and any compounding equipment. Sterile water for irrigation should also be used if 2% bleach (or other agent) is used for intermittent hand decontamination. Spray-bottle

(Continues on page 18)

Photo courtesy of ITW Texwipe



Lint-free wipes dipped in diluted cleaning agent can be used to clean ISO Class 5 to 8 areas.



Photo courtesy of SoluNet, LLC

Equipment used to clean an ISO Class 6 or 7 area should not be used to clean an ISO Class 8 area.

CLEANING PROCEDURES (Continued from page 16)

solutions must be changed every seven days with newly prepared solution, labeled with their expiry dates, and kept immediately outside the ISO Class 5 area (on a cart outside the hood or workbench) for use in re-sanitizing hands prior to reentry. Tap water may be used with the appropriate cleaning agent for all other surfaces including walls, ceilings, production/storage bins, cleanroom-grade-steel furniture, and exterior surfaces of the workbench or hood. (Visit www.pppmag.com/articles.php for a sample Cleaning Solution Preparation Log.)

Cleaning Equipment and Supplies

Buckets and other cleaning equipment, such as mop handles, heads, and covers, must be dedicated to the area where they are used. To prevent cross-contamination, equipment used to clean walls and ceilings should not be used to clean floors, nor should they be taken outside of the pharmacy area. Equipment used to clean an ISO Class 6 or 7 area should not be used to clean an ISO Class 8 area. Because different equipment is required for different areas, a “mop forest”—a variety of mop handles hanging on the walls, beside a myriad of buckets inverted on racks—may grow in your anteroom where space is usually at a premium. To tackle this problem, consider investing in stainless-steel handles that can be used in a variety of areas and bucket-less systems.

Conventional mops with cellulose heads (\$6 to \$8 each) generally begin shedding after two days and should be changed at least every 48 hours. Conventional plastic mop handles (\$12 to \$16 each) also do not stand up well to cleaning and need to be replaced about once a month. Buckets must be metal free and made of heavy-duty plastic. Such buckets generally cost \$27 to \$30 each. Be sure to select a bucket big enough to accommodate your mop heads, but small enough to fit in the sink to be filled.

Ergonomics are another consideration for buckets. Large, heavy-duty buckets can weigh up to 18 pounds when filled with water, putting employees at risk for injury or fatigue. A better solution is to employ a bucket-less mop system to clean floors and a two-gallon sprayer filled with a designated cleaning agent, along with a swivel mop head and cover, to clean walls and ceilings. This method is also less expensive annually than using buckets: you will save on equipment and supplies, as well as staff hours, not to mention the benefit of improved staff morale. The set-up cost for this system is approximately \$300, but the stainless-steel mop handles can be reused indefinitely. Furthermore, because mop head covers can be changed, fewer mop handles are required, thus eliminating the “mop forest” effect.

Lint-free wipes (about \$10 to \$12 for a 150- to 300-count bag) should be used in ISO Class 5 to 8 areas. Larger wipes are generally preferred as they cover more surface area, resulting in fewer used wipes. More economical than pre-moistened wipes, lint-free wipes dipped in the diluted cleaning agent can be used to clean workbenches and hoods and to wipe molding, doors, handles, furniture, product storage bins, as well as to wipe products before they enter the cleanroom and to dry hands. If you choose pre-moistened wipes, read the package insert carefully, as some may contain “hazardous” agents that cannot be disposed of in unregulated trash.

Based on OSHA regulations, it is strongly recommended to issue each staff member his or her own pair of safety glasses to wear when there is a likelihood of being splashed by chemicals or drugs. Some pharmacies require that compounding staff wear safety glasses at all times, but it is strongly recommended to wear them during cleaning processes as well, as there is a high likelihood of eye exposure to solutions during ceiling cleanings, for instance. Safety glasses cost between \$2.15 and \$6.50 per pair,

but before making a purchase, obtain samples for your staff to try on, as goggles with elastic can be uncomfortable or foggy and some safety glasses can slip down the nose.

In addition, the persons responsible for cleaning must “garb up” and wash their hands in the same manner as compounding personnel. Appropriate garb (costing about \$5 to \$6 a day) includes lint-free shoe covers, bouffant caps, masks, safety glasses, and gowns or frocks, as well as beard covers, if needed.

Where and When to Clean?

Cleaning should generally occur from the cleanest area to the dirtiest—from an ISO Class 6 or 7 cleanroom to the ISO Class 8 anteroom. Generally, cleaning should be done from top to bottom. For example, the order for a monthly cleaning would be ceilings; walls, windows, and horizontal surfaces; workbench shields; ISO Class 5 surfaces; workbench or hood legs; and finally, the floor. Daily cleanings should be performed at the end of the compounding day.



Photo courtesy of SoluNet LLC

The ceilings of your controlled environments should be cleaned on a monthly basis.

Figure 1: Activities to be accomplished during daily, weekly, and monthly cleanings.

ACTIVITIES IN CONTROLLED ENVIRONMENTS	DAILY	WEEKLY	MONTHLY
Empty waste receptacles and replace liners	(Or as often as needed)	X	X
Remove hazardous-waste receptacles	X	X	X
Remove biohazardous materials	X	X	X
Cleanse ISO class 5 workstations (including compounders residing in the workstations)	X	X	X
Clean sinks, countertops, cart tops, stool tops, and exterior of sharps containers	X	X	X
Mop floors	X	X	X
Clean windows, walls, and all other horizontal surfaces, including doors and side, front, and back of hoods, from top to bottom		X	X
Empty, clean, and sanitize storage shelving and bins		X	X
Clean and sanitize any other non-compounding furniture (carts, stools, waste containers)		X	X
Clean and sanitize interior and exterior of refrigerators and incubators (not kept in controlled environment)			X
Clean ceilings of all controlled environments			X

(Visit www.pppmag.com/articles.php for a sample cleaning log for compounding rooms.)

For related editorial, see page 24,

"The Importance of Environmental Monitoring, Part 2: Surface Testing."

For additional tables and charts, please visit www.pppmag.com/articles.php, where you will also find the following related editorial:

"The Importance of Environmental Monitoring, Part 1: Air Quality"

"A Practical Guide to Aseptic Technique Verification"

"Outsourcing Your Sterile Product Preparation"

"Understanding Pharmacy Cleanroom Design Requirements"

ISO Class 5 workstation work surfaces (IV bar to the bench surface, end panels, interior walls, and compounders) should be wiped with the designated agent at the beginning of each compounding day. In the event of a drug spill, wipe the spill with sterile water, if in the ISO Class 5 area, or with tap water, using a lint-free wipe, followed by the designated cleaning agent. This process will avoid the occurrence of chemical reactions between pharmaceutical components and cleaning agents.

It is important to make certain that all surfaces are thoroughly coated and wetted with the cleaning agent. The mop must go over every surface of the cleanroom wall, molding, ceiling, return grills, doors, window, handles, etc. It is usually easiest to use lint-free cloths dampened with the cleaning agent to clean molding, door handles, and other areas that are not entirely flat. It may be necessary to keep a stainless-steel or plastic step stool in the compounding room for the manual cleaning of hard to reach areas. It is difficult to accurately benchmark the time it takes to perform daily, weekly, and monthly cleaning since the size of the facility and the number and experience of the people performing the cleaning will differ vastly between organizations. Generally speaking, daily cleaning of a 15-by-15-foot cleanroom and 15-by-10-foot anteroom will take between 45 and 60 minutes, weekly cleaning will take about 80 minutes, and monthly cleaning will take about two hours.

There are many factors to consider in designing a cleaning program for a compounding facility. Policies and procedures must be established and staff competencies developed. The cost of cleaning is related to labor costs and the staff's time more than it is to physical products. Pharmacy directors can comply with <797>'s gowning, hand-washing, and cleaning requirements now, even if you are waiting for approval to build a cleanroom or to install secondary engineering controls. A \$200,000 cleanroom is not worth much if it is not used and maintained correctly. You and your team can make a difference by implementing policies and procedures for cleaning now. **R&P**

Kate Douglass, chief operating officer of SoluNet LLC, served as a reviewer for ASHP's Sterile Product Preparation CD-ROM: A Multimedia Learning Tool, 1st and 2nd editions, and has co-authored several articles on aseptic com-

pounding quality and outsourcing. Over the past three years, Douglass has supervised the design, engineering, and build operations of four pharmacy compounding complexes that meet and exceed USP <797> facility requirements.

References and Additional Reading:

1. McDonnell G and Russell A. Antiseptics and Disinfectants: Activity, Action and Resistance. *Clinical Microbiology Reviews*. 1999;12(1):147-179.
2. Kopis E. Answers to the 10 Most Common Questions Regarding Microbial Control in Cleanrooms. *Cleanrooms*. 1997:1.
3. Connor DE and Eckman MK. Rotation of Phenolic Disinfectants. *Pharmaceutical Technology*. 1992;16(9):48-160.
4. Matthew RA. Playing by the rules. *Cleanrooms*. 1999;13:42.
5. Kastango ES. Blueprint for implementing USP Chapter 797 for compounding sterile preparations. *Am J Health-Syst Pharm*. 2005;62(12):1271-1288.
6. Denny VF, Kopis EM, and Marsik, FJ. Elements for a Successful Disinfection Program in the Pharmaceutical Environment. *PDA J Pharm Sci Technol*. 1999;53(3):115-24.

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A cleaning log to meet documentation requirements:

Cleaning Log for Compounding Room (Initial each activity when completed)							
Form # _____ Issue Date: 05/27/05							
Date	Daily			Weekly			Monthly
	ISO 5 Workstations	Compounders	Floors	Walls & Windows	Shelving & Bins	Carts & Chairs	Ceilings
<p>This page would continue for a total of 31 lines so all cleaning for 1 month on 1 page; boxes are completed with the initials of the operator performing the cleaning; initials must correspond to a pharmacy signature log.</p>							
<p>_____ Signature of Pharmacy Manager (Designee)</p>				<p>_____ Date Reviewed</p>			

A sample cleaning solution preparation log:

CLEANING SOLUTION PREPARATION LOG																													
Facility: _____			Month: _____																										
			Year: _____																										
Form # Release Date: 05/27/05																													
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