

# Revisions to USP Compounding Standards 〈795〉 and 〈797〉

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# Approach to Revisions after the Appeals



- ▶ Stakeholder Engagement
  - Reviewed feedback, including *PF* public comments and issues raised in the appeals
  - Held stakeholder semi-structured interviews (May 2020)
  - Roundtable session (July 28, 2020)
  - Open forums (September 15, 2020 & September 2021)
  
- ▶ Identified key stakeholder engagement discussion topics as a framework
  
- ▶ Also had general considerations throughout the review process
  - Scientifically robust, risk-based approach to assigning BUDs
  - Physical and chemical stability considerations
  - Sterility assurance in ⟨797⟩
  - Operational implications
  - Balancing the need for patient access to cost-effective compounded preparations with rigorous quality standards
  - Implications on regulatory oversight and enforcement

# Overview of Revised General Chapter (795) *Pharmaceutical Compounding – Nonsterile Preparations*



## Chapter Outline

- ▶ 1. Introduction and Scope
- ▶ 2. Personnel Training and Evaluation
- ▶ 3. Personal Hygiene and Garbing
- ▶ 4. Buildings and Facilities
- ▶ 5. Cleaning and Sanitizing
- ▶ 6. Equipment and Components
- ▶ 7. Master Formulation and Compounding Records
- ▶ 8. Release Inspections and Testing
- ▶ 9. Labeling
- ▶ 10. Establishing Beyond-Use Dates
- ▶ 11. SOPs
- ▶ 12. Quality Assurance and Quality Control
- ▶ 13. CNSP Packaging and Transporting
- ▶ 14. Documentation
- ▶ Glossary

## Section 1. Introduction and Scope

### ▶ Scope

- Added information on types of Compounded Nonsterile Preparations (CNSPs)

### ▶ Hazardous Drugs

- Removed all information on handling of hazardous drugs and added references to General Chapter ⟨800⟩ *Hazardous Drugs – Handling in Healthcare Settings*

### ▶ Affected Personnel and Settings

- Added roles and responsibility of the designated person
  - Designated person = One or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of CNSPs



## Section 2. Personnel Training and Evaluation

- ▶ Added guidance on training and core competencies
- ▶ Included steps in training procedures

## Section 3. Personal Hygiene and Garbing

- ▶ Added Box on Hand Hygiene Procedures
- ▶ Included description of garb and glove requirements
  - Gloves are required for all compounding activities
  - Other garb must be used as appropriate for the type of compounding

# ⟨795⟩ Revisions



## Section 4. Buildings and Facilities

- ▶ Added requirement for a designated area for nonsterile compounding
- ▶ Area must be well lit and be maintained in a clean, orderly, sanitary condition and in a good state of repair
- ▶ There should not be carpet in the compounding area

## Section 5. Cleaning and Sanitizing

- ▶ New table on minimum frequencies for cleaning and sanitizing surfaces, including:
  - Work surfaces
  - Floors
  - Walls
  - Ceilings
  - Storage Shelving



# ⟨795⟩ Revisions



## Section 6. Equipment and Components

- ▶ Weighing, measuring, or otherwise manipulating components that could generate airborne chemical particles (e.g., APIs, added substances, and conventionally manufactured products) must be evaluated to determine if these activities must be performed in a closed-system processing device
  - Containment Ventilated Enclosure (CVE) must be cleaned and sanitized
  - CVE must be certified at least annually
- ▶ Components
  - In the United States, APIs must be manufactured by an FDA-registered facility
    - Each API must be accompanied by a valid COA
  - In the United States, all components other than APIs should be obtained from an FDA-registered facility
  - Packaging systems of components that lack a vendor's expiration must not be used after 3 years from the date of receipt





## Section 7. Master Formulation And Compounding Records

- ▶ Boxes include required elements of Master Formulation Records and Compounding Records

## Section 8. Release Inspections and Testing

- ▶ Confirm CNSP and labeling match Compounding Records
- ▶ Visual inspections to determine if physical appearance is as expected
- ▶ Other tests to ensure quality (e.g., pH, assays)

## Section 9. Labeling

- ▶ Requirements for *labels* (labeling on the immediate container)
- ▶ Requirements for *labeling* (all matter on container or in any packaging system or wrapper)

## Section 10. Establishing Beyond-Use Dates

### ▶ Terminology

- Expiration Date applies to conventionally manufactured drug products
- BUD applies to CNSPs calculated in terms of hours, days, or months

### ▶ Parameters to consider

- Water activity ( $a_w$ )
- Chemical and physical stability
- Compatibility of container closure system
- Degradation of container closure system
- Potential for microbial proliferation
- Deviations from essential compounding steps and procedures

# <795> Revisions



## Section 10. Establishing Beyond-Use Dates

▶ *Table 4. BUD Limit by Type of Preparation in the **Absence** of a USP–NF Compounded Preparation Monograph or CNSP-Specific Stability Information <sup>a</sup>*

Type of Preparation	BUD (days)	Storage Temperature <sup>b</sup>
<b>Aqueous Dosage Forms (<math>a_w \geq 0.60</math>)</b>		
Nonpreserved aqueous dosage forms <sup>c</sup>	14	Refrigerator
Preserved aqueous dosage forms <sup>c</sup>	35	Controlled room temperature or refrigerator
<b>Nonaqueous Dosage Forms (<math>a_w &lt; 0.60</math>)</b>		
Oral liquids (nonaqueous) <sup>d</sup>	90	Controlled room temperature or refrigerator
Other nonaqueous dosage forms <sup>e</sup>	180	Controlled room temperature or refrigerator

a A shorter BUD must be assigned when the physical and chemical stability of the CNSP is less than the BUD limit stated in the table (see 10.4 CNSPs Requiring Shorter BUDs).

b See *Packaging and Storage Requirements* <659>.

c An aqueous preparation is one that has an  $a_w$  of  $\geq 0.6$  (e.g., emulsions, gels, creams, solutions, sprays, or suspensions).

d A nonaqueous oral liquid is one that has an  $a_w$  of  $< 0.6$ .

e Other nonaqueous dosage forms that have an  $a_w$  of  $< 0.6$  (e.g., capsules, tablets, granules, powders, nonaqueous topicals, suppositories, and troches or lozenges).

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## Nonaqueous Dosage Forms: $a_w < 0.6$

Dosage Form	Description	$a_w$
Animal treat	Animal treat (oil flavor)	0.507
Capsule (oil filled)	Olive oil encapsulated	0.468
Capsule (powder filled)	Powder base encapsulated	0.435
Gel (glycol based)	Propylene glycol, ethoxy diglycol, or hydroxypropyl cellulose gel	0.056
Lollipop (sorbitol based)	Sorbitol-based lollipop	0.460
Ointment	Hydrophilic petrolatum	0.396
Ointment	Polyethylene and mineral oil gel base	0.459
Oral solution (glycol based)	20% Polyethylene glycol and 80% propylene glycol	0.009
Oral solution (oil based)	Medium chain triglycerides oil	0.338
Oral suspension (fixed oil)	Fixed oil with thickener	0.403
Powder for inhalation	Encapsulated powder for inhalation	0.402
Stick	Lip balm	0.181
Suppository	Polyethylene glycol base	0.374
Suppository	Fatty acid base	0.385
Tablet (compressed)	Compressed tablet	0.465
Tablet (triturate)	Tablet triturate (lactose and/or sucrose)	0.427
Troche or lozenge (gelatin based)	Gelatin troche or lozenge with NMT 3% aqueous flavor	0.332
Troche or lozenge (glycol based)	Polyethylene glycol troche or lozenge with NMT 3% aqueous flavor	0.571

## Aqueous Dosage Forms: $a_w \geq 0.6$

Dosage Form	Description	$a_w$
Animal treat	Animal treat with 15%–18% aqueous flavor	0.716
Cream	Cream vehicle (oil in water emulsion, petrolatum free)	0.968
Cream	Emollient cream (petrolatum and mineral oil)	0.984
Cream	Cream (oil in water emulsion with natural oils)	0.989
Foam	Foaming surfactant solution	0.983
Gel (water based)	Alcohol-free aqueous gel	0.990
Gel (water based)	Hydroxypropyl methylcellulose (HPMC) gel	1.000
Lotion	Lotion (oil in water emulsion)	0.986
Nasal spray	Nasal spray	0.991
Oral solution (water based)	Low-sucrose syrup vehicle	0.906
Oral solution (water based)	90% Water and 10% glycerin	0.958
Oral suspension (water based)	Oral suspension base	0.992
Rinse	Polymer gel with 30% water	0.960
Shampoo	Shampoo	0.976
Simple syrup	Simple syrup	0.831
-	-	-
-	-	-
-	-	-

## Section 10. Establishing Beyond-Use Dates

- ▶ In the Presence of CNSP-Specific Stability Information
  - BUD may be extended up to a maximum of 180 days
  - Stability-indicating analytical method for the API(s), CNSP formulation, and material of composition of the container closure that will be used
  - An aqueous CNSP must be tested for ⟨51⟩ antimicrobial effectiveness at the end of the BUD
    - Bracketing can be utilized to provide flexibility
  - If compounding from a *USP–NF* compounded preparation monograph, the BUD must not exceed the BUD specified in the monograph
- ▶ Shorter BUDs may be required
  - If components have an earlier expiration date or BUD
  - If ingredients are known to be susceptible to decomposition

# Overview of Revised General Chapter (797) *Pharmaceutical Compounding – Sterile Preparations*



## Chapter Outline

1. Introduction and Scope
  2. Personnel Training and Evaluation
  3. Personal Hygiene and Garbing
  4. Facilities and Engineering Controls
  5. Certification and Recertification
  6. Microbiological Air and Surface Monitoring
  7. Cleaning, Disinfecting, and Applying Sporicidal Disinfectants and Sterile 70% IPA
  8. Introducing Items into the SEC and PEC
  9. Equipment, Supplies, and Components
  10. Sterilization and Depyrogenation
  11. Master Formulation and Compounding Records
  12. Release Inspections and Testing
  13. Labeling
  14. Establishing Beyond-Use Dates
  15. Use of Conventionally Manufactured Products as Components
  16. Use of CSPs as Components
  17. SOPs
  18. Quality Assurance and Quality Control
  19. CSP Handling, Storage, Packaging, Shipping, and Transport
  20. Documentation
  21. Compounding Allergenic Extracts
- ▶ Glossary

# ⟨797⟩ Revisions



## Administration is out of the scope of the chapter

- ▶ Sterile compounding is defined as:
  - Combining
  - Admixing
  - Diluting
  - Pooling
  - Reconstituting
  - Repackaging
  - Otherwise altering a drug or bulk drug substance to create a sterile preparation



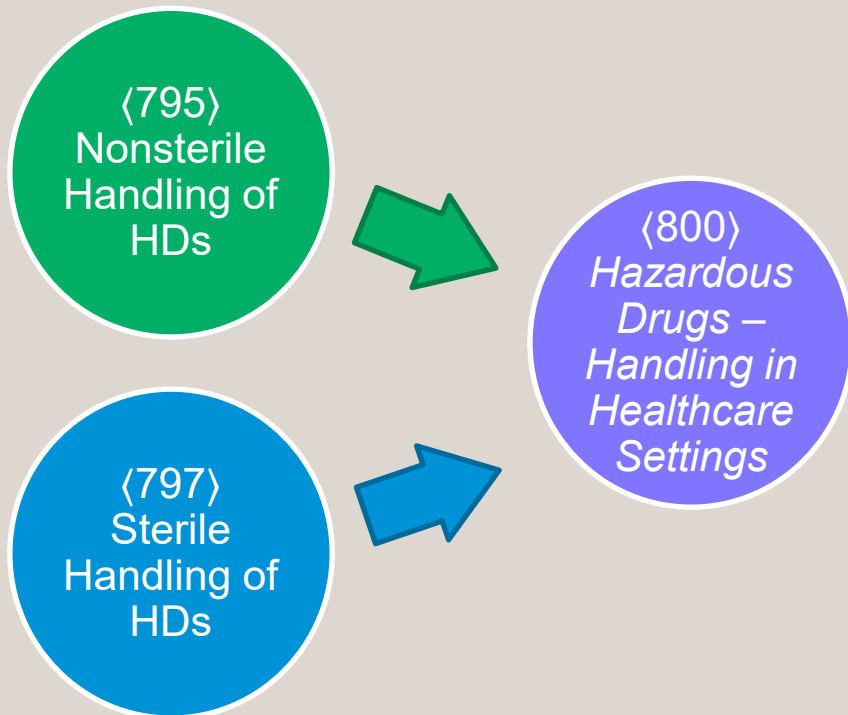


# ⟨797⟩ Revisions

## Scope

- ▶ Removes provisions for handling of hazardous drugs
  - Compounded sterile hazardous drugs *are subject to ⟨800⟩*

- ▶ Removes provisions for radiopharmaceuticals
  - Compounding radiopharmaceuticals *are subject to ⟨825⟩*  
*Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging*



## Alternative Technologies

- ▶ The use of technologies, techniques, materials, and procedures other than those described in this chapter is not prohibited as long as they are noninferior to those described herein and validated for the intended purpose (e.g., *Validation of Alternative Microbiological Methods* ⟨1223⟩ and *Validation of Compendial Procedures* ⟨1225⟩).

## Immediate-Use CSPs

### Requirements for Immediate-Use CSPs

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.

**Personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and the facility's SOPs.**

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).

The preparation involves not more than 3 different sterile products.

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.

**Administration begins within 4 hours** following the start of preparation. If administration has not begun within 4 hours following the start of preparation, it must be promptly, appropriately, and safely discarded.

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-hour time period within which administration must begin.

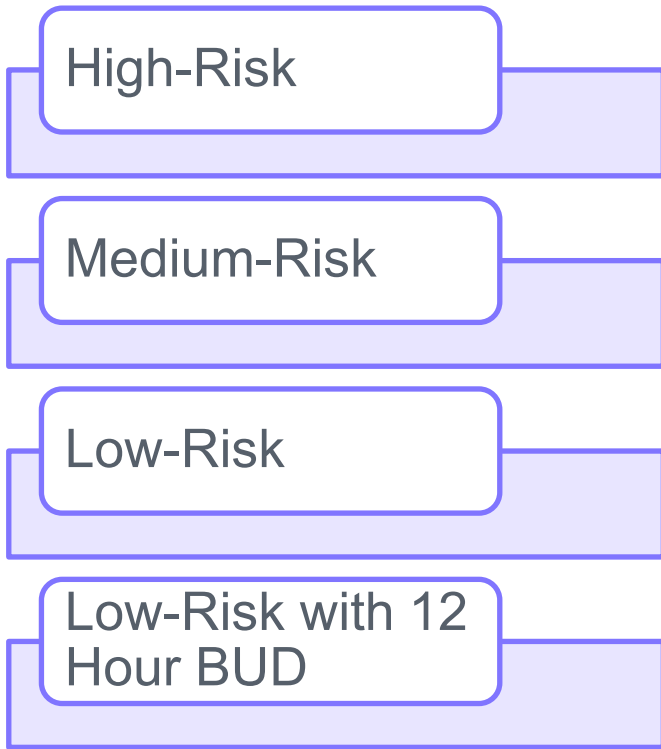
## Preparation Per Approved Labeling

- ▶ Clarifies that compounding does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling or supplemental materials provided by the product's manufacturer
- ▶ Preparing a conventionally manufactured sterile product in accordance with the directions in the manufacturer's approved labeling is out of scope of this chapter only if:
  - The product is prepared as a single dose for an individual patient; and
  - The approved labeling includes information for the diluent, the resultant strength, the container closure system, and storage time
- ▶ Proprietary bag and vial systems
  - Docking and activation 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 ISO Class 5 environment
  - Docking for *future activation* and administration is considered compounding and must be performed in accordance with this chapter, with the exception of 14. *Establishing Beyond-Use Dates*. BUDs for proprietary bag and vial systems must not be longer than those specified in the manufacturer's labeling

# <797> Revisions



## Categories of CSPs



### Category 1 CSPs

- Must be prepared in a PEC that may be located in an unclassified segregated compounding area
- Assigned a BUD of  $\leq 12$  hours at controlled room temperature or  $\leq 24$  hours when refrigerated

### Category 2 CSPs

- Must be prepared in a cleanroom suite
- May be assigned a BUD of  $> 12$  hours at controlled room temperature or  $> 24$  hours if refrigerated

### Category 3 CSPs

- Have additional requirements that must be met at all times
- May be assigned a BUD longer than established for Category 2 CSPs, up to 180 days

# ⟨797⟩ Revisions



## Assigning Longer BUDs than in the Chapter\*

2008 Last Official Chapter	2015 Revision Proposed in <i>PF</i>	2018 Revision Proposed in <i>PF</i>	2019 Revision Published in <i>USP-NF</i> (subsequently remanded)	Revised Chapter
BUDs could be assigned up to the duration indicated by appropriate information sources for the same or similar formulations and by personal experience	The ability to assign longer BUDs was not described	BUDs could be assigned up to a maximum of 90 days if supported by stability data	BUDs could only be assigned up to the limits described in the chapter	Category 3 describes the requirements a compounding site must ensure at all times for assigning longer BUDs than those established for Category 2 CSPs, up to a maximum of 180 days

\* If there is a compounded preparation monograph for a particular CSP formulation, the BUD in the monograph can be assigned if the CSP is prepared according to the monograph and all monograph requirements are met, including sterility testing.

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## Personnel Qualifications

	2008 Last Official Chapter	2015 Revision Proposal	2018 Revision Proposal	2019 Remanded Chapter	Revised Chapter
Visual observation of hand hygiene and garbing	Annually	Every 3 months	Every 6 months	Every 6 months	<b>Category 1 &amp; 2:</b> <u>Every 6 months</u> <b>Category 3:</b> <u>Every 3 months</u> for personnel who compound Category 3 CSPs
Gloved fingertip and thumb sampling	<b>Low/Medium-Risk CSPs:</b> <u>Annually</u> <b>High-Risk CSPs:</b> <u>Semi-annually</u>	Every 3 months	Every 6 months	Every 6 months	<b>Category 1 &amp; 2:</b> <u>Every 6 months</u> <b>Category 3:</b> <u>Every 3 months</u> for personnel who compound Category 3 CSPs as part of garbing competency and aseptic competency
Media-fill testing	<b>Low/Medium-Risk CSPs:</b> <u>Annually</u> <b>High-Risk CSPs:</b> <u>Semi-annually</u>	Every 3 months	Every 6 months	Every 6 months	<b>Category 1 &amp; 2:</b> <u>Every 6 months</u> <b>Category 3:</b> <u>Every 3 months</u> for personnel who compound Category 3 CSPs

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## Minimum Garbing Requirements

2008 Last Official Chapter	2015 Revision Proposal	2018 Revision Proposal	2019 Remanded Chapter	Revised Chapter
<ul style="list-style-type: none"> <li>• Gown</li> <li>• Dedicated shoes or shoe covers</li> <li>• Head and facial hair covers</li> <li>• Face masks</li> <li>• Sterile gloves</li> </ul>	<p>Determined based on:</p> <ul style="list-style-type: none"> <li>• Category</li> <li>• Type of PEC</li> </ul> <p>Included:</p> <ul style="list-style-type: none"> <li>• Gown or coveralls</li> <li>• Disposable covers for shoes</li> <li>• Disposable covers for head and facial hair</li> <li>• Sterile gowns or sleeves</li> <li>• Sterile gloves</li> </ul>	<ul style="list-style-type: none"> <li>• Gown</li> <li>• Disposable covers for shoes</li> <li>• Disposable covers for head and facial hair</li> <li>• Face mask</li> <li>• Sterile gloves</li> </ul> <p>If using RABS → disposable gloves inside of gauntlet gloves</p>	<ul style="list-style-type: none"> <li>• Gown</li> <li>• Disposable covers for shoes</li> <li>• Disposable covers for head and facial hair</li> <li>• Face mask</li> <li>• Sterile gloves</li> </ul> <p>If using RABS → disposable gloves inside of gauntlet gloves</p>	<ul style="list-style-type: none"> <li>• Low-lint garment with sleeves that fit snugly around the wrists and an enclosed neck (e.g., gown or coverall)</li> <li>• Low-lint covers for shoes</li> <li>• Low-lint cover for head that covers the hair and ears, and if applicable, cover for facial hair</li> <li>• Low-lint face mask</li> <li>• Sterile powder-free gloves</li> <li>• 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</li> </ul>



## Minimum Garbing Requirements

### Revised Chapter – Category 3

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:

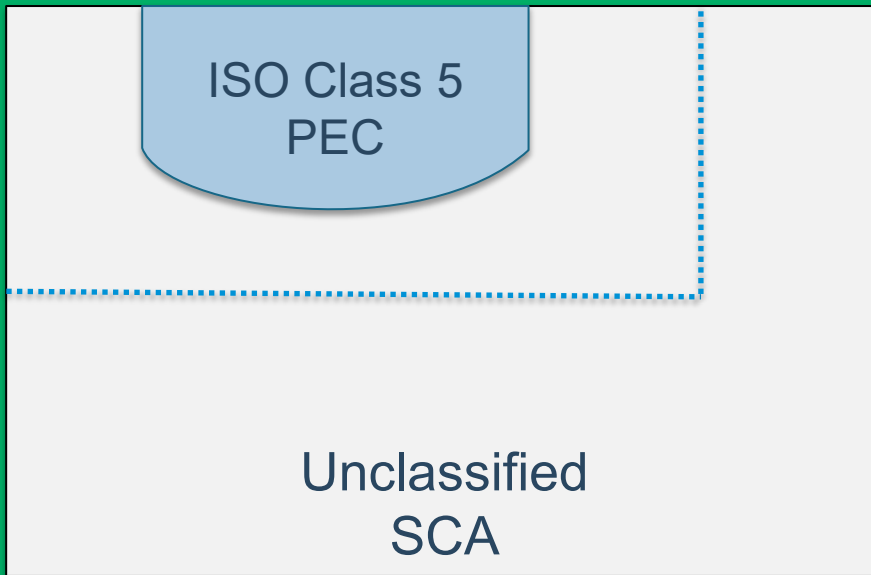
1. Do not allow any exposed skin in the buffer room. (i.e., face and neck must be covered).
2. All low-lint outer garb must be sterile, including the use of sterile sleeves over gauntlet sleeves when a RABS is used.
3. Disposable garbing items must not be reused, and laundered garb must not be reused without being laundered and resterilized with a validated cycle.
4. The facility's SOPs must describe disinfection procedures for reusing goggles, respirators, and other reusable equipment.

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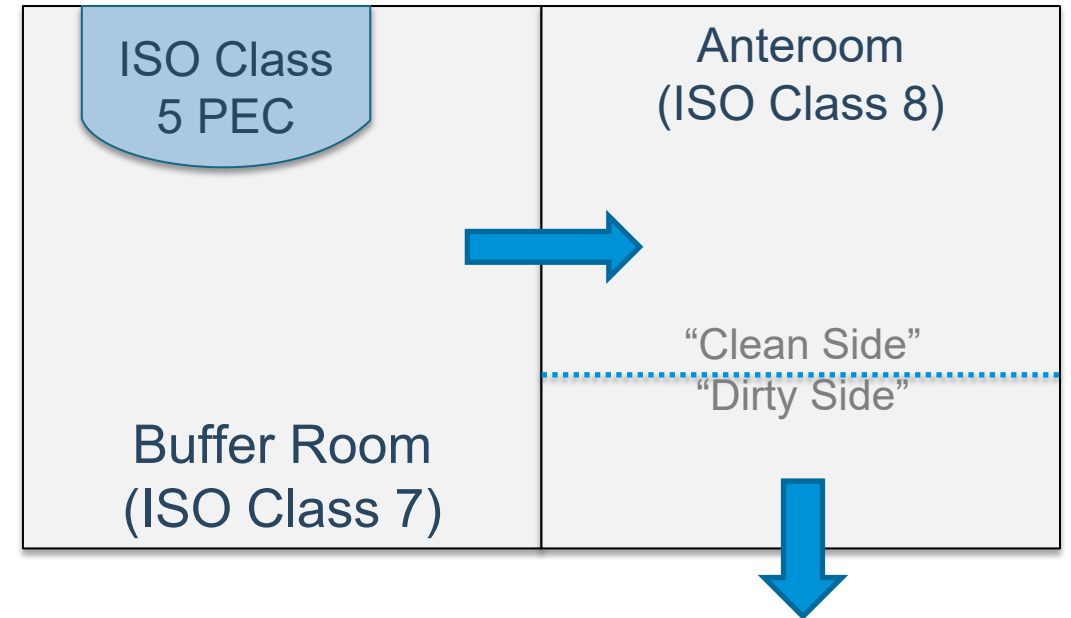


## Minimum PEC Placement

### Category 1 CSPs



### Category 2 or 3 CSPs



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## Microbiological Air and Surface Monitoring

	2008 Last Official Chapter	2015 Revision Proposal	2018 Revision Proposal	2019 Remanded Chapter	Revised Chapter
Viable air sampling	Every 6 months	Monthly	Every 6 months	Every 6 months	<b>Category 1 &amp; 2:</b> <u>Every 6 months</u> <b>Category 3:</b> <u>Monthly</u>
Surface sampling	Periodically	Monthly	Monthly	Monthly	<b>Category 1 &amp; 2:</b> <u>Monthly</u> <b>Category 3:</b> <u>Weekly</u>

## Cleaning, Disinfecting, and Applying Sporocidal Disinfectants and Sterile 70% IPA

- ▶ Frequencies specified for separate activities
  - Cleaning
  - Disinfecting
  - Applying a sporocidal disinfectant
  
- ▶ Cleaning and disinfecting supplies (e.g., wipers, sponges, pads, and mop heads)
  - Must be low-lint
  - Should be disposable
  - Reusable cleaning tools must be dedicated for use

## Cleaning, Disinfecting, and Applying Sporicidal Disinfectants and Sterile 70% IPA

- ▶ Cleaning, disinfecting and sporicidal agents used within the PEC must be sterile
- ▶ Cleaning and disinfecting supplies used in the PEC must be sterile with the exception of tool handles and holders, which must be cleaned and disinfected prior to use in a PEC
- ▶ 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

## Release Inspections and Testing

### Visual Inspection

### Sterility Testing

- ▶ Required for **Category 2** CSPs assigned a BUD that requires sterility testing, and for all **Category 3** CSPs
- ▶ **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 *USP* ⟨71⟩, *Table 3*, additional units must be compounded to perform sterility testing
  - If between 1 and 39 CSPs, test a number of units equal to 10% of CSPs prepared
  - If >40 CSPs, test based on *USP* ⟨71⟩, *Table 3*
- ▶ 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

## Establishing Beyond-Use Dates

### Quality factors

- 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)

### Sterility factors

- Conditions of the environment in which the CSP is prepared
  - Cleanroom suite or SCA
- Aseptic processing and sterilization method
- Starting components
  - Sterile or nonsterile starting ingredients
- Whether or not sterility testing is performed
- Storage conditions
  - Packaging and temperature

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## Category 1 CSP BUD Limits

Storage Conditions	
Controlled Room Temperature (20°–25°)	Refrigerator (2°–8°)
≤ 12 hours	≤ 24 hours

2008 Last official ⟨797⟩

Low-Risk Level CSP in SCA

12 hours



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## Category 2 CSP BUD Limits

Preparation Characteristics		Storage Conditions		
Compounding Method	Sterility Testing Performed & Passed	Controlled Room Temperature (20°–25°)	Refrigerator (2°–8°)	Freezer (-25° to -10°)
Aseptically processed CSPs	No	Prepared from one or more nonsterile starting component(s): 1 day	Prepared from one or more nonsterile starting component(s): 4 days	Prepared from one or more nonsterile starting component(s): 45 days

### 2008 Last official <797>



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## Category 2 CSP BUD Limits

Preparation Characteristics		Storage Conditions		
Compounding Method	Sterility Testing Performed & Passed	Controlled Room Temperature (20°–25°)	Refrigerator (2°–8°)	Freezer (–25° to –10°)
Aseptically processed CSPs	No	Prepared from only sterile starting components: 4 days	Prepared from only sterile starting components: 10 days	Prepared from only sterile starting components: 45 days

### 2008 Last official ⟨797⟩

Medium-Risk Level CSPs	30 hours	9 days	45 days
Low-Risk Level CSPs	48 hours	14 days	45 days

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## Category 2 CSP BUD Limits

Preparation Characteristics		Storage Conditions		
Compounding Method	Sterility Testing Performed & Passed	Controlled Room Temperature (20°–25°)	Refrigerator (2°–8°)	Freezer (–25° to –10°)
Aseptically processed CSPs	No	Prepared from one or more nonsterile starting component(s): 1 day	Prepared from one or more nonsterile starting component(s): 4 days	Prepared from one or more nonsterile starting component(s): 45 days
		Prepared from only sterile starting components: 4 days	Prepared from only sterile starting components: 10 days	Prepared from only sterile starting components: 45 days
	Yes	30 days	45 days	60 days
Terminally sterilized CSPs	No	14 days	28 days	45 days
	Yes	45 days	60 days	90 days

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## Category 3 CSP BUD Limits

Preparation Characteristics	Storage Conditions		
	Controlled Room Temperature (20°–25°)	Refrigerator (2°–8°)	Freezer (-25°–10°)
Compounding Method			
Aseptically processed, sterility tested, and passing all applicable tests for Category 3 CSPs	60 days	90 days	120 days
Terminally sterilized, sterility tested, and passing all applicable tests for Category 3 CSPs	90 days	120 days	180 days

## Additional Requirements for Category 3 CSPs

- ▶ Category 3 CSPs undergo sterility testing, supplemented by endotoxin testing when applicable, and have more requirements than Category 2 CSPs for
  - Personnel qualification
  - Use of sterile garb
  - Frequency of applying sporicidal disinfectants
  - Frequency of environmental monitoring
  - Stability determination
  
- ▶ The maximum batch size for all CSPs requiring sterility testing must be limited to 250 final yield units

## Multiple-Dose CSPs

- ▶ A multiple-dose CSP must be prepared as a Category 2 or Category 3 CSP
- ▶ For preserved aqueous multiple-dose CSPs, antimicrobial effectiveness testing must be passed in accordance with *USP* ⟨51⟩
- ▶ Time within which multiple-dose preserved CSPs must be used:
  - Whichever is shorter:
    - BUD limit assigned based on if CSP is compounded as Category 2 or Category 3
    - Up to 28 days after container is initially entered or punctured, if supported by ⟨51⟩ testing
- ▶ Time within which multiple-dose, nonpreserved, aqueous topical, and topical ophthalmic CSPs must be used:
  - BUD limit assigned based on if CSP is compounded as Category 2 or Category 3, and
  - Discarded 24 hours after first opening if stored at room temperature, or 72 hours if refrigerated

# Next Steps



# Next Steps



- ▶ The Compounding Expert Committee decided to delay the implementation of the <797> revision until November 1, 2023
- ▶ USP Compounding Workshop
  - February 7, 2023, 8:00 AM – 5:30 PM ET
  - February 8, 2023, 8:00 AM – 3:30 PM ET
- ▶ Sign up for updates to <795>, <797>, and other topics related to USP Healthcare Quality and Safety Standards
  - <https://www.usp.org/hqs-signup-form>
- ▶ Send questions to: [CompoundingSL@usp.org](mailto:CompoundingSL@usp.org)



# Thank You



**The standard of trust**

# Stay Connected

Sign up for updates: <https://www.usp.org/hqs-signup-form>

Email questions to [CompoundingSL@USP.org](mailto:CompoundingSL@USP.org)



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