

By Eric S. Kastango, MBA, RPh, FASHP

# A Review of USP's Updates to Chapter <797>: Don't Just Know *About* It

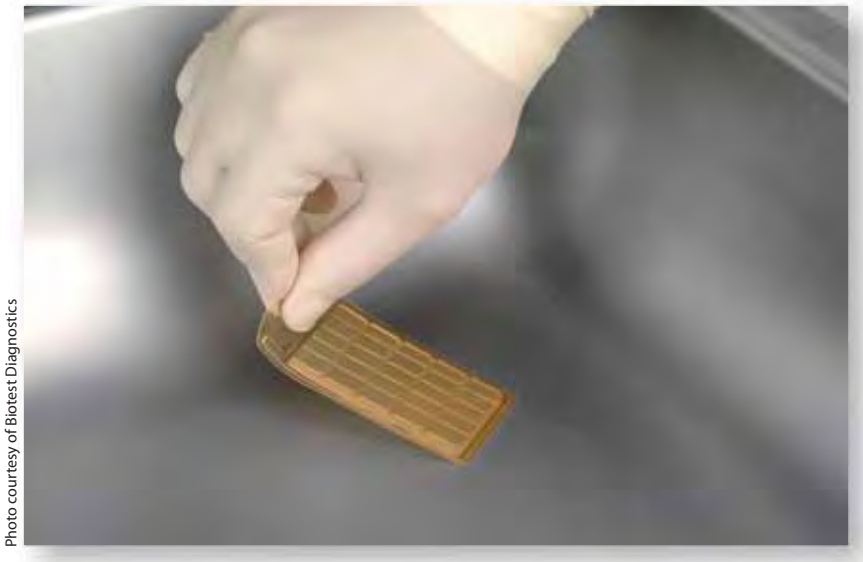

Photo courtesy of Biotest Diagnostics

**The revised section on environmental monitoring discusses requirements for total particle counts (semi-annual certifications), surface sampling, air sampling, and personnel glove fingertip sampling.**

THE PUBLICATION OF USP CHAPTER <797> provided pharmacy's first required and legally enforceable compounding standard of practice. A number of state boards of pharmacy changed their regulations as a result, and JCAHO informed its accredited organizations that compliance, via a gap analysis and an action plan, was required. Although there has been some backpedaling from JCAHO on whether or not they will require future compliance, the committee still requires a gap analysis and action plan as evidence of compliance with the USP chapter.

Shortly after USP Chapter <797> was published, significant feedback was given to USP, identifying issues that needed to be corrected, harmonized, or otherwise addressed. Comments from five USP-sponsored workshops, in addition to hundreds of individually submitted comments, were used to create the first set of proposed chapter revisions at the end of 2004. These proposed changes were published in 2005. However, because these proposed changes were not final or complete, they were left for the members of the 2005-2010 SCC (Sterile Compounding Committee) to address.

> These changes may have a **significant impact** on the day-to-day practices of all persons involved in the handling, preparation, and storage of CSPs.

Beginning in July 2005, the current members of the SCC Committee held multiple meetings to consider additional changes based on the expertise of the SCC's seven new members, as well as the plethora of comments from individuals and organizations. The committee sought guidance in modifying the standard from other organizations such as NIOSH, the FDA, the CDC, the American Society of Microbiology (ASM), and the Controlled Environment Testing Association (CETA). Some of the newest members of the SCC brought with them a perspective that extends beyond the pharmacy. Their areas of expertise include microbiology, infection control, and engineering controls. The extensive revisions to the official text, formally titled "In-Process Revision of USP Chapter <797>", have been published in the May-June 2006 edition of *Pharmacopeial Forum*.

In the past, news of proposed changes was disseminated solely through the *Pharmacopoeial Forum*. However, for the current changes to Chapter <797>, USP has made the In-Process Revision available on its website at www.usp.org/ USPNF/pf/generalChapter797.html. Two versions of the proposed changes (with and without the markups) can be downloaded. In addition, viewers may submit comments online.

It is very important that pharmacists, technicians, and all other interested parties, including nurses and physicians, download a copy of the proposed changes, read it, and submit comments to USP. The comment period will be closed after August 15, 2006. The USP SCC will review all comments received by that date. Depending on the comments received, additional changes to <797> may be required, and in turn, another In-Process Revision and comment period will begin. It is anticipated that the next official version of USP Chapter <797> will be published in 2007.

The following is a summary of some of the proposed revisions that can be found in the complete text of the proposed changes. They include new definitions and new sections, as well as revisions to the standard published in 2004. There are now 59 sections and subsections in <797>, with major revisions/additions noted in the following chapters.

## Introduction

This section was reorganized, with new and updated terms in a glossary. Some of the new terms used consistently throughout the proposed chapter include: *preparation*, *product*, *primary and secondary engineering control*, *compounding aseptic isolators (CAIs)*, *critical site*, and *gravimetric and volumetric sampling*. The introduction also emphasizes that the chapter applies to all

pre-administration activities only. Once a CSP is administered to the patient or instilled in the pump for administration, <797> no longer applies.

It is **very important** that pharmacists, technicians, and all other interested parties, including nurses and physicians, download a copy of the proposed changes, read it, and submit comments to USP.

### Immediate-Use Compounded Sterile Preparations (CSPs)

This new section is intended to allow exemptions when CSPs are prepared in urgent situations (i.e. in emergency rooms and during codes and similar circumstances when ISO Class 5 air cleanliness is not available). Immediate-use compounding should not be viewed as a loophole to avoid complying with the chapter standards. State boards of pharmacy will be looking at the situations surrounding immediate-use compounding to prevent abuses. Hazardous drugs and radiopharmaceuticals are prohibited from being prepared under the immediate-use provisions.

### Hazardous Drugs as CSPs

The first version of <797> preceded the NIOSH Hazardous Drug Alert, which was published in the fall of 2004. The proposed changes include a new section requiring that all compounding personnel be fully trained in the handling, storage, and disposal of hazardous drugs. Because of the nature of these types of medications, education is an important step in protecting workers who interact with hazardous drugs. Properly trained employees can work to minimize any unnecessary exposures to these agents.

Photo courtesy of NuAire


Photo courtesy of Germfree

**The revisions to USP Chapter <797> allow the contributions from primary engineering controls, such as laminar airflow workbenches (left) or and compounding aseptic isolators (far left) to count towards the total number of air changes per hour required to meet ISO Class 7 air cleanliness.**

### Radiopharmaceuticals as CSPs

This new section describes risk levels associated with compounding radiopharmaceuticals and the respective environmental requirements. The use of highly particulate-generating material (lead shipping containers and shielding) is required to protect the employees handling, preparing, and storing these types of CSPs. Because it is difficult to maintain the same level of air cleanliness with all of the lead shielding, ISO Class 8 air is permitted. This section also refers practitioners who compound radiopharmaceuticals to another USP General Chapter (Radiopharmaceuticals for Positron Emission Tomography Compounding, Chapter <823>) for additional information. USP Chapter <823> was the first USP chapter to fully articulate a process related to the practice of pharmacy.

> The revisions related to facitlity design and environmental controls reduce the cost burden originally associated with creating an **ISO Class 7 cleanroom**.

### Facility Design and Environmental Controls

This section has been revised extensively to describe environmental design and primary engineering control areas, such as buffer and anterooms, cleanrooms, CAIs (formerly known as barrier isolators), and HEPA filters. It also clarifies the ISO air cleanliness requirements for compounding facilities, and the placement of equipment in those facilities. The revisions related to facility design and environmental controls reduce the cost burden originally associated with creating an ISO Class 7 cleanroom. It allows the contributions from primary engineering controls (laminar airflow workbenches or hoods, biological safety cabinets, and CAIs) to count towards the total number of air changes per hour required to meet ISO Class 7 air cleanliness.

### Environmental Monitoring

This section has been completely revised to discuss requirements for total particle counts (semi-annual certifications), surface sampling, air sampling, and personnel glove fingertip sampling. Glove sampling was added to the standard's requirements as a means to identify microbial colony-forming units as a quality assessment and improvement tool. Poor aseptic technique and touch contamination is one of the more probable and dangerous causes of contaminated CSPs.

### Personnel Cleansing and Garbing

This section has been revised to provide a clear understanding of personnel cleansing and garbing procedures, as well as the disinfecting process. The CDC's 2002 Guideline for Hand Hygiene in Healthcare Settings heavily influenced this section.

It is important to note that this list of highlights does not represent all of the proposed changes to USP Chapter <797>. It is incumbent upon the reader to visit the USP website, download the document, and read it in its entirety. These changes may have a significant impact on the day-to-day practices of all persons involved in the handling, preparation, and storage of CSPs.

The famed educator and physicist Richard Feynman once said, "You can know the name of a bird in all the languages of the world, but when you're finished, you'll know absolutely nothing whatsoever about the bird...So let's look at the bird and see what it's doing — that's what counts. I learned very early the difference between knowing the name of something and knowing something." This applies very well to our situation with USP Chapter <797>: Don't just know *about* it; know it. ■

*Eric S. Kastango, RPh, MBA, FASHP, provides expertise in aseptic processing, medical-device manufacturing, and the implementation of extemporaneous compounding quality systems through his New Jersey-based consulting company, Clinical IQ, LLC.*