

USP Chapter 797 Final Requirements

Because
Practice Matters!
to the AAAAI

Which Will You Choose?

When USP provides an implementation date, each practice will need to implement changes to adhere to new USP Chapter 797 rules. This includes the use of an ISO Class 5 PEC hood, or constructing a dedicated allergenic extract compounding area (AECA).

BOTH AREAS WILL NEED TO ADHERE TO THE FOLLOWING:

- Must be located away from unsealed windows, doors that connect outdoors, and traffic flow
- May not be located adjacent to environmental control challenges (restrooms, warehouses, food prep areas)
- Must be at least 1 foot away from sinks
- Impact of activities around or adjacent to PEC or AECA must be considered

Dedicated Allergenic Extracts Compounding Area (AECA) OR ISO Class 5 PEC

- Needs a visible perimeter
- While compounding, the area must be restricted to authorized personnel
- During compounding activities, no other activity is permitted in the AECA
- Surfaces around AECA must be cleanable and kept clean (ceilings, walls, floors, fixtures, shelving, counters, cabinets)
- No carpet
- Surfaces should be resistant to damage by cleaning and sanitizing agents
- Surfaces in AECA upon which allergenic extract prescription sets are prepared must be smooth, impervious, free from cracks and crevices, and non-shedding for optimal cleaning
- Must minimize overhangs and ledges, and when present, must be cleanable (utility pipes, windowsills)
- Must be a well-lit environment with temperature and humidity controls

CLEANING

- All work surfaces in AECA where direct compounding occurs must be cleaned and disinfected at the beginning and end of each compounding shift, when there are spills, and when surface contamination is known or suspected
- Vial stoppers on packages of conventionally manufactured sterile ingredients must be disinfected by careful wiping with sterile 70% IPA swabs to ensure that the critical sites are wet and allowed to dry before they are used to compound allergenic extracts prescription sets.

- PEC must be certified every 6 months

CLEANING

- All interior surfaces of PEC must be cleaned and disinfected at the beginning and end of each compounding shift, when there are spills, and when surface contamination is known or suspected.
- The horizontal work surface must be disinfected between each prescription set
- Vial stoppers on packages of conventionally manufactured sterile ingredients must be disinfected by careful wiping with sterile 70% IPA swabs to ensure that the critical sites are wet and allowed to dry before they are used to compound allergenic extracts prescription sets.

This information is based on a draft of USP Chapter 797 from 2018. When USP provides an implementation date, each practice will be responsible for evaluating how to implement the final version. Visit aaaai.org and read Practice Matters! for important updates.

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Additional information is available in USP General Chapter <797> Pharmaceutical Compounding-Sterile Preparations.

If you have questions, contact advocacy@aaaai.org.