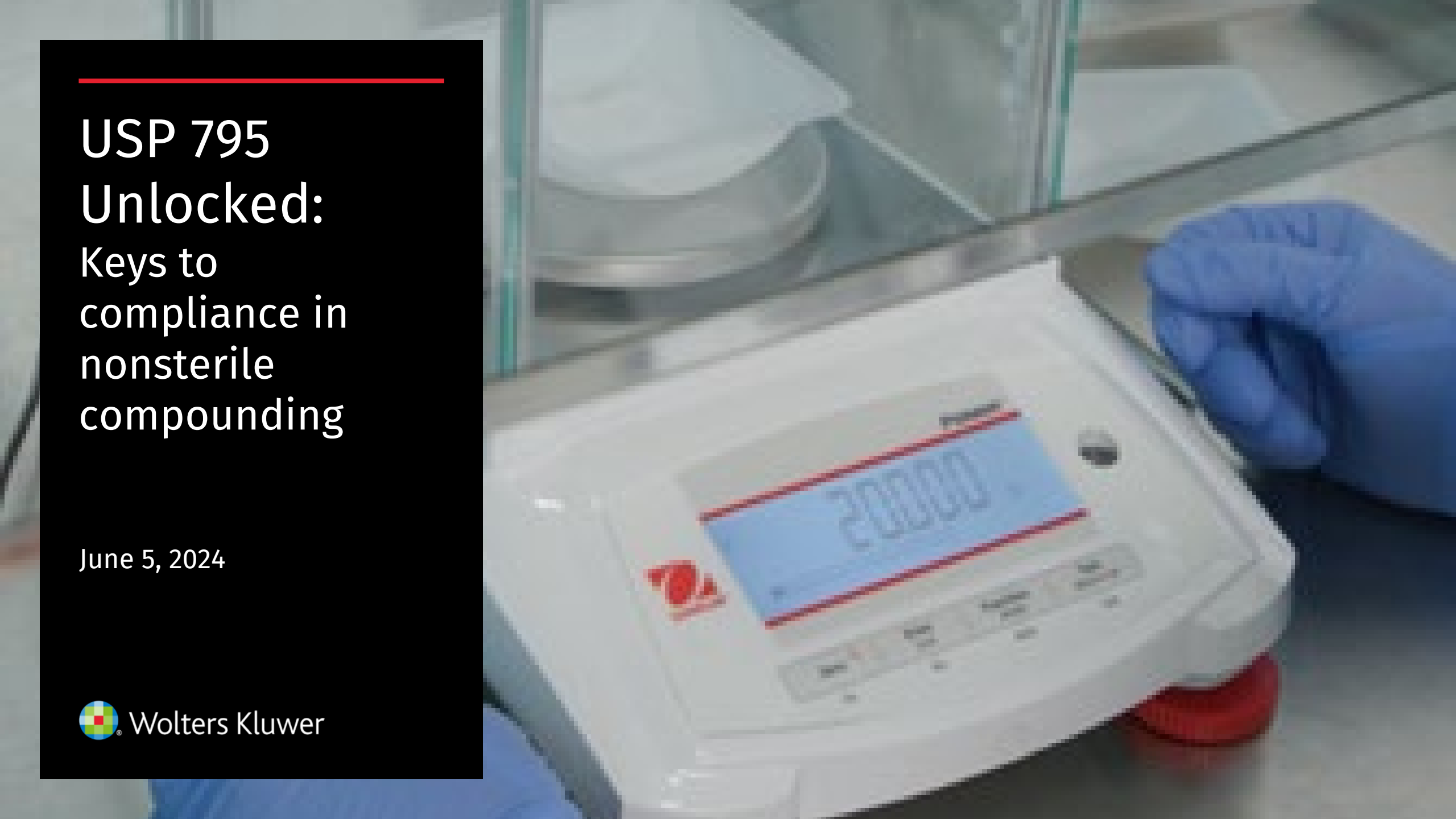
USP 795 Unlocked:

Keys to compliance in nonsterile compounding

June 5, 2024



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Introductions

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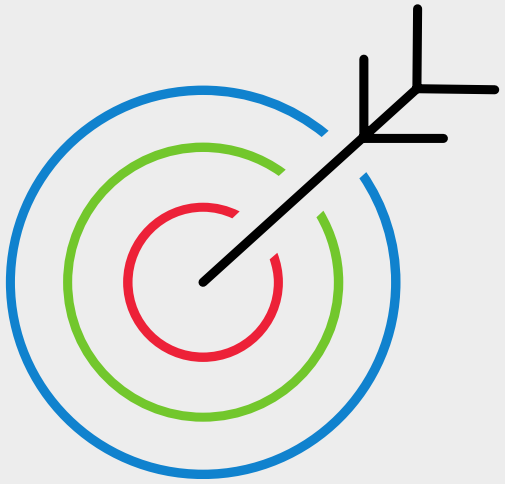
Learning Objectives



1. **Identify and apply key areas of compliance** with updated USP 795 standards and impacts on pharmacy operations.

2. **Compare and contrast practices from USP 795, 797, and 800,** highlighting the unique requirements including commonalities and differences in the requirements and core skills.

3. **Apply a standard framework for decision-making** related to the implementation of USP 795 and ongoing compliance in your daily practice.

Polling Question

What best describes your current pharmacy practice setting?

A. Independent or retail pharmacy

B. Rural or community hospital with less than 50 beds

C. Mid-size hospital (51-400 beds)

D. Large medical center (400+ beds)

E. Other non-acute setting

Polling Question

What is your experience level with USP <795> standards?

A. **Novice** — little to no experience, just beginning

B. **Advanced beginner** — some experience, have read 795

C. **Competent** — moderate experience, comfortable navigating 795

D. **Proficient** — significant experience, understand nuances of 795

E. **Expert** — years (10+) of experience, 795 trainer or DP

USP <795>

Introduction and Scope:

> This chapter describes the **minimum standards** to be followed for the preparation of compounded nonsterile preparations (CNSPs) for humans and animals." (emphasis added)

USP <795> *Pharmaceutical Compounding – Nonsterile Preparations*. In: USP-NF. Rockville, MD: USP; November 1, 2023.

Decision-making framework

- Quality in nonsterile compounding requires more than USP <795>.
- Make decisions based on the risk to preparation and the risk to the compounder.
- Utilize what you have learned from USP <797> and/or USP <800> principles.
- Avoid “only” being concerned about hazardous drug containment.

USP <795>

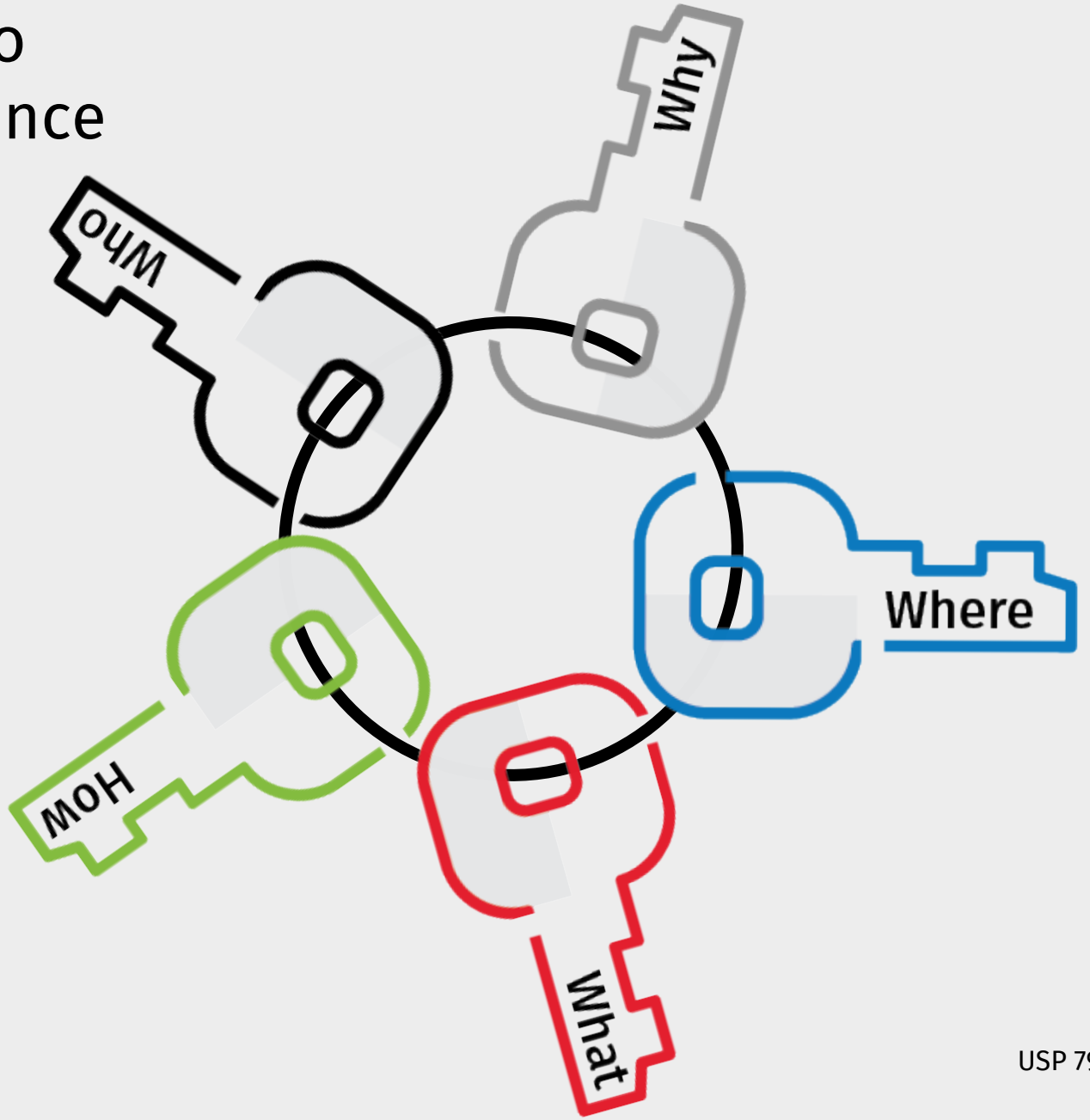
Introduction and Scope:

"The requirements in this chapter must be followed to minimize harm, including death, to human and animal patients that could result from:

1. excessive microbial contamination,
2. variability from the intended strength of correct ingredients (e.g., ±10% of the labeled strength),
3. physical and chemical incompatibilities,
4. chemical and physical contaminants, and/or
5. use of ingredients of inappropriate quality."

USP <795> *Pharmaceutical Compounding – Nonsterile Preparations*.
In: USP-NF. Rockville, MD: USP; November 1, 2023.

5 Keys to Compliance



Where

Environment

Key areas of compliance

Environment

Nonsterile compounding environment

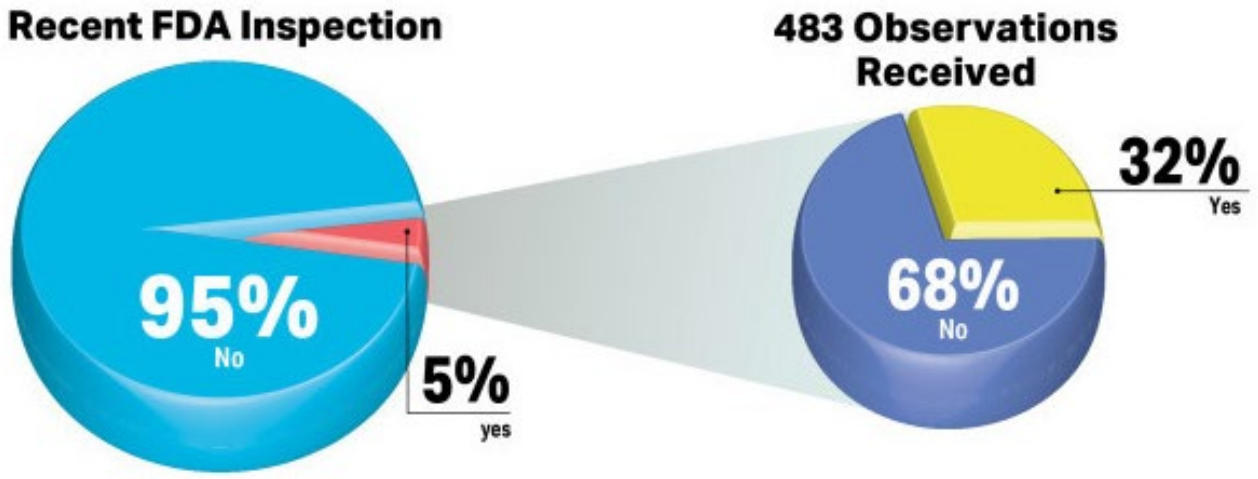
- Designated area
  - “clean, orderly, sanitary condition and in a good state of repair”
  - No other activities in the area during compounding
  - How will you designate the area?
  - Sink (water = microbial growth)
- USP 800
  - Sink is 3 feet from the PEC

Key areas of compliance

Where

Environment

Insanitary conditions



FDA inspections remain rare. Nevertheless, 5% of all hospital pharmacies have been inspected by the FDA in the past 2 years, up from just 2% in 2022. The likelihood of receiving a 483 observation during such an inspection skyrocketed: Last year, just 6% of FDA inspections resulted in 483 observations, while 32% of this year's inspections included 483 observations.

State of Pharmacy Compounding 2024. Pharmacy Purchasing & Products Magazine, April 2024; 21(4): 16. Available at: https://www.pppmag.com/article/3248, accessed May 24, 2024

Key areas of compliance

Environment

FDA Guidance

- Insanitary Conditions at Compounding Facilities
- Hospital and Health System Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act
  - "The drug products are compounded in accordance with all other applicable requirements of the FD&C Act and FDA regulations (e.g., **the drug products are not made under insanitary conditions** (section 501(a)(2)(A)) or misbranded (e.g., section 502(g))." (emphasis added)

OBSERVATION 7

Non-microbial contamination was observed in your production area.

Specifically, we observed what appeared to be rust inside the cabinet storing both hazardous bulk drug substances and hazardous chemicals. The bottom door hinges and the bottom shelf on this cabinet had visible rust shavings.

Specifically,

a) The ceiling of your (b) (4) Room, which is used to manufacture drug products containing

hormones, contains two air inlet vents, one of which was visibly covered with apparent dust build-up on 02/24/22. That same day, I observed the manufacture of the following drug product lots in the (b) (4) Room while air could be felt actively being blown into the room through the vents:

- Liothyronine (T3)/Methocel (Veg) (b) (4) mcg capsules, (b) (4) units, lot 02232022:96
- Progesterone (b) (4) mg per (b) (4) mL drops, (b) (4) mL, lot 02232022:24
- Estradiol (b) mg/Estriol (b) mg/Progesterone (b) (4) mg/Testosterone (b) mg per gm cream, (b) (4) gm, lot 02242022:63
- Progesterone (b) (4) mg suppositories, (b) (4) units, lot 02242022:42

https://www.fda.gov/media/159208/download https://www.fda.gov/media/159423/download

OBSERVATION 7

OBSERVATION 2

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Key areas of compliance

Environment

Section 6.1 Equipment

> Weighing, measuring, or otherwise manipulating components that could generate airborne chemical particles (e.g., active pharmaceutical ingredients [APIs], added substances, and conventionally manufactured products) must be evaluated to determine if these activities must be performed in a closed-system processing device **to reduce the potential exposure to personnel or contamination of the facility or CNSPs**." (emphasis added)

USP <795> *Pharmaceutical Compounding – Nonsterile Preparations*.
In: USP-NF. Rockville, MD: USP; November 1, 2023.

Assessment Question

USP <795> requires the following for the nonsterile compounding environment:

A. Dedicated area, sanitary condition

B. Designated area, insanitary condition

C. Designated area, sanitary condition

D. Dedicated area, insanitary condition

Assessment Question

What distance is specified in USP <800> between the PEC and a sink?

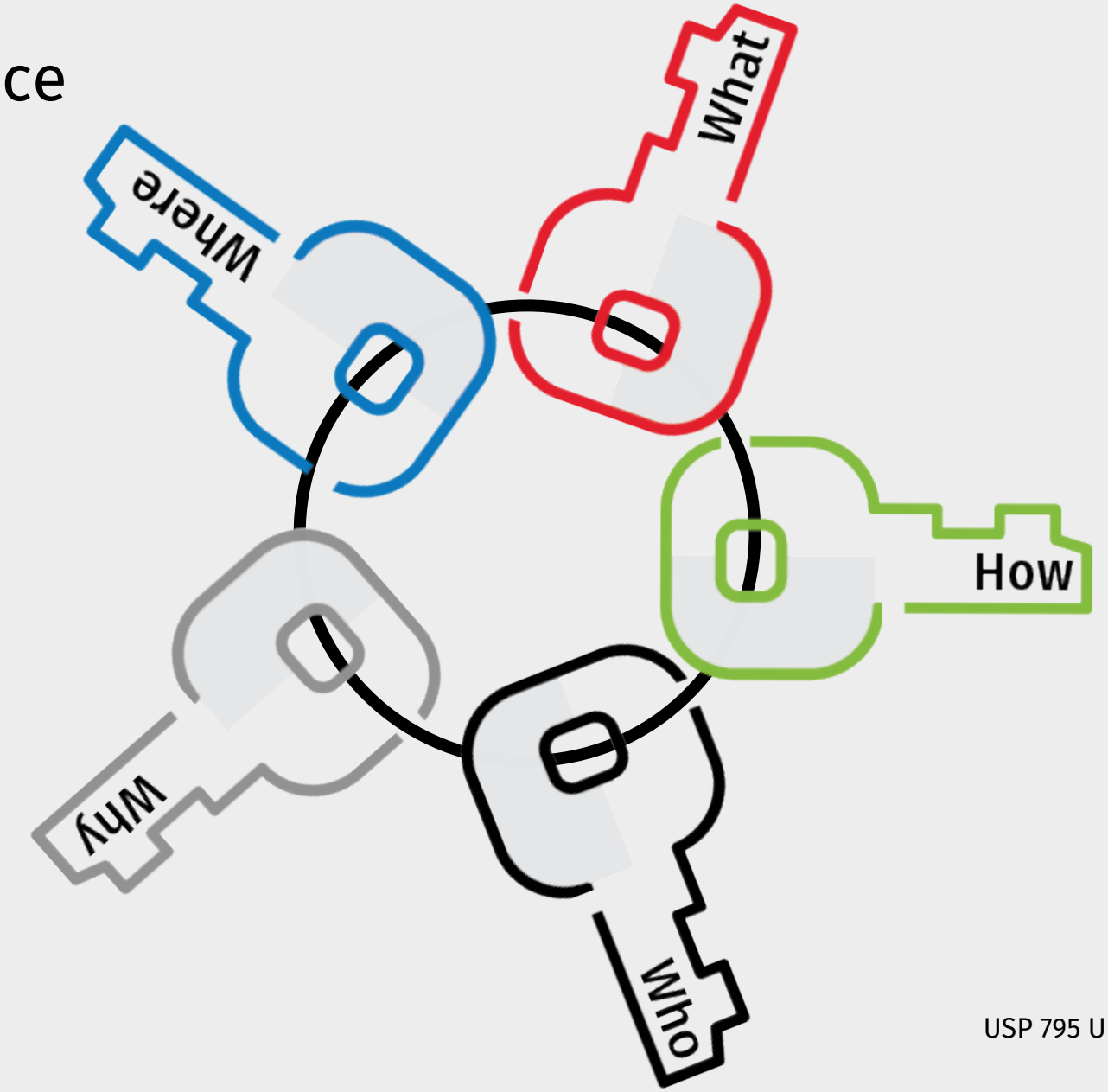
A. 3 meters

B. 30 inches

C. 3 centimeters

D. 3 feet

5 Keys to Compliance



How

Process

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Key areas of compliance

Standard Operating Procedures

- PPE considerations, what else is important - think like a 797 compounder
  - USP 795 requires gloves and then you make decisions
  - “Other garb must be appropriate for the type of compounding performed and should be worn as needed for the protection of personnel from chemical exposures and for prevention of CNSP contamination.”

Section 3.3 Garb and Glove Requirements.
USP <795> *Pharmaceutical Compounding – Nonsterile Preparations* .
In: USP-NF. Rockville, MD: USP; November 1, 2023.

Key areas of compliance

Process

Hand Hygiene Procedures

- Wash hands with soap and water for at least 30 seconds.
- Dry hands completely with disposable towels or wipers.
- Allow hands to dry thoroughly before donning gloves.

USP <795> *Pharmaceutical Compounding – Nonsterile Preparations*. In: USP-NF. Rockville, MD: USP; November 1, 2023.

Assessment Question

What PPE combination below would best protect the compounder and the CNSP?

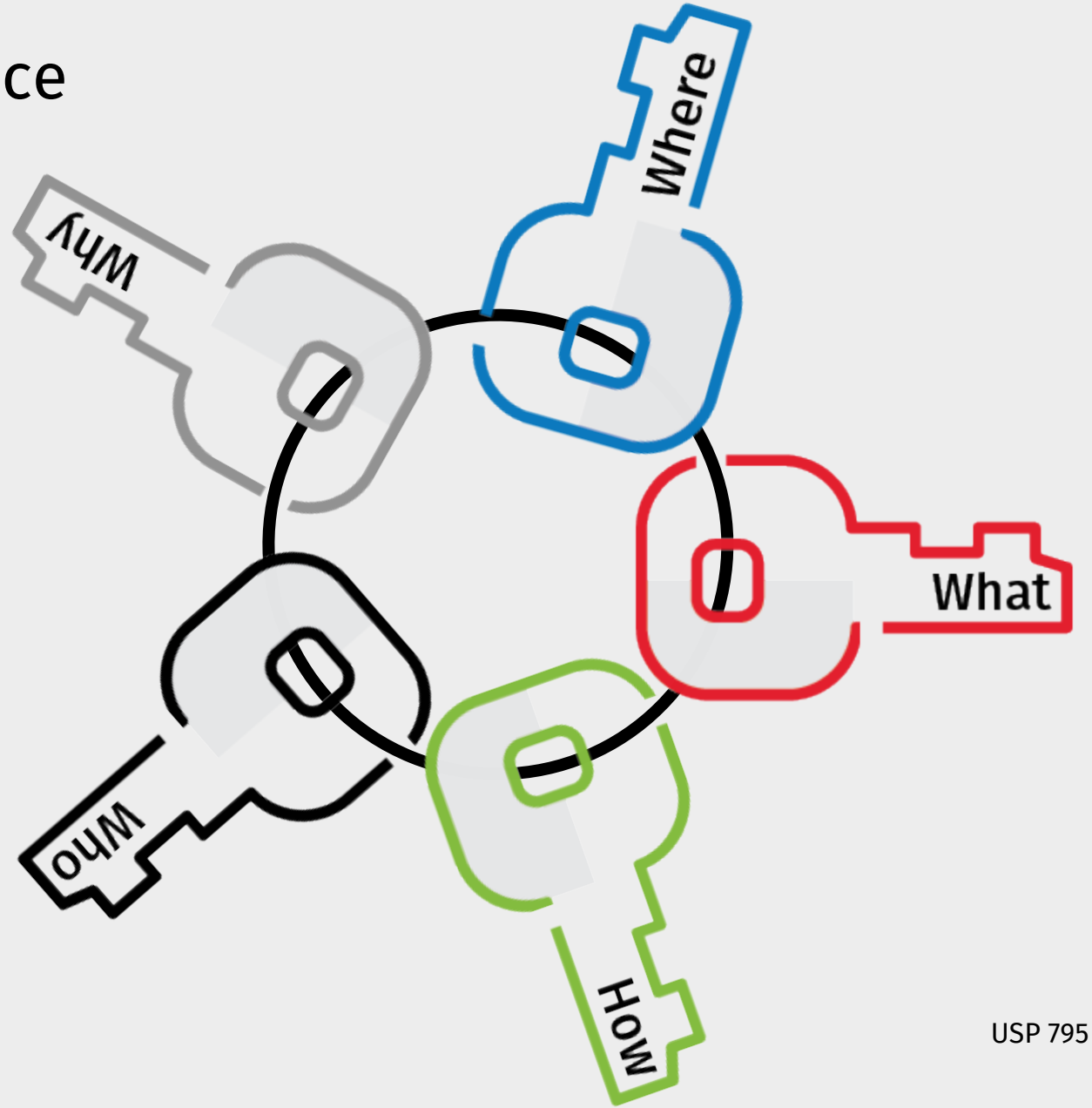
A. Gloves only

B. No PPE is required

C. Gloves, gown, facemask, hair cover

D. Face mask, facial hair cover, hair cover, shoe covers, gown, gloves

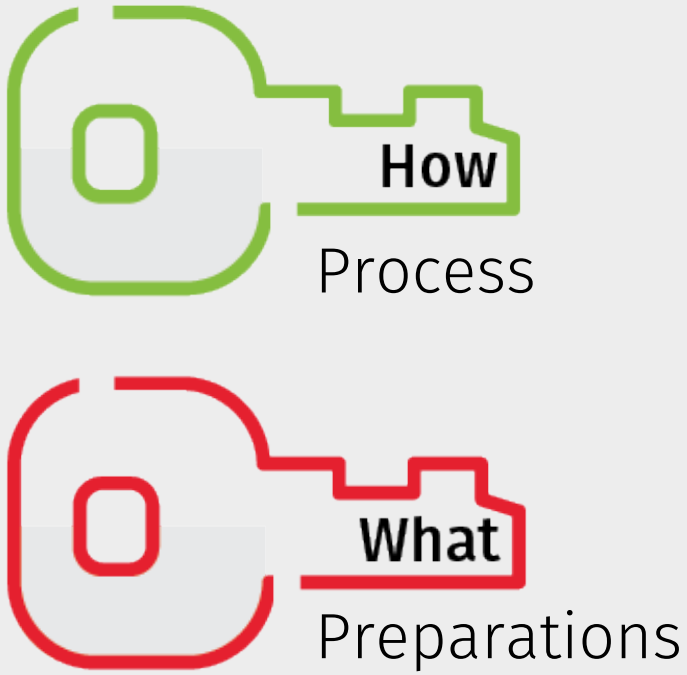
5 Keys to Compliance



What

Preparations

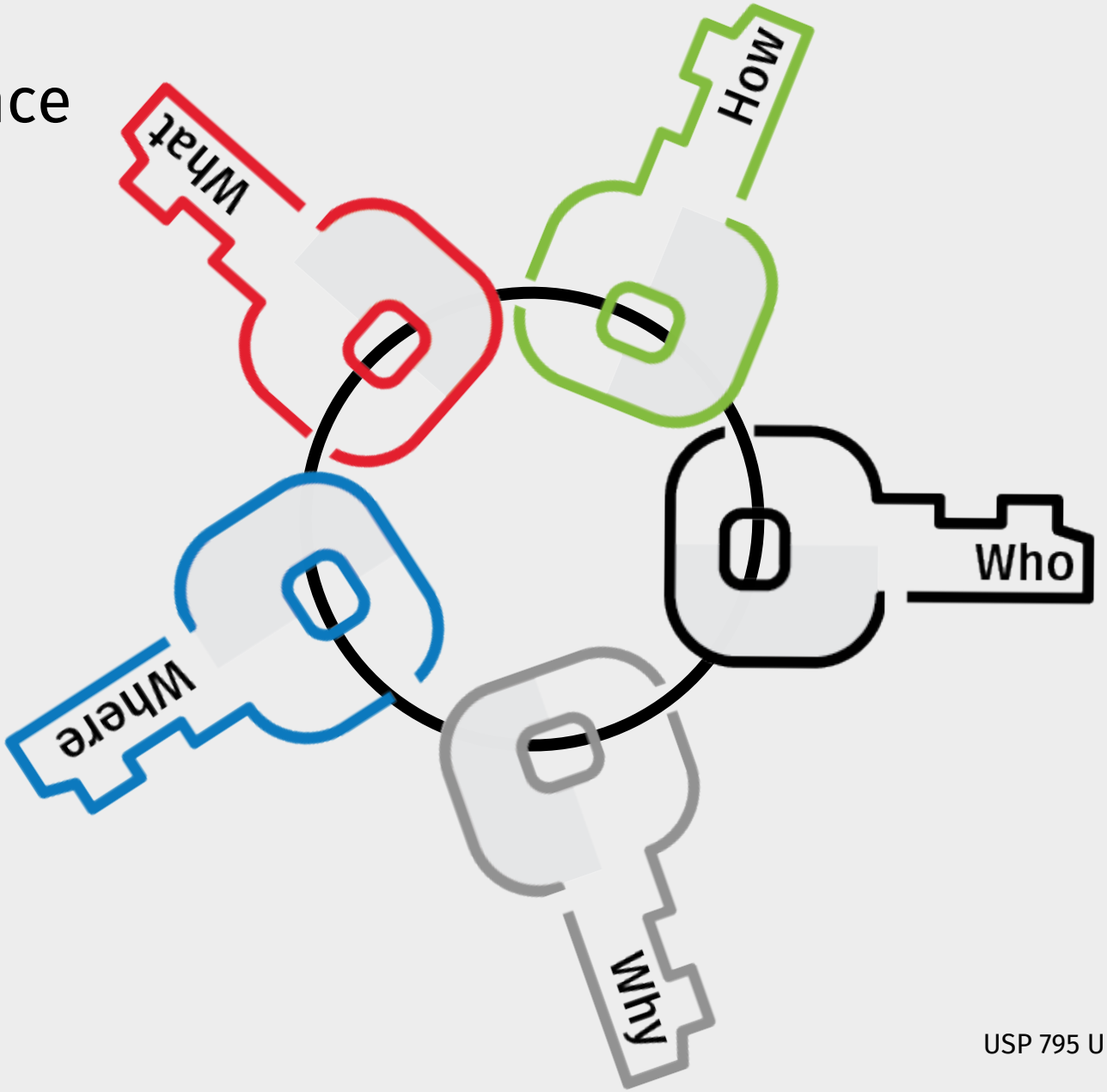
Key areas of compliance



Process and preparations

- Master formulation record
- Component selection
- Certificate of analysis (COA)
- Beyond-use dates
- Testing
  - Antimicrobial effectiveness testing
  - Stability indicating assays

5 Keys to Compliance



Who

People

Key areas of compliance

Compounding Personnel

- Compounders
- Direct oversight of compounding
- Designated Person
- Assigned trainer

Other Personnel:

- In-process or final verification check
- Dispensing of CNSPs
- Cleaning
- Receiving, restocking, shipping

Initially and every 12 months

Per facility SOPs

Applicable to their assigned tasks

Designated Person(s)

One or more individuals **responsible & accountable** for all aspects of nonsterile compounding operation

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Designated Person

Key areas of compliance

<795> Designated Person

- Component selection and COAs
- Monitoring and observing CNSP activities
- Standard Operating Procedures (SOPs)
- MFRs, BUDs, testing
- QA/QC program

Assessment Question

Compared to other USP <797> and <800>, the Designated Person(s) for Nonsterile Compounding is uniquely responsible for:

A. Facility SOPs

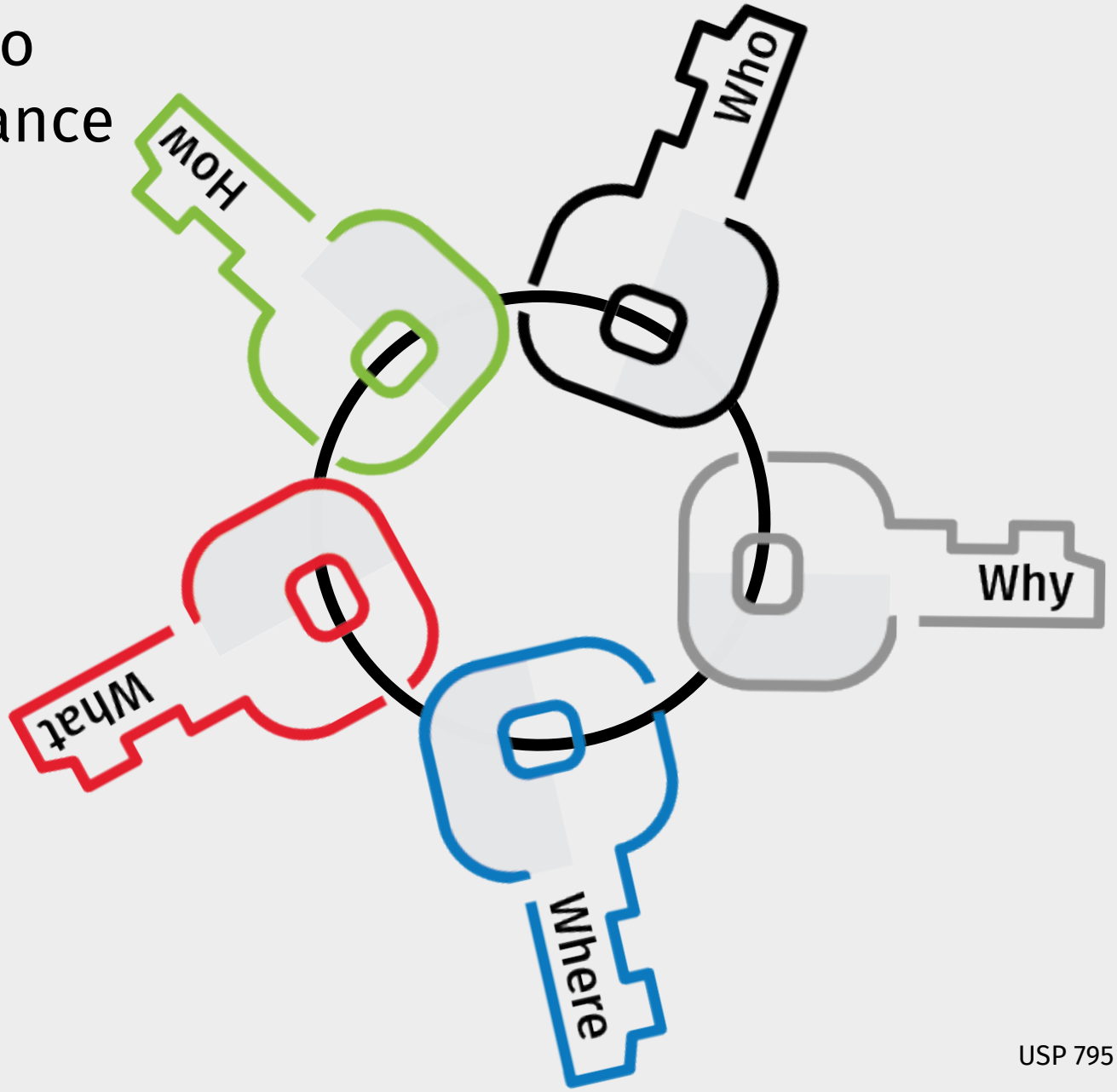
B. Component selection

C. Personnel training and competency

D. Particle containment device evaluation

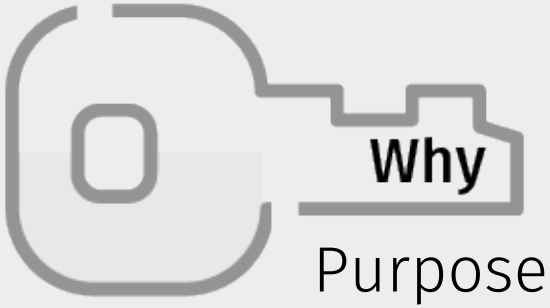
E. All of the above

5 Keys to Compliance

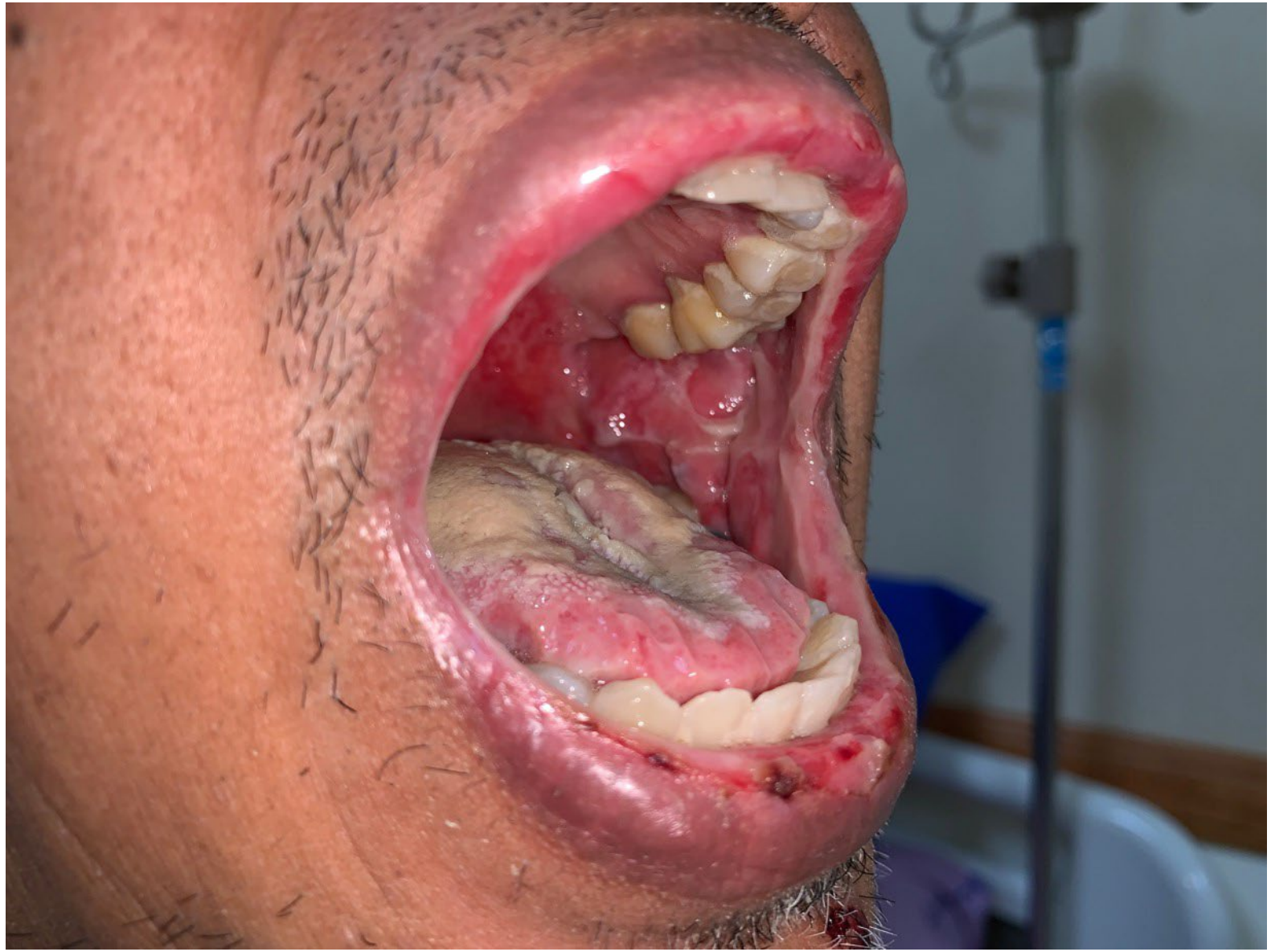


Why
Purpose

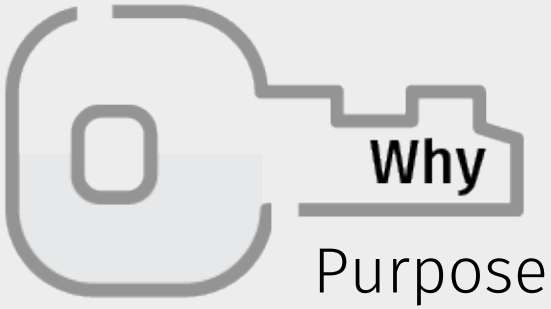
Key areas of compliance



Purpose



Key areas of compliance



It's not *just* Magic Mouthwash or butt paste

- Nonsterile compounding requires:
  - Attention to the compounding environment and equipment
  - Reliable and repeatable processes
  - Trained and competent personnel
  - Quality components, evidence, and testing

To ensure safe and high-quality custom medications for each and every patient.

USP 795 Unlocked: Keys to compliance in nonsterile compounding

Resources

- Wolters Kluwer resources
  - Simplifi® 797 compounding compliance software solution, including 795 module
  - CE Webinar USP <795> Final Version: Overview of the updated requirements, April 2023
- PCCA resources

  www.pccarx.com/healthsystems

  https://www.pccarx.com/uspupdate/usp795
- FDA resources
  - Insanitary Conditions Guidance https://www.fda.gov/media/124948/download
  - Hospital and Health System Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act https://www.fda.gov/media/97353/download
- USP resources
  - 795 FAQ: https://go.usp.org/USP_GC_795_FAQs

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