The Scoop on <797> and <795>: What's New and What's Changed?

Selma Mitiche, PharmD
Senior Scientist II, USP Compounding Expert Committee,
Healthcare Quality and Safety

USP Standards for Compounding

USP provides 3 types of public standards for compounding

USP General Chapters

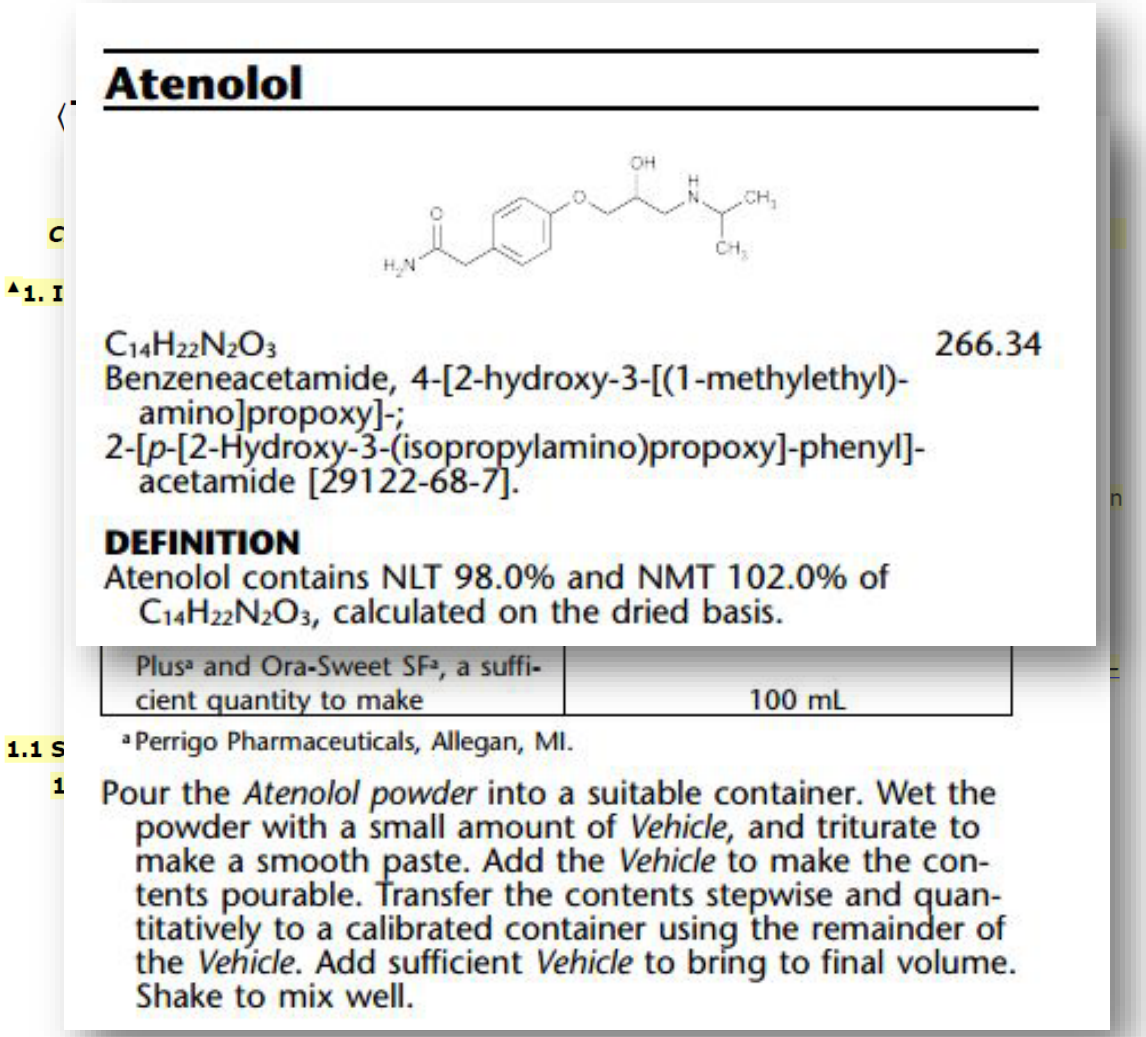
- Establish practice standards to help ensure the quality of compounded preparations

USP Compounded Preparation Monographs

- Contain formulations for specific preparations for which there is no suitable commercially available product

USP Monographs for Bulk Drug Substances and Other Ingredients

- Provide standards for identity, quality, purity, strength, packaging and labeling for bulk substances and other ingredients that may be used in compounded preparations



Atenolol

$C_{14}H_{22}N_2O_3$ 266.34

Benzeneacetamide, 4-[2-hydroxy-3-[(1-methylethyl)-amino]propoxy]-;
2-[*p*-[2-Hydroxy-3-(isopropylamino)propoxy]-phenyl]-acetamide [29122-68-7].

DEFINITION

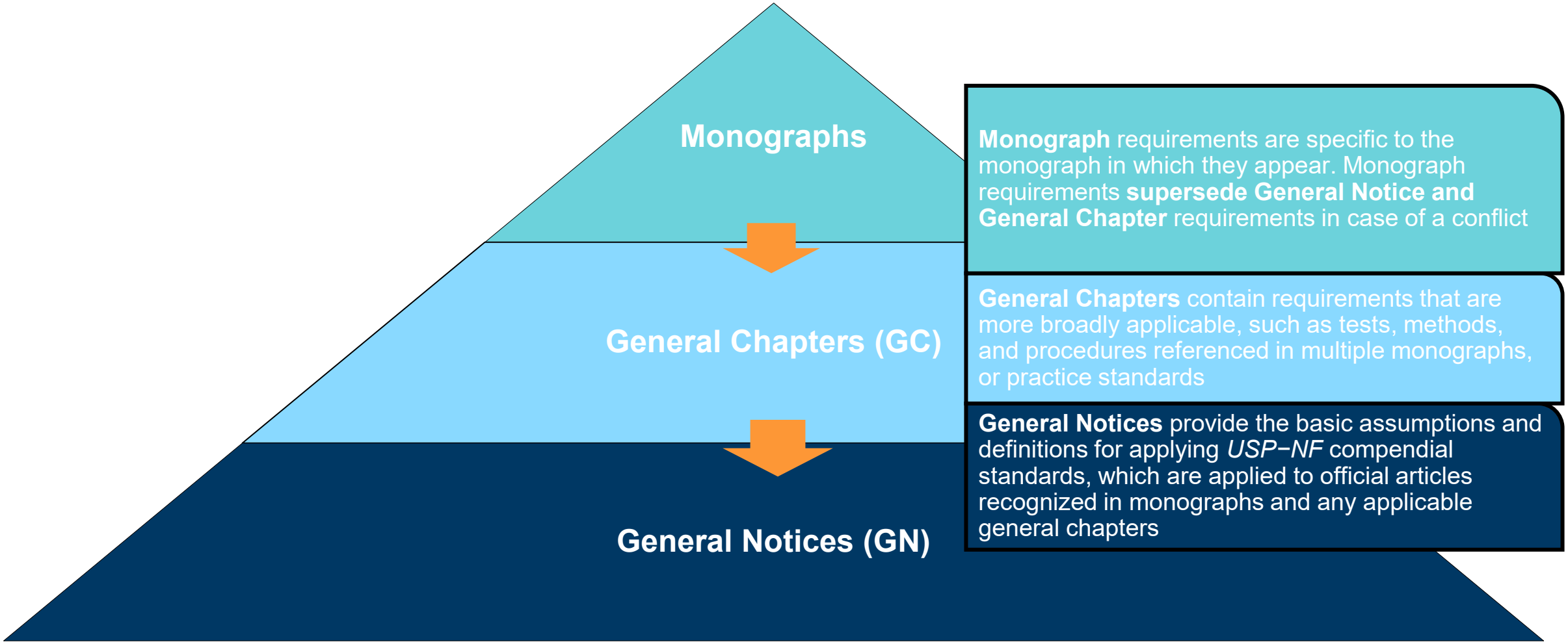
Atenolol contains NLT 98.0% and NMT 102.0% of $C_{14}H_{22}N_2O_3$, calculated on the dried basis.

Plus[a] and Ora-Sweet SF[a], a sufficient quantity to make	100 mL

[a] Perrigo Pharmaceuticals, Allegan, MI.

Pour the *Atenolol powder* into a suitable container. Wet the powder with a small amount of *Vehicle*, and triturate to make a smooth paste. Add the *Vehicle* to make the contents pourable. Transfer the contents stepwise and quantitatively to a calibrated container using the remainder of the *Vehicle*. Add sufficient *Vehicle* to bring to final volume. Shake to mix well.

USP Monographs, General Chapters, and General Notices



Monograph requirements are specific to the monograph in which they appear. Monograph requirements **supersede General Notice and General Chapter** requirements in case of a conflict

General Chapters contain requirements that are more broadly applicable, such as tests, methods, and procedures referenced in multiple monographs, or practice standards

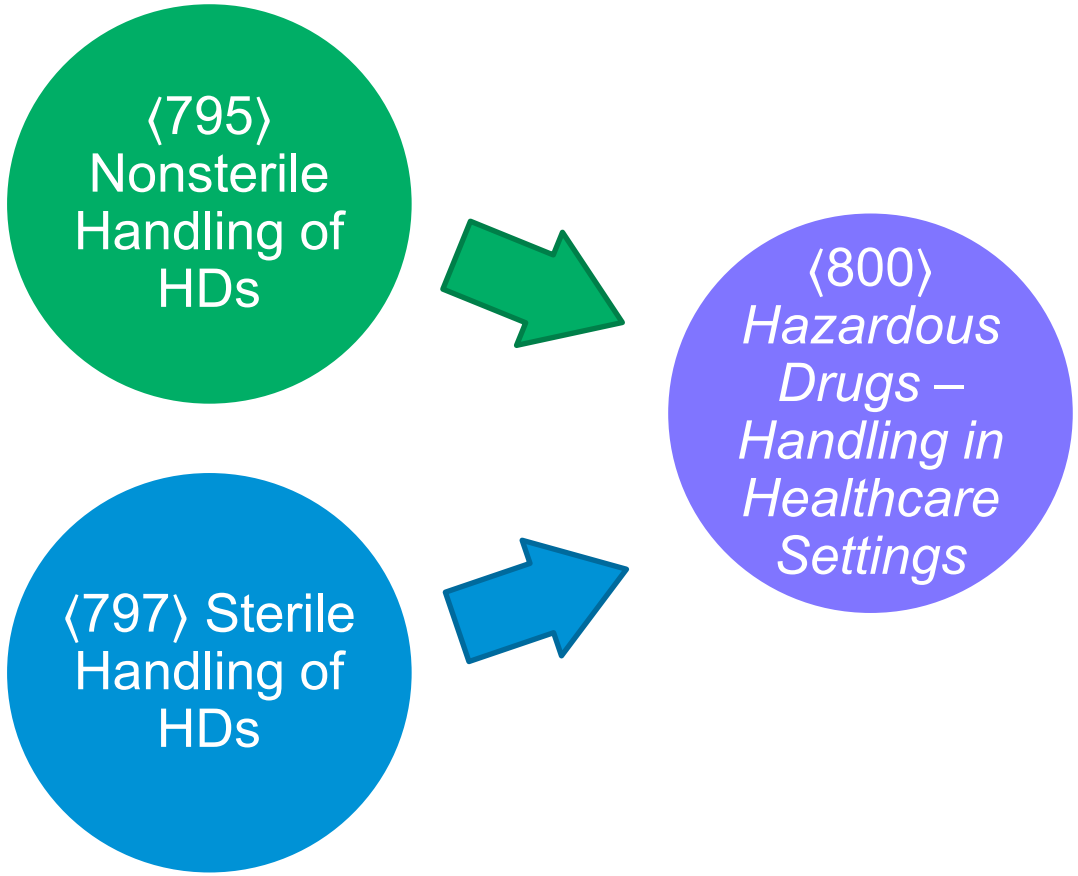
General Notices provide the basic assumptions and definitions for applying *USP–NF* compendial standards, which are applied to official articles recognized in monographs and any applicable general chapters

General Chapters: Compendial Applicability

- **Required and compendially applicable if:**
  - Numbered below <1000> **and** referenced in *General Notices*, a monograph, or another applicable chapter below <1000>
- **Informational if:**
  - Numbered below <1000> and not referenced in GN, monograph or other applicable chapter
  - Numbered <1000> to <1999>
- **Specific for dietary supplements if:**
  - Numbered above <2000>
- **Terminology**
  - Must → requirement
  - Should → recommendation

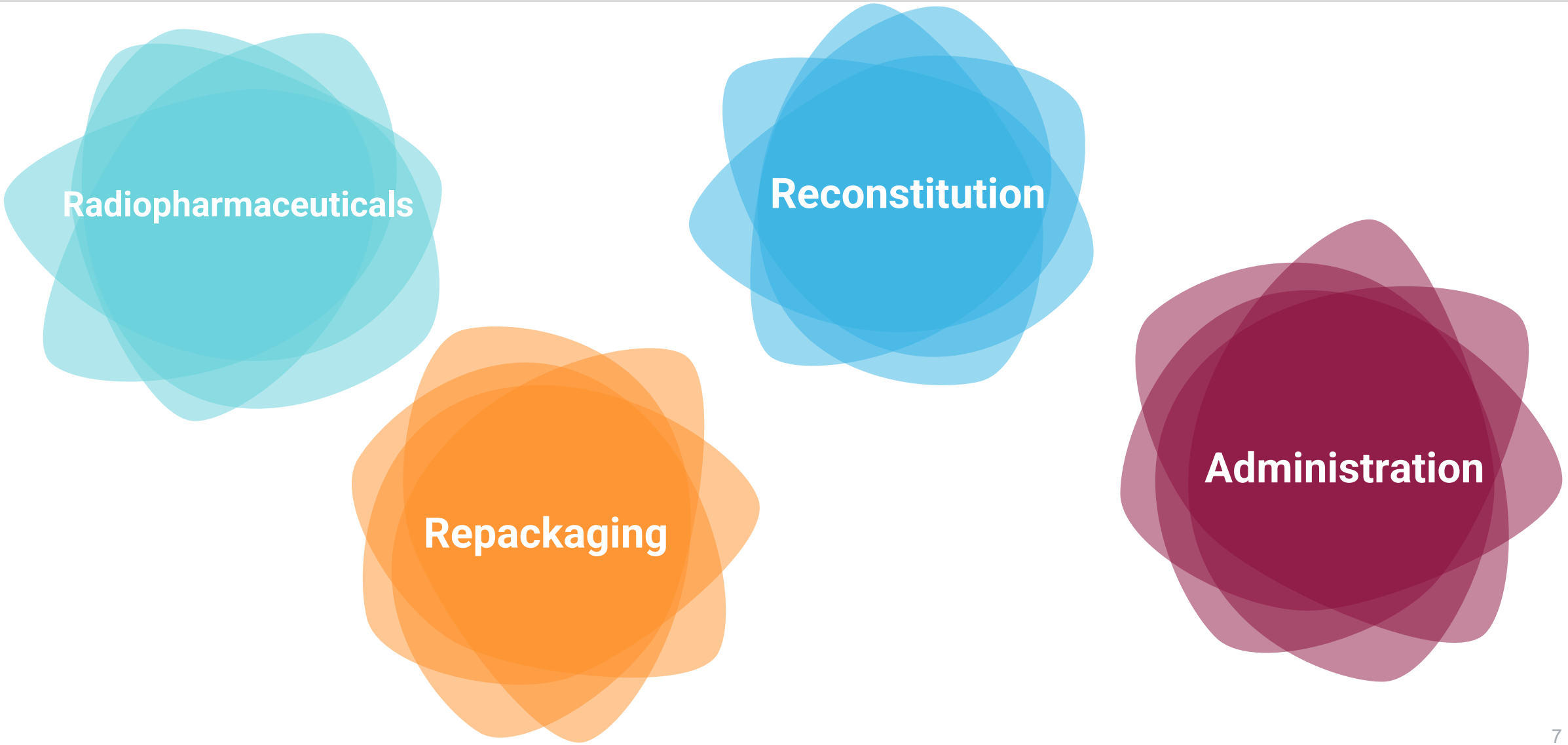
Hazardous Drugs

- Provisions have been removed for handling of hazardous drugs
  - Compounded hazardous drugs are subject to ⟨800⟩



Overview of Revised General Chapter ⟨795⟩ *Pharmaceutical Compounding – Nonsterile Preparations*

Out of Scope Practices



Flavoring

- Nonsterile compounding is defined as combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance to create a nonsterile preparation

- Adding components (such as flavors) not stipulated in the labeling to conventionally manufactured products is compounding as defined in ⟨795⟩ and has been within the scope of ⟨795⟩ since the chapter was first published in 2000

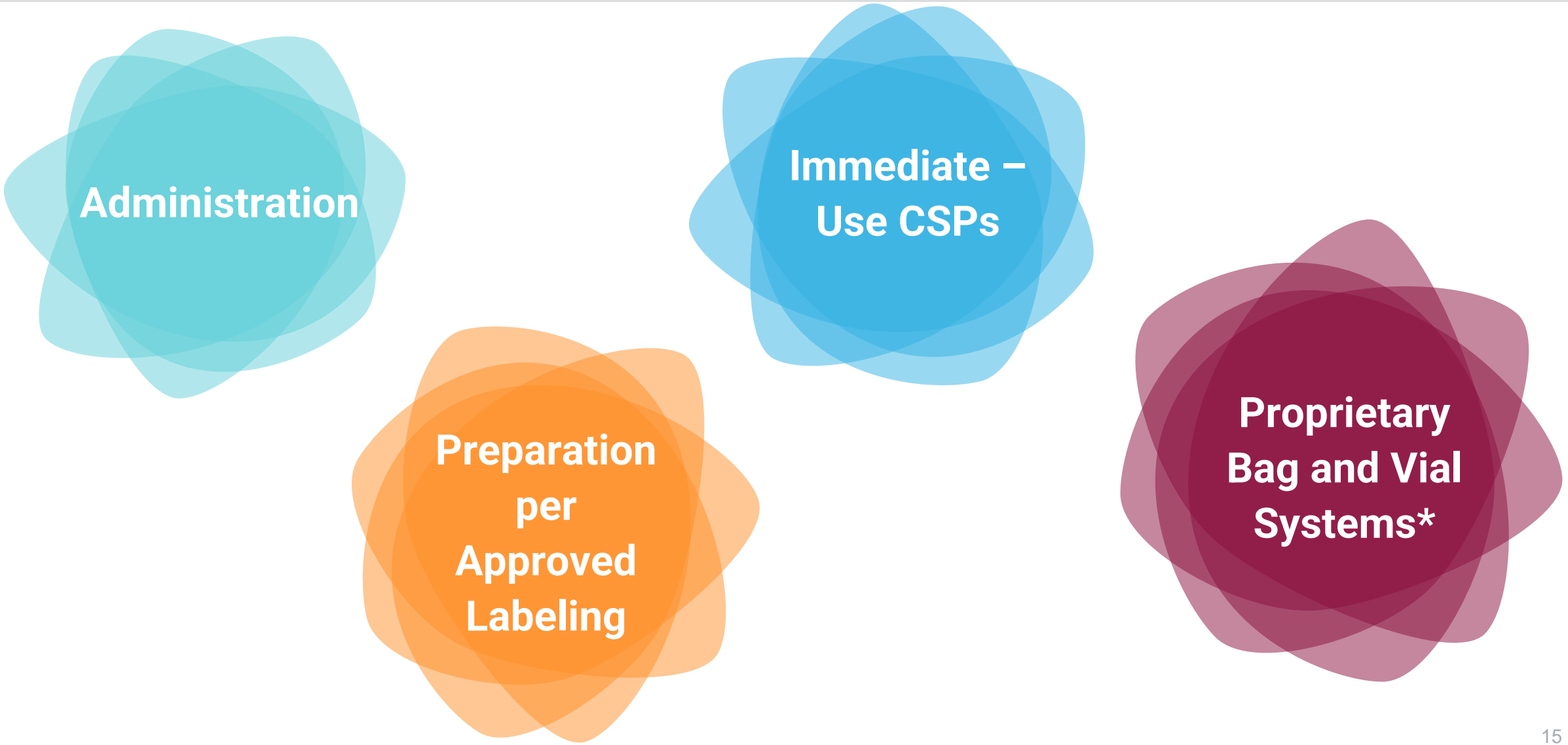
Flavoring

- Reactive functional groups

- The effect of adding these substances, even in very small quantities or concentrations, to conventionally manufactured products is unpredictable due to the potential for a variety of chemical reactions

Overview of Revised General Chapter ⟨797⟩ *Pharmaceutical Compounding – Sterile Preparations*

Out of Scope Practices



Immediate-Use: Requirements

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 for the individual patient 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 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 exact 4-hour time period within which administration must begin.

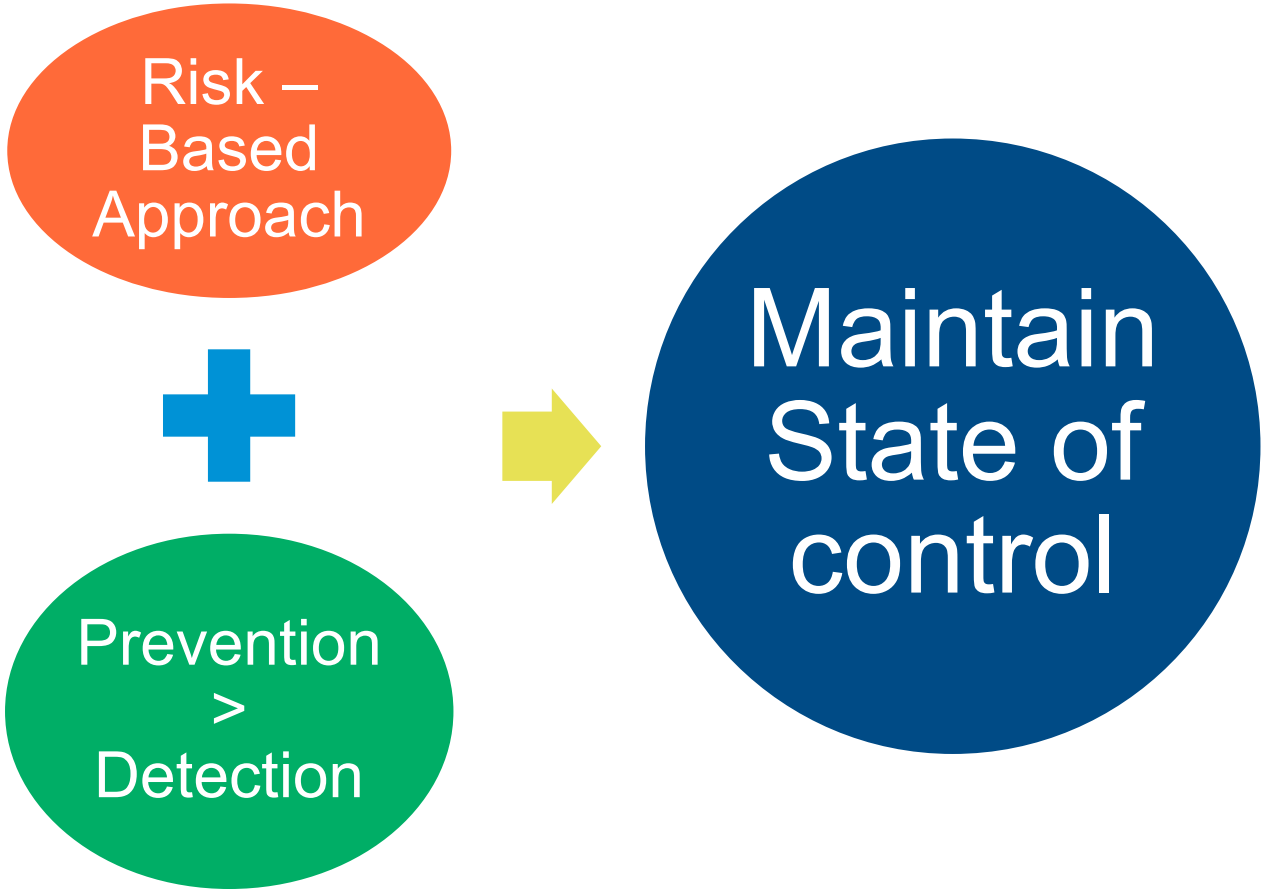
Immediate-Use: Key Changes

Currently Official	Revised <797>
Emergency Situation	Direct and immediate administration, as long as listed requirements are met
Low-risk level CSPs only	Category 1, 2, 3 CSPs
3 or less sterile packages	3 or less sterile products
BUD 1 hour	BUD 4 hours
Compounding continuous process not to exceed 1 hour	Not specified; SOPs required
Only nonhazardous products	HDs must be in compliance with <800>
Aseptic technique	Aseptic technique and SOPs in place; personnel are trained as related to assigned tasks and SOPs

Other Practices

- Cross references to *USP* <800> *Hazardous Drugs – Handling in Healthcare Settings*
- *USP* <825> *Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging*
- Allergenic extracts, handling blood derived products

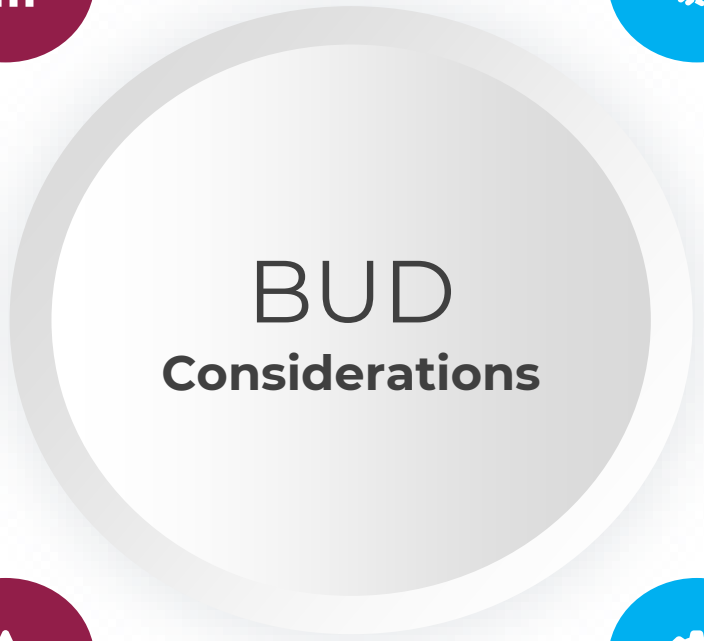
But why?



BUD Considerations

Sterility

- **Environment & Storage Conditions**
- **Aseptic Processing and Sterilization Method**
- **Starting Components**
- **Sterility Testing**



Stability

- **Chemical Stability**
- **Physical Stability**
- **Container Closure System**
- **Compatibility**

Question

- USP standards keep getting more difficult to comply with, and create an increasing burden on the barrier to entry for servicing clients. Where will this end? On this pace there will only be mini manufacturers.

History of <795>

- **First Nonsterile Compounding Standard**
  - USP <1161> *Pharmacy Compounding Practices* **(1996)**

- **General Chapter <795>**
  - Published in USP 24–NF 19 **(2000)**
  - Revised in USP 27–NF 22 **(2004)**
  - Revised in USP 34–NF 29 **(2011)**
    - Incorporated USP <1075> *Good Compounding Practices*
  - Revision Bulletin **(2014)** Clarified that the BUDs in <795> are specific for nonsterile preparations and do not apply to sterile preparations
  - Revised in USP 2023 (Nov 1, 2023) CURRENTLY OFFICIAL

History of <797>

- **First Sterile Compounding Standard**
  - <1074> Dispensing Practices for Sterile Drug Products Intended for Home Use (1992)
  - <1206> Sterile Drug Products for Home Use (1996)

- **General Chapter <797>**
  - Published in USP27-NF22 (2004)
    - Incorporated <1206> Sterile Drug Products for Home Use
  - Revised in USP USP31-NF26 2S (2008)
  - Revised in USP 2023 (Nov 1, 2023) CURRENTLY OFFICIAL

Purpose of Current Revision to <795> and <797>

Intent of Current Revision

- To review latest science and best practices
- To respond to stakeholder input received throughout the last cycle and after the 2019 appeals
- To clarify topics that are frequently queried and misconstrued
- To align with published ⟨800⟩, <825> and other new USP chapters

Current ⟨795⟩ & <797> Served as Template

- Many sections were “summary” statements and were expanded to add clarity and additional information
- Revision proposal was modeled alongside current revision efforts for other USP chapters

Inclusion of Supplementary Materials

- available here

Question

- In the new version of 797, rinses for wounds are not mentioned as needing to be sterile, but they were specifically called out as a sterile item in the old version. Was that intentional? Does USP feel wound rinses need to be sterile?

Question

- **1.1 Scope**
- **1.1.1 CSPs affected:**

- The requirements in this chapter must be met to ensure the sterility of any CSP. Although the list below is not exhaustive, the following must be sterile: Injections, including infusions

- Irrigations for internal body cavities (i.e., any space that does not normally communicate with the environment outside of the body, such as the bladder cavity or peritoneal cavity). [NOTE—IRRIGATIONS FOR THE MOUTH, RECTAL CAVITY, AND SINUS CAVITY ARE NOT REQUIRED TO BE STERILE.]

Question

- If a vendor published a stability study for a sterile product, must the compounder purchase the active from that same vendor or can the study be used as a reference for extended BUD if the ingredients are USP grade and are the same as the formula in the study? (Assuming all other facility and personnel requirements are met for Category 3.)

<797> FAQ 177

177. Do Category 3 CSP BUDs have to be based on published stability studies?

The USP Compounding Expert Committee has compiled the Formulation and Stability Reference Document for Pharmaceutical Compounding posted here to help compounders understand when a stability study is suitable for assigning Category 3 BUDs to CSPs. While every CSP must meet release testing requirements for each batch to ensure sterility, evidence to prove the physicochemical stability of a CSP may be obtained from any stability-indicating assay method study, either published or unpublished, and does not have to be repeated for each batch as long as the formula, procedures, and container closure systems in the study are exactly the same for the CSP being prepared.

Conformance to monographs

- **4. MONOGRAPHS AND GENERAL CHAPTERS**
- **4.10. Monographs**
- Monographs set forth the article's name, definition, specification, and other requirements related to packaging, storage, and labeling. The specification consists of tests, procedures, and acceptance criteria that help ensure the identity, strength, quality, and purity of the article. For general requirements relating to specific monograph sections, see section *5. Monograph Components*.
- Because monographs may not provide standards for all relevant characteristics, some official substances may conform to the *USP* or *NF* standard but differ with regard to nonstandardized properties that are relevant to their use in specific preparations. To assure substitutability in such instances, users may wish to ascertain functional equivalence or determine such characteristics before use.

Question

- If a pharmacy makes a NS non-aqueous stock solution that is to be later used in a Sterile product (appropriately sterilized), can it be given a 180 day BUD?

Question

- Category 2 CSPs, aseptically processed, sterility tested can use a 60 day frozen BUD, but it takes many days to receive your sterility test results even if you do rapid testing. This effectively drops the BUD to the 45 days you can get if you don't test. I have heard from many colleagues that they're not going to "waste their money on testing" now. This seems to have dis-incentivized compounders to test which is concerning. Any thoughts or comments? Did USP consider this when assigning BUDs?

BUDs and sterility testing

- Commentary
- 18.1 Notification About and Recall of Out-of-specification dispensed CSPs
  - Products can be released before sterility testing results are obtained, as long as there is a process for recall
- Limitations of <71> Sterility testing
  - “These Pharmacopeial procedures are not by themselves designed to ensure that a batch of product is sterile or has been sterilized. This is accomplished primarily by validation of the sterilization process or of the aseptic processing procedures.”
  - FAQs 159 and 160
  - Parametric release (see <1211> Sterility Assurance, <1222> Terminally sterilized pharmaceutical products – parametric release. ,

Question

- Why is there a lack of community compounders on the USP committee on compounding? It seems it's made up of consultants and not practitioners.

Question

- Why is there a need for monthly 797 testing when it takes approximately 3 weeks to get results back from the testing? It defies logic.

⟨797⟩ Revisions

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	**Category 1 & 2:** Every 6 months **Category 3:** Monthly
Surface sampling	Periodically	Monthly	Monthly	Monthly	**Category 1 & 2:** Monthly **Category 3:** Weekly

FAQ 108

- 108. Why has the frequency of surface sampling changed?
- Surface sampling was previously required “periodically”, which was interpreted differently by users (e.g., monthly, quarterly, or biannually). The change requiring minimum frequencies based on the category of CSP the facility compounds is intended to provide an additional measure of control and monitoring in between viable air monitoring and certification requirements. Regular surface sampling provides additional data for trending and allows for monitoring of contamination risks.

Thank You

The standard of trust

Appendix

The following slides summarize updates to other sections of <797> not mentioned in today's presentation as well as provide additional detail.

For follow-up questions, please contact us at CompoundingSL@usp.org

⟨797⟩ : Chapter Outline

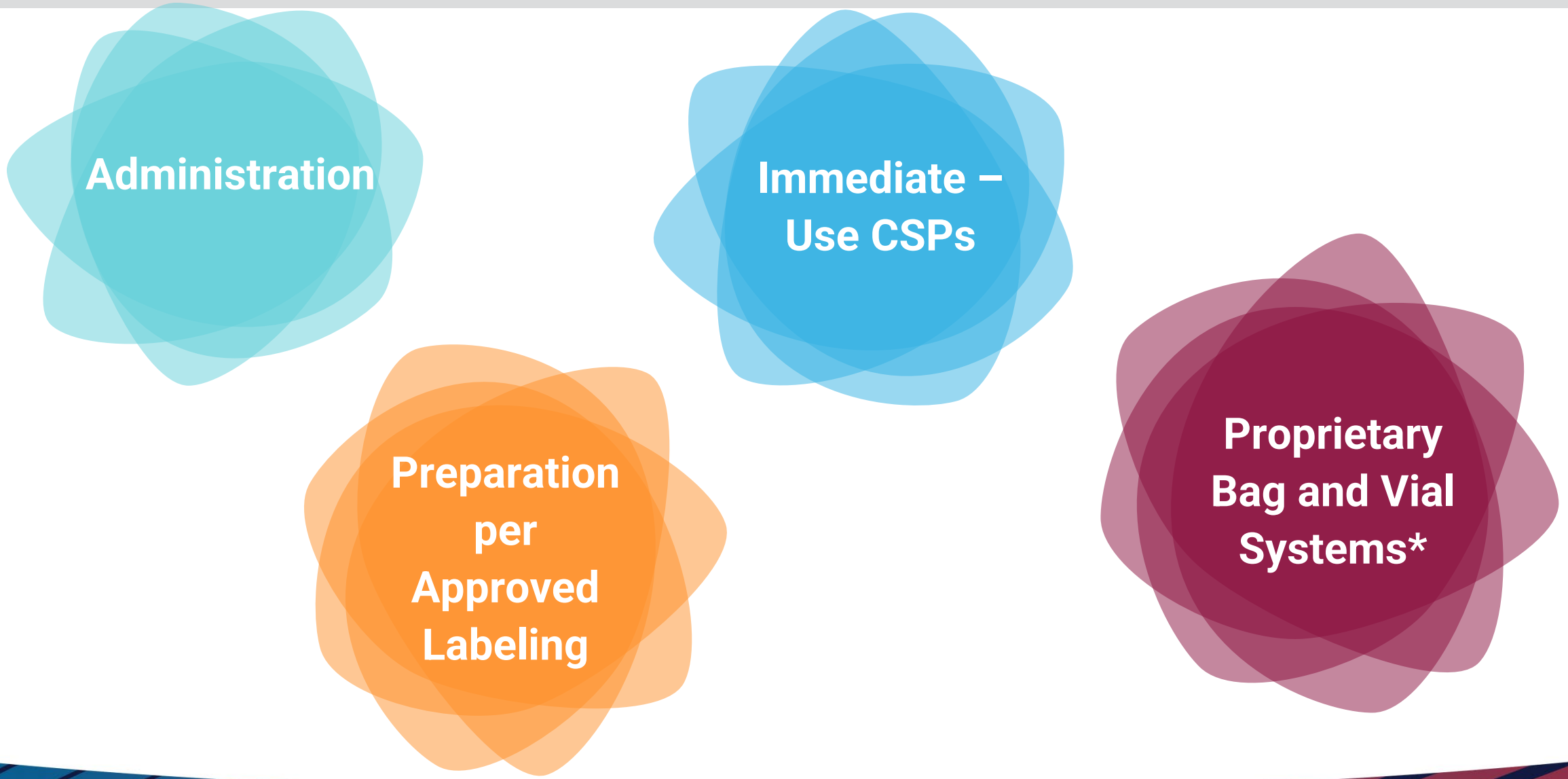
1. Introduction and Scope
2. Personnel Training and Evaluation
3. Personal Hygiene and Garbing
4. Facilities and Engineering Controls
5. Certification and Recertification
6. Microbiological Air and Surface Monitoring
7. Cleaning, Disinfecting, and Applying Sporicidal Disinfectants and Sterile 70% IPA
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

Definition

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

Out of Scope Practices



Out of Scope Practices

Direct application of a sterile product or preparation to a single patient by:

- Injecting
- Infusing
- Otherwise providing a sterile product or preparation in its final form

Out of Scope Practices

Preparation per Approved Labeling

1. Prepared as a single dose for a single patient
2. Labeling includes information for:

- ❑ Diluent
- ❑ Resultant strength
- ❑ Container closure system
- ❑ Storage time

Out of Scope Practices

Docking and activation in accordance with the manufacturer's labeling ***for immediate administration**

Out of Scope Practices

- Docking and activation in accordance with the manufacturer's labeling **for immediate administration**
- Docking **for future activation and administration is compounding**, must be performed in ISO Class 5 in accordance with <797>
- **BUD?**

Out of Scope Practices

- Docking and activation in accordance with the manufacturer's labeling **for immediate administration**
- Docking **for future activation and administration is compounding**, must be performed in ISO Class 5 in accordance with <797>
- **BUD:** As specified in the manufacturer's labeling

Out of Scope Practices

Immediate – Use CSPs

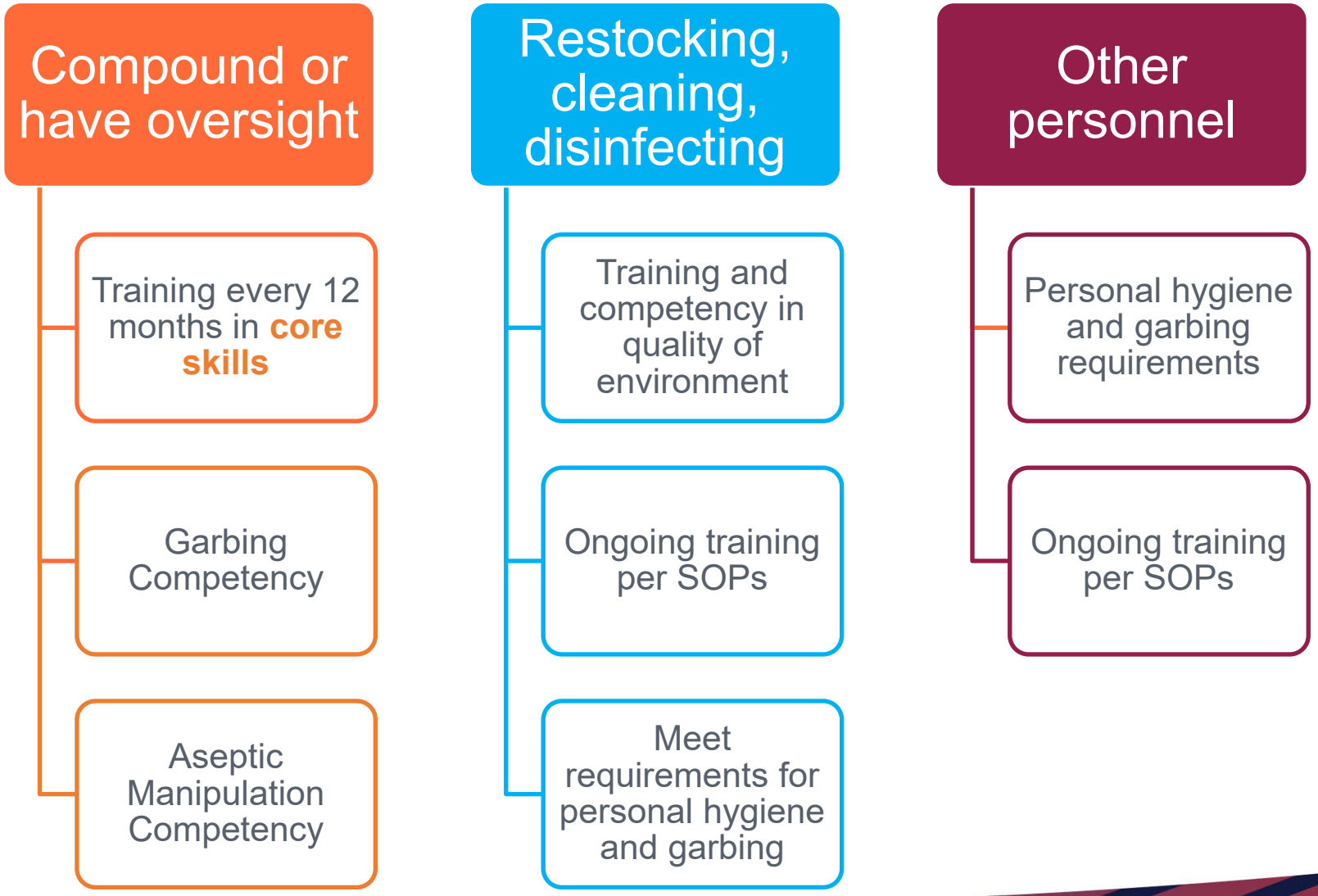
1. Combining no more than **3 different sterile products** for immediate and direct administration to a patient
2. Within **4 hours** following the start of preparation
3. All listed requirements in 1.3 met
4. Must comply with <800>

Other Practices

- Cross references to *USP* <800> *Hazardous Drugs – Handling in Healthcare Settings*
- *USP* <825> *Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging*
- Allergenic extracts, handling blood derived products

<797> Personnel Training and Evaluation

Overview of Training Requirements Based on Personnel



Competency of Core Skills

Proficiency in the following core competencies must be demonstrated at least every 12 months:

- Hand hygiene and 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 Records, Compounding Records)
- Principles of high-efficiency particulate air (HEPA)-filtered airflow
- Proper use of primary engineering controls (PECs)
- Principles of movement of materials and personnel within the compounding area

Garbing Competency

What does it consist of?

1. Hand hygiene with visual audit
2. Garbing with visual audit
3. Gloved fingertip and thumb sampling on both hands (GFT)
4. For initial competency: must repeat competency (Steps 1-3) and pass 3 times in a row

How often?

- **Category 1 & 2:** Every 6 months
- **Category 3:** Every 3 months
- **Direct oversight but do not compound:** every 12 months

Aseptic Manipulation

What does it consist of?

1. Visual observation
2. Media-fill testing
3. GFT on both hands inside PEC
4. Surface Sampling of the DCA

How often?

- **Category 1 & 2:** Every 6 months
- **Category 3:** Every 3 months
- **Direct oversight but do not compound:** every 12 months

Aseptic Manipulation: Media Fill

What does it consist of?

1. Visual observation
2. Media-fill testing
3. Gloved fingertip and thumb sampling on both hands (GFT)
4. Surface Sampling of the DCA

- Simulate most difficult and challenging compounding procedures.
  - ✓ Factors associated with length of process that can pose contamination risk, such as operator fatigue, quality of equipment
  - ✓ Number of aseptic additions or transfers
  - ✓ Number, type, complexity of manipulations
  - ✓ Number of personnel in buffer room or SCA

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	**Category 1 & 2:** Every 6 months **Category 3:** Every 3 months for personnel who compound Category 3 CSPs
Gloved fingertip and thumb sampling	**Low/Medium-Risk CSPs:** Annually **High-Risk CSPs:** Semi-annually	Every 3 months	Every 6 months	Every 6 months	**Category 1 & 2:** Every 6 months **Category 3:** Every 3 months for personnel who compound Category 3 CSPs as part of garbing competency and aseptic competency
Media-fill testing	**Low/Medium-Risk CSPs:** Annually **High-Risk CSPs:** Semi-annually	Every 3 months	Every 6 months	Every 6 months	**Category 1 & 2:** Every 6 months **Category 3:** Every 3 months for personnel who compound Category 3 CSPs

<797> Garbing Requirements

Garbing Requirements

2008 Last Official Chapter	2015 Revision Proposal	2018 Revision Proposal	2019 Remanded Chapter	Revised Chapter
• Gown • Dedicated shoes or shoe covers • Head and facial hair covers • Face masks • Sterile gloves	Determined based on: • Category • Type of PEC Included: • Gown or coveralls • Disposable covers for shoes • Disposable covers for head and facial hair • Sterile gowns or sleeves • Sterile gloves	• Gown • Disposable covers for shoes • Disposable covers for head and facial hair • Face mask • Sterile gloves If using RABS → disposable gloves inside of gauntlet gloves	• Gown • Disposable covers for shoes • Disposable covers for head and facial hair • Face mask • Sterile gloves If using RABS → disposable gloves inside of gauntlet gloves	• 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

Garbing Requirements

SOPs to determine:

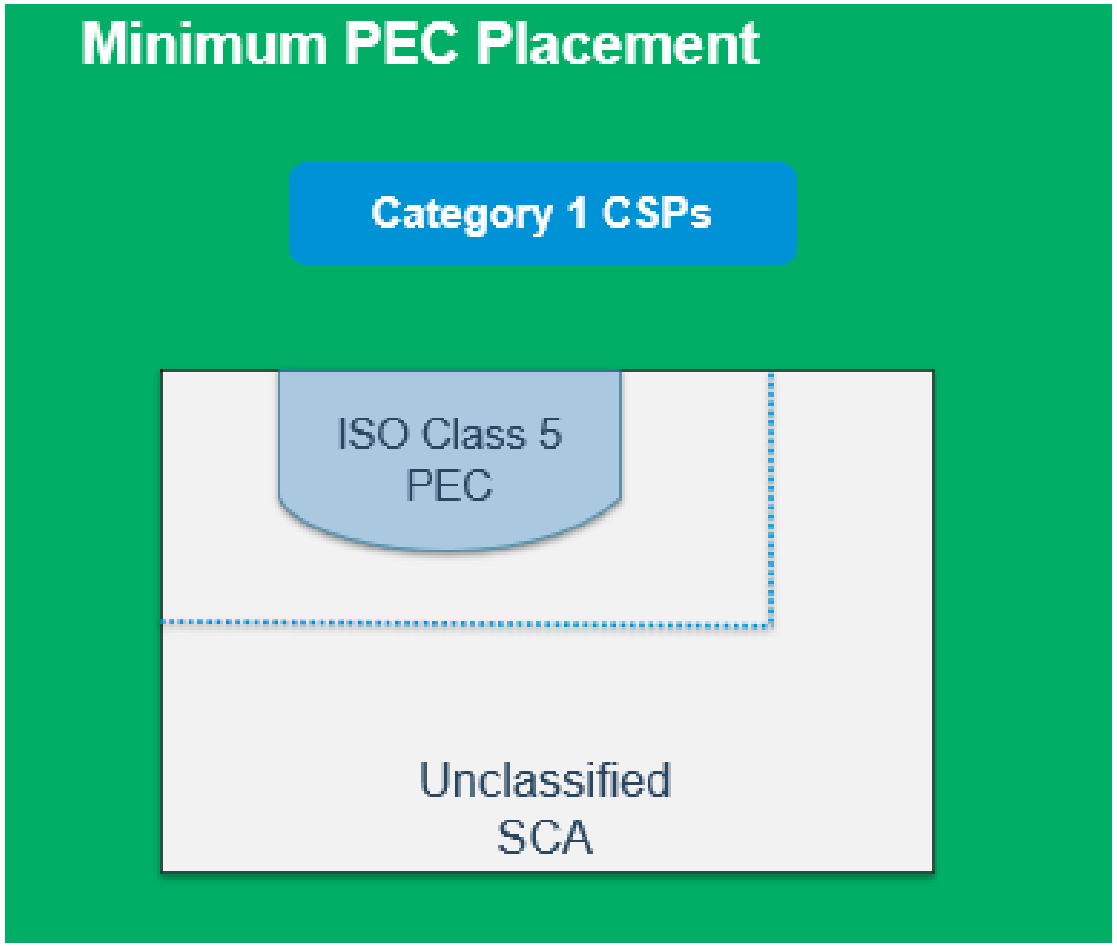
- Order of garbing
  - Must be in an order that reduces risk of contamination
  - Donning and doffing should not occur in the anteroom or SCA at the same time
- Garb required to enter a compounding area
- Storage
  - Must be stored in a way that minimizes contamination
- Disinfection procedures for reusable equipment

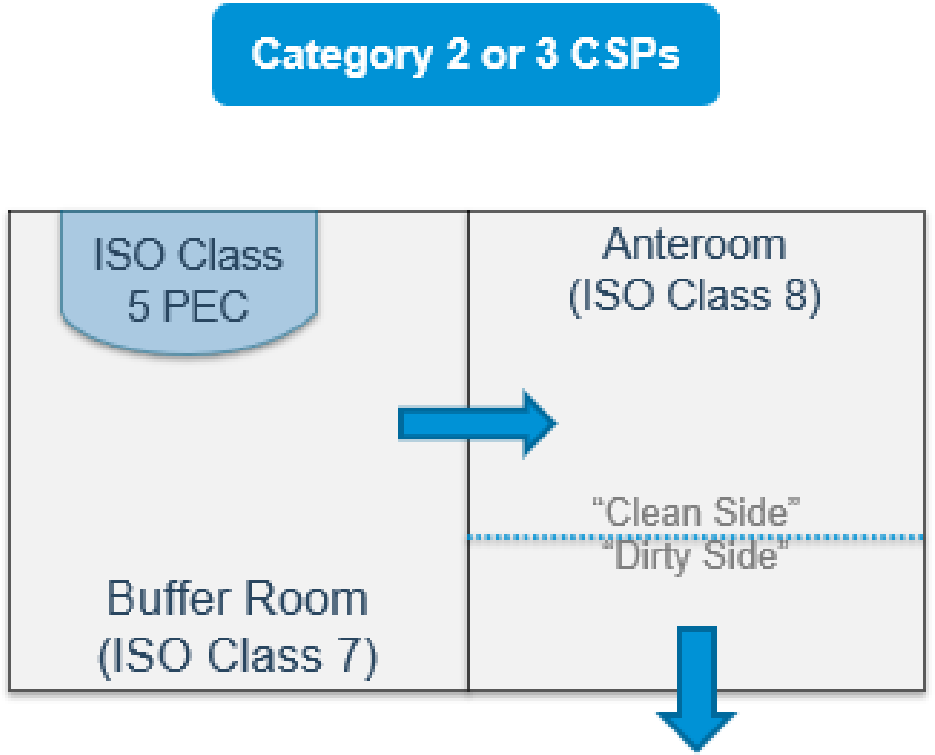
Additional Garbing Requirements: Category 3 CSPs

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

<797> Facility Design

Facility Design





<797> Environmental Monitoring

Microbiological Air & Surface Monitoring

Goals:

- Detect if contamination is present
- Assess whether proper procedures are being followed
- Monitor effectiveness of cleaning and disinfecting procedures
- Establish trends

Microbiological Air & 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	**Category 1 & 2:** Every 6 months **Category 3:** Monthly
Surface sampling	Periodically	Monthly	Monthly	Monthly	**Category 1 & 2:** Monthly **Category 3:** Weekly

Microbiological Air & Surface Monitoring

	Viable Air Sampling	Surface Sampling
Category 1 and 2 CSPs	Every 6 months	Monthly
Category 3 CSPs	30 days before commencing; then monthly	• Prior to assigned extended BUD, then weekly • Inside PEC after each batch of CSP and prior to cleaning/disinfecting

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

- Table 10: Activities and frequencies clarified
- 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, Applying Sporicidal Disinfectants and Sterile 70% IPA

Sterile

agents and supplies

IN THE PEC

Sterilization and Depyrogenation

Terminal Sterilization Methods and Aseptic Processing

- A CSP may be prepared by the following methods:
  - Terminal sterilization is the preferred method of sterilization
    - Steam
    - Dry heat
    - Irradiation

    } Probability of a nonsterile unit (PNSU) of 10^{-6}
  - Aseptic processing
    - Compounding with only sterile starting ingredient(s), or
    - Compounding with nonsterile ingredient(s) followed by sterilization by filtration

MFRs and CRs

MFR

1. All CSPs prepared from nonsterile ingredient(s)
2. CSPs prepared for more than one patient

CR

1. All Category 1, Category 2, and Category 3 CSPs
2. Immediate-use CSPs prepared for more than one patient

Release Inspections & Testing

Visual Inspection

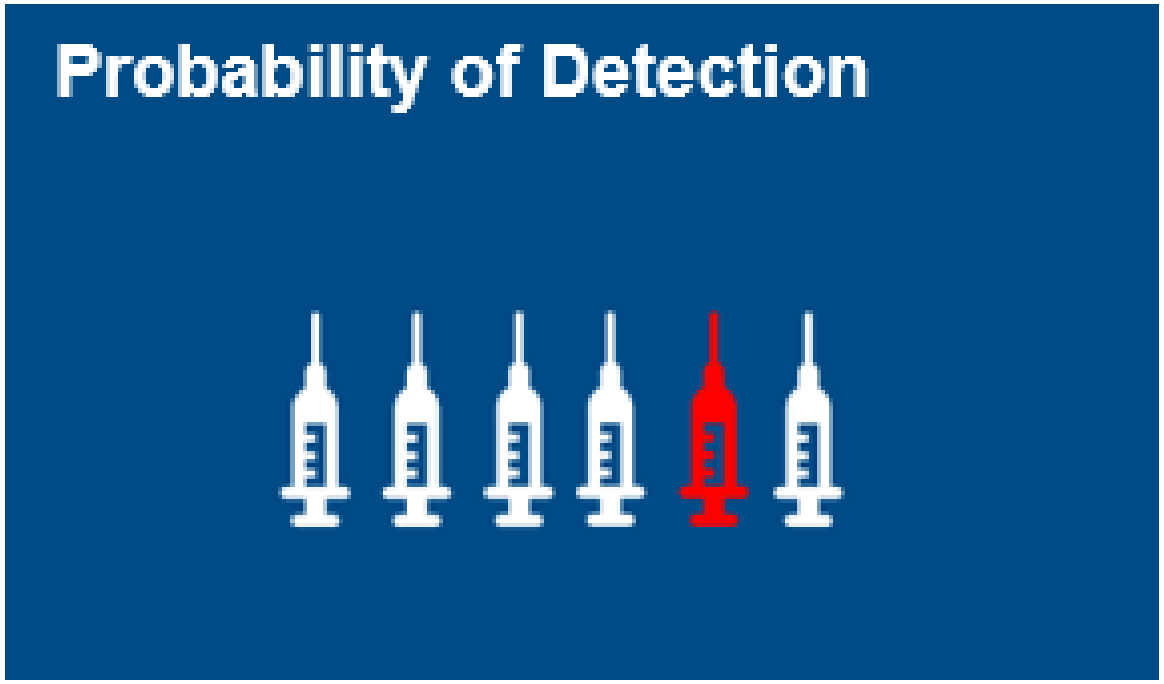
- Physical Appearance
- Labeling
- Container-closure

Release Inspections & Testing

Sterility Testing

- All Category 3 CSPs
- Category 2 CSPs with BUDs that require it per Table 13
- Maximum batch size of 250 final yield
- Investigate failure, identify microorganisms

Sterility Test: Batch Size Limit



- Layered approach to mitigating risk
- In the case of a contaminated unit, the impact is greater with larger batches

Release Inspections & Testing

Bacterial Endotoxin Testing

Category 3 from nonsterile components

Category 2 if from nonsterile components + assigned a BUD that required sterility testing

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

Use of Conventionally Manufactured Products as Components

- Addresses the time within which an entered or punctured conventionally manufactured product must be used

Type of Container	Time within which product must be used
Single-Dose Container	ISO Class 5 → 12 hours
Multiple-Dose Container	28 days
Pharmacy Bulk Package	As specified by the manufacturer

Use of CSPs as Components

- Addresses the use of CSPs (e.g., multiple-dose CSPs, single-dose CSPs, and compounded stock solutions) as components to prepare final CSPs

Type of Container	Time within which product must be used
Single-Dose CSP and CSP Stock Solution	ISO Class 5 → 12 hours
Multiple-Dose CSP	28 days

⟨797⟩ Quality Assurance and Quality Control

- 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
  - Recall any unused dispensed CSPs and quarantine any stock remaining
  - Investigate if other lots are affected and recall if necessary

- An SOP for recall must contain procedures:
  - To determine the severity and the urgency
  - To determine the distribution of any affected CSP
  - To identify patients who have received the CSP
  - For disposal and documentation of the recalled CSP
  - To investigate and document the reason for failure

CSP Handling, Storage, Packaging, Shipping, and Transport

- Provides further guidance regarding temperature monitoring and documentation
- Temperature must be monitored each day, either manually or by a continuous recording device
- 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