

## **USP 797: Sterile compounding and room design**

by Douglas Theobald, CFM

Health care organizations that compound sterile formulations are getting a head start on compliance with the USP 797 guidelines, courtesy of the JCAHO (Joint Commission on Accreditation of Healthcare Organizations).

According to the American Society of Health Systems Pharmacists, beginning July 1, the JCAHO will be surveying health care institutions, pharmacies, physician practices and other facilities in which sterile compounding is performed. The purpose is to verify compliance with the "major requirements of General Tests and Assays Chapter 797 regardless of whether an organizations state, by virtue of law or regulation, requires such compliance".

One of the 19 elements slated to be surveyed is "environment design of drug preparation rooms." The critical elements we are going to focus on here are, room design, material/personnel flow, equipment layout, surface materials and serviceability. Whether the subject room is new or one that is being modified, the most critical element is good planning. We all know that no matter how much we plan, there will always be deviations. With that in mind, let's talk about what we can do to get the most out of the "controllable" elements of room design.

The role of the designer and the builder is distinct. Whether separate entities or a design-build company is your choice, the most critical prerequisite is how familiar they are with the specific environment you need to achieve and maintain. This is true regardless of whether you are building a new facility or upgrading an existing facility.

In the case of a sterile compounding environment, the goal is an aseptic or sterile environment in which you can control the risk of microbial contamination and cross-contamination of admixtures or compounds. Contamination can be found on surfaces as well as in the air, but what you are concerned about is beyond simple particulate contamination.

The first question you and the designer or design-builder should ask is: "what type of contamination is of concern?" It is not enough for a room to achieve a "classification" that reflects only the ability to remove and maintain a standard of particulate control. A designer-builder must demonstrate an understanding of this concept as well as significant experience relative to your specific type of environment.

There are some basic guidelines in the USP 797 that address room design. This is where you need to stop and assess the space to be built or modified. For the "low to medium risk" rooms, there must be an ante room, or more accurately, an ante area. This area does not need to be separated by a physical wall, as is the case for "high-risk" rooms.

The ante room or area can be achieved with something as simple as a strip curtain, preferably outside of the cleanroom. This area is provided as a processing area for personnel, materials and equipment. The ante room/area should be sized based on the number of technicians that will be working in the compounding room at any given time. The area should be able to store an adequate amount of gowning supplies (we will talk more specifically about gowning and recommended components to don for the various environments next time). Also, if possible, the ante room/area should not be part of a high traffic area or corridor.

## **A room that works**

The key to a controlled environment is control. This cannot be stressed enough in regards to every aspect of a sterile compounding room. The room itself should be well thought out in regards to material handling, personnel flow and equipment layout. Probably the most efficient quality system for the sterile compounding room is the "5 S" approach. In short this approach is to "Sort, Set, Shine, Standardize and Sustain." These elements are traditionally applied to a "lean manufacturing" facility, however it is very effective in environmental control.

The folks at IEST (Institute of Environmental Sciences and Technology; [www.iest.org](http://www.iest.org)) have been doing an outstanding job of developing standards for controlled environments. ISO 14644 contains, among other extremely valuable standards, the standard for the design, construction, installation and testing of separative devices. Regardless of whether you are using separative devices, such as laminar flow hoods, or glove boxes, it is best to design the room to sustain a contamination-free environment. Compounding of aseptic manipulations must be performed in an ISO Class 5 or Fed 209E Class 100 environment.

For the surrounding areas, it is recommended that the cleanliness and classification be as stringent as possible because the materials to be handled and compounded should pass through a progressively cleaner environment before being extracted and manipulated. This is where procedures and training of personnel become critical.

## Surface materials

Finished surfaces, such as walls, floors, fixtures and ceilings, should be durable and smooth. For the walls, in the case of "hard-wall construction," two-part epoxy paint is the best option, providing a continuous smooth, durable and washable barrier. If the decision is made to use modular construction methods, a surface material such as FRP (fiberglass reinforced plastic) is an excellent option. Either way the idea is to have the ability to clean and sanitize the surface regularly while avoiding the possibility of the material degrading or "shedding."

The same holds true for fixtures, such as glove boxes, storage cabinets and work surfaces. It is best to install "seamless" or "welded seam" flooring with a continuous cove base. If a "T-Bar ceiling" is used, the ceiling tiles should also be smooth, durable and washable. The tiles can be surfaced with vinyl or FRP. To prevent the possibility of harboring or growing contamination, do not use a gasketed T-Bar grid; ceiling tiles should lay as flush as possible to the grid. For aseptic and sterile environments these tiles should be caulked in place with a caulking that will not "off-gas."

The best way to envision a well-designed controlled environment is, with the exception of the air supply and exhaust, a room that is "waterproof." Any materials used in the construction of the controlled environment should have technical data available to verify their serviceability and whether they are appropriate for a specific application.

## The big picture

If time is taken to research materials and the standards that apply to a specific environment, you will effectively reduce the time and cost of building and maintaining the controlled environment. The cost to build new or retrofit an existing environmentally controlled room is one time, but the cost to maintain it and produce defect-free results is ongoing and, in the case of defects, can be incalculable.

Careful planning and design, with a focus on the ability to maintain the controlled environment, will let you focus on the objective of providing high quality and safe solutions in the healthcare industry.

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