USP <797>
Key Changes

HARDY DIAGNOSTICS
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The following represents key changes from the currently enforceable version of USP Chapter <797> (last major revision in 2008) to the revised USP Chapter <797> (official as of November 1, 2023). The following are the major changes and are not meant to be an exhaustive list of the entirety of all changes made. Some changes will be reported as direct text excerpts from the respective chapter (notated by quotation marks), while others will be reported as a general comment describing the text or change. Note: Bolding has been added to the text below for emphasis.

Category	USP <797>, 2008[1]	USP <797>, 2023[2]
Initial garbing competency evaluations  **Hardy Products:** **PART #:W520** SterEM™ Tryptic Soy Agar (TSA) with Lecithin and Tween® 80, USP, Irradiated, Triple Bagged	Compounders need to pass garbing competency evaluations before beginning to prepare CSPs	**Garbing competency evaluations include:** • **Visual observation** • **Gloved fingertip and thumb sampling (GFT) of both hands** **Compounders and those who have direct oversight of compounders** • **" ... must complete an initial garbing competency evaluation no fewer than 3 separate times. The 3 successful completions must be in succession ... "** **Remediation of failed competency** • **" ... failure of any of the 3 initial garbing competency evaluations requires repeat testing until personnel successfully completes 3 evaluations in a row."**
Ongoing garbing competency evaluations *The frequency for "visual observation of hand hygiene and garbing" has increased.  **Hardy Products:** **PART #:W520** SterEM™ Tryptic Soy Agar (TSA) with Lecithin and Tween® 80, USP, Irradiated, Triple Bagged	Visual observation of hand hygiene and garbing • At least annually Gloved fingertip and thumb sampling • Low/medium risk – at least annually • High-risk – at least semiannually	**Compounders** • **Category 1 and 2: at least every 6 months** • **Category 3: at least every 3 months** **Those who have direct oversight of compounders** • **At least every 12 months**

Category	USP <797>, 2008 [1]	USP <797>, 2023 [2]
Ongoing aseptic manipulation competency evaluations  **Hardy Products:** HardyVAL™ Test kits and HardyVAL™ a la carte items	"Each person authorized to compound in a low-risk or medium-risk level environment: At least annually" "Each person authorized to compound in a high-risk level environment: At least semiannually"	**Compounders** • **Category 1 and 2: at least every 6 months** • **Category 3: at least every 3 months** **Those who have direct oversight of compounders:** • **At least every 12 months**
Viable air sampling – timing and locations  **Hardy Products:** TRIO.BAS™ active air samplers, and culture media for samplers. Please see our air sampling catalog or **hardydiagnostics.com/triobas**	At least every 6 months for all compounds	**Category 1 and Category 2:** • **At least every 6 months** **Category 3** • **Within 30 days before the start of any Category 3 compounding** • **At least monthly**
Surface sampling – timing and locations *The frequency for "surface sampling" has now been defined. **Hardy Products:** **Part #: P520** LokTight™ Tryptic Soy Agar (TSA), w/Lecithin and Tween®, USP, Irradiated, Triple Baggage 	"Surface sampling shall be performed in all ISO classified areas on a periodic basis"	**Locations:** • **Equipment contained within the PEC** • **Staging or work area(s) near the PEC** • **Frequently touched surfaces** **Category 1 and 2** • **At least monthly** **Category 3** • **At least weekly** • **Prior to assigning a BUD longer than the limits established for Category 2 CSPs**

References

1. United States Pharmacopeial Convention. General chapter <797> pharmaceutical compounding—nonsterile preparations. USP43-NF38. Rockville, MD: U.S. Pharmacopeial Convention; 2019.

2. United States Pharmacopeial Convention. General chapter <797> pharmaceutical compounding—sterile preparations. USP-NF 2023, Issue 1, November 1, 2022, official as of November 1, 2023.

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Kevin and Patti are members of the USP Compounding Expert Committee, but this resource is not affiliated with or endorsed by USP.