

Controlled Environment Air Sampling

Meet USP's Environmental Monitoring Guidelines to Achieve <797> Compliance

The goal of the revised USP Chapter <797> is to provide increased patient safety and consistent recommendations for activities related to sterile compounding, and these guidelines apply to all entities that prepare compounded sterile preparations (CSPs). This article is intended to provide a brief summary of USP <797>'s environmental monitoring requirements, with an emphasis on the updated guidance for air sampling and quality controls. However, it is incumbent upon the reader to refer to the chapter itself for further explanation and detail on the issues discussed herein.



Pharmacies are now required to use electronic air samplers to monitor viable contaminants in the controlled environment.

The Purpose of Environmental Monitoring

According to USP <797>, "protection of critical sites by precluding physical contact and airborne contamination shall be given the highest priority in sterile compounding practice." Effective environmental monitoring can both verify that primary and secondary engineering controls are working correctly, and also identify any areas of concern regarding the people working in the compounding environment, such as their aseptic technique and cleaning practices. Primary and secondary engineering controls are designed to provide airflow with little to no particulates, but even when they are functioning correctly, larger particles introduced by personnel movement and activities in the compounding area have the potential to lead to CSP contamination by settling on critical sites – even in an ISO Class 5 environment. With this in mind, the revised <797> identifies compounding personnel as the most likely source of CSP contamination. So, while the importance of achieving the recommended environmental controls has not been minimized, proper garbing, aseptic technique, and personnel movement in the cleanroom area should be viewed as your first lines of defense against CSP microbial contamination. Perfect room controls will not eliminate the potential for touch contamination; therefore, appropriate staff training, observation, and validation of aseptic technique are essential.

Air Sampling Frequency Guidelines

USP <797> has set forth six-month minimal frequency guidelines for environmental air sampling programs. Sampling should also be performed under the following conditions, at a minimum:

- As part of the certification of new and remodeled facilities and new equipment, such as LAFWs and cleanroom HEPA filters
- Following any servicing of cleanroom equipment and room systems
- As part of the regular six-month re-certification of primary and secondary engineering controls
- In response to identified positive end-product testing, positive employee media-fill testing, or concerns about observed staff technique
- In response to patient-related infections, if a CSP is a potential source of contamination

Monitoring Your Controlled Environments

As mentioned earlier, an effective environmental monitoring program assists in identifying viable and nonviable particulate sources of contamination. As there tends to be confusion regarding the difference between these sources of contamination, it is

Pertinent Definitions

An understanding of the following terms is critical to developing an effective environmental monitoring program.

- **Critical Site** – Any component or fluid pathway surface (injection port, vial septa, beaker, etc.) or opening (ampoule, needle, etc.) exposed and at risk of direct contact with ambient room air or HEPA-filtered air, moisture (oral or mucosal secretions), or touch contamination. Risk of microbial particulate contamination of the critical site increases with the size of openings and exposure time.

- **Primary Engineering Control (PEC)** – A device or room that provides an ISO Class 5 environment for the exposure of critical sites when compounding CSPs. Such devices include laminar airflow workbenches (LAFWs), biological safety cabinets (BSCs), compounding aseptic isolators (CAIs), and compounding aseptic containment isolators (CACIs).

- **Secondary Engineering Control (SEC)** – The cleanroom and ante-room/ante area are considered secondary engineering controls. The SEC contains HEPA-filtered air, at positive or negative pressure to the surrounding areas, and achieves the required air changes per hour. The PECs are located within the SEC.

worth taking a closer look at the definitions and applications of each of them.

Nonviable particulate contaminants are measured as part of the certification of primary and secondary engineering controls. This process is commonly referred to as a “particle count” and involves the use of an electronic particle counter to measure the number of particles per cubic millimeter present in the engineering controls. Some organizations own their own particle counters, while others opt to have a certification company perform particle counts every six months, as required by USP <797>.

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We perform these measurements because nonviable particles can transport microbial contaminants, otherwise known as viable particles, which can cause patient harm. Particle counters only identify the number of particles in an environment; they do not detect microbial contaminants. Increased particle counts could indicate a problem with your cleanroom's HEPA-filtration/HVAC system or a problem with your primary engineering controls, such as a malfunctioning fan motor or a damaged HEPA filter. The total particle count of a primary or secondary engineering control establishes which ISO Class it meets, i.e. ISO Class 5 for direct compounding areas; ISO Class 7 for cleanrooms or buffer areas; and ISO Class 8 for anterooms.

Each organization must also monitor for potential **viable contaminants** in their controlled environments' air, with a minimal frequency of every six months for low- and medium-risk compounding. As with particle counts, this function may be performed by an outside company or internally by qualified staff with appropriate sample collection and incubation equipment.

To quote the revised chapter, "For low-, medium-, and high-risk level compounding, air sampling shall be performed at locations that are prone to contamination during compounding activities and during other activities, such as staging, labeling, gowning, and cleaning. Locations shall include zones of air backwash turbulence within LAFW and other areas where air backwash turbulence may enter the compounding area." Previously, organizations could use settling plates, such tryptic soy agar (TSA) plates, to perform air-sampling activities. The plate would be exposed to the environment for one to three hours, then incubated for 48 hours. The revised chapter sets forth a requirement to use the impaction method for air sampling, as settling plates rely on gravity to impart air onto the plate surface and, as such, may not collect a representative sampling of air or particles due to personnel movements in the area.

To monitor viable contaminants in controlled environments' air, an electronic, or impaction, air sampler must be used, according to the revised USP <797>. As with particle counts, electronic air sampling should be performed every six months at a minimum.

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Several different brands of electronic air samplers are available. The manufacturer's operating instructions will provide information on the volume of air to be tested, the proper collection of samples, and recommendations for calibration and maintenance of the equipment. Additionally, organizations should refer to USP Chapter <1116> for more information on the use of electronic air samplers.

Electronic air samplers impact air onto TSA growth media, which should then be incubated at 30°C to 35°C for 48 to 72 hours. TSA media is used for low-, medium-, and high-risk compounding activities. Facilities performing high-risk compounding should also use malt extract agar (MEA) media to sample for fungal contamination. MEA samples should be incubated at 26°C to 30°C for five to seven days. Any colony forming units (CFUs) that grow on the collection media will need further microbiological identification. This can be accomplished by sending the samples collected to a lab familiar with these types of identifications. Your certifier may also perform microbiological identification, but not all do.

Based on the CFU counts, action levels are to be established for all sampling areas, defined in a written policy. Per USP <797>, "counts of CFUs are to be used as an approximate measure of the environmental microbial bioburden. Action levels are determined on the basis of CFU data gathered at each sampling location and trended over time...Regardless of the number of CFUs identified in the pharmacy, further corrective actions will be dictated by the identification of microorganisms recovered (at least the genus level) by an appropriate credentialed laboratory of any microbial bioburden captured as a CFU using an impaction air sampler. Highly pathogenic microorganisms (e.g., gram-negative rods, coagulase positive staphylococcus, molds, and yeasts) can be potentially fatal to patients receiving CSPs and must be immediately remedied, regardless of CFU count, with the assistance of a competent microbiologist, infection control professional, or industrial hygienist."

Your written environmental monitoring plan should define sampling sites, action levels, and what will be done if collected samples indicate microbial contaminants above



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the action level. A convenient way to define areas for sampling is to mark testing areas on a floor plan of the facility and incorporate this illustration into the written policy. Sampling sites should include locations within each ISO Class 5 environment, as well as areas in the ISO Class 7 and 8 rooms (cleanrooms and anterooms), including pass-through windows. The written plan should also define the frequency of sampling, the method of collection, the volume of air sampled, and the time of day that testing should be performed.

Measuring HVAC Functionality

In addition to viable and nonviable particle testing, your total environmental program should include assurance that all room controls are functioning effectively, including the HVAC system. Additional measures of HVAC functionality include pressure and temperature monitoring.

A pressure gauge should be used to measure the pressure differential between rooms (i.e., the general work area, anteroom, and positive and negative pressure cleanrooms). The pressure should be documented on a log at least once daily. Additionally, USP sets forth requirements for the maintenance of the temperature and humidity of controlled areas. These values should be documented on a daily log as well. Refer to USP <797> for the specific guidelines related to air pressure, temperature, and humidity.

Conclusion

An ongoing environmental monitoring plan is an important step in maintaining your compounding environment to enhance patient safety. Be proactive in identifying the potential CSP contamination, rather than react to an instance of patient harm or death after it has occurred.

Remember that even diligent environmental monitoring and sampling is just a snapshot in time. Perfect results on your documentation logs do not indicate perfect conditions at every minute of every compounding day. Continue to observe compounding personnel, enhance training programs, and solicit employee feedback as part of your total compounding quality assurance process. ■



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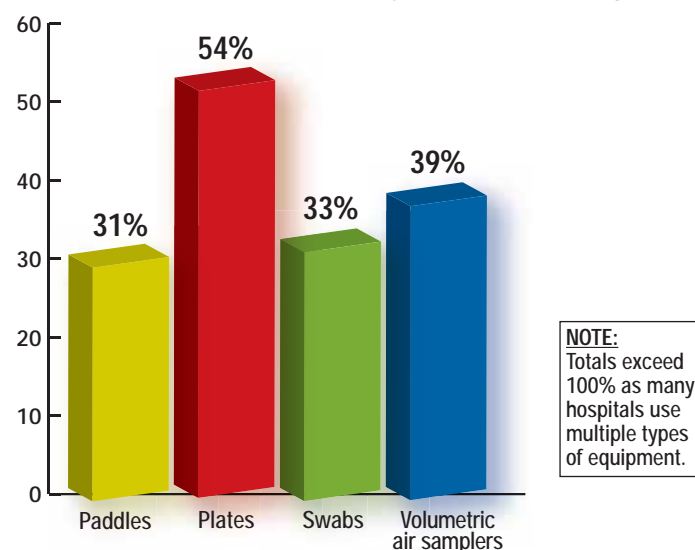
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References:

1. The United States Pharmacopeia (USP) General Chapter <797> Pharmaceutical Compounding – Sterile Preparations Revision Bulletin. Available at: www.usp.org/pdf/EN/USPNF/generalChapter797.pdf. Accessed December 15, 2007.

Environmental Monitoring Equipment in Use

PP&P's 2008 "State of Pharmacy Compounding" survey unveiled numerous trends related to hospital pharmacies' efforts to achieve USP <797> compliance — among them their use of a variety of environmental monitoring equipment. To view the complete results of the survey, visit www.pppmag.com.



Volumetric air samplers enjoy a 39% adoption rate. Given the revised chapter's requirement for active air sampling, growth in volumetric air sampler use is expected.

Source: State of Pharmacy Compounding. *Pharm Purch Prod*. 2008;4(suppl):7.



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