AN ONGOING CE PROGRAM
of the University of Connecticut
School of Pharmacy

EDUCATIONAL OBJECTIVES
After participating in this activity pharmacists and pharmacy technicians will be able to:
- Define the United States Pharmacopeia’s functions and its responsibility for the USP <797>
- Describe recent changes to USP <797> and affected clinicians
- Compare sterile and non-sterile compounding and differentiate between the categories of Compounded Sterile Products.
- Describe the parts of a cleanroom suite and discuss cleaning procedures
- Identify recommended training requirements, general monitoring, and sampling procedures

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Pharmacists and pharmacy technicians are eligible to participate in this application-based activity and will receive up to 0.2 CEU (2 contact hours) for completing the activity, passing the quiz with a grade of 70% or better, and completing an online evaluation.

Statements of credit are available via the CPE Monitor online system and your participation will be recorded with CPE Monitor within 72 hours of submission

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ABSTRACT: Proposed changes to the United States Pharmacopeia General Chapter <797> will go into effect on December 1, 2019 in most states. Individuals who work in sterile compounding will need to make workplace changes and document their efforts. This continuing education homestudy reviews basic requirements, describes the cleanroom suite, and covers training and evaluation. In addition, it provides some guidelines for creating written tests that are fair and reliable.

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FACULTY DISCLOSURE: The authors have no actual or potential conflicts of interest associated with this article.

DISCLOSURE OF DISCUSSIONS OF OFF-LABEL and INVESTIGATIONAL DRUG USE: This activity may contain discussion of off label/unapproved use of drugs. The content and views presented in this educational program are those of the faculty and do not necessarily represent those of the University of Connecticut School of Pharmacy. Please refer to the official prescribing information for each product for discussion of approved indications, contraindications, and warnings.

INTRODUCTION
Whether you work in a hospital, home care facility or any setting that prepares sterile intravenous (IV) or other sterile medications, the odds are you’ve heard of USP <797>, but what is it really? Let’s start from the beginning with an introduction to the USP. The United States Pharmacopeia and National Formulary (USP-NF) is a compendium of standards, definitions, and best practices prepared by three non-profit volunteer groups:
- A non-governmental convention (up to 600 people)
- A board of trustees (11-14 people) and
- A council of experts (currently 24 people).

Since 1820, these groups have overseen and set standards pertaining to drugs, drug information, and many other aspects of drugs. They create product quality standards for prescription drugs, over-the-counter drugs, food ingredients, and dietary supplements. The USP has no role in enforcing the standards it creates;
the US Food and Drug Administration (FDA), other governmental authorities, and most state boards of pharmacy enforce the standards. According to the USP, not all state boards follow USP <797>. Many states are now voting to determine whether they will accept all or parts of this revised chapter or reject it entirely. Based on a National Association of Boards of Pharmacy (NABP) survey performed in 2016, 87% of all states required full compliance or incorporated several parts of USP <797> into state law.

To learn more about compounding requirements in your state, go to [https://www.usp.org/compounding/legal-considerations](https://www.usp.org/compounding/legal-considerations). The Joint Commission also has a document that lists compounding regulations by state ([https://www.jointcommission.org/assets/1/6/Feb_2017_States_Compounding_Regulations.pdf](https://www.jointcommission.org/assets/1/6/Feb_2017_States_Compounding_Regulations.pdf)); please note it was last updated in 2017.

The USP Pharmacopeia consists of several general chapters and monographs. The general chapters describe procedures and other standards that are intended to provide uniform quality among drug products. Chapters designated with numbers below 1000 are considered enforceable, whereas chapters numbered above 1000 are suggestions for good practices.

Chapters important to compounding personnel, which you might have heard of, include USP <795>, which is a chapter governing non-sterile, non-hazardous compounding. USP <797> is the chapter on sterile non-hazardous sterile medications. Both chapters provide guidelines that if followed, ensure product protection and patient safety. USP <800> pertains to handling of hazardous drugs and contains policies to protect healthcare workers. When compounding hazardous sterile drugs, both USP <797> and USP <800> apply, since <797> refers to patient safety and <800> pertains to healthcare worker’s protection.

On June 1, 2019, the USP released major revisions to chapters <795> and <797>. These chapters will be fully enforceable on December 1, 2019, giving affected facilities little time to prepare. Major revisions to USP <797> include:

- Section reorganization
- Placement of important procedures in informational boxes
- Collapse of three compounded sterile product (CSP) categories down to two
- Removal of sterile hazardous drug procedures from this chapter, and
- Additional information about specific practices such as repackaging and handling allergic extracts and blood products.

**Pause and Ponder:** The USP uses words like should, shall, and must. "Should" is a suggestion for best practice. For example, you should eat four servings of fruits and vegetables every day. Do we always do that? "Shall" and "must" are mandates. Do you think that the USP is right in using this tactic or should it be changed?

**What is sterile compounding?**
Compounding as defined by the USP is “combining, admixing, diluting, pooling [mixing together] reconstituting, repackaging, or otherwise altering a drug or bulk drug to create a sterile medication.” The following products must be sterile:

- Baths and soaks for live organs and tissues
- Implants
- Injections, including infusions
- Irrigations for internal body cavities (i.e., any space that does not normally communicate with the environment outside of the body such as the bladder cavity or peritoneal cavity). [NOTE—Irrigations for the mouth, rectal cavity, and sinus cavity are not required to be sterile.]
- Ophthalmic dosage forms
- Preparations for pulmonary inhalation. [NOTE—Nasal dosage forms intended for local application are not required to be sterile.]

Source: USP <797> Section 1.1

**Who Does This Affect?**
These changes affect pharmacists and pharmacy technicians, but also have repercussions for physicians, dentists, veterinarians, naturopaths, chiropractors, and nurses. Most professionals who prepare injectable medications must comply. For example, when a physician prepares an injection in his office for a patient or when your dentist draws up that anesthetic for your procedure, he or she will follow this chapter. Most of this continuing education activity will focus on pharmacy-based situations.

Compounding facilities must now designate one or more individuals to be responsible for the performance and operation of the facility and personnel who prepare CSPs and perform functions covered in general chapter <797>. For the purpose of this continuing education, let’s call this “designated person” the quality manager. Any person entering a sterile compounding area, whether preparing a CSP or not, must be trained and meet all personal hygiene and garbing requirements.

**What Locations Does USP <797> Affect?**
Standards apply to all healthcare institutions, including hospitals, patient treatment sites, infusion facilities, pharmacies, and physician and veterinarian practice sites. Employees at these organizations must follow the standards when preparing compounded sterile drugs for humans and animals. To comply with the standards in <797>, each compounding facility must do three things consistently:

1. Develop a well-described written training program.
2. Develop a written process for visually evaluating individuals’ performance when preparing CSPs.
3. Provide appropriate knowledge and train personnel in required skills.

The USP <797> update also addresses specific practices such as repackaging, and the compounding of allergenic extracts, and
includes a statement on blood-derived and biologic materials. CSPs intended for immediate use and prepared according to the approved labeling (for example an immune globulin, which comes with diluent and drug components to be mixed together) are addressed. If your facility uses nonsterile starting components to compound sterile preparations, take a closer look at the full text. The revised <797> has 21 sections, with full sections addressing facilities and engineering controls, facility certification and recertification, air and surface sampling, monitoring, compounding and manufacturing records, and much more. This continuing education will not delve fully into those topics, but instead will focus on the revisions that will affect cleanroom personnel more significantly.

The Cleanroom Suite
You might have heard the term “cleanroom suite” before. Let’s review and clarify its parts. A cleanroom suite consists of an anteroom and a buffer room.

- There are primary and secondary engineering controls (PEC and SEC, respectively) within the rooms for maintaining the high level of “clean” required for sterile compounding.
  - PECs are the devices that provide an ISO class 5 air quality environment. An example of a PEC is a laminar flow hood.
  - SECs are the rooms in which the PECs are located. SECs are rooms specifically designed to reduce risk of contaminants in the compounding area.
- An anteroom is a room located before the entrance to the buffer room. The anteroom is where employees perform hand hygiene and garbing. This room must have an air quality level of at least ISO 8. ISO air quality levels are set by the International Organization for Standardization (ISO). Each level specifies the maximum number of particles of dust and other contaminants in the air (see Table 1).
- A buffer room is the room where the PECs (compounding cabinets or hoods) are located. This room can only be accessed by going through the anteroom. The air in the buffer room must be ISO 7 or better. Not all facilities have cleanroom suites; some have segregated compounding areas (SCAs). An SCA is a room which is not classified but holds a PEC. An SCA must be located away from doors or unsealed windows, away from areas of high traffic, and away from areas that may have poor air quality. Only Category 1 CSPs (defined below) can be compounded in an SCA.

Pause and Ponder: For the purposes of this CE, I have used the job title “quality manager.” The USP uses the term “designated person(s).” Do you think that one person should be designated for all responsibilities assigned to the “designated person(s)” or would a team approach be better? Does this quality manager have to be a pharmacist?

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Pause and Ponder: The suggested temperature in a cleanroom suite is no higher than 20°C (68°F). Given that bacteria and fungi grow in warm places and that the staff wears gowns or coveralls over clothing, do you agree with this suggested temperature? What is the temperature in your cleanroom? What would you do if the temperature exceeded 20°C?

Cleanroom suite monitoring includes surface and air testing. Here are the basics:

Monitoring also includes airflow testing, integrity testing of the high-efficiency particulate air (HEPA) filters located in the ceiling and PECs, particle count testing, and dynamic airflow smoke pattern tests. These tests are to be performed under dynamic conditions, meaning that they must be done with the number of staff usually working in the room to simulate normal working conditions. Many states also mandate that facilities video tape their smoke tests, and send them to the state for review.

Surface sampling is to be performed at least monthly to determine the level of microbial contamination. Samples are taken on surfaces in all classified areas. Examples of sampling locations include the work surface of the PEC, equipment within the PEC, pass-through chambers, carts, and frequently touched surfaces. These surface samples must be taken at the end of the compounding activity, but before the area has been cleaned. Table 2 describes the acceptable numbers of colony forming units (cfu) on the sample plates, indicating the number of viable microorganisms in the sample.

One significant change to the standards in the revised <797> is that there are no longer different action levels for “highly pathogenic microorganisms.” If sample results exceed the acceptable levels, the quality manager must take some corrective action to reduce the contamination. Depending on your facility’s standard operating procedures (SOPs), corrective action may include

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**Table 1. ISO Classification of Particulate Matter in Room Air**

<table>
<thead>
<tr>
<th>ISO Class</th>
<th>Particle Count$/m^3$</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>35.2</td>
</tr>
<tr>
<td>4</td>
<td>352</td>
</tr>
<tr>
<td>5</td>
<td>3520</td>
</tr>
<tr>
<td>6</td>
<td>35200</td>
</tr>
<tr>
<td>7</td>
<td>352000</td>
</tr>
<tr>
<td>8</td>
<td>3520000</td>
</tr>
</tbody>
</table>

*Adapted from ISO 14644-1, Cleanrooms and associated controlled environments—Part 1: Classification of air cleanliness by particle concentration.*

*Limits for number of particles ≥0.5 mcum measured under dynamic operating conditions.*

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sending the sample out to a laboratory for re-testing, cleaning and disinfecting the area, personnel retraining, and or process improvements. The revised <797> requires documentation of the corrective action and confirmation of its effectiveness. Some states also require the quality manager to notify one of its agencies if they find positive results (meaning they find unacceptable contamination) and take corrective actions within a certain timeline.

There are additional requirements for air sampling that have similar action level tables.

An important revision is the change in categories of CSPs, dropping them from three down to two. Instead of low, medium and high-risk levels, the USP has created Category 1 and Category 2, which are primarily based on the conditions in which preparations are made, the probability for microbial growth in the preparation, and the time within which the preparation must be given.

- Category 1 CSPs are preparations that will be used quickly. They have a beyond use date (BUD) of 12 hours or less at room temperature or 24 hours or less under refrigeration when mixed in an unclassified SCA.

- Category 2 CSPs are medications that may be given a longer BUD—more than 12 hours at room temperature or longer than 24 hours under refrigeration. Facilities must establish BUDs conservatively to ensure the CSP’s stability and sterility. Category 2 CSPs are made in a cleanroom suite at no more than 20° C (or 68° F) and 60% humidity.

Thankfully, multiple dose containers, which are vials that contain more than one dose and usually contain a preservative, can still be used for 28 days. Single dose vials can be used for up to 12 hours from the time they are punctured in ISO 5 air.

Pharmacy bulk packages, for example a 10 gram vancomycin vial, may now be used according to the manufacturer’s directions. This represents a change from the previous requirement for use within four hours. Stock solutions or components used for sterile compounding may be used for up to 12 hours or its assigned BUD, whichever is shorter.

### Training and Evaluation

Personnel training and evaluation has greatly changed. As before, the quality manager or designated trainer must train all personnel until they demonstrate compounding proficiency, but now each compounding facility must create its own training program and document its effectiveness. The quality manager must ensure that anyone entering the cleanroom suite, whether to compound or to clean, will maintain the environmental quality.

Personnel must complete training every 12 months in sterile compounding principles and practices and must also complete a written or electronic test every 12 months. The USP does not provide this test, so facilities will need to develop their own. Development of an appropriate test is a prodigious task, as test-writing is a science in its own right, and not generally taught in pharmacy curriculum. Individuals who need to develop tests should begin by ensuring they know what they need employees to know. In educational lingo, this means creating learning objectives and developing the training around those objectives. When they write test questions, they should ensure that each question tracks to a learning objective and is written in a fair way. (Part 2 of this continuing education activity provides some guidance on how to write good test questions.)

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### Table 2. Action Levels for Surface Sampling

<table>
<thead>
<tr>
<th>Action Level</th>
<th>CFU Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>&gt;3 cfu</td>
</tr>
<tr>
<td>7</td>
<td>&gt;5 cfu</td>
</tr>
<tr>
<td>8</td>
<td>&gt;50 cfu</td>
</tr>
</tbody>
</table>

Source: USP <797> Section 6

### SIDEBAR: Is mixing proprietary bag systems (i.e. ADD-Vantage, Minibag Plus, or other products) considered compounding? The answer: No and Yes!

Docking and activation of proprietary bag and vial systems (e.g., ADD–Vantage) in accordance with manufacturers’ labeling for immediate use is not considered compounding and may be performed outside of an International Organization for Standardization (ISO) 5 environment.

Docking of the proprietary bag and vial systems for future activation and administration by nurses or homecare patients is considered compounding and must be performed in accordance with this chapter. Proprietary beyond use dates must not be longer than those specified in the manufacturer’s labeling.

**Is a beyond use date the same as an expiration date? Not exactly.**

The USP defines a BUD as the “date, or hour and date after which a CSP must not be used.” The BUD is established when the CSP is prepared. This applies to all CSPs.

An expiration date is the time which a medication “can be expected to meet the requirements of the compendial monograph, if one exists, or maintain expected quality provided it is kept under the specified storage conditions.” Expiration dates apply to conventionally manufactured products, to active product ingredients (APIs), and added substances.
Each person involved in compounding must demonstrate knowledge of theoretical principles. He or she must show proficiency of skills for performing sterile manipulations and possess knowledge about how to attain—and maintain—appropriate environmental conditions. Staff must prove their competency every 12 months in at least the following:

- Achieving and/or maintaining sterility and apyrogenicity
- Aseptic technique
- Calculations, measuring, and mixing
- Cleaning and disinfection
- Documentation of the compounding process (e.g., master formulation and compounding records)
- Garbing
- Hand hygiene
- Principles of HEPA-filtered unidirectional airflow within the ISO Class 5 area
- Principles of movement of materials and personnel within the compounding area
- Proper use of PECs
- Use of equipment

Along with training and testing, the quality manager must visually observe compounding personnel every six months. Minimum observations include handwashing and garbing. If you are new to sterile compounding or working for the first time in a different facility, you will need to do an initial competency evaluation which, with handwashing and garbing, includes a media fill test and a gloved fingertip and thumb sampling, three separate times.

The media fill test assesses sterile technique. Media fill tests should simulate the most difficult or complex compounding procedures that you will perform in your facility and must be completed every six months. An example of a difficult compounding procedure might be a solution that requires several medications to be added, requiring puncturing the port on a bag several times, such as a parenteral nutrition infusion. Sterile growth media, which is usually a soybean-casein digest in place of actual drug, will give any contaminants food for growth.

Media fill test samples are incubated for seven days at 20-25°C, inspected for growth, then the temperature is increased to 30-35°C for another seven days, and inspected for growth again. In facilities that have an incubator, the quality manager observes and documents the results and takes any required action. If the facility does not have an incubator, the samples must be sent to an outside laboratory for testing.

Fingertip and thumb sampling on agar plates must occur after handwashing and full garbing, but the USP designates no time restriction or time interval between tests. Previously, this needed be done in the ISO 5 hood. Now for initial tests, the location has been downgraded to a classified area within the Segregated Compounding Area (SCA). Once this initial testing is done and the employee passes with zero cfus, meaning no groups of bacteria on the agar plates, cleanroom staff must complete fingertip tests every six months. This must be completed after the media fill test and in the ISO 5 PEC. These subsequent fingertip
tests are considered passing if there are less than or equal to a total of three cfu for both hands. Table 3 is a handy guide to gloved fingertip and thumb sampling.

### Table 3. Gloved Fingertip and Thumb Sampling Procedures

- Use one sampling device (e.g., plates, paddles, or slides) per hand containing general microbial growth agar [e.g., trypticase soy agar] supplemented with neutralizing additives (e.g., lecithin and polysorbate 80). This agar supports both bacterial and fungal growth.
- Label each sampling device with a personnel identifier, whether it was from the right or left hand, and the date and time of sampling.
- Do not apply sterile 70% isopropyl alcohol (IPA) to gloves immediately before touching the sampling device; this could cause a false-negative result.
- Using a separate sampling device for each hand, collect samples from all gloved fingers and thumbs from both hands by rolling finger pads and thumb pad over the agar surface.
- Incubate the sampling device at a temperature of 30°–35° for no less than 48 hours and then at 20°–25° for no less than five additional days. Store media devices during incubation to prevent condensate from dropping onto the agar and affecting the accuracy of the cfu reading (e.g., invert plates).
- Record the number of cfu per hand (left hand, right hand).
- Determine whether the cfu action level is exceeded by counting the total number of cfu from both hands.

**SOURCE:** USP <797> section 2.3, box 2.2

The update of USP <797> thoroughly describes personal hygiene and garbing. The USP now dictates that “personnel must report any rashes, recent tattoos, oozing sores, conjunctivitis, or active respiratory conditions” to the quality manager. The quality manager determines whether the staff person may work in the compounding area, and if not, when he or she is eligible to return. This is a significant responsibility for the quality manager since there are no clear guidelines in place. Quality managers should be prepared to make reasonable decisions, have written SOPs, or refer the employee to the employee health or his or her personal physician if there are any questions.

### SIDE BAR: The Job Isn’t Finished until the Paperwork is Done

Documentation must include at least:

- Personnel training, competency assessments, and qualification records including corrective actions for any failures
- Certification reports, including corrective actions for any failures
- Environmental air and surface monitoring procedures and results
- Equipment records (e.g., calibration, verification, and maintenance reports)
- Receipt of components
- SOPs, master formulation records (when used), and compounding records
- Release inspection and testing records
- Information related to complaints and adverse events
- Results of investigations and corrective actions

“Documentation must comply with all laws and regulations of the applicable jurisdiction. Records must be legible and stored in a manner that prevents their deterioration and/or loss. All required compounding records for a particular CSP must be readily retrievable for at least three years after preparation or as required by laws and regulations of the applicable regulatory jurisdiction, whichever is longer.” (USP <797> Section 20)

In other words, if it hasn’t been documented, it hasn’t been done.

Facilities must review their SOPs every 12 months, document changes, and communicate changes to the staff. Once again, it is the quality manager’s responsibility to ensure that every employee is informed about the changes. He or she should keep copies of the correspondence and document who was informed, how, and when. Using multiple communication forms (e.g. e-mail, notices on bulletin boards, communication books, announcements at meetings) ensures everyone is informed.
Most of the previous pre-cleanroom requisites are still in place. In addition, USP has addressed earbuds and glasses in this version. Below is a list of items that cleanroom personnel should leave in the general pharmacy:

- All cosmetics because they shed flakes and particles
- All hand, wrist, and other exposed jewelry including piercings that could interfere with the effectiveness of garbing (e.g., the fit of gloves, cuffs of sleeves, and eye protection) or otherwise increase risk of contaminating the CSP. Cover any jewelry that cannot be removed
- Earbuds or headphones
- Electronic devices unnecessary for compounding or other required tasks into the compounding area
- Personal outer garments (e.g., bandanas, coats, hats, jackets, sweaters, vests)

In addition, personnel need to

- Keep nails clean and neatly trimmed to minimize particle shedding and avoid glove punctures. Nail products (e.g., polish, artificial nails, and extenders) must not be worn.
- Wipe eyeglasses, if worn.

The quality manager may “permit accommodations as long as the quality of the CSP and environment will not be affected.” For example, some facilities allow post earrings if they are completely covered with the head cover. Some facilities also allow flat wedding bands if they are smooth and will not puncture gloves. However, the quality manager or facility management should clearly define any accommodations in your SOPs.

Hand Hygiene: Basic, Essential

Touch is the number one source of contamination and hand hygiene is a major factor to help keep medications sterile. All the basic hand washing rules are still in place:

- Start by using a disposable nail pick to remove visible debris from under the fingernails under running water.
- Wash hands and forearms up to the elbows for at least 30 seconds and dry hands and forearms completely with low lint wipes. The USP does not describe the exact method of hand washing, but best practice would be to start by washing at the fingers and wash toward the elbows. The same routine should be followed with drying, start with the fingertips and dry toward the elbows.
- Personnel must not use brushes to scrub hands and must not use electric hand dryers, which create air turbulence.
- Facilities must now install a closed system of soap with non-refillable containers to reduce contamination. This is a new requirement. There are several “hands free” models on the market today which are reasonably priced.
- Once hands are washed, employees must apply an alcohol-based hand rub in the manufacturer’s recommended amount, rub both hands together covering all surfaces, and then wait until hands are dry before donning sterile gloves. Inspect sterile gloves for holes or tears and spray them with 70% IPA regularly throughout compounding. Each time your hands leave the ISO 5 PEC or whenever hands touch non-sterile surfaces, you must apply sterile alcohol to the gloves.

Store all personal garb away from sinks to avoid splashing. Personal garb includes gowns or coveralls that fit snugly around the neck and wrists, shoe covers, head and beard cover if needed, face masks, and sterile powder-free gloves. This revision makes no mention or requirement of safety glasses, which leaves that decision up to each facility. Personnel should not don and doff in the anteroom at the same time. When the gown or coverall is removed, a large number of skin cells may be released into the air, therefore it would be unwise to don garb in the immediate vicinity of another staff member who is doffing.

When exiting the buffer room, employees must discard all garb, except for the gown, which can be reused within the same shift if it is kept within the segregated area.
Cleaning: Love It, Hate It, but Do It Right

My favorite section in USP <797> is section 7: Cleaning, Disinfecting, and Applying Sporicidal Agents in Compounding Areas. Yes, my nickname is “Mrs. Clean.” You either love cleaning, or you hate it. Since cleaning is a specialized task performed by a few highly trained staff, most cleanroom personnel never have to think about it, but if you do, here is the newest scoop.

Three types of agents should be used in a cleanroom suite.
- Cleaning agents remove dirt, debris, and drug residue
- Disinfectants kill viruses and bacteria
- Sporicidal agents are used to destroy bacterial and fungal spores

In general, cleaners should always be used first, since they remove dirt and residue that could reduce the effectiveness of the disinfectants. The disinfectant of choice is usually 70% IPA. The general rule is to clean from dirtiest to cleanest and from top to bottom; this is similar to the way cleaners recommend you clean your home. The new USP <797> includes a sentence in very small type that discusses the cleaning of ceilings. “Ceilings are required to be cleaned, disinfected, and applied with sporicidal agent only when visibly soiled and when surface contamination is known or suspected.” This means that facilities no longer need to clean the ceilings weekly.

New developments in disinfectants make cleaning easier for cleanroom staff. Some products are both cleaner and disinfectant, which eliminates one step and a considerable amount of time. Check with the EPA to see if your cleaner is one of them (https://www.epa.gov/pesticides/antimicrobial-pesticides). Don’t be alarmed when you see that they are listed as pesticides, you are “killing” bacteria after all. Of course, the people who do the cleaning must note and adhere to the manufacturer’s recommended contact time (the amount of time needed for a product to work). The USP provides a clear table of what should be cleaned and disinfected and when.

USP <797> clarifies the procedure for cleaning an ISO 5 PEC (laminar air hood for example). It indicates the hood’s surfaces must first be cleaned with water, then cleaner, then disinfectant daily. A sporicidal agent must then be used monthly Table 4 describes the cleaning schedule required by USP for full compliance with <797>.

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Task</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daily</td>
<td>Clean and disinfect: PECs, work surfaces outside the PEC, pass-through chambers, floors, and sinks. Work from cleanest to dirtiest.</td>
</tr>
<tr>
<td>Monthly</td>
<td>Clean and disinfect: ceilings, walls, doors and door frames, storage shelving and bins, and equipment outside the SEC. Work from top to bottom, cleanest to dirtiest. Apply sporicidal to all sites/surfaces</td>
</tr>
</tbody>
</table>

Now that the room is clean, how do we transport items in without compromising it? Section 8 tells us! Before any product can enter through a pass-through or the clean side of the anteroom, when “packaging integrity will not be compromised,” staff who are wearing gloves must wipe it with a “sporicidal agent, EPA registered disinfectant, or 70% IPA, using low-lint wipes.” Most facilities use sterile 70% IPA. The mandate of wearing gloves when introducing items into the anteroom is new, and may necessitate changes to some workflow procedures. The important part to remember: the alcohol should be allowed to dry and that the wiping process should not be so vigorous or enthusiastic that it wipes off important information on the label. Additionally, just before placing an item into the PEC, it must be wiped down with 70% IPA again unless it is an item that has an outer covering that keeps the item sterile. If an item has an outer covering, staff may remove the outer covering and introduce the item into the PEC without wiping the outer covering.

Conclusion

The standards in the new USP general chapter <797> become enforceable on December 1, 2019. Now is the time for you to become involved in your facility’s implementation planning and make a difference. I urge you and your team to be proactive and collaborate with other technicians, pharmacists and managers, to comply with or exceed the new USP <797> standards at your facility, which will further increase your patients’ safety.
INTRODUCTION
If you are a quality manager (or “designated person”), you are responsible for developing a written test for your sterile compounding staff to take annually. Writing good test questions isn’t easy. Poorly written questions confuse your employees and erode their confidence. They’ll be unable to choose the correct answer and you will have wasted your time. Taking a few minutes to understand how to write a reliable test will help you develop a tool that measures what you wanted to measure, and also ensures that your employees are competent.

There are two ways to ascertain employees’ competence and sterile compounding using a written test. The first is to develop a test that uses essay questions. Many people prefer essay questions because they don’t feel boxed in by having to select one answer from a list. Others find essay questions difficult, and have poor writing skills. For the person who has to administer the test— that’s you—preparing the essay questions can take quite a bit of time, and grading the tests once they are completed can be subjective. For this reason, many people use multiple-choice tests.

MULTIPLE CHOICE TESTS
To completely understand multiple-choice tests, you need to understand the parts of a multiple-choice question:
- The stem is the part that poses your question.
- Underneath the stem, you generally include a list of items, one of which is the answer, and the others are the distractors (or the alternatives).

Let’s talk about the parts of the question first, and then we’ll talk about how to develop your test.

A test should confirm that the learner has a good understanding of essential concepts and skills and can distinguish between plausible distractors (possible answers) and the one correct answer. When writing the question’s stem, you can simply ask a question, tell the test-taker to “select” or “choose” from the answers, or provide an incomplete sentence for the test-taker to finish. Many educators encourage people who write tests to make the stem a question, because questions make it very clear what information you’re seeking. If you put a blank in the stem for test-takers to fill in, try to put it at the end of the stem.2

When you write the stem, it’s critical to include only relevant information. If you include irrelevant information, the test-taker will spend time reading the stem repeatedly and often become confused. In addition, write your stem using positive language. In plain English, it means that you avoid stems that use the word “not” or FALSE. Stems should not include exclusionary terms (all, none, always, never, every, only, must, must not). There is rarely a clear “always” or “never” in healthcare. Another thing to remember when you’re creating distractors is to avoid “all of the above” or “none of the above” answers.1,2

Another type of question that are very difficult to write well is the “K-type” question. A K-type question is a complex multiple choice question that offers several alternatives, and also offers multiple correct answers (i.e., a & b, a & d, two of the above, etc.). Educational researchers have shown that K-type questions are more difficult, and less discriminating. That’s educational jargon meaning fewer test-takers choose the correct answer, and individuals who know the material well do not do better compared to those who don’t.2

By now, you’re probably thinking, “What about true/false questions?” Many people who simply want to fulfill the testing requirement may create tests full of easy questions, or true/false questions. Often true/false tests contain more true answers than false answers, and test-takers who guess may pass without knowing the material, making these questions unreliable. Keep in mind these questions can only measure memorization.
Next, when you start to write your possible answers, think about how many options you want to include. Traditionally, multiple-choice questions have had four or five options—one correct and three or four distractors. Increasingly, educators are determining that offering three choices is approximately as effective as offering four or five possible answers. (It’s generally easy to come up with two distractors, but a third or fourth can be a real challenge. Often, the third or fourth distracters are silly and implausible.) So consider offering three choices—one correct answer and two distractors.

Several times, we have used the word “plausible.” Your alternatives should be plausible. For example, your distractor might be something that employees would do, but not under the conditions in the stem. Including incorrect distractors that are totally implausible doesn’t test knowledge. It just takes time for your test-taker to read the possible answers. This is another reason that offering three answer choices is a good idea. Table 1 provides a few more test writing tips.

Creating Your Questions
Some of your questions will be knowledge-based. This means that you simply want your employees to recall an important fact. For example, you might have a question that asks them to identify how many colony forming units are acceptable in the initial gloved finger tip test. The answer that question is simple recall. Here’s another example:

1. What is the purpose of surface sampling?
   A. Determining if scheduled cleaning has been done
   B. Determining if microbial growth is present*
   C. Determining if employees can start working

If you really want to test competence, you may consider moving to application-based questions.

Application-based questions are more complex than simple recall questions. Often, application-based questions include a description of situations that could occur in the workplace, followed by possible answers that relate back to the data provided in the situation. A good way to make a question application-based is to describe a situation and then ask one of the following questions:

- If this situation occurs, then the next step would be....
- Which of the following steps would be performed first?
- How would you calculate...?
- If THIS happened, how would it affect our system or procedure?

A key to writing good application-based questions is to write the question in a way that prompts the learner to begin formulating a choice or an answer before he or she reads the choices provided.

By now, you’re probably ready for an example of an application-based question. Here’s one:

1. It’s shift change and Sally is leaving the clean room suite. Josh, who is scheduled on the next shift, arrives in the anteroom just as she enters the anteroom. She begins removing her gloves, head cover, and gown as Josh puts on his gloves, head cover, and gown. What is wrong with this situation?
   a. Sally and Josh should not don or doff protective clothing in the anteroom.
   b. It would be unwise to donn garb when another staff member is doffing.*
   c. Sally should give change of shift report in the clean room suite after Josh enters.

Begin with the End in Mind
Now that we’ve covered how to write questions, let’s talk about what questions to write. Before you start writing questions—and in fact, before you start training employees—you need to identify what your employees need to know to be considered competent. Table 2 lists the sections of Chapter and testable items.
<table>
<thead>
<tr>
<th>Knowledge or Skill</th>
<th>Testable Elements</th>
</tr>
</thead>
</table>
| Testable Elements                          | ● How far should hands and arms be washed?  
● Using a nail pick  
● Using hand rub  
● Steps of sterile gloving  
● Duration of handwashing  
● Gown/coverall design  
● Items prohibited in cleanroom |
| Cleaning and disinfection                  | ● Frequency of PEC cleaning, disinfection, and sporidical use for walls, ceilings, shelving, doors, pass-throughs, work surfaces and floors?  
● Difference between a cleaner, a disinfectant, and a sporidical  
● Order of cleaner, disinfectant, and sporidical use  
● Cleaner, disinfectant, and sporidical contact time  
● Low lint wipes |
| Calculations, measuring, and mixing        | ● Reconstitute vial with x, dose is y, Calculate amount needed for dose.  
● You have x amount of drug, dose is Y, how many doses can you get…..  
● Possible percentage question  
● Possible °C to °F question  
● Abbreviations  
● LVP, flow rates, calc. # bags needed |
| Aseptic technique                          | ● Airflow in PEC  
● Setbacks (inches from back/sides) needed when preparing CS  
● Critical sites to wipe with alcohol swab  
● Introducing items into PEC  
● Introducing items into the SEC  
● Coring and beveling needle  
● Syringe size selection |
| Maintaining sterility                      | ● Clean room suite testing  
● Personnel testing – media fill  
● Fingertip and glove sampling  
● Incubation times  
● cfu numbers  
● Optimal room temperatures |
| Equipment Use                              | ● Use of facility-specific equipment  
● Appropriate equipment cleaning  
● Equipment calibration and testing frequency  
● Movement of equipment and carts in or out of the clean room suite |
| Documentation & quality control            | ● Master formulation records and other records  
● Information required on a compounding record  
● Length of document retention  
● Quality control/visual inspection processes  
● Labeling  
● General BUD questions |
| HEPA airflow principles and proper movement in cleanroom suite | ● ISO levels  
● Frequency of testing  
● Surface sampling  
● Air sampling  
● ACPH |
Another good way to construct questions is to select related information from several parts of the material. Create a situation that is based on that information, and then present various situations. The narrative should hint at the symptoms or salient points, but not ask directly about a specific condition. Here’s an example:

1. Our facility has organized tasks required by USP <797> so that we do all monthly tasks on the 15th of the month. What (among other things) needs to be done on the 15th of the month?
   A. Perform a dynamic smoke flow pattern test and fingertip test; clean and disinfect ceilings
   B. Perform surface sampling; clean and disinfect the SEC; apply sporicidal to all sites/surfaces*
   C. Review/document Master Formulation Records, and communicate changes to the staff

How Many Questions?
It can be difficult to determine how many questions you need, and there is no exact formula. Table 3 provides some guidelines.

Finishing Up
Once you’ve assembled your test, ask someone (or several “someones”) to proofread it. Consider asking someone who is a logical person but unfamiliar with the material to proofread the test, and then take the test. If that person scores very well on the test, your test may be too easy. Ask a subject matter expert to look at it, too. Put your test aside for a few days, and then re-read it carefully. Correct any obvious problems.

Once you administer the test, look at the test average and data for each question. If more than half of your employees answered a question incorrectly, ask yourself if you worded the question poorly, or your training failed to explain the material well. If the former is true (the question is poorly worded) drop the question from your scores calculations, and re-grade the test. If the latter is true (training failed to convey important information), keep the question but revise your training.

CONCLUSION
All done? No, sorry! USP <<797>> requires the quality manager to test employees annually. Next year, you’ll do this again! Most people save their test questions and re-use them, but try to avoid administering the same test every year. Consider developing a question bank—a folder of appropriate questions that you rotate in future tests.

Table 3. Determining an Adequate Number of Questions

- Make a list of the key principles and facts a competent employee needs to know
  - It’s perfectly acceptable (and good, even) to tell employees what they will need to know in general terms; this is called articulating the learning goals

- Avoid focusing too much on specific information and excluding other information
  - Identify information or processes that are critical, or that have been identified as a needing improvement in your facility, and (1) be sure to train employees thoroughly, and (2) include focused questions on this information

- If you write one question for every testable element listed in Table 2, you would have a test with 45 questions.
  - Determine if you need this many questions, or if you need to write fewer or more questions for certain sections
REFERENCES

Part 1.

Part 2.