Illinois Department of Financial and Professional Regulation Division of Professional Regulation
Drug Compliance Unit
9511 Harrison Street, Suite 300, Des Plaines, IL 60016
320 W. Washington Street, 2nd Floor, Springfield, IL 62786
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(Read this Page Carefully)

STERILE COMPOUNDING-Self Inspection Form

Pharmacy Self-Inspection Form-USP Chapter 797 and Admin Code 1330.640
Pharmaceutical Compounding Standards

Illinois Law holds the Pharmacist-in-Charge (PIC) and all pharmacists on duty responsible for ensuring pharmacy compliance with all state and federal laws governing the practice of pharmacy.

The primary objective of this report, and your self-inspection, is to provide an opportunity to identify and correct areas of non-compliance with state and federal law. The inspection report also serves as a necessary document used by the Drug Compliance investigators during an inspection to evaluate a pharmacy's level of compliance. When a Drug Compliance investigator discovers an area of non-compliance, he or she may issue either a Deficiency Notice or a Notice of Non-Compliance. Both require a written response from the PIC. Identifying or correcting an area of non-compliance prior to a Drug Compliance investigator inspection may eliminate the receipt of a Deficiency Notice/Notice of Non-Compliance for that item.

Failure to complete this report by December 31st of each year may result in Disciplinary Action. (Section 1330.800)
Every licensed pharmacy shall conduct an annual self-inspection using forms provided by the Division. The annual self-inspection shall be conducted during the same month, annually, as determined by the pharmacy. Documentation of the self-inspection shall be maintained at the pharmacy for 5 years. The primary objective of the self-inspection is to create an opportunity for a pharmacy to identify and correct areas of noncompliance with State and federal law. This includes, but is not limited to, recordkeeping, inventory, labeling and sanitation requirements.

NOTE: Neither the self-inspection nor a Drug Compliance investigator inspection evaluates your complete compliance with all Laws and Rules of the practice of pharmacy. Further, nothing herein shall constitute a waiver of IDFPR enforcement discretion or constitute compliance with all applicable Laws and Rules governing the practice of pharmacy. This report is not final agency action and is intended as guidance. This report is not intended, nor can it be relied upon to create any rights enforceable by any party in litigation or in any enforcement action brought by IDFPR.

STATE OF ILLINOIS DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
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(KEEP CURRENT THROUGHOUT THE YEAR, AS NEEDED)

CATEGORY 1 CSP STERILE COMPOUNDING

BUSINESS NAME	HOURS		DEA REGISTRATION NUMBER	EXPIRES	DATE OF INSPECTION
	M				
	T				
	W				
ADDRESS	TH		ICSA LICENSE NUMBER	EXPIRES	PHARMACY LICENSE NUMBER
	F				
	SAT				
	SUN				
CITY ZIP CODE	OTHER HOURS EXCEP		TELEPHONE ( )		

OWNERSHIP	OWNERS	TELEPHONE AFTER HOURS	PHARMACY E-MAIL ADDRESS
Individual pharmacist Individual Non-pharmacist Partnership Corporation LLC	PERSON IN CHARGE	OWNER'S E-MAIL ADDRESS	COUNTY

NAME OF LICENSEE	LICENSE NUMBER
R Ph IN CHARGE	

If the Pharmacist in charge listed above is the PIC in other pharmacies, list here			
NAME		ADDRESS	PHONE NUMBER
1.			
2.			

Pharmaceutical Compounding Standards (Section 1330.640)					
	COMPLIANT			AUTHORITY	
REQUIREMENTS	YES	NO	N/A	68 ADMINISTRATIVE CODE	NOTES
All sterile pharmaceutical compounding conducted at the facility is governed by the USP Chapter 797				Section 1330.640	
It shall be the ongoing responsibility of the pharmacist-in-charge to ensure that all pharmacists, student pharmacists, registered certified pharmacy technicians, and registered pharmacy technicians who participate in compounding activities are adequately trained for the type of compounding in which they participate. Documentation of this training shall be maintained by the pharmacy at all times.				Section 1330.640(h)	
Sterile compounding for office use is prohibited unless the pharmacy is in full compliance with 21 USC 353b, including becoming registered as an outsourcing facility and licensed as a wholesale drug distributor pursuant to the Wholesale Drug Distribution Licensing Act [225 ILCS 120]. However, a sterile compounded drug may be delivered to the prescribing practitioner's office for administration pursuant to a valid patient-specific prescription.				Section 1330.640(c)	
Sales of compounded drugs to other pharmacies not under common ownership, or to clinics, hospitals, or manufacturers, other than as provided in subsection (d), are not allowed, except for sales provided by pharmacies contracted to provide centralized prescription filling services pursuant to Section 25.5 of the Act, including compounding in anticipation of				Section 1330.640(e)(10)	

receiving a prescription or order based on routine, readily observed dispensing patterns.					
Notwithstanding any other provision of this Section, a pharmacy may compound a reasonable quantity of sterile drug products for office use by a veterinarian.				Section 1330.640(g)	
The pharmacist-in-charge shall ensure that records are maintained for 5 years, are readily retrievable and in a format that provides enforcement agents an accurate and comprehensive method of monitoring distribution via an audit trail. The records shall include at least the following information: • Purchase records • Patient profile or medication				Section 1330.640(e)(8)(D)	
The pharmacist-in-charge shall ensure the environmental control of all preparations shipped or delivered off site. Therefore, any compounded pharmaceutical must be shipped or delivered to a patient in temperature controlled (as defined by USP Standards) delivery containers.				Section 1330.640(e)(9)	
A pharmacist shall be accessible at all times to enable each licensed facility to respond to patients' and health professionals' questions and needs. A 24-hour telephone number shall be included on the prescription label of compounded drugs and medication infusion devices if used off site.				Section 1330.640(f)(2)	
Pharmacies that dispense compounded sterile drugs to patients in facilities off site or for administration in the patient's residence shall stock supplies and medications appropriate for treatment of allergic or other common adverse effects, to be dispensed upon the prescription or				Section 1330.640(f)(3)	

order of an authorized prescriber.					
Pharmacy has the current edition of the USP Compounding compendium. Can be electronic or available as a subscription via the internet.				Section 1330.640(e)(5)	
Pharmacy has "Plumb's Veterinary Drug Handbook" or any other similar publication approved by the Division, if engaged in veterinary drug compounding.				Section 1330.640(e)(6)	
Pharmacy maintains current resource materials and texts in the pharmacy, may be in electronic format, to the Pharmacy Act and Section 1330.640, the Illinois Controlled Substances Act [720 ILCS 570] and 77 Ill. Adm. Code 3100, 21 CFR (Food and Drugs), and the Illinois Hypodermic Syringes and Needles Act [720ILCS 635].				Section 1330.640(f)(1)(A)	
Pharmacy has one compatibility reference available, such as: i) ASHP's Handbook on Injectable Drugs. ii) King's Guide to Parenteral Admixtures; or iii) Any other Division-approved publication				Section 1330.640(f)(1)(B)	
Pharmacy maintains a file or reference on extended (more than 24 hours) stability data given to finished preparations.				Section 1330.640(f)(1)(C)	
A logbook or record keeping system to track each compounded drug, which must include the lot number, expiration date of components used, and beyond-use date of compounded drug. This applies to each sterile compounded drug with a beyond-use date greater than 24 hours.				Section 1330.640(e)(4)	
Must have a pharmacy generated patient profile or medication record system that shall be maintained in addition to the prescription file that contains at a minimum: • Patient’s name				Section 1330.640(e)(8)(A)	

• Date of birth • Gender • Compounded drug dispensed • Date dispensed • Date compounded • Drug content and quantity • Patient directions • Other drugs or supplements the patient is receiving if provided by the patient or his or her agent • Known Drug sensitivities and allergies to drugs and foods					
Each compounded drug dispensed to patients shall be labeled with the following information, using a permanent label: • Name address and telephone number of the licensed pharmacy, if not used within the facility. • Date dispensed and identifying number • Name of each drug component, strength, amount, and dosage form • Directions for use • Prescriber's name • Required controlled substance transfer warnings • Beyond-use-Date • Identity of compounding and dispensing pharmacist or other authorized individual • Auxiliary label with storage requirements • On the label or an auxiliary label, the following: "This prescription was specifically compounded in our pharmacy for you at the direction of your prescriber."				Section 1330.640(e)(8)(B)	
Compounded drugs dispensed to patients				Section 1330.640(e)(8)(C)	

shall have on the label or an auxiliary label the following: "This prescription was specifically compounded in our pharmacy for you at the direction of your prescriber."					
USP CHAPTER 797 STANDARDS					
	COMPLIANT				
	Y	**N**	**N/A**	**REFERENCE**	**NOTES**
Introduction and Scope					
1. Are manipulations of patient's blood-derived or other biological material separated from other compounded activities and equipment used to prepare CSP and controlled to avoid cross-contamination? biological fluids, and mix-ups with other products or CSPs.				**USP <797> 1.1.2 Specific practices** Blood-derived and other biological materials: When compounding activities require the manipulation of a patient's blood-derived or other biological material (e.g., autologous serum), the manipulations must be clearly separated from other compounding activities and equipment used in CSP preparation activities, and they must be controlled by specific standard operating procedures (SOPs) to avoid any cross- contamination. Handling of blood components and other biological materials must additionally comply with laws and regulations of the applicable regulatory jurisdiction.	
2. Does the compounding facility have a designated person(s)responsible for the performance and operation of the facility and personnel? ****Enter the name of designated person(s) in the Notes field*				**1.1.3 Personnel and settings affected:** The compounding facility must designate one or more individuals (i.e., the designated person(s)) to be responsible and accountable for the performance and operation of the facility and personnel in the preparation of CSPs and for performing other functions as described in this chapter.	
3. Does immediate-use compounding meet all requirements?				**USP <797> 1.3 Immediate-Use CSPs** When all of the following conditions are met, compounding of CSPs for direct and immediate administration is not subject to the requirements for Category 1, Category 2, or Category 3 CSPs: 1. Aseptic techniques, processes, and procedures are followed, and written SOPs are in place to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other conventionally manufactured products or CSPs. 2. Personnel are trained and demonstrate competency in aseptic processes as they relate	

				to assigned tasks and the facility's SOPs. 3. The preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs (e.g., approved labeling, stability and compatibility studies). 4. The preparation involves not more than 3 different sterile products. 5. Any unused starting component from a single-dose container must be discarded after preparation is complete. Single-dose containers must not be used for more than one patient. 6. Administration begins within 4 h following the start of preparation. If administration has not begun within 4 h following the start of preparation, it must be promptly, appropriately, and safely discarded. 7. Unless directly administered by the person who prepared it or administration is witnessed by the preparer, the CSP must be labeled with the names and amounts of all active ingredients, the name or initials of the person who prepared the preparation, and the 4-h time period within which administration must begin.	
4. Is docking of proprietary bag and vial systems for future use performed in an ISO Class 5 environment and the BUD assigned per manufacturer's labeling?				**USP <797> 1.4 Preparation Per Approved Labeling** Proprietary bag and vial systems: Docking and activation of proprietary bag and vial systems in accordance with the manufacturer's labeling for immediate administration to an individual patient is not considered compounding and may be performed outside of an International Organization for Standardization (ISO) Class 5 environment. Docking of the proprietary bag and vial systems for future activation and administration is considered compounding and must be performed in an ISO Class 5 environment in accordance with this chapter, with the exception of 14. Establishing Beyond-Use Dates. Beyond-use dates (BUDs) for proprietary bag and vial systems must not be longer than those specified in the manufacturer's labeling.	
5. When CSPs are prepared using any nonsterile components, is the component sterilized, is sterility				**USP <797> 1.5 CSP Categories** If one or more of the starting components being used to compound is not sterile, the sterility of the compounded	

maintained if subsequently manipulated, and are bacterial endotoxins mitigation strategies employed?				preparation must be achieved through a sterilization process (e.g., terminal sterilization in the final sealed container) or sterilizing filtration, and then sterility must be maintained if the CSP is subsequently manipulated. When compounding with nonsterile starting components, supplies, or equipment, the quality of the components, the effectiveness of the sterilization step, and bacterial endotoxin mitigation strategies are critical to achieving a sterile preparation that is free from excessive bacterial endotoxins.	
Personnel Training and Evaluation					
6. Has the designated person(s) created and implemented a written training program for initial and ongoing training completed and documented for personnel who compound and those who have direct oversight of compounding personnel?				**2. PERSONNEL TRAINING AND EVALUATION** All personnel who compound or have direct oversight of compounding personnel must be initially trained and qualified by demonstrating knowledge and competency in compounding CSPs according to the requirements in this section before being allowed to perform their job functions independently. Designated person(s) are responsible for creating and implementing a training program for personnel and for ensuring that compounders, personnel who have direct oversight of compounders, and personnel who perform restocking or cleaning and disinfection duties are initially trained and qualified by demonstrating knowledge and competency in maintaining the quality of the sterile compounding environment before being allowed to perform their job functions independently. Personnel who compound or have direct oversight of compounding personnel must complete training initially and at least every 12 months in appropriate sterile compounding principles and practices as described below (see *2.1 Demonstrating Knowledge and Competency of Core Skills*). Personnel who only perform restocking or cleaning and disinfecting duties outside of the primary engineering control (PEC) must complete ongoing training as required by the facility's SOPs. Each compounding facility must develop a written training program that describes the required training, the frequency of training, and the process for evaluating the performance of individuals who compound, have direct oversight of compounding personnel, perform in- process checks, final verification, and dispensing of CSPs.	
7. Is training documentation of core				**2.1 Demonstrating Knowledge and Competency of**	

competencies on file for required personnel?				**Core Skills** Before beginning to compound CSPs independently or have direct oversight of compounding personnel, personnel must complete training and be able to demonstrate knowledge of principles and competency of skills for performing sterile manipulations and achieving and maintaining appropriate environmental conditions as applicable to their assigned job functions. This must be completed initially and at least every 12 months in at least the following: Hand hygiene Garbing Cleaning and disinfection Calculations, measuring, and mixing Aseptic technique Achieving and/or maintaining sterility (and apyrogenicity if compounding with nonsterile components)Use of equipment Documentation of the compounding process (e.g., master formulation and compounding records)Principles of high-efficiency particulate air (HEPA)-filtered unidirectional airflow within the ISO Class 5 area Proper use of PECs Principles of movement of materials and personnel within the compounding area If the facility has only one person in the compounding operation, that person must document that they have obtained training and demonstrated competency, and they must comply with the other requirements of this chapter.	
8. Do all personnel successfully complete three initial garbing competencies prior to performing compounding or having oversight of compounding personnel?				**2.2 Demonstrating Competency in Garbing and Hand Hygiene** Before beginning to compound Category 1, Category 2, or Category 3 CSPs or have direct oversight of compounding personnel, personnel must successfully complete an initial garbing competency evaluation no fewer than 3 separate times. The 3 successful completions must be in succession—failure of any of the 3 initial garbing competency evaluations requires repeat testing until personnel successfully complete 3 evaluations in a row. The garbing competency evaluation consists of a visual observation and gloved fingertip and thumb sampling (GFT) of both hands (see Box 1). Each of the 3 initial competency evaluations must occur after performing a separate and complete hand hygiene and full garbing procedure. All	

				garbing competencies must be completed with gloved fingertip and thumb sampling after garbing (see Box 1) and a documented visual audit while performing hand hygiene and garbing procedures (see 3. Personal Hygiene and Garbing). Gloved fingertip and thumb sampling after garbing, but before applying sterile 70% IPA to gloves, must be performed on donned sterile gloves on both hands in a classified area or segregated compounding area (SCA).	
9. In the event of a garbing competency failure are results of the evaluation and corrective actions documented and retained?				**2.2 Demonstrating Competency in Garbing and Hand Hygiene** Failure is indicated by visual observation of improper hand hygiene and garbing procedures and/or gloved fingertip and thumb sampling results that exceed the action levels in Table 1. Results of the evaluation and corrective actions, in the event of failure, must be documented and the documentation maintained to provide a record and long-term assessment of personnel competency.	
10. Does documentation of hand hygiene and garbing competency include all required elements?				**2.2 Demonstrating Competency in Garbing and Hand Hygiene** Documentation must at a minimum include the name of the person evaluated; evaluation date and time; media and components used including manufacturer, expiration date, and lot number; starting temperature foreach interval of incubation; dates of incubation; results and identification of the observer and personnel reading and documenting the results. Microbial identification of the colony-forming units (cfu) is not required for gloved fingertip and thumb sampling.	
11. Do compounding personnel successfully complete ongoing garbing competency at the required intervals?				**2.2 Demonstrating Competency in Garbing and Hand Hygiene** After the initial garbing competency evaluations, compounding personnel must successfully complete the garbing competency (see Table 1) at least one time every 6 months for personnel compounding Category 1 and Category 2 CSPs, and at least one time every 3 months for personnel compounding Category 3 CSPs.	
12. Do personnel who only have direct oversight of compounding personnel complete a successful garbing				**2.2 Demonstrating Competency in Garbing and Hand Hygiene** Personnel who have direct oversight of compounding personnel, but do not compound, must	

competency evaluation every 12 months?				complete a garbing competency evaluation every12 months. The evaluation should correspond to the type of garbing activities of the personnel they oversee. Personnel who have direct oversight of compounding personnel must not compound unless they successfully complete the garbing competency evaluation at the same intervals required for compounding personnel.	
13. Do required personnel successfully complete an aseptic manipulation competency assessment at the required intervals?				**2.3 Competency Testing in Aseptic Manipulation** Before beginning to compound Category 1, Category 2, or Category 3 CSPs independently or have direct oversight of compounding personnel, personnel must successfully complete an aseptic manipulation competency evaluation. The aseptic manipulation competency evaluation consists of a visual observation, media-fill testing, followed by a gloved fingertip and thumb sampling on both hands, and surface sampling of the direct compounding area to assess aseptic technique and related practices (see Box 2). For personnel compounding Category 1 and Category 2 CSPs, the aseptic manipulation competency must occur initially and at least every 6 months thereafter. For personnel compounding Category 3 CSPs, the aseptic manipulation competency must occur initially and at least every 3 months thereafter. Personnel who have direct oversight of compounding personnel must complete an aseptic manipulation competency evaluation annually. Personnel who have direct oversight of compounding personnel must not compound unless they successfully complete the aseptic manipulation competency evaluation that simulates the most difficult and challenging aseptic compounding procedures encountered by the person at the same intervals required for compounding personnel.	
14. Do media-fill test procedures simulate the most difficult and challenging aseptic compounding procedures?				**2.3 Competency Testing in Aseptic Manipulation** When performing a media-fill test, simulate the most difficult and challenging aseptic compounding procedures encountered by the person replacing all the components used in the CSPs with soybean–casein digest media. The simulation must capture elements that could potentially affect the sterility of the	

				CSP including but not limited to: • Factors associated with the length of the process that can pose contamination risk (e.g., operator fatigue, quality of equipment • Number of aseptic additions or transfers • Number, type, and complexity of manipulations • Number of personnel in the buffer room or SCA	
15. Does sterile microbial growth media support growth as demonstrated by a COA from the supplier or by growth promotion testing for growth media prepared in house?				**2.3 Competency Testing in Aseptic Manipulation** If using commercial sterile microbial growth media, a certificate of analysis (COA) must be obtained from the supplier stating that the lot of the growth media will support the growth of microorganisms. Store microbial growth media in accordance with manufacturer instructions and initiate the media-fill test by the expiration date of the media. If preparing sterile microbial growth media in-house for sterile-to-sterile media-fill testing, the growth promotion capability of the media must be demonstrated for each batch and documented as described in *Sterility Tests* ⟨71⟩*, Culture Media and Incubation Temperatures, Growth Promotion Test of Aerobes, Anaerobes, and Fungi*.	
16. Is gloved fingertip and thumb sampling performed on both hands immediately following the media-fill test inside an ISO Class 5 PEC?.				**2.3 Competency Testing in Aseptic Manipulation** Immediately following the media-fill test, gloved fingertip and thumb sampling must be performed on both hands and inside of an ISO Class 5 PEC. If conducting gloved fingertip and thumb sampling in a compounding aseptic isolator (CAI), compounding aseptic containment isolator (CACI), or a pharmaceutical isolator, samples must be taken from the sterile gloves placed over the gloves attached to the restricted-access barrier system (RABS) or pharmaceutical isolator sleeves.	
17. Is surface sampling of the direct compounding area performed following media-fill testing?				**2.3 Competency Testing in Aseptic Manipulation** Surface sampling of the direct compounding area must occur in accordance with the requirements in 6.3 Monitoring Surfaces for Viable Particles. A failure in the media fill, gloved fingertip and thumb sampling, or surface sample constitutes an overall failure of the aseptic manipulation competency.	
18. Are the results of evaluation and				**2.3 Competency Testing in Aseptic Manipulation**	

<table>
<tr><td>corrective actions documented and maintained to provide long-term assessment of personnel competency?</td><td></td><td></td><td></td><td>Results of the evaluation and corrective actions must be documented, and the documentation maintained to provide a record and long-term assessment of personnel competency.</td><td></td></tr>
<tr><td>19. Does documentation of media-fill testing include all required elements?</td><td></td><td></td><td></td><td>2.3 Competency Testing in Aseptic Manipulation
Documentation must at a minimum include
• the name of the person evaluated,
• evaluation date and time,
• media and components used including their manufacturer or supplier,
• expiration dates and lot numbers,
• starting temperature foreach interval of incubation, 6) dates of incubation,
• the results, and
• the names or other identification of the observer and the person who reads and documents the results.</td><td></td></tr>
<tr><td>20. Are action levels for gloved fingertip and thumb sampling set at the appropriate thresholds?</td><td></td><td></td><td></td><td>2.3 Competency Testing in Aseptic Manipulation
Table 1. Action Levels for Gloved Fingertip and Thumb Sampling<table><tr><td>Gloved Fingertip and Thumb Sampling</td><td>Action Levels (CFU, total from both hands)</td></tr><tr><td>After garbing</td><td>>0</td></tr><tr><td>After media-fill testing</td><td>>3</td></tr></table></td><td></td></tr>
<tr><td colspan="6">Personal Hygiene and Garbing</td></tr>
<tr><td>21. Do personnel that have a higher risk of contaminating a CSP or the environment report their conditions to the designated person(s)?</td><td></td><td></td><td></td><td>USP <797> PERSONAL HYGIENE AND GARBING
Individuals that may have a higher risk of contaminating the CSP and the environment (e.g., personnel with rashes, recent tattoos, oozing sores, conjunctivitis, or active respiratory infections) must report these conditions to the designated person(s). The designated person(s) may permit accommodations to personnel preparation as long as the quality of the CSP and environment will not be affected. Accommodations must be documented.</td><td></td></tr>
<tr><td>22. Are food and drinks prohibited from anterooms, buffer rooms, and SCAs?</td><td></td><td></td><td></td><td>USP <797> 3.1 Personnel Preparation
Food (including mints, gum, etc.) and drinks must not enter anterooms, buffer rooms, or segregated compounding areas.</td><td></td></tr>
</table>

23. Before entering a compounding area do personnel remove unnecessary items and items not easily cleanable?				**USP <797> 3.1 Personnel Preparation** Before entering a compounding area, individuals must remove any items that are not easily cleanable or are not necessary for compounding. At a minimum, individuals must: • Remove personal outer garments (e.g., bandanas, coats, hats, jackets, sweaters, vests) • Remove all cosmetics because they shed flakes and particles • Remove 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 the risk of contamination of the CSP. Cover any jewelry that cannot be removed. • Not wear earbuds or headphones • Not bring electronic devices that are not necessary for compounding or other required tasks into the compounding area • 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	
24. Are hand hygiene requirements met before initiating compounding activities?				**USP <797> 3.2 Hand Hygiene** Any person entering a compounding area where Category 1, Category 2, or Category 3 CSPs are prepared must wash hands and forearms up to the elbows with soap and water before initiating compounding activities. Brushes must not be used for hand hygiene. Hand dryers must not be used. To minimize the risk of extrinsic contamination, disposable soap containers must not be refilled or topped off. Hands must be sanitized with alcohol-based handrub before donning sterile gloves (see Box 4).	
25. Are sterile gloves donned in a classified room or SCA?				**USP <797> 3.2 Hand Hygiene** Sterile gloves must be donned in a classified room or SCA.	
26. Are all persons entering a compounding area properly garbed following facility SOPs?				**USP <797> 3.3 Garbing Requirements** Any person entering a compounding area where Category 1, Category 2, or Category 3 CSPs are prepared must be properly garbed. Garb must be donned and doffed in an order that reduces the risk of contamination. The required garb, manner of storage,	

				and order of garbing must be determined by the facility and documented in the facility's SOPs. If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb.	
27. Is skin exposure prohibited inside the ISO Class 5 PEC?				**USP <797> 3.3 Garbing Requirements** Skin must not be exposed inside the ISO Class 5 PEC (e.g., gloves must not be donned or doffed inside the ISO Class 5 PEC exposing bare hands).	
28. Are garbing requirements for preparing Category 1 and Category 2 CSPs followed?				**USP <797> 3.3 Garbing Requirements** The minimum garbing requirements for preparing Category 1 and Category 2 CSPs include the following: • Low-lint garment with sleeves that fit snugly around the wrists and an enclosed neck (e.g., gown or coverall) • Low-lint covers for shoes • Low-lint cover for head that covers the hair and ears, and if applicable, cover for facial hair • Low-lint face mask • Sterile powder-free gloves • If using a RABS (i.e., a CAI or CACI), disposable gloves should be worn inside the gloves attached to the RABS sleeves. Sterile gloves must be worn over the gloves attached to the RABS sleeve	
29. Is garb replaced immediately if soiled or if integrity is compromised, stored to minimize contamination, and discarded or laundered as appropriate?				**USP <797> 3.3 Garbing Requirements** Garb must be replaced immediately if it becomes visibly soiled or if its integrity is compromised. Gowns and other garb must be stored in a manner that minimizes contamination (e.g., away from sinks to avoid splashing). When personnel exit the compounding area, garb, except for gowns, cannot be reused and must be discarded or laundered before reuse.	
30. Does the facility have SOPs that describe the disinfection procedure for reusable goggles, respirators, and other equipment?				**USP <797> 3.3 Garbing Requirements** The facility's SOPs must describe disinfection procedures for reusing goggles, respirators, and other reusable equipment.	
31. Do facilities that compound Category 3 CSPs follow additional garbing requirements?				**USP <797> 3.3 Garbing Requirements** If the facility compounds Category 3 CSPs, additional garbing requirements must be continuously met in the buffer room in which Category 3 CSPs are prepared. The following additional garbing requirements must be followed in the buffer room where Category 3 CSPs are prepared for all personnel regardless of whether Category 3 CSPs are compounded on a given day:	

				1. Do not allow any exposed skin in the buffer room (i.e., face and neck must be covered). 2. All low-lint outer garb must be sterile, including the use of sterile sleeves over gauntlet sleeves when a RABS is used 3. Disposable garbing items must not be reused, and laundered garb must not be reused without being laundered and re-sterilized with a validated cycle. 4. The facility's SOPs must describe disinfection procedures for reusing goggles, respirators, and other reusable equipment.	
32. Is 70% sterile IPA appropriately applied to gloves and are gloves inspected as required?				**USP <797> 3.3 Garbing Requirements Gloves:** Application of sterile 70% IPA to gloves must occur immediately before compounding and regularly throughout the compounding process. All gloves must be inspected for holes, punctures, or tears and must be replaced immediately if such defects are detected.	
Facilities and Engineering Controls					
33. Are facilities designed to meet air quality classifications?				**USP <797> 4.1.2 Design requirements to maintain air quality:** Facilities used for compounding CSPs must be designed so that air quality improves with movement through separate operational areas to the PEC. Classified areas in which the air quality is controlled (see Table 4) include anterooms, buffer rooms, and PECs. • Anterooms providing access only to positive-pressure buffer rooms must meet at least ISO Class 8 classification. Anterooms providing access to negative-pressure buffer rooms must meet at least ISO Class 7 classification (see ⟨800⟩). Typically, personnel hand hygiene and garbing procedures, staging of components, and other activities that potentially generate higher levels of particulates are performed in the anteroom. Anterooms are also transition areas to ensure that proper air classification and pressure relationships are maintained between classified and unclassified areas. • A buffer room must meet at least ISO Class 7 air quality. Activities in the buffer room must be controlled to minimize any effects on air quality in the area where CSPs are prepared. • Category 1, Category 2, and Category 3 CSPs	

				must be compounded in an ISO Class 5 or better PEC. If compounding only Category 1 CSPs, the PEC may be placed in an unclassified SCA.	
34. Are the anteroom and buffer room appropriately constructed and equipped with a pressure-differential monitoring system?				**USP <797> 4.2.1 Types of SECs and design Cleanroom suite:** The ISO-classified anteroom and buffer room must be separated from the surrounding unclassified areas of the facility by fixed walls and doors, and controls must be in p lace to minimize the flow of lower-quality air into the more controlled areas. The classified rooms must be equipped with a pressure-differential monitoring system.	
35. Does the cleanroom suite have ceiling mounted HEPA filters?				**USP <797> 4.2.1 Types of SECs and design Cleanroom suite:** Air supplied to the cleanroom suite must be introduced through HEPA filters that are located in the ceiling of the buffer room and anteroom.	
36. If the cleanroom suite does not have low wall returns do smoke studies confirm the absence of stagnant airflow?				**USP <797> 4.2.1 Types of SECs and design Cleanroom suite:** Air returns in the cleanroom suite must be low on the wall unless a visual smoke study demonstrates an absence of stagnant airflow.	
37. Are smoke studies and environmental monitoring completed when equipment is moved, or other room alterations occur?				**USP <797> 4.2.1 Types of SECs and design Cleanroom suite:** This smoke study along with environmental monitoring must be repeated whenever a change is made to the placement of equipment within the room or any other alteration is performed within the cleanroom suite that affects the quality of the air (e.g., HVAC alterations, change of HEPA filter units).	
38. Does the anteroom have a demarcation method to separate the clean side from the dirty side?				**USP <797> 4.2.1 Types of SECs and design Cleanroom suite:** The anteroom must have a line of demarcation to separate the clean side from the dirty side. Alternatively, facilities may be designed with two separate anterooms—a dirty anteroom and a clean anteroom. The anteroom is entered through the dirty anteroom, and the clean anteroom is the area closest to the buffer room.	
39. Are pass-through chambers prohibited from having both doors opened simultaneously?				**USP <797> 4.2.1 Types of SECs and design Cleanroom suite:** If a pass-through chamber is used, both doors must never be opened at the same time, and doors should be interlocking.	

40. Are tacky mats prohibited within ISO-classified areas?				**USP <797> 4.2.1 Types of SECs and design Cleanroom suite:** Tacky mats must not be placed within ISO-classified areas.	
41. When compounding both sterile and nonsterile preparations are the PECs appropriately placed?				**USP <797> 4.2.1 Types of SECs and design Cleanroom suite:** If compounding both sterile and nonsterile preparations (e.g., pre-sterilization procedures), the respective PECs must be placed in separate rooms unless those PECs are sufficiently effective that the room can continuously maintain ISO Class 7 classification. If the PECs used for sterile and nonsterile compounding are placed in the same room, they must be placed at least 1 m apart, and particle-generating activity must not be performed when sterile compounding is in process.	
42. Are SCAs limited to Category 1 CSPs and located away from environmental challenges that could negatively affect air quality?				**USP <797> 4.2.1 Types of SECs and design Segregated compounding area:** The SCA must be located away from unsealed windows, doors that connect to the outdoors, and traffic flow, all of which may adversely affect the air quality in the PEC. An SCA must not be located where environmental control challenges (e.g., restrooms, warehouses, or food preparation areas) could negatively affect the air quality of the PEC within the SCA. The impact of activities (e.g., patient care activities) that will be conducted around or adjacent to the SCA must be considered carefully when designing such an area.	
43. Do PECs meet ISO Class 5 under dynamic conditions and maintain appropriate airflow?				**USP <797> 4.2.2 The CSP compounding environment** The PEC must be certified to meet ISO Class 5 or better conditions (see *Table 4*) during dynamic operating conditions and must be designed to minimize the risk of contamination during compounding of CSPs. Unidirectional airflow must be maintained in the PEC. HEPA-filtered air must be supplied by the PEC at a velocity sufficient to sweep particles away from critical sites and maintain unidirectional airflow during operations.	
44. Is there sufficient room to clean around the PEC?				**USP <797> 4.2.3 Types of PECs and placement** Placement of the PEC must allow for cleaning around the PEC.	
45. Are LAFS located in areas appropriate				**USP <797> 4.2.3 Types of PECs and**	

for the type of compounding performed and are smoke studies completed as required?				**placement** **Placement of LAFS** The LAFS must be located out of traffic patterns and away from Room air currents that could disrupt the intended airflow patterns inside the PEC. If used to prepare Category 2 or Category 3 CSPs, the LAFS must be located within a cleanroom suite with an ISO Class 7 or better buffer room with an ISO Class 8 or better anteroom. A dynamic airflow smoke pattern test must be performed in the PEC initially and at least every 6 months to ensure that 1) the LAFS is properly placed into the facility and 2) compounders understand how to utilize the unidirectional airflow to maintain first air in the DCA.	
46. Is air exchange into the CAI HEPA filtered?				**USP <797> 4.2.3 Types of PECs and placement** **Compounding aseptic isolator** Air exchange into the CAI from the surrounding environment must not occur unless the air has first passed through a HEPA filter.	
47. Are RABS appropriately located according to the type of compounding performed?				**USP <797> 4.2.3 Types of PECs and placement** **Placement of RABS** If used to prepare only Category 1 CSPs, the ISO Class 5 environment may be achieved by placing the RABS in an unclassified SCA. If used to prepare Category 2 or Category 3 CSPs, the RABS must be located within a cleanroom suite with an ISO Class 7 or better buffer room with an ISO Class 8 or better anteroom. When a RABS is used, the recovery time after opening the transfer chamber to achieve ISO Class 5 air quality must be documented (e.g., by the manufacturer), and internal procedures must be developed to ensure that adequate recovery time is allowed after opening and closing the RABS, both before and during compounding operations.	
48. Are transfer chamber recovery time procedures in place to ensure ISO 5 is achieved before and during compounding?				**USP <797> 4.2.3 Types of PECs and placement** **Placement of RABS** When a RABS is used, the recovery time after opening the transfer chamber to achieve ISO Class 5 air quality must be documented (e.g., by the manufacturer), and internal procedures must be developed to ensure that adequate recovery time is allowed after opening and	

				closing the RABS, both before and during compounding operations.	
49. If used to prepare Category 2 or Category 3 CSPs is the pharmaceutical isolator placed in an ISO Class 8 or better room and are dynamic airflow smoke studies performed as required?				**USP <797> 4.2.3 Types of PECs and placement** **Placement of Pharmaceutical Isolators** If the pharmaceutical isolator is used to prepare Category 2 or Category 3 CSPs, the pharmaceutical isolator must be placed in an ISO Class 8 or better room. If a robotic enclosure is used as the PEC, or placed within the PEC, a dynamic airflow smoke pattern test must be performed initially and at least every 6 months thereafter to ensure that 1) it is properly integrated into the facility, 2) there is no turbulence or refluxing at any critical site(s), 3) room air does not enter the PEC where sterile products and/or preparations may be exposed, and 4) all processes can be performed without introducing contamination to the DCA(s).	
50. Do ISO class 7 rooms meet air supply requirements?				**USP <797> 4.2.4 Air exchange requirements** A minimum of 30 total HEPA-filtered ACPH must be supplied to ISO Class 7 rooms: --The total HEPA-filtered air change rate must be adequate to maintain ISO Class 7 during dynamic operating conditions considering the factors listed above --At least 15 ACPH of the total air change rate in a room must come from the HVAC through HEPA filters located in the ceiling --The HEPA-filtered air from the PEC, when added to the HVAC- supplied HEPA-filtered air, must increase the total HEPA-filtered ACPH to at least 30 ACPH --If the PEC is used to meet the minimum total ACPH requirements, the PEC must not be turned off except for maintenance --Rooms where activity levels are high may require more HEPA-filtered ACPH to maintain ISO Class 7 air quality under dynamic operating conditions --The ACPH from HVAC, ACPH contributed from the PEC, and the total ACPH must be documented on the certification report	
51. Do ISO class 8 rooms meet air supply requirements?				**USP <797> 4.2.4 Air exchange requirements** A minimum of 20 total HEPA-filtered ACPH must be supplied to ISO Class 8 rooms: --The total HEPA-filtered air change rate must be	

				adequate to maintain ISO Class 8 under dynamic operating conditions considering the factors listed above --At least 15 ACPH of the total air change rate in a room must come from the HVAC through HEPA filters located in the ceiling --Rooms where activity levels are high may require more HEPA- filtered ACPH to maintain ISO Class 8 air quality under dynamic operating conditions --The total ACPH must be documented on the certification report	
52. Is the pressure differential between the anteroom and the unclassified areas at least 0.020-inch water column?				**USP <797> 4.2.5 Establishing and maintaining pressure differentials** The pressure differential between the anteroom and the Unclassified area must not be less than 0.020-inchwater column.	
53. Are pressure differential monitoring device continuously monitored?				**USP <797> 4.2.5 Establishing and maintaining pressure differentials** Where pressure differentials are required, a pressure differential monitoring device must be used to continuously monitor the pressure differentials.	
54. Are results from the pressure monitoring device reviewed and documented at least daily on days when compounding occurs?				**USP <797> 4.2.5 Establishing and maintaining pressure differentials** The quantitative results from the pressure monitoring device must be reviewed and documented at least daily on the days when compounding is occurring.	
55. When preparing Category 2 or Category 3 CSPs from nonsterile components are presterilization requirements met?				**USP <797> 4.2.6 Facilities preparing Category 2 or Category 3 CSPs from nonsterile starting components** If preparing Category 2 or Category 3 CSP from nonsterile component(s), presterilization procedures, such as weighing and mixing, must be completed in an ISO Class 8 or better environment (e.g., anteroom or buffer room). Presterilization procedures must be performed in single-use containment glove bags, containment ventilated enclosures (CVEs), BSCs, or CACIs to minimize the risk of airborne contamination. CVEs, BSCs, or CACIs used for presterilization procedures must be certified at least every 6 months. Presterilization procedures must not adversely affect the required air quality of the SEC as demonstrated during certification under dynamic operating conditions.	
56. Is the cleanroom suite appropriately constructed to facilitate cleaning and				**USP <797> 4.3.1 Cleanroom suite** The surfaces of ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and	

minimize spaces where contaminants can accumulate?				cabinets in the classified area must be smooth, impervious, free from cracks and crevices, and non-shedding so they can be cleaned and disinfected and to minimize spaces in which microorganisms and other contaminants can accumulate. Junctures between the ceiling and the walls and between the walls and the floor must be sealed to eliminate cracks and crevices where dirt can accumulate. If ceilings consist of inlaid panels, the panels must be caulked around each panel to seal them to the support frame. Walls must be constructed of, or may be covered with, durable material (e.g., epoxy painted walls or heavy-gauge polymer) and the integrity of the surface must be maintained. Panels must be joined together and sealed to each other and the support structure. Floors must include coving to the sidewall, or the juncture between the floor and the wall must be caulked. If overhangs or ledges are present, they must be easily cleanable. The exterior lens surface of ceiling light fixtures must be smooth, mounted flush, and sealed. Any other penetrations through the ceiling or walls must be sealed.	
57. Is the SCA and the surfaces within the SCA clean, uncluttered, and dedicated to compounding?				**USP <797> 4.3.2 SCA** The SCA and all surfaces (e.g., walls, floors, counters, and equipment) in the SCA must be clean, uncluttered, and dedicated to compounding. If overhangs or ledges are present, they must be easily cleanable.	
58. Are compounding facilities designed and maintained so that activities such as hand hygiene and garbing do not adversely affect PEC function?				**USP <797> 4.4 Water Sources** The facility where CSPs are prepared must be designed so that activities such as hand hygiene and garbing will not adversely affect the ability of the PEC to function as designed. Sinks should be hands-free use. Surfaces of the sink(s) must be cleaned and disinfected each day of use, and a sporicidal disinfectant must be applied at least monthly (see *7.1 Agents and Supplies for Cleaning, Disinfecting, and Applying Sporicidal Disinfectants*).	
59. Are water sources appropriately placed?				**USP <797> 4.4 Water Sources** In facilities with a cleanroom suite, the sink used for hand hygiene may be placed either inside or outside of the anteroom. If the sink is located outside of the anteroom, it must be located in a clean space to minimize the risk of bringing contaminants into the anteroom. If the sink is located inside the anteroom, it	

				may be placed on either the clean side or the dirty side of the anteroom. [NOTE—The order of hand washing and garbing depends on the placement of the sink (see 3.2 Hand Hygiene and 3.3 Garbing Requirements)]. The buffer room must not contain plumbed water sources [e.g., sink(s), eyewash(es), shower(s), or floor drain(s)]. The anteroom must not contain floor drain(s). In a facility with an SCA design, a hand-washing sink must be placed not closer than 1 m to the PEC and may be either inside the SCA or in close proximity to the SCA.	
60. Are items other than furniture, equipment, and other materials necessary for performing compounding activities cleanable and installed not to impact air quality?				**USP <797> 4.5 Placement and Movement of Materials** Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in a classified area or SCA, and they should be low-shedding and easily cleaned and disinfected. Their number, design, location, and manner of installation must not impact environmental air quality and must promote effective cleaning and disinfecting.	
61. Are shipping cartons, corrugated cardboard, or uncoated cardboard prohibited in classified areas or SCAs?				**USP <797> 4.5 Placement and Movement of Materials** No shipping carton(s) or other corrugated or uncoated cardboard are allowed in a classified area or SCA.	
62. Are transport carts appropriately constructed to facilitate cleaning?				**USP <797> 4.5 Placement and Movement of Materials** Carts used to transport components or equipment into classified areas must be constructed from nonporous materials with cleanable casters and wheels to promote mobility and ensure ease of cleaning and disinfection. In a cleanroom suite, carts must not be moved from the dirty side to the clean side of the anteroom unless the entire cart, including casters, is cleaned and disinfected.	
63. Is proper placement of equipment in the PEC verified by a dynamic airflow smoke pattern test initially and when equipment is moved?				**USP <797> 4.5 Placement and Movement of Materials** Only equipment necessary for performing compounding activities is permitted in the PEC. Proper placement of equipment in a PEC must be initially verified by a dynamic airflow smoke pattern test to demonstrate minimal disruption in airflow. The dynamic airflow smoke pattern test must be repeated if equipment is placed in a different location.	
64. Do items used in a classified area or SCA remain in place except for				**USP <797> 4.5 Placement and Movement of Materials**	

maintenance?				Equipment and other items used in a classified area or SCA should not be removed except for calibration, servicing, cleaning, or other activities associated with maintenance. If removed, these items must be cleaned and wiped with sterile 70% IPA or a suitable disinfectant before they are returned to the classified area or the SCA.	
65. Are materials exposed in patient care and treatment areas prohibited from entry into anterooms, buffer rooms, or SCAs unless thoroughly cleaned and disinfected?				**USP <797> 4.5 Placement and Movement of Materials** Materials necessary for performing compounding activities that have been exposed in patient care and treatment areas must not enter anterooms, buffer rooms, or segregated compounding areas unless thoroughly cleaned and disinfected.	
Certification and Recertification					
66. Do certifications of classified areas and PECs meet all requirements?				**USP <797> 5. Certification and Recertification** Certification of the classified areas including the PEC must be performed initially, and recertification must be performed at least every 6 months and must include: • Airflow testing: Airflow testing is performed to determine acceptability of the air velocity, the room air exchange rate, and the room pressure differential in doorways between adjacent rooms to ensure consistent airflow and that the appropriate quality of air is maintained under dynamic operating conditions. The ACPH from HVAC, ACPH contributed from the PEC, and the total ACPH must be documented on the certification report. • HEPA filter integrity testing: HEPA filters must be leak tested at the factory and then leak tested again after installation and as part of recertification. • Total particle count testing: (See 5.1 Total Airborne Particle Sampling.) Total particle count testing must be performed under dynamic operating conditions using calibrated electronic equipment. • Dynamic airflow smoke pattern test: Smoke pattern tests must be performed for each PEC during dynamic operating conditions to demonstrate unidirectional airflow and sweeping action over and away from the preparation(s).	
67. Are classified areas recertified				**USP <797> 5. Certification and Recertification** Classified areas additionally must be recertified if there	

following changes to the classified areas or PECs?				are changes to the area such as redesign, construction, replacement or relocation of any PEC, or alteration in the configuration of the room that could affect airflow or air quality.	
68. Are certification and recertification records reviewed by the designated person(s)?				**USP <797> 5. Certification and Recertification** All certification and recertification records must be reviewed by the designated person(s) to ensure that the classified environments meet the minimum requirements in this chapter.	
69. Is the number of personnel present in each PEC and SEC documented for total particle-count and dynamic airflow smoke-pattern tests?				**USP <797> 5. Certification and Recertification** The number of personnel present in each PEC and SEC during total particle-count tests and dynamic airflow smoke-pattern tests must be documented. Records must be maintained in accordance with the requirements in *20. Documentation*.	
70. Is a corrective action plan implemented and documented if out- of-range results occur?				**USP <797> 5. Certification and Recertification** A corrective action plan must be implemented and documented in response to any out-of-range results. Data collected in response to corrective actions must be reviewed to confirm that the actions taken have been effective.	
71. Do SOPs describe particle sampling sites and procedures?				**USP <797> 5.1 Total Airborne Particle Sampling** Total airborne particle sampling sites must be selected in all classified areas. Measurements of total airborne particles must be taken in each PEC at locations where there is greatest risk to the exposed CSPs, containers, and closures. All sampling sites and procedures must be described in the facility's SOPs.	
72. If action levels of air samples are exceeded is the cause investigated, and corrective actions taken and documented.				**USP <797> 5.1 Total Airborne Particle Sampling** Data evaluation and action levels: If levels measured during the total air sampling program exceed the criteria in *Table 4* for the ISO classification of the area sampled, the cause must be investigated and corrective action taken and documented. Data collected in response to corrective actions must be reviewed to confirm that the actions taken have been effective. Some examples of corrective action include process or facility improvements or HEPA filter replacement or repair. The extent of the investigation should be consistent with the deviation and should include an evaluation of trends.	
Microbiological Air and Surface Monitoring					
73. Is sampling data reviewed for trends in				**USP <797> 6.1 General Monitoring Requirements**	

conjunction with personnel data?				Regular review of the sampling data must be performed to detect trends, and the results of the review must be documented. In addition, results from microbiological air and surface sampling must be reviewed in conjunction with personnel data (i.e., training records, visual observations, competency assessments) to assess the state of control and to identify potential risks of contamination.	
74. Is corrective action taken and resulting data reviewed in response to adverse findings?				**USP <797> 6.1 General Monitoring Requirements** Corrective action in response to any adverse findings is required to maintain the necessary environmental quality for preparation of CSPs. Data must also be reviewed following corrective actions to confirm that the actions taken have been effective in achieving the required microbiological air and surface quality levels (see *Table 4*, *Table 7*, and *Table 8*).	
75. Is microbiological air and surface monitoring performed initially and at minimum frequencies as described in the facility's SOPs?				**USP <797> 6.1 General Monitoring Requirements** Microbiological air and surface monitoring must be performed initially for sterile compounding facilities to establish a baseline level of environmental quality. After initial sampling, the environment in which sterile compounding activities are performed must be monitored according to the minimum frequencies described in this section to ensure that the environment remains suitable for sterile compounding. Microbiological air and/or surface monitoring must be conducted in all classified areas during dynamic operating conditions to confirm that the required environmental quality is maintained. In addition to the specific sampling frequencies described in this section, sampling must be performed in the following circumstances: • In conjunction with the certification of new facilities and equipment • After any servicing of facilities or equipment (see 4. Facilities and Engineering Controls) • In response to identified problems (e.g., positive growth in sterility tests of CSPs) • In response to identified trends (e.g., repeated positive gloved fingertip and thumb sampling results, failed media fill testing, or repeated observations of air or surface contamination) In response to changes that could impact the sterile compounding environment (e.g., change in cleaning	

				agents) The microbiological air and surface monitoring program must be clearly described in the facility's SOPs, which must include a diagram of the sampling locations, procedures for collecting samples, frequency of sampling, size of samples (e.g., surface area, volume of air), time of day of sampling in relation to activities in the compounding area, and action levels that will trigger corrective action. To obtain air and surface samples that are representative of the typical compounding conditions at the facility, in all PECs and classified rooms, air sampling must be conducted during dynamic operating conditions and surface sampling should be performed at the end of a compounding activity or shift but before the area has been cleaned and disinfected. The monitoring program must be designed and conducted in a manner that minimizes the chance that the sampling itself will contribute to contamination of the CSP or the environment. All impaction air samplers must be serviced and calibrated as recommended by the manufacturer.	
76. Is viable air sampling of all classified areas conducted at required frequencies under dynamic conditions?				**USP <797> 6.2.1 Viable air sampling—timing and locations** Volumetric active air sampling of all classified areas using an impaction air sampler must be conducted in each classified area [e.g., ISO Class 5 PEC and ISO Class 7 and 8 room(s)] during dynamic operating conditions. For entities compounding Category 1 and Category 2 CSPs, this must be completed at least every 6 months. For entities compounding any Category 3 CSPs, this must be completed within 30 days prior to the commencement of any Category 3 compounding and at least monthly thereafter regardless of the frequency of compounding Category 3 CSPs. Air sampling sites must be selected in all classified areas.	
77. Does air sampling media support growth, meet requirements, and are temperatures monitored during incubation with results documented per facility SOPs?				**USP <797> 6.2.2 Viable air sampling procedures** When conducting sampling of the PEC, care should be taken to avoid disturbing unidirectional airflow. See *Box 5* for active air sampling procedures. A general microbiological growth media that supports the growth of bacteria and fungi must be used (e.g., TSA). COAs from the manufacturer must verify that the sampling media devices meet the expected growth promotion,	

<table>
<tr><td></td><td></td><td></td><td></td><td>pH, and sterilization requirements. The incubator temperature must be monitored during incubation, either manually or by a continuous recording device, and the results must be reviewed and documented as described in the facility's SOPs. The incubator must be placed in a location outside of the sterile compounding area.</td><td></td></tr>
<tr><td>78. If a viable air sample exceeds an action level is the cause investigated, and corrective action taken?</td><td></td><td></td><td></td><td>USP <797> 6.2.3 Viable air sampling data evaluation and action levels
Table 7> Action Levels for Viable Airborne Particle Air Sampling
<table><tr><td>ISO Class</td><td>Air Sampling Action Levels</td></tr><tr><td>5</td><td>>1</td></tr><tr><td>7</td><td>>10</td></tr><tr><td>8</td><td>>100</td></tr></table>If levels measured during the viable air monitoring program exceed the levels in Table 7 for the ISO classification levels of the area sampled, the cause must be investigated, and corrective action must be taken.</td><td></td></tr>
<tr><td>79. Are surface sampling sites and procedures described in the facility's SOPs?</td><td></td><td></td><td></td><td>USP <797> 6.3 Monitoring Surfaces for Viable Particles
All sampling sites and procedures must be described in the facilities SOP's</td><td></td></tr>
<tr><td>80. Are all classified areas and connecting pass-throughs sampled for microbial contamination at the required frequencies</td><td></td><td></td><td></td><td><797> 6.3.1 Surface sampling—timing and locations
Each classified area, including each room and the interior of each ISO Class 5 PEC and pass-through chambers connecting to classified areas, must be sampled for microbial contamination using a risk-based approach. For entities compounding Category 1 and Category 2 CSPs, surface sampling of all classified areas, and pass-through chambers connecting to classified areas, must be conducted at least monthly (see Microbiological Control and Monitoring of Aseptic Processing Environments ⟨1116⟩). For entities compounding any Category 3 CSPs, surface sampling of all classified areas, and pass-through chambers connecting to classified areas, must be completed prior to assigning a BUD longer than the limits established in Table 13, and at least weekly (see ⟨1116⟩) on a regularly scheduled basis regardless of the frequency of compounding Category 3 CSPs. Additionally, surface sampling must be conducted within the PEC used to</td><td></td></tr>
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				prepare Category 3 CSPs, at the end of each batch before cleaning and disinfection occurs, unless a self-enclosed robotic device is used. When a self-enclosed robotic device is used as the PEC to prepare Category 3 CSPs, surface sampling must be conducted at least once daily at the end of compounding operations, before cleaning and disinfection occurs, unless a self-enclosed robotic device is used. When a self-enclosed robotic device is used as the PEC to prepare Category 3 CSPs, surface sampling must be conducted at least once daily at the end of compounding operations, before cleaning and disinfection occurs. facility's SOPs	
81. Does surface sampling media support growth, meet requirements, and are temperatures monitored during incubation with results documented per facility SOPs?				**USP <797> 6.3.2 Surface sampling procedures** Surface sampling media devices (e.g., plates, paddles, or slides) containing microbial growth media must be used for sampling flat surfaces. COAs from the manufacturer must verify that the sampling media devices meet the expected growth promotion, pH, and sterilization requirements. Surface sampling media devices must contain general microbial growth media (e.g., TSA) supplemented with neutralizing additives (e.g., lecithin and polysorbate 80) to neutralize the effects of any residual disinfecting agents. Surface sampling media devices must have a raised convex surface. After sampling, the sampled area must be thoroughly cleaned and disinfected (see *7. Cleaning, Disinfecting, and Applying Sporicidal Disinfectants and Sterile 70% IPA*). The incubator temperature must be monitored during incubation, either manually or by a continuous recording device, and the results must be reviewed and documented. The incubator must be placed in a location outside of the sterile compounding area.	
82. Are results of surface sampling evaluated and corrective action taken when required?				**USP <797> 6.3.3 Surface sampling data evaluation and action levels** If two sampling media devices are collected at a single location, all recovered growth on each must be documented and action levels applied to each sampling media device separately. If levels measured during surface sampling exceed the levels in *Table 8*, an attempt must be made to identify any microorganism recovered to the genus level (see ⟨1113⟩) with the assistance of a microbiologist. Data collected in response to corrective actions must be reviewed to	

				confirm that the actions taken have been effective. The corrective action plan must be dependent on the cfu count and the microorganism recovered. The corrective action plan must be documented.	
Cleaning, Disinfecting, and Applying Sporicidal Disinfectants and Sterile 70% IPA					
83. Is sIPA 70% applied to surfaces of a PEC as required?				**USP <797> 7. Cleaning, Disinfecting, and Applying Sporicidal Disinfectants and Sterile 70% IPA** Additionally, in a PEC, sterile 70% IPA must be applied after cleaning and disinfecting, or after the application of a one-step disinfectant cleaner or sporicidal disinfectant, to remove any residue. Sterile 70% IPA must also be applied immediately before initiating compounding. During the compounding process sterile 70% IPA must be applied to the horizontal work surface, including any removable work trays, of the PEC at least every 30 min if the compounding process takes 30 min or less. If the compounding process takes more than 30 min, compounding must not be disrupted, and the work surface of the PEC must be disinfected immediately after compounding.	
84. Are surfaces of a PEC cleaned prior to being disinfected or cleaned using an EPA-registered one-step disinfectant cleaner?				**USP <797> 7. Cleaning, Disinfecting, and Applying Sporicidal Disinfectants and Sterile 70% IPA** Surfaces must be cleaned prior to being disinfected with an EPA- registered disinfectant (or equivalent for entities outside the US) unless an EPA-registered (or equivalent for entities outside the US) one-step disinfectant cleaner is used to accomplish both the cleaning and disinfection in one step.	
85. Are personnel performing cleaning and disinfecting activities trained to wear appropriate garb, and use facility approved agents as described in written SOPs?				**USP <797> 7. Cleaning, Disinfecting, and Applying Sporicidal Disinfectants and Sterile 70% IPA** All cleaning and disinfecting activities must be performed by trained and appropriately garbed personnel using facility- approved agents and procedures, which must be described in written SOPs. Personnel must be trained if there are any changes in the cleaning and disinfecting procedures. The frequency, method(s), and location(s) of cleaning, disinfecting, and applying sporicidal disinfectants must be established in written SOPs, in accordance with the manufacturer’s instructions and must be followed by all cleaning personnel.	
86. Are cleaners, disinfectants, and sporicidal agents applied according to the				**USP <797> 7. Cleaning, Disinfecting, and Applying Sporicidal Disinfectants and Sterile 70% IPA**	

facility's SOPs?				Cleaning must be performed in the direction of clean to dirty areas. The same floor mop may be used in both the buffer and anteroom, but only in that order. The frequency, method(s), and location(s) of cleaning, disinfecting, and applying sporicidal disinfectants must be established in written SOPs, in accordance with the manufacturer's instructions and must be followed by all cleaning personnel. The manufacturer's directions or published data for the minimum contact time must be followed for each of the cleaning, disinfecting, and sporicidal disinfectants used. When sterile 70% IPA is used, it must be allowed to dry. All cleaning, disinfecting, and application of sporicidal disinfectants must be documented according to the facility's SOPs.	
87. Are cleaning and disinfecting agents allowed proper dwell time?				**USP <797> 7.1 Agents and Supplies for Cleaning, Disinfecting, and Applying Sporicidal Disinfectants 7.1.1 Agents** Considerations when selecting and using disinfectants include their antimicrobial activity, inactivation by organic matter, residue, shelf life, preparation requirements of the agent, and suitability for surfaces being disinfected. After the disinfectant or sporicidal disinfectant is applied to the surface, the agent must be allowed to dwell for the minimum contact time specified by the manufacturer**.**	
88. Are all agents used within a PEC sterile?				**USP <797> 7.1 Agents and Supplies for Cleaning, Disinfecting, and Applying Sporicidal Disinfectants 7.1.1 Agents** Cleaning, disinfecting and sporicidal agents used within the PEC must be sterile. When diluting concentrated cleaning and disinfecting agents for use in the PEC, sterile water must be used.	
89. Are all cleaning and disinfecting supplies low lint and are disposable supplies discarded after cleaning activity?				**USP <797> 7.1 Agents and Supplies for Cleaning, Disinfecting, and Applying Sporicidal Disinfectants 7.1.2 Supplies** All cleaning and disinfecting supplies (e.g., wipers, sponges, pads, and mop heads) with the exception of tool handles and holders must be low lint. If disposable cleaning supplies are used, they must be discarded after each cleaning activity.	
90. Do reusable cleaning tools remain in the classified area or SCA and are tools				**USP <797> 7.1 Agents and Supplies for Cleaning, Disinfecting, and Applying Sporicidal Disinfectants**	

cleaned and disinfected before and after each use?				**7.1.2 Supplies** Reusable cleaning tools must be made of cleanable materials (e.g., handles should not be made of wood or any other porous material) and must be cleaned and disinfected before and after each use. Reusable cleaning tools must be dedicated for use in the classified areas or SCA and must not be removed from these areas except for disposal. Cleaning supplies used in the classified areas and SCAs must be disposed of in a manner that minimizes the potential for dispersing contaminants into the air (e.g., with minimal agitation, away from work surfaces).	
91. Is the PEC interior cleaned and disinfected at the minimum frequencies following required procedures?				**USP <797> 7.2 Procedures for Cleaning, Disinfecting, and Applying Sporicidal Disinfectants and Sterile 70% IPA in the PEC** Clean, disinfect, and apply a sporicidal disinfectant to equipment and all interior surfaces in the PEC at the minimum frequencies specified in Table 10. See Box 7 and Box 8 for procedures for cleaning, disinfecting, and applying a sporicidal disinfectant in the PEC.	
Introducing Items into the SEC and PEC					
92. Are all items wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sIPA 70% prior being introduced into the clean side of an anteroom, placed in a pass-through, or brought into the SCA?				**USP <797> 8.1 Introducing Items into the SEC** Before any item is introduced into the clean side of anteroom(s), placed into pass-through chamber(s), or brought into the SCA, providing that packaging integrity will not be compromised, it must be wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% IPA using low-lint wipers by personnel wearing gloves. If an EPA-registered disinfectant or sporicidal disinfectant is used, the agent must be allowed to dwell for the minimum contact time specified by the manufacturer. If sterile 70% IPA is used, it must be allowed to dry. The wiping procedure should not compromise the packaging integrity or render the product label unreadable.	
93. Are items wiped with sIPA 70% prior to introduction into the PEC?				**USP <797> 8.2 Introducing Items into the PEC** Just before any item is introduced into the PEC, it must be wiped with sterile 70% IPA using sterile low-lint wipers and allowed to dry before use. When sterile items are received in sealed containers designed to keep them sterile until opening, the sterile items may be removed from the covering as the supplies are introduced into the ISO Class 5 PEC without the need to	

				wipe the individual sterile supply items with sterile 70% IPA. The wiping procedure must not render the product label unreadable.	
94. Are critical sites wiped with sIPA 70% to remove contaminants and allowed to dry prior to use in the PEC?				**USP <797> 8.3 Use of Sterile 70% IPA on Critical Sites within the PEC** Critical sites (e.g., vial stoppers, ampule necks, and intravenous bag septums) must be wiped with sterile 70% IPA in the PEC to provide both chemical and mechanical actions to remove contaminants. The sterile 70% IPA must be allowed to dry before personnel enter or puncture stoppers and septums or break the necks of ampules.	
Equipment, Supplies, and Components					
95. Are SOPs for equipment use, cleaning, and maintenance followed?				**USP <797> 9.1 Equipment** Equipment that must be brought into classified areas must be wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% IPA using low-lint wipers. Equipment must be placed in a manner that facilitates sterile compounding operations. The equipment must be capable of operating properly and within required performance parameters. Compounding personnel must follow established SOPs for the calibration, maintenance, cleaning, and use of the equipment based on the manufacturer's recommendations. Personnel must maintain records from equipment calibration, verification, and maintenance in accordance with the requirements i**n *20 Documentation*.**	
96. When using ACDs or similar equipment, do personnel conduct and document accuracy assessments on days the equipment is used?				**USP <797> 9.1 Equipment** Before using ACDs or other similar equipment, compounding personnel must conduct an accuracy assessment before the first use and again each day the equipment is used to compound CSPs. The precision of the equipment can be monitored based on an assessment of day-to-day variations in its accuracy measures. Compounding personnel must maintain a daily record of the accuracy measurements on the days the equipment is in use. Corrective actions must be implemented if accuracy measurements are outside the manufacturer's specification.	
97. Are components that could generate airborne particles evaluated to determine if manipulations must be performed in a PEC				**USP <797> 9.1 Equipment** Weighing, measuring, or otherwise manipulating components that could generate airborne chemical	

or other closed system processing device in accordance with facility SOPs?				particles (e.g., active pharmaceutical ingredients [APIs], added substances, conventionally manufactured products) must be evaluated to determine if these activities must be performed in a PEC or other closed system processing device (e.g., single use containment glove bag) to reduce the potential exposure to personnel or contamination of the facility or CSPs (See *4.2.6 Facilities preparing Category 2 or Category 3 CSPs from nonsterile starting component(s)*). The process evaluation must be carried out in accordance with the facility's SOPs and the assessment must be documented.	
98. Are supplies that come into direct contact with CSPs sterile and depyrogenated?				**USP <797> 9.1 Equipment** Supplies (e.g., beakers, utensils, needles, syringes, filters, and tubing sets) should be of suitable composition such that the surfaces that contact components are not reactive or sorptive. Supplies in direct contact with the CSP must be sterile and depyrogenated.	
99. Do personnel follow facility SOPs which address CSP component selection, receipt, handling, and storage?				**USP <797> 9.3 Components** Compounding personnel must follow the facility's SOPs, which must address the selection, receipt, evaluation, handling, storage, and documentation of all CSP components, including all ingredients and container closures.	
100. Do all APIs and components other than APIs used to prepare CSPs meet minimum quality standards? facility's SOPs.				**USP <797> 9.3.1 Component selection** When APIs are used: --Must comply with the criteria in the USP–NF monograph, if one exists --Must have a COA that includes the specifications (e.g., compendial requirements for quality) and that test results for the component show that the API meets expected quality --In the United States, must be manufactured by an FDA- registered facility --Outside of the United States, must comply with the laws and regulations of the applicable regulatory jurisdiction For all components other than APIs: --Must comply with the criteria in the USP–NF monograph, if one exists --Must be accompanied by documentation (e.g., COA, labeling) that includes the specifications, and test results and shows that the component meets the	

				specifications: --In the US, should be manufactured by an FDA-registered facility --If a component cannot be obtained from an FDA-registered facility, the designated person(s) must select an acceptable and reliable source (see Good Distribution Practices for Bulk Pharmaceutical Excipients ⟨1197⟩). --The compounding facility must establish the identity, strength, purity, and quality of the ingredients obtained from that supplier by reasonable means. Reasonable means may include but are not limited to visual inspections, evaluation of a COA supplied by the manufacturer, and/or verification by analytically testing a sample to determine conformance with the COA or other specifications. Outside of the US, must comply with the laws and regulations of the applicable regulatory jurisdiction All APIs and other components used must be evaluated for suitability for use in sterile drug preparation. Components labeled with “not for pharmaceutical use”, “not for injectable use”, “not for human use” or an equivalent statement must not be used to compound for these purposes.	
101. Is documentation available for sterilization and depyrogenation of containers and closures? monthly for entities compounding Category 1 CSPs				**USP <797> 9.3.1 Component selection** Each lot of commercially available sterile, depyrogenated containers and container closure systems must be accompanied by a COA or other documentation showing conformance with established specifications (i.e., sterility and depyrogenation requirements). If sterilization and depyrogenation of supplies or container closure systems are performed on site, the efficacy of each process must be established and documented (see *Sterilization of Compendial Articles* ⟨1229⟩).	
102. Are external packaging, labeling and condition of components examined upon receipt and are components rejected if unacceptable quality?				**USP <797> 9.3.2 Component receipt** Upon receipt of each lot of a component, the external packaging must be examined for evidence of deterioration and other aspects of unacceptable quality. Facility personnel must verify the labeling and condition of the component [e.g., whether the outer packaging is damaged and whether temperature-sensing indicators show that the component has been exposed to excessive temperature(s)]. Any component found to be	

				of unacceptable quality must be promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal. Any other lots of that component from that vendor must be examined to determine whether other lots have the same defect.	
103. Are APIs which lack a manufacturer's expiration date marked with the date of receipt and assigned a conservative expiration date?				**USP <797> 9.3.2 Component receipt** The date of receipt by the compounding facility must be clearly marked on each API or added substance package that lacks a vendor expiration date. Packages of components (i.e., API and added substances) that lack a vendor's expiration date must be assigned a conservative expiration date, not to exceed 1 year after receipt by the compounding facility.	
104. Are components properly evaluated prior to use?				**USP <797> 9.3.3 Component evaluation before use** Compounding personnel must ascertain before use that components for CSPs are of the correct identity, appropriate quality, within expiry date and have been stored under appropriate conditions. All components must be reinspected before use. All packages must be reinspected to detect container breaks, looseness of the cap or closure, and deviation from the expected appearance, aroma, and/or texture of the contents that might have occurred during storage. Sterile container closures must be visually reinspected to ensure that they are free from defects that could compromise sterility and that they are otherwise suitable for their intended use. Any component found to be of unacceptable quality must be promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal. Any other lots of that component from that vendor must be examined to determine whether other lots have the same defect.	
105. Are components handled and stored as required?				**USP <797> 9.3.4 Component handling and storage** All components must be handled and stored in a manner that prevents contamination, mix-ups, and deterioration. Components must be stored in closed containers under temperature, humidity, and lighting conditions consistent with those indicated in official monographs or specified by the suppliers and/or manufacturers. Personnel must monitor temperature in the area(s) where components are stored either manually at least once daily on days that the facility is open or by a continuous temperature recording device	

				to determine whether the temperature remains within the appropriate range. The results of the temperature readings must be documented on a temperature log or stored in the continuous recording device and must be retrievable. All monitoring equipment must be calibrated or verified for accuracy as recommended by the manufacturer or every 12 months if not specified by the manufacturer.	
Sterilization and Depyrogenation					
106. Does the facility follow SOPs for sterilization and depyrogenation?				**USP <797> 10. Sterilization and Depyrogenation** Injectable compounded preparations that contain nonsterile components or that come into contact with nonsterile devices (e.g., containers, tubing) during any phase of the compounding procedure must be sterilized within 6 h after completing the preparation to minimize the generation of bacterial endotoxins in CSPs. A description of the terminal sterilization and depyrogenation process, including the temperature, pressure (if applicable), duration, permissible load conditions for each cycle, and the use of biological indicators and endotoxin challenge vials (ECVs) must be included in the facility's SOPs. SOPs must include training and competency of personnel on all sterilization methods and equipment used by the facility. In addition, the SOPs must include a schedule and method for establishing and verifying the effectiveness of the terminal sterilization and depyrogenation methods selected, as well as the methods for maintaining and cleaning the sterilizing and depyrogenation equipment.	
107. Does depyrogenation occur as described in the facility SOPs to render glassware, metal, and other thermostable containers and components pyrogen free to comply with requirements?				**USP <797> 10.1 Depyrogenation** Dry heat depyrogenation must be used to render glassware, metal, and other thermostable containers and components pyrogen free. The duration of the exposure period must include sufficient time for the items to reach the depyrogenation temperature. The items must remain at the depyrogenation temperature for the duration of the depyrogenation period. The effectiveness of the dry heat depyrogenation cycle must be established initially and verified annually using ECVs to demonstrate that the cycle is capable of achieving a ≥3-log reduction in endotoxins (see Bacterial Endotoxins Test ⟨85⟩). The effectiveness of the depyrogenation cycle must be re- established if there are changes to the	

				depyrogenation cycle described in SOPs (e.g., changes in load conditions, duration, or temperature). This verification must be documented. Items that are not thermostable must be depyrogenated by multiple rinses with sterile, nonpyrogenic water (e.g., *Sterile Water for Injection* or *Sterile Water for Irrigation*) and then thoroughly drained or dried immediately before use in compounding See *Depyrogenation by Rinsing* ⟨1228.4⟩.	
108. Does the designated person ensure appropriate sterilizing filters are used and tested to meet the requirements?				**USP <797> 10.2 Sterilization by Filtration** CSPs that were prepared using a filter that failed integrity tests must be discarded or, after investigating the cause of the failure and selection of an appropriate filter, refiltered for sterilization not more than one additional time.	
109. When filters fail integrity testing is the CSP discarded, or if appropriate is the CSP refiltered?				**USP <797> 10.2 Sterilization by Filtration** CSPs that were prepared using a filter that failed integrity tests must be discarded or, after investigating the cause of the failure and selection of an appropriate filter, refiltered for sterilization not more than one additional time.	
110. Does the process of steam sterilization meet all requirements?				**USP <797> 10.3 Sterilization by Steam Heat** To achieve sterility when steam sterilization is used, all materials must be directly exposed to steam under adequate pressure for the length of time necessary, as determined by use of appropriate biological indicators, to render the items sterile (e.g., 20−60 min at 121° saturated steam under a pressure of 15 psi, depending on the volume or size of the CSP being sterilized). The duration of the exposure period must include sufficient time for the entire contents of the CSP and other items to reach the sterilizing temperature. The CSP and other items must remain at the sterilizing temperature for the duration of the sterilization period. CSPs must be placed in the autoclave to allow steam to reach the CSPs without entrapment of air. Flat, stainless-steel trays with low sides or ventilated bottoms will permit steam contact. When preparing items that must be wrapped for steam sterilization, wrap them in low-lint protective fabric or paper or seal in envelopes that will permit steam penetration and are designed to minimize the risk of post-sterilization microbial contamination. For CSPs, immediately before filling containers that will be steam sterilized, solutions must be passed through a filter with	Click or tap here to enter text.

				a nominal pore size of not larger than 1.2 µm for removal of particulate matter. Sealed containers must be able to generate steam internally. Stoppered and crimped empty vials must contain a small amount of sterile water to generate steam.	
111. Is the effectiveness of steam sterilization verified and documented with each load using appropriate biological indicators?				**USP <797> 10.3 Sterilization by Steam Heat** The effectiveness of steam sterilization must be verified and documented with each sterilization run or load by using appropriate biological indicators, such as spores of *Geobacillus stearothermophilus* (ATCC12980, ATCC 7953, or equivalent; see *Biological Indicators for Sterilization* ⟨1229.5⟩), and other confirmation methods such as physicochemical indicators (see *Physicochemical Integrators and Indicators for Sterilization* ⟨1229.9⟩).	
112. Does steam heat sterilization follow the required processes and documentation?				**USP <797> 10.3 Sterilization by Steam Heat** The steam supplied must be generated using water per the manufacturer's recommendation. A calibrated data recorder or chart must be used to monitor each cycle and to examine for cycle irregularities (e.g., deviations in temperature or pressure). The date, run, and load numbers of the steam sterilizer used to sterilize a CSP must be documented in the CR.	
113. Does the process of dry heat sterilization meet all requirements?				**USP <797> 10.4 Sterilization by Dry Heat** The CSP and other items must remain at the sterilizing temperature for the duration of the sterilization period. Immediately before filling ampules and vials that will be sterilized by dry heat, CSP solutions must be passed through a filter with a nominal pore size of not larger than 1.2 µm for removal of particulate matter. Dry heat sterilization is usually performed in an oven designed for sterilization at 160° or higher. If lower temperatures are used, they must be shown to achieve effective sterilization (see ⟨1229.8⟩, Validation of Dry Heat Sterilization, Biological Indicators). Heated air must be evenly distributed throughout the chamber, which is typically accomplished by an air blower. The calibrated oven must be equipped with temperature controls and a timer. During sterilization, sufficient space must be left between materials to allow for circulation of the hot air. A calibrated data recorder or chart must be used to monitor each cycle and the data must be reviewed to identify cycle irregularities (e.g., deviations in temperature or exposure time).	

				The effectiveness of the dry heat sterilization method must be verified and documented with each sterilization run or load using appropriate biological indicators such as spores of *Bacillus atrophaeus* (ATCC 9372; see ⟨1229.5⟩) and other confirmation methods (e.g., temperature-sensing devices). The date, run, and load numbers of the dry heat oven used to sterilize a CSP must be documented in the CR.	
Master Formulation and Compounding Records					
114. Is an MFR created for CSPs prepared from nonsterile ingredients or prepared for more than one patient?				**USP <797> 11.1 Creating Master Formulation Records** A master formulation record (MFR) is a detailed record of procedures that describes how the CSP is to be prepared. An MFR must be created for all CSPs prepared from nonsterile ingredient(s) or CSPs prepared for more than one patient.	
115. Are all changes for MFRs approved and documented per facility SOPs?				**USP <797> 11.1 Creating Master Formulation Records** Any changes or alterations to the MFR must be approved and documented according to the facility's SOPs	
116. Do MFRs contain all required elements?				**USP <797> 11.1 Creating Master Formulation Records Box 9 Master Formulation Records** An MFR must include at least the following information: --Name, strength or activity, and dosage form of the CSP --Identities and amounts of all ingredients; if applicable, relevant characteristics of components (e.g., particle size, salt form, purity grade, solubility) --Type and size of container closure system(s) --Complete instructions for preparing the CSP, including equipment, supplies, a description of the compounding steps, and any special precautions --Physical description of the final CSP --BUD and storage requirements --Reference source to support the stability of the CSP --Quality control (QC) procedures (e.g., pH testing, filter integrity testing) --Other information as needed to describe the compounding process and ensure repeatability (e.g., adjusting pH and tonicity; sterilization method, such as steam, dry heat, irradiation, or filter)	

117. Is a CR created for all Category 1, Category 2, and Category 3 CSPs or immediate-use CSPs prepared for more than one patient?				**USP <797> 11.2 Creating Compounding Records** A CR must be created for all Category 1, Category2, and Category 3 CSPs. A CR must also be created for immediate-use CSPs prepared for more than one patient.	
118. Do CRs contain all required elements?				**USP <797> 11.2 Creating Compounding Records** **Box 10 Compounding Records** CRs must include at least the following information: --Name, strength or activity, and dosage form of the CSP --Date and time of preparation of the CSP --Assigned internal identification number (e.g., prescription, order, or lot number) --A method to identify the individuals involved in the compounding process and individuals verifying the final CSP --Name of each component --Vendor, lot number, and expiration date for each component for CSPs prepared for more than one patient and for CSPs prepared from nonsterile ingredient(s) --Weight or volume of each component --Strength or activity of each component --Total quantity compounded --Final yield (e.g., quantity, containers, number of units) --Assigned BUD and storage requirements --Results of QC procedures (e.g., visual inspection, filter integrity testing, pH testing) If applicable, the CR must also include: --MFR reference for the CSP --Calculations made to determine and verify quantities and/or concentrations of components	
Release Inspections and Testing					
119. Are all out-of-specification results investigated with a corrective action implemented and documented as the part of QA and QC program?				**USP <797> 12. Release Inspections and Testing** Any out-of-specification results must be investigated, and a corrective action plan must be implemented and documented as part of the quality assurance (QA) and QC program (see *18. Quality Assurance and Quality Control*).	
120. Are visual inspections of CSPs conducted for physical appearance, appropriate labeling, and container closure integrity?				**USP <797> 12.1 Visual Inspection** At the completion of compounding, before release and dispensing, the CSP must be visually inspected to determine whether the physical appearance of the CSP	

				is as expected (e.g., free of inappropriate visible particulates or other foreign matter, discoloration, or other defects). The CSP label must be visually inspected to confirm that the CSP and its labeling match the prescription or medication order. The inspection also must include a visual inspection of container closure integrity (e.g., checking for leakage, cracks in the container, or improper seals)	
121. Are CSPs inspected and approved for release or rejected and investigated if found to be of unacceptable quality according to facility SOPs?				**USP <797> 12.1 Visual Inspection** Any CSP found to be of unacceptable quality (e.g., observed defects) must be promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal. When a CSP will not be released or dispensed on the day of preparation, a visual inspection must be conducted immediately before it is released or dispensed to make sure that the CSP does not exhibit any defects such as precipitation, cloudiness, or leakage, which could develop during storage. Defects that indicate sterility or stability problems must be investigated to determine the cause according to the facility's SOPs (see *18. Quality Assurance and Quality Control*).	
122. Is sterility testing by approved methods conducted for Category 2 CSPs assigned a BUD that requires sterility testing and all Category 3 CSPs?				**USP <797> 12.2 Sterility Testing** For Category 2 CSPs assigned a BUD that requires sterility testing (see *Table 13*) and all Category 3 CSPs, the testing must be performed according to ⟨71⟩ or a validated alternative method (see ⟨1223⟩) that is noninferior to ⟨71⟩ testing. The maximum batch size for all CSPs requiring sterility testing must be limited to 250 final yield units. If the number of CSPs to be compounded in a single batch is less than the number of CSPs needed for testing as specified in ⟨71⟩*, Table 3*, additional units must be compounded to perform sterility testing as follows: • If 1–39 CSPs are compounded in a single batch, the sterility testing must be performed on a number of units equal to 10% of the number of CSPs prepared, rounded up to the next whole number. For example: o If 1 CSP is compounded, 10% of 1 rounded up to the next whole number would indicate that 1 additional CSP must be	

				prepared for sterility testing o If 39 CSPs are compounded, 10% of 39 rounded up to the next whole number would indicate that 4 additional CSPs must be prepared for sterility testing • If more than 40 CSPs are prepared in a single batch, the sample sizes specified in ⟨71⟩*, Table 3* must be used. If sterility testing is performed according to ⟨71⟩, the *Method Suitability Test* from that chapter must be performed to ensure that contamination can be recovered. If an alternative method is used for sterility testing, the method must be validated (see ⟨1223⟩) and demonstrated to be suitable for that CSP formulation.	
123. Are sterility test failures investigated, and corrective actions documented?				**USP <797> 12.2 Sterility Testing** Sterility tests resulting in failures must prompt an investigation into the possible causes and must include identification of the microorganism, as well as an evaluation of the sterility testing procedure, compounding facility, process, and/or personnel that may have contributed to the failure. The source(s) of the contamination, if identified, must be corrected, and the facility must determine whether the conditions causing the sterility failure affect other CSPs. The investigation and resulting corrective actions must be documented.	
124. Is endotoxin testing completed as required?				**USP<797> 12.3 Bacterial Endotoxins Testing** Category 2 injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility testing (see Table 13) and Category 3 injectable CSPs compounded from one or more nonsterile component(s) must be tested to ensure that they do not contain excessive bacterial endotoxins (see <85>). Category 2 injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that does not require sterility testing should be tested for bacterial endotoxins. In the absence of a bacterial endotoxin limit in an official USP–NF monograph or other CSP formula source, the CSP must not exceed the endotoxin limit calculated as described in <85>for the appropriate route of administration for humans. CSPs for nonhuman species must not exceed the endotoxin limit calculated as described in <85> based on the largest recommended dose and weight (or average weight for more than a single animal) of the	

				target animal species unless a different limit is scientifically supported.	
Labeling					
125. Are Category 1, Category 2, and Category 3 CSPs labeled to prevent errors during storage, dispensing, and use?				**USP <797> 13. Labeling** Category 1, Category2, and Category 3 CSPs must be labeled with appropriate, legible identifying information to prevent errors during storage, dispensing, and use. The term *labeling* designates all labels and other written, printed, or graphic matter on the immediate container or on or inside any package or wrapper in which it is enclosed, except any outer shipping container. The term *label* designates that part of the labeling that is on the immediate container. See *Labeling* ⟨7⟩.	
126. Do CSP labels on immediate containers contain all required elements?				**USP <797> 13. Labeling** The label on each immediate container of the CSP must, at a minimum, display prominently and legibly the following information: --Assigned internal identification number (e.g., barcode, prescription, order, or lot number) --Active ingredient(s) and their amount(s), activity(ies), or concentration(s) --Storage conditions if other than controlled room temperature --BUD --Dosage form --Total amount or volume if it is not obvious from the container --If it is a single-dose container, a statement stating such when space permits --If it is a multiple-dose container, a statement stating such The labeling on the CSP must display the following information, as applicable: --Route(s) of administration --Special handling instructions --Warning statements --Compounding facility name and contact information if the CSP is to be sent outside of the facility or healthcare system in which it was compounded	
Establishing Beyond-Use Dates					
127. Are all parameters that may affect quality considered when establishing a				**USP <797> 14.2 Parameters to Consider in Establishing a BUD** When establishing a BUD for a	

BUD?				CSP, compounders must consider parameters that may affect quality, including but not limited to: --Chemical and physical stability properties of the drug and/or its formulation --Materials of composition of the container closure system and compatibility of the container closure system with the final preparation (e.g., leachables, interactions, adsorption, and storage conditions)	
128. Are container closure systems appropriate to withstand frozen storage conditions when applicable?				**USP <797> 14.2.4 Storage conditions** If the CSP will be stored in a frozen state, the container closure system must be able to withstand the physical stress (i.e., without breaking or cracking) during storage in a freezer.	
129. Are frozen CSPs thawed and stored under appropriate conditions?				**USP <797> 14.2.4 Storage conditions** The CSP must be thawed in appropriate conditions to avoid compromising the physical and chemical stability of the preparation and its components (e.g., do not heat in a microwave). Once the CSP is thawed, the CSP must not be refrozen.	
130. If the storage conditions of a CSP change, is the BUD modified for the new storage conditions?				**USP <797> 14.2.4 Storage conditions** CSPs may be stored under different storage conditions before they are used (e.g., CSPs may first be frozen, then thawed in the refrigerator, and finally kept at controlled room temperature before administration).The storage time of a CSP must not exceed the original BUD placed on the CSP for its labeled storage condition, and BUDs must not be additive.	
131. Are assigned BUDs limited to the shortest expiration date or BUD of any component as appropriate?				**USP <797> 14.3 Establishing a BUD for a CSP** Additionally: --The BUD must not exceed the shortest remaining expiration date of any of the commercially available starting components. --For CSPs prepared from one or more compounded components, the BUD should generally not exceed the shortest BUD of any of the individual compounded components. However, there may be acceptable instances when the BUD of the final CSP exceeds the BUD assigned to compounded components (e.g., pH-altering solutions). If the assigned BUD of the final CSP exceeds the BUD of the compounded components, the physical, chemical, and microbiological quality of the final CSP must not be negatively impacted.	

132. Are Category 1 CSP BUDs established as required?				**USP <797> 14.3 Establishing a BUD for a CSP Table 12. BUD Limits for Category 1 CSPs** Storage Conditions: Controlled Room Temperature (20°–25°) -- ≤12 h Refrigerator (2°–8°) -- ≤24 h	
133. Are Category 2 CSP BUDs established as required?				**USP <797> 14.3 Establishing a BUD for a CSP Table 13. BUD Limits for Category 2 CSPs** Aseptically processed CSPs: -No Sterility Testing Performed/Passed --Prepared from one or more nonsterile starting component(s): Controlled room temperature 1 day; Refrigerator 4 days; Freezer 45 days --Prepared from only sterile starting components: Controlled room temperature 4 days, Refrigerator 10 days, Freezer 45 days -Sterility Testing Performed/Passed --Controlled room temperature 30 days; Refrigerator 45 days; Freezer 60 days Terminally sterilized CSPs: -No Sterility Testing Performed/Passed --Controlled room temperature 14 days; Refrigerator 28 days; Freezer 45 days -Sterility Testing Performed/Passed --Controlled room temperature 45 days; Refrigerator 60 days; Freezer 90 days	
134. Are assigned BUDs for Category 3 CSPs supported by stability data using a stability indicating method?				**USP <797> 14.4.3 Stability Requirements for Category 3 CSPs** The BUD assigned to a Category 3 CSP must be supported by stability data obtained using a stability-indicating analytical method that is able to distinguish the active ingredient from its degradants and impurities (e.g., by forced degradation studies) and quantify the amount of the active ingredient. • The Category 3 CSP must be prepared according to the exact formulation (API and other ingredients of identical grade and procedures) from which the stability data are derived. • The Category 3 CSP must be packaged and stored in a container closure of the same materials of composition as that used in the study. • The analytical method must be validated based on characteristics such as those	

				described in ⟨1225⟩. • The compounding facility must have documentation of the stability study, including a description of the methodology (e.g., number of samples taken, storage conditions), validation of the method, the stability-indicating analytical method, and all of the results of the study.	
135. Are Category 3 CSP BUDs established as required?				**USP <797> 14.4.4 Establishing a BUD for a CSP Table 14. BUD Limits for Category 3 CSPs** -Aseptically processed, sterility tested, and passing all applicable tests for Category 3 CSPs: CRT 60 days; Refrigerator 90 days; Freezer 120 days -Terminally sterilized, sterility tested, and passing all applicable tests for Category 3 CSPs: CRT 90 days; Refrigerator 120 days; Freezer 180 days	
136. Do multiple-dose CSPs pass antimicrobial effectiveness testing as required?				**USP <797> 14.5 Multiple-Dose CSPs** The use of preservatives must be appropriate for the CSP formulation and the route of administration. A multiple-dose CSP must be prepared as a Category 2 or Category 3 CSP. An aqueous multiple-dose CSP must additionally pass antimicrobial effectiveness testing in accordance with *Antimicrobial Effectiveness Testing* ⟨51⟩. Antimicrobial effectiveness testing may be performed on a low concentration and a high concentration of the active ingredient in the formulation to establish preservative effectiveness across various strengths of the same formulation (e.g., bracketing). The concentration of all other ingredients (including preservatives) must be the same throughout the bracketing study.	
137. Is the BUD of a punctured multiple-dose CSP limited to the shorter of the assigned BUD or 28 days if supported by antimicrobial testing results?				**USP <797> 14.5 Multiple-Dose CSPs** After a multiple-dose CSP container is initially entered or punctured, the multiple-dose container must not be used for longer than the assigned BUD or 28 days if supported by antimicrobial effectiveness testing results (see ⟨51⟩) on the CSP, whichever is shorter.	
138. Do container closure systems for multiple-dose CSPs conform to container closure integrity?				**USP <797> 14.5 Multiple-Dose CSPs** The container closure system used to package the multiple-dose CSP must be evaluated for and conform to container closure integrity (see ⟨1207⟩).	
139. Are multiple-dose, non-preserved,				**USP <797> 14.5 Multiple-Dose CSPs**	

aqueous topical, and topical ophthalmic CSPs prepared and assigned BUDs within allowed limitations?				**Multiple-dose, non-preserved, aqueous topical, and topical ophthalmic, CSPs** The beyond-use date of a multiple-dose, aqueous, non-preserved CSP intended for topical, including topical ophthalmic, administration may be assigned in accordance with 14.5 Multiple- Dose CSPs. However, unpreserved aqueous, topical, including topical ophthalmic, formulations, are at high risk of microbial proliferation if contaminated during preparation or use. To minimize the risk of patient harm, the requirement for passing antimicrobial effectiveness testing in accordance with ⟨51⟩ is not required only if the preparation is: -Prepared as a Category 2 or Category 3 CSP -For use by a single patient -Labeled (in the label or labeling) to indicate that once opened, it must be discarded after 24 h when stored at controlled room temperature and/or that once opened, it must be discarded after 72 hours when stored under refrigeration.	
Use of Conventionally Manufactured Products as Components					
140. Are punctured or opened conventionally manufactured single- dose containers used within allowed limitations?				**USP <797> 15.1 Use of Conventionally Manufactured Single- Dose Containers** If a single-dose vial is entered or punctured only in an ISO Class 5 or cleaner air, it may be used up to 12 h after initial entry or puncture as long as the labeled storage requirements during that 12-h period are maintained. Opened single-dose ampules must not be stored for any time period.	
141. Are punctured conventionally manufactured multiple-dose containers used within allowed limitations?				**USP <797> 15.2 Use of Conventionally Manufactured Multiple- Dose Containers** Once initially entering or puncturing the multiple-dose container, the multiple-dose container must not be used for more than 28 days (see ⟨51⟩) unless otherwise specified by the manufacturer on the labeling.	
142. Are pharmacy bulk packages used within allowed limitations?				**USP <797> 15.3 Use of Conventionally Manufactured Pharmacy Bulk Packages** The pharmacy bulk package must be used according to the manufacturer's labeling (see ⟨659⟩, *General Definitions, Injection Packaging Systems*). The pharmacy bulk package must be entered or punctured only in an ISO Class 5 PEC.	
Use of CSPs as Components					

143. Are multiple-dose compounded CSPs stored under the conditions on which the BUD is based?				**USP <797> 16.1 Use of Compounded Multiple-Dose CSPs** Multiple-dose CSPs must be stored under the conditions upon which its BUD is based (e.g., refrigerator or controlled room temperature). After a multiple-dose CSP is initially entered or punctured, the multiple-dose CSP must not be used for longer than the assigned BUD or 28 days, which ever is shorter. This time limit for entering or puncturing is not intended to restrict the BUD of the final CSP.	
144. If single-dose CSPs or CSP stock solutions are used as components in compounding additional CSPs, are the components entered or punctured in appropriate air classifications, with appropriate storage conditions and BUDs assigned?				**USP <797> 16.2 Use of Compounded Single-Dose CSPs and CSP Stock Solutions** When a compounded single-dose CSP or CSP stock solution is used as a component to compound additional CSPs, the original compounded single-dose CSP or CSP stock solution must be entered or punctured in ISO Class 5 or cleaner air and must be stored under the conditions upon which its BUD is based (e.g., refrigerator or controlled room temperature). The component CSP may be used for sterile compounding for up to 12 h or its assigned BUD, whichever is shorter, and any remainder must be discarded. This time limit for entering or puncturing is not intended to restrict the BUD of the final CSP.	
Standard Operating Procedures					
145. Do facilities develop SOPs under the direction of the designated person(s) for compounding processes and activities performed?				**USP <797> 17. SOPs** Facilities that prepare CSPs must develop SOPs for the compounding process and other support activities. SOPs must include the types of CSPs that are prepared (i.e., Category 1, Category 2, Category 3). A designated person(s) must ensure that SOPs are appropriate and are implemented, which includes ensuring that personnel demonstrate competency in performing every procedure that relates to their job function. A designated person(s) must follow up to ensure that corrective actions are taken if problems, deviations, failures, or errors are identified. The corrective action must be documented.	
146. Are all personnel who perform or oversee compounding or support activities trained in the SOPs?				**USP <797> 17. SOPs** All personnel who perform or oversee compounding or support activities must be trained in the SOPs. All compounding personnel must be trained to: --Recognize potential problems, deviations, failures, or	

				errors associated with preparing a CSP (e.g., those related to equipment, facilities, materials, personnel, the compounding process, or testing) that could potentially result in contamination or other adverse impact on CSP quality --Report any problems, deviations, failures, or errors to the designated person(s).	
147. Are SOPs reviewed and updated at appropriate intervals by the designated person(s)?				**USP <797> 17. SOPs** SOPs must be reviewed initially and at least every 12 months by the designated person(s) to ensure that they reflect current practices, and the review must be documented. Any changes or alterations to an SOP must be made only by a designated person(s) and must be documented. Revisions to SOPs must be communicated to all personnel involved in these processes and procedures, and personnel should document acknowledgment of the communication.	
Quality Assurance and Quality Control					
148. Does the facility have established and documented QA and QC programs which are detailed in the facility SOPs?				**USP <797> 18. Quality Assurance and Quality Control** A facility's QA and QC programs must be formally established and documented in the facility's SOPs that ensure that all aspects of the preparation of CSPs are conducted in accordance with the requirements in this chapter (⟨797⟩) and the laws and regulations of the applicable regulatory jurisdiction. Designated person(s) must ensure that the facility has formal, written QA and QC programs that establish a system of: 1. Adherence to procedures 2. Prevention and detection of errors and other quality problems 3. Evaluation of complaints and adverse events 4. Appropriate investigations and corrective actions	
149. Does the facility have notification and recall procedures in place for CSPs released prior to known testing results?				**USP <797> 18.1 Notification About and Recall of Out-of- Specification Dispensed CSPs** If a CSP is dispensed or administered before the results of release testing are known, the facility must have procedures in place to: --Immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (e.g., sterility, strength, purity, bacterial endotoxin, or other quality attributes)	

				--Recall any unused dispensed CSPs and quarantine any stock remaining in the pharmacy --Investigate if other lots are affected and recall if necessary.	
150. Does the facility have SOPs for recalling out-of-specification dispensed CSPs?				**USP <797> 18.1 Notification About and Recall of Out-of- Specification Dispensed CSPs** An SOP for recall of out-of-specification dispensed CSPs must contain: --Procedures to determine the severity of the problem and the urgency for implementation and completion of the recall --Procedures to determine the distribution of any affected CSP, including the date and quantity of distribution --Procedures to identify patients who have received the CSP --Procedures for disposal and documentation of the recalled CSP --Procedures to investigate and document the reason for failure	
151. Does the facility document and report recalls as required?				**USP <797> 18.1 Notification About and Recall of Out-of- Specification Dispensed CSPs** The sterile compounding facility must document the implementation of the recall procedures. The recall must be reported to appropriate regulatory bodies as required by laws and regulations of the applicable regulatory jurisdiction.	
152. Does the facility have SOPs, and a review and investigation process for handling complaints?				**USP <797> 18.2 Complaint Handling** Compounding facilities must develop and implement SOPs for handling complaints. Complaints may include but are not limited to concerns or reports on the quality, labeling, or possible adverse reactions related to a specific CSP. A designated person(s) must review all complaints to determine whether the complaint indicates a potential quality problem with the CSP. If it does, a thorough investigation into the cause of the problem must be initiated and completed. The investigation must consider whether the quality problem extends to other CSPs. Corrective action, if necessary, must be implemented for all potentially affected CSPs. A readily retrievable written or electronic record of each complaint must be kept by the facility, regardless of the	

				source of the complaint (e.g., email, telephone, or mail). The record must contain the name of the complainant or other unique identifier, the date the complaint was received, the nature of the complaint, and the response to the complaint. In addition, to the extent that the information is known, the following should be recorded: the name and strength of the CSP and the assigned internal identification number (e.g., prescription, order, or lot number). The record must also include the findings of any investigation and any follow-up. Records of complaints must be easily retrievable for review and evaluation for possible trends and must be retained in accordance with the record-keeping requirements in *20. Documentation*. A CSP that is returned in connection with a complaint must be quarantined until it is destroyed after completion of the investigation and in accordance with laws and regulations of the applicable regulatory jurisdiction.	
153. Are adverse events potentially associated with the quality of CSPs reported in accordance with the facility's SOPs?				**USP <797> 18.3 Adverse Event Reporting** Adverse events potentially associated with the quality of CSPs must be reported in accordance with the facility's SOPs and all laws and regulations of the applicable regulatory jurisdiction. If the investigation into an adverse event reveals a quality problem with a CSP that is likely to affect other patients, those patients and prescribers potentially affected must be informed.	
CSP Handling, Storage, Packing, Shipping, and Transport					
154. Are personnel trained in processes and techniques for handling storing, packaging, and transporting CSPs as outlined in the facility SOPs?				**SP <797> 19. CSP HANDLING, STORAGE, PACKAGING, SHIPPING, AND TRANSPORT** Processes and techniques for handling, storing, packaging, and transporting CSPs must be outlined in the facility's SOPs. Personnel who will be handling, storing, packaging, and transporting CSPs within the facility must be trained in accordance with the relevant SOPs, and the training must be documented.	
155. Are temperatures of drug storage areas monitored and documented as required?				**USP <797> 19.1 Handling and Storing CSPs** To help ensure that CSP quality is maintained during storage at the compounding facility, personnel must monitor conditions in the storage areas. A controlled temperature area (see ⟨659⟩) must be established and monitored to ensure that the temperature remains within the appropriate range for the CSP. The temperature must be monitored each day, either manually or by a	

				continuous recording device. The results of the temperature readings must be documented in a temperature log per facility SOPs or stored in the continuous temperature recording device and must be retrievable. Temperature monitoring devices must be verified for accuracy at least every 12 months or as required by the manufacturer.	
156. Does the facility detect and minimize temperature excursions and evaluate exposed CSPs for product integrity?				**USP <797> 19.1 Handling and Storing CSPs** The compounding facility must detect and minimize temperature excursions that are outside the temperature limits within the controlled temperature areas. When it is known that a CSP has been exposed to temperatures either below or above the storage temperature limits for the CSP, a designated person(s) must determine (e.g., by consulting literature or analytical testing) whether the CSP is expected to retain its integrity or quality. If this cannot be determined, it must be discarded.	
157. Does the facility select appropriate shipping containers and packaging materials based on product specifications, information from vendors, and mode of transport?				**USP <797> 19.2 Packaging of CSPs** The facility must select appropriate shipping containers and packaging materials based on the product specifications, information from vendors, and the mode of transport. Alternative modes of transport and/or special packaging (e.g., tamper-evident closures) may be needed to protect the quality of CSPs. If the CSP is sensitive to light, light-resistant packaging materials must be used. In some cases, the CSP must be packaged in a special container (e.g., a cooler) to protect it from temperature fluctuations.	
158. Do personnel select modes of transport and note specific handling instructions on the exterior container?				**USP <797> 19.3 Shipping and Transporting CSPs** Compounding personnel must select modes of transport that are expected to deliver properly packed CSPs in an undamaged, sterile, and stable condition. When shipping or transporting CSPs that require special handling (e.g., CSPs with stability concerns), personnel must include specific handling instructions on the exterior of the container.	
Documentation					
159. Does the facility maintain all required documentation?				**USP <797> 20. Documentation** All facilities where CSPs are prepared must have and maintain written or electronic documentation to demonstrate compliance with the requirements in this	

				chapter. This documentation must include, but is not limited to, the following: --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, MFRs (if required), and CRs (if required) --Release inspection and testing records --Information related to complaints and adverse events including corrective actions taken --Results of investigations and corrective actions	
Compounding Allergenic Extracts					
160. Are personnel who compound allergenic extracts appropriately trained?				**USP <797> 21.1 Personnel Qualifications for Compounding Allergenic Extract Prescription Sets** Allergenic extract prescription sets must follow standards at least as stringent as those in this section as follows: --A designated person(s) with training and expertise in allergen immunotherapy is responsible for ensuring that personnel who will be preparing allergenic extract prescription sets are trained, evaluated, and supervised. --Before beginning to independently prepare allergenic extracts, all compounding personnel must complete training and be able to demonstrate knowledge of principles and skills for sterile compounding. --Annual personnel training and competency must be documented. Personnel must demonstrate knowledge and competency in these procedures by passing written or electronic testing before they can be allowed to compound allergenic extract prescription sets. --Before being allowed to independently compound, all compounders must successfully complete gloved fingertip and thumb sampling on both hands (see *Box 1* and *Table 1*) no fewer than 3 separate times. Each	

				fingertip and thumb evaluation must occur after performing separate and complete hand hygiene and garbing procedures. After the initial competency evaluation, compounding personnel must successfully complete gloved fingertip and thumb sampling on both hands at least every 12 months thereafter. --Compounding personnel must have their sterile technique and related practices evaluated at least every 12 months as demonstrated by successful completion of a media-fill test (see *Box 2*). If compounding outside of a PEC, the post-media-fill surface sample is not required. --Personnel who fail competency evaluations must successfully pass reevaluations in the deficient area(s) before they can resume compounding of allergenic extract prescription sets. The designated person(s) must identify the cause of failure and determine appropriate retraining requirements. --Personnel who have not compounded an allergenic extract prescription set in more than 6 months must be evaluated in all core competencies before resuming compounding duties.	
161. Do personnel compounding allergenic extracts perform hand hygiene and garbing procedures per facility SOPs ?				**USP <797> 21.2 Personnel Hygiene and Garbing for Compounding Allergenic Extract Prescription Sets** Before beginning compounding of allergenic extract prescription sets, personnel must perform hand hygiene (see *Box 3*) and garbing procedures according to the facility's SOPs. The minimum garb requirements include: --A low-lint garment with sleeves that fit snugly around the wrists and an enclosed neck (e.g., gowns) --A low-lint, disposable head cover that covers the hair and ears and, if applicable, a disposable cover for facial hair --Face mask --Sterile powder-free gloves Throughout the compounding process, personnel must apply sterile 70% IPA onto all surfaces of the gloves and allow them to dry thoroughly.	
162. Is compounding performed in an ISO Class 5 PEC or a dedicated allergenic extract compounding area (AECA)?				**USP <797> 21.3 Facilities for Compounding Allergenic Extract Prescription Sets** • The compounding process must occur in an ISO Class	

				5 PEC or in a dedicated allergenic extract compounding area (AECA). The PEC or AECA used to compound allergenic extract prescription sets must be located away from unsealed windows, doors that connect to the outdoors, and traffic flow, all of which may adversely affect the air quality. Neither a PEC nor an AECA may be located where environmental control challenges (e.g., restrooms, warehouses, or food preparation areas) could negatively affect the air quality. The PEC or the worksurfaces in the AECA must be located at least 1 m away from a sink. The impact of activities that will be conducted around or adjacent to the PEC or AECA must be considered carefully when designing such an area. • If used, the PEC must be certified at least every 6 months (see *5. Certification and Recertification*). • If used, a visible perimeter must define the AECA. --Access to the AECA during compounding must be restricted to authorized personnel. --During compounding activities, no other activity is permitted i the AECA. --The surfaces of walls, floors, fixtures, shelving, counters, and cabinets in the AECA must be cleanable. --Carpet is not allowed in the AECA. --Surfaces should be resistant to damage by cleaning and disinfecting agents. --The surfaces in the AECA upon which the allergenic extract prescription sets are prepared must be smooth, impervious, free from cracks and crevices, and non-shedding to allow for easy cleaning and disinfecting. --Dust-collecting overhangs such as utility pipes, ledges, and windowsills should be minimized. If overhangs or ledges are present, they must be easily cleanable. --The AECA must be designed and controlled to provide a well-lighted working environment, with temperature and humidity controls for the comfort of compounding personnel wearing the required garb.	
163. Are all interior surfaces of the PEC and the required surfaces in the AECA				**USP <797> 21.4 Cleaning and Disinfecting for Compounding Allergenic Extract Prescription Sets**	

cleaned and disinfected as specified?				• In a PEC, all interior surfaces of the PEC must be cleaned and disinfected each day of use before compounding begins and when surface contamination is known or suspected. Apply sterile 70% IPA to the horizontal work surface between each prescription set. • In an AECA, all work surfaces in the AECA where direct compounding is occurring must be cleaned and disinfected each day of use before compounding begins and when surface contamination is known or suspected. Apply sterile 70% IPA to the horizontal work surface between each prescription set. -If present, walls, doors, and doorframes within the perimeter oft he AECA must be cleaned and disinfected monthly and when surface contamination is known or suspected. -Ceilings within the perimeter of the AECA must be cleaned and disinfected when visibly soiled and when surface contamination is known or suspected.	
164. Are vial stoppers of packages of conventionally manufactured sterile ingredients wiped with sIPA 70% and allowed to dry before use?				**USP <797> 21.4 Cleaning and Disinfecting for Compounding Allergenic Extract Prescription Sets** Vial stoppers on packages of conventionally manufactured sterile ingredients must be wiped with sterile 70% IPA to ensure that the critical sites are wet and allowed to dry before they are used to compound allergenic extract prescription sets.	
165. Are BUDs appropriately established for allergenic extract prescription sets?				**USP <797> 21.5 Establishing BUDs for Allergenic Extract Prescription Sets** The BUD for the prescription set must be no later than the earliest expiration date of any allergenic extract or any diluent that is part of the prescription set, and the BUD must not exceed 1 year from the date the prescription set is mixed or diluted.	
166. Does the label for an allergenic extract prescription set include all required elements?				**USP <797> 21.6 Labeling for Allergenic Extract Prescription Sets** The label of each vial of an allergenic extract prescription set must display the following prominently and understandably: --Patient name --Type and fractional dilution of each vial, with a corresponding vial number --BUD --Storage conditions	
167. Do shipping and transport labels for				**USP <797> 21.7 Shipping and Transporting**	

allergenic extract prescription sets include specific handling instructions on the exterior of the container?				**Allergenic Extract Prescription Sets** When shipping or transporting allergenic extract prescription sets that require special handling, personnel must include specific handling instructions on the exterior of the container.	
168. Does the facility maintain all required documentation?				**USP <797> 21.8 Documentation for Compounding Allergenic Extract Prescription Sets** All facilities where allergenic extract prescription sets are prepared must have and maintain written or electronic documentation to include, but not limited to, the following: --SOPs describing all aspects of the compounding process --Personnel training records, competency assessments, and qualification records including corrective actions for any failures --Certification reports of the PEC, if used, including corrective actions for any failures --Temperature logs for refrigerator(s) --CRs for individual allergenic extract prescription sets (see *Box 10*) --Information related to complaints and adverse events including corrective actions taken --Investigations and corrective actions	

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KEEP IN THE PHARMACY FOR DRUG COMPLIANCE INVESTIGATOR'S REVIEW. COPIES SENT TO THE DEPARTMENT WILL BE DISCARDED.

I hereby certify that I have verified that this pharmacy is in compliance with all laws and rules related to the practice of pharmacy in the State of Illinois and the answers marked on this report are true and correct to the best of my knowledge.

PIC NAME: _____ LICENSE NUMBER:_____

PIC SIGNATURE:_____ DATE:_____ _____