

Nuclear Pharmacy: Departments Questions when 795, 797, and 825 are Official - Part 1

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CARE PHARMACY SERVICES Helping to Keep the Pharmacy Running

Nuclear Pharmacy Conference: October 7-8, 2023

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Financial Disclosures

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Learning Objectives

- Describe the changes taking place with the implementation of USP 825, 797, and 795.
- Identify the additional USP Chapters that are applicable to nuclear pharmacy.
- Describe how internal procedures and parameters are determined and why they matter.

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Outline

Part 1

- USP <825> Radiopharmaceuticals - Preparation, Compounding, Dispensing, and Repackaging
- USP <795> Pharmaceutical Compounding - Nonsterile Preparations
- USP <797> Pharmaceutical Compounding - Sterile Preparations

Part 2

- USP <7> Labeling
- USP <71> Sterility Tests
- USP <85> Bacterial Endotoxins Test
- USP <659> Packaging and Storage Requirements
- USP <790> Visible Particulates in Injections
- USP <1116> Microbiological Control and Monitoring of Aseptic Processing Environments

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Get to Know the Attendees

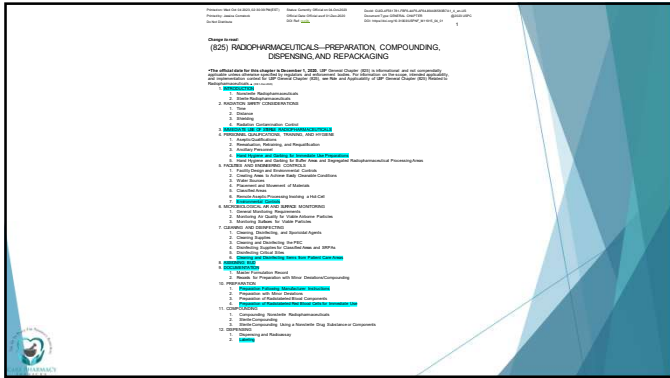
- ▶ What practice area do you work in?
 - ▶ 📍 Primarily SPECT
 - ▶ ❤️ Primarily PET
 - ▶ 🏠 I get to handle both PET and SPECT products
- ▶ How long have you been practicing?
 - ▶ 📅 Up to 5 years
 - ▶ ❤️ 5-20 years
 - ▶ 🏠 More than 20 years
- ▶ Where do you practice?
 - ▶ 📍 In Florida
 - ▶ ❤️ Outside of Florida

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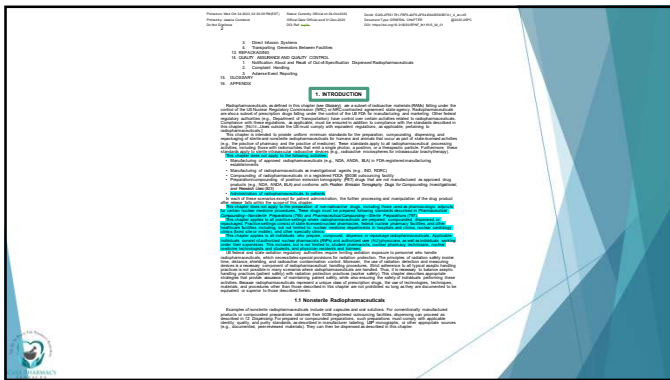
USP <825> Radiopharmaceuticals - Preparation, Compounding, Dispensing, and Repackaging

- ▶ Official: December 1, 2020
- ▶ Joint Commission Revised Requirements Released:
 - ▶ Revised Requirements for Medication Compounding to Align with USP Revisions for Medication Compounding Certificate: June 20, 2023
 - ▶ Revised Requirements Related to Medication Compounding for Hospitals: August 21, 2023
 - ▶ Revised Requirements Related to Medication Compounding for Critical Access Hospitals: August 21, 2023
- ▶ Enforceable: November 1, 2023
- ▶ Joint Commission Revised Requirements Effective: January 1, 2024

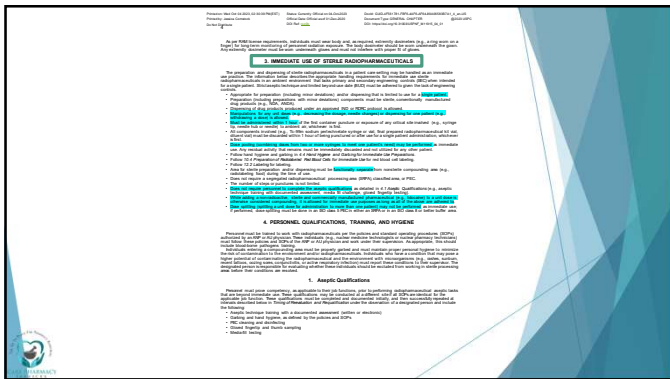
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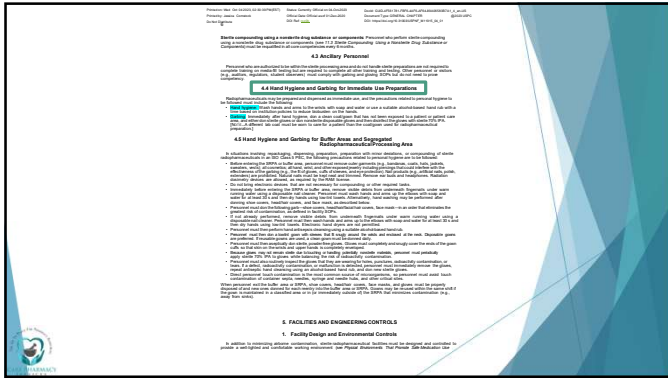
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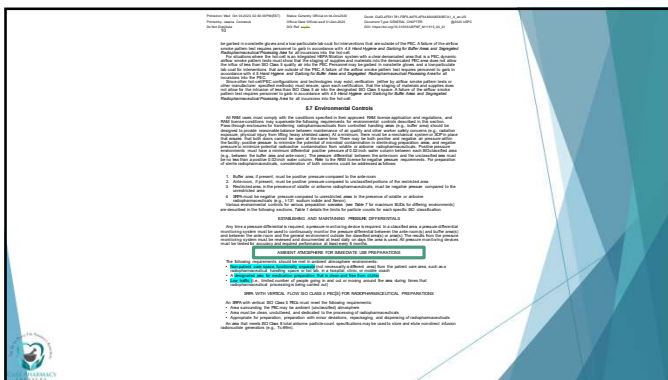


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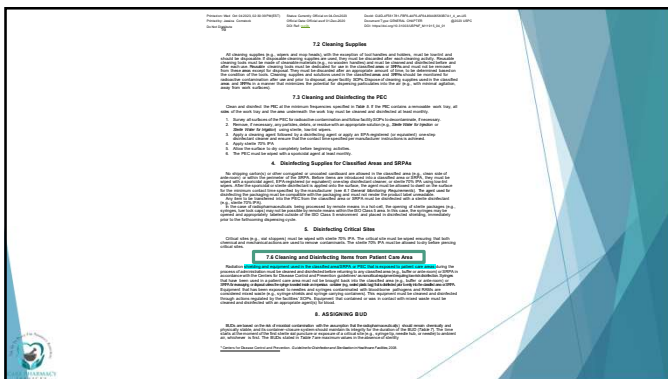
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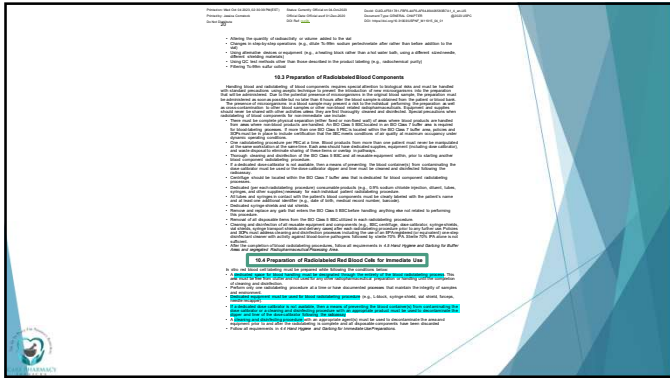
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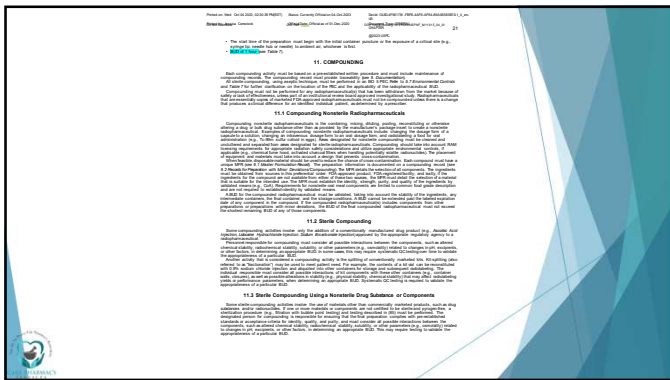


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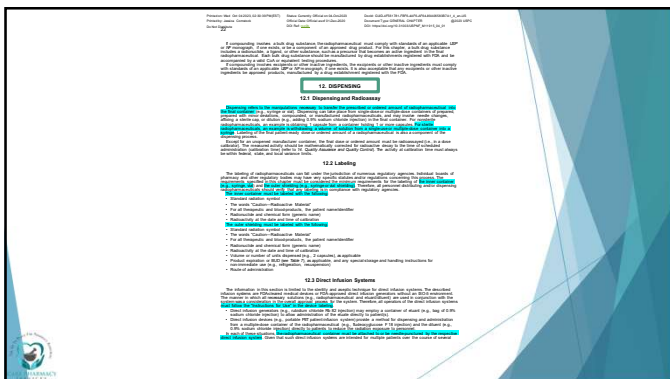
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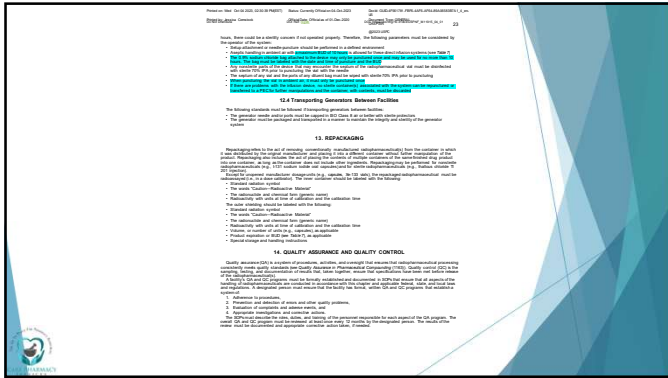
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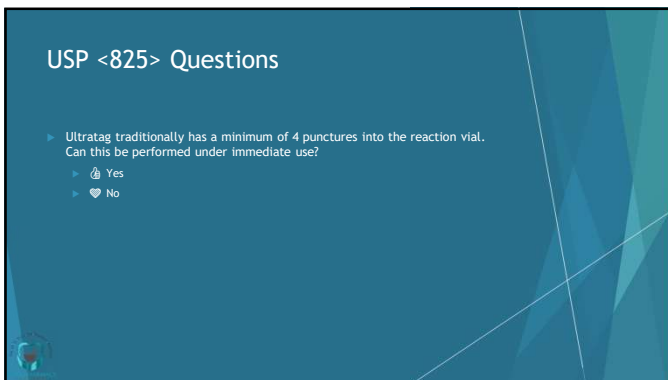
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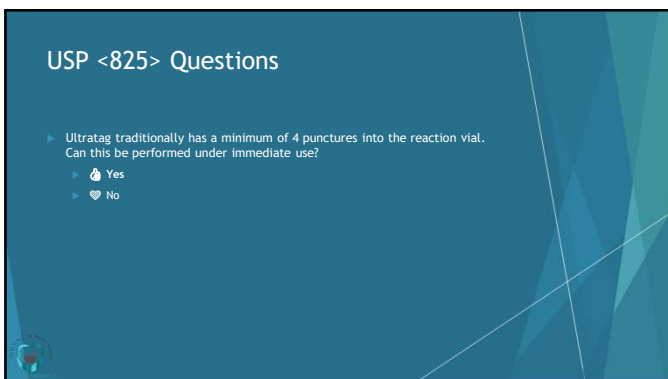
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USP <825> Questions

- ▶ When an MAA kit is prepared in the nuclear medicine department per package insert, does quality control testing need to be done?
 - ▶ Yes
 - ▶ No

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USP <825> Questions

- ▶ When an MAA kit is prepared in the nuclear medicine department per package insert, does quality control testing need to be done?
 - ▶ Yes
 - ▶ No

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USP <795> Pharmaceutical Compounding - Nonsterile Preparations

- ▶ Joint Commission Revised Requirements Released:
 - ▶ Revised Requirements for Medication Compounding to Align with USP Revisions for Medication Compounding Certificate: June 20, 2023
 - ▶ Revised Requirements Related to Medication Compounding for Hospitals: August 21, 2023
 - ▶ Revised Requirements Related to Medication Compounding for Critical Access Hospitals: August 21, 2023
- ▶ Official: November 1, 2023
- ▶ Enforceable: November 1, 2023
- ▶ Joint Commission Revised Requirements Effective: January 1, 2024

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USP <795> Questions

- ▶ In a traditionally nuclear pharmacy setting, does USP 795 apply to any of the activities performed?
 - ▶ Yes
 - ▶ No

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USP <797> Pharmaceutical Compounding - Sterile Preparations

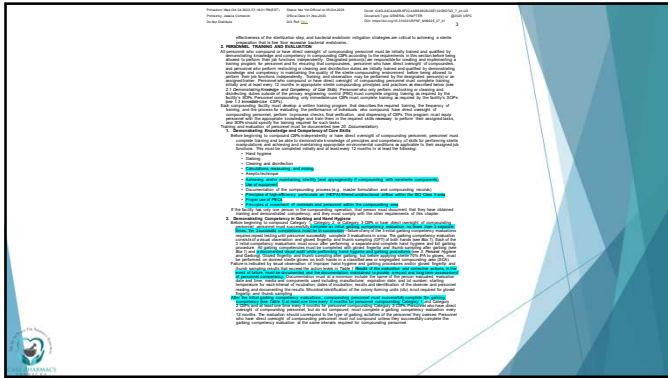
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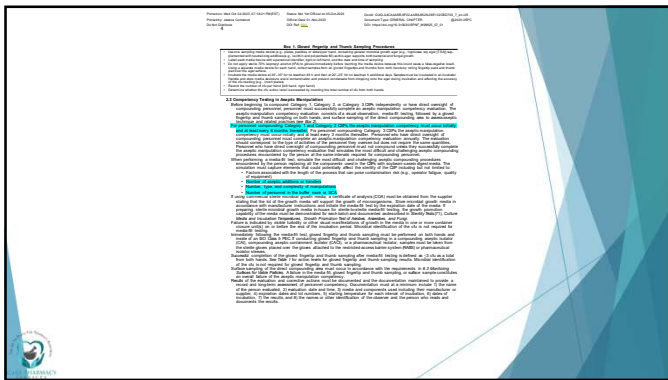
USP <797> Questions

- ▶ In a traditionally nuclear pharmacy setting, does USP 797 apply to any of the activities performed?
 - ▶ Yes
 - ▶ No

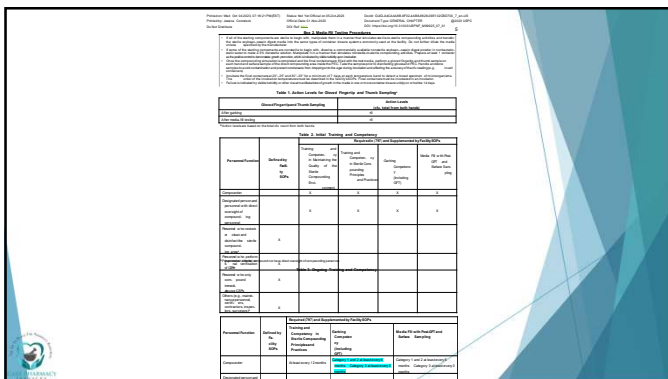
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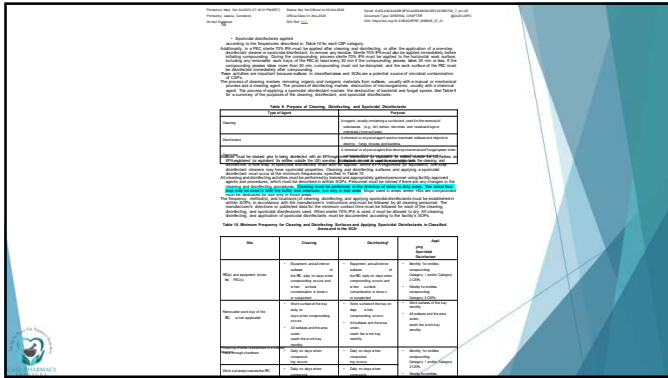
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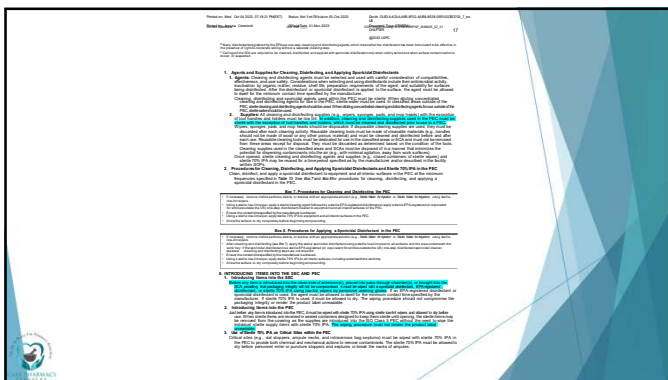
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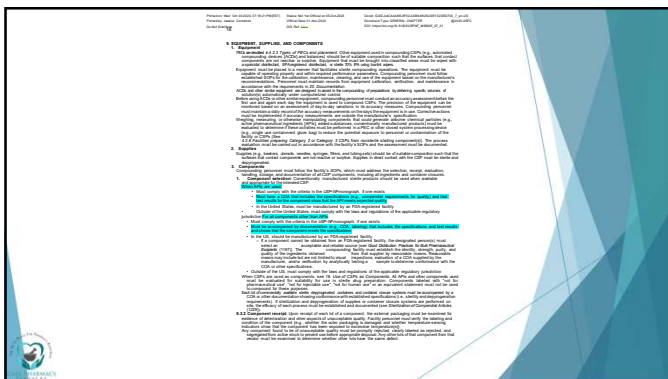
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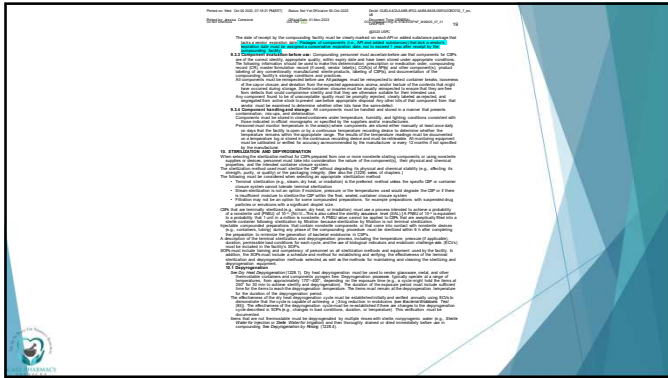
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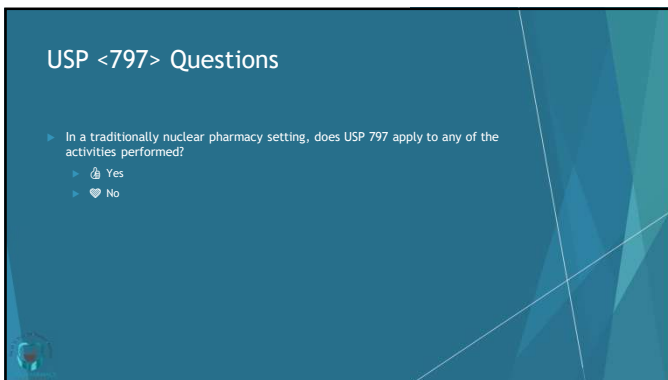
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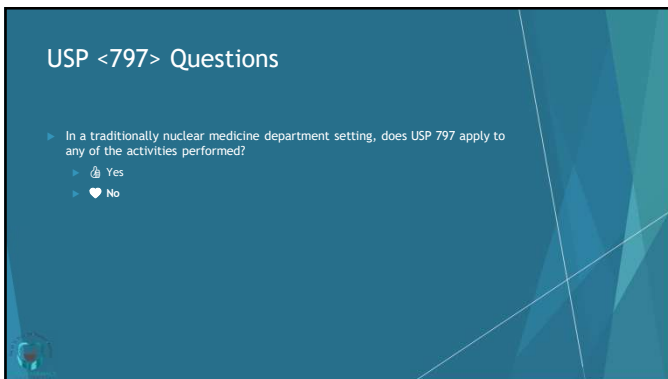
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USP <797> Questions

▶ In a traditionally nuclear medicine department setting, does USP 797 apply to any of the activities performed?

- ▶ Yes
- ▶ No

