USP <797> Table 2 vs. Table 3: What's the Difference — and Why It Matters for Ongoing Competency

One of the most common sources of confusion in USP <797> compliance is the relationship between Table 2 and Table 3. At first glance, these tables appear similar: both outline personnel training and competency expectations. In practice, however, they serve very different purposes — and misunderstanding that difference can leave compounding programs exposed.



More importantly, one critical competency listed in Table 2 does not carry over into Table 3, even though the risk it addresses does not go away once personnel are initially qualified. That gap is where strong training programs distinguish themselves from minimum compliance.

This blog breaks down the intent of each table, clarifies what is *required* versus what is *recommended*, and explains why compounders should strongly consider including all Table 2 competencies in their ongoing training and assessment programs, even when they are not explicitly repeated in Table 3.

The Purpose of Table 2: Initial Training and Qualification

Table 2 in USP <797> is focused on initial training and qualification of compounding personnel. Its role is straightforward: no one may compound sterile preparations independently until they have demonstrated competency in the knowledge and skills necessary to prevent contamination.

Table 2 includes the following requirements:

- Training and Competency in Maintaining the Quality of the Sterile Compounding Environment
- Training and Competency in Sterile Compounding Principles and Practices
- Garbing Competency including gloved fingertip testing (GFT)
- Media fill with post-GFT and surface sampling

Importantly, Table 2 includes media-fill testing as part of the initial qualification process — a direct, observable assessment that the individual can compound a sterile preparation without introducing microbial contamination.

The intent here is baseline assurance. Before a person compounds, the organization must be confident that they can do so safely.

The Purpose of Table 3: Ongoing Maintenance of Competency

Table 3, by contrast, applies to ongoing competency assessment after initial qualification. It defines how organizations must periodically confirm that compounding personnel continue to meet expectations over time.

Table 3 includes the following requirements:

- Training and Competency in Sterile Compounding Principles and Practices
- Garbing Competency including gloved fingertip testing (GFT)
- Media fill with post-GFT and surface sampling

This table reflects the reality that sterile compounding competency is not static. Skills can drift. Habits can change. Systems evolve.

However, notably training and competency in maintaining the quality of the sterile compounding environment is not listed in Table 3 — even though it appears as a core competency in Table 2.

This omission often leads organizations to assume that maintaining the quality of the sterile compounding environment is only an initial requirement. From a strict compliance perspective, that interpretation may appear defensible. From a risk and quality perspective, it deserves closer scrutiny.

The Missing Competency — and Why It Matters

Maintaining the quality of the sterile compounding environment is unique among competency assessments because it evaluates the entire aseptic process as a system, not just individual behaviors. Removing that assessment after initial qualification assumes that once a compounder demonstrates they are able to maintain the quality of the sterile compounding environment, the risk of poor cleanroom behavior permanently disappears. In reality, the opposite is often true.

Why USP <797> Separates the Tables

USP <797> separates Table 2 and Table 3 intentionally. Table 2 establishes entry competence, while Table 3 defines minimum ongoing assurance.

That does not mean Table 3 is meant to be exhaustive.

USP standards consistently distinguish between:

- Required minimums, and
- Risk-based best practices

Table 3 lists what must be reassessed. It does not prohibit facilities from reassessing additional competencies.

This distinction is critical for leadership teams and designated persons making defensible decisions about quality systems.

Why Organizations Should Include Table 2 Competencies in Ongoing Programs

Organizations that mature beyond checklist compliance often choose to incorporate maintaining the quality of the sterile compounding environment into ongoing training and assessment, even though it is not explicitly repeated in Table 3.

Including periodic assessment of cleanroom behavior as part of continuing competency signals that the organization understands sterile compounding as a process under continuous control, not a one-time qualification hurdle.

Importantly, this approach aligns with broader quality principles emphasized throughout USP <797>: prevention, verification, and documentation of control — not reaction after failure.

Final Takeaway

Table 2 and Table 3 in USP <797> are not interchangeable — they serve different but complementary functions. Table 2 qualifies personnel to enter sterile compounding. Table 3 maintains baseline assurance over time. However, the absence of competency from Table 3 does not mean the risk it addresses disappears. In sterile compounding, compliance is the floor — control is the goal.