

USP Chapter 797 Final Requirements

Because
Practice Matters!
to the AAAAI

When USP determines an implementation date, Chapter 797 Standards require that compounding of allergen extracts must occur in an ISO Class 5 PEC (Primary Engineering Control) or a dedicated allergenic extract compounding area (AECA).

EITHER FACILITY MUST:

- Be located away from unsealed windows, doors that connect outdoors, and traffic flow.
- Not be located adjacent to environmental control challenges (restrooms, warehouses, food prep areas).
- Be at least 1 meter away from sinks.
- Consider impact of activities around or adjacent to PEC or AECA.

Which Will You Choose?

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 easy cleaning and disinfecting
- Must minimize overhangs and ledges, and when present, must be cleanable (utility pipes, windowsills)
- Must be a well-lighted environment with temperature and humidity controls

CLEANING

- All work surfaces in AECA where direct compounding occurs must be cleaned and disinfected daily and when surface contamination is known or suspected.
- Apply sterile 70% IPA to the horizontal work surface between each prescription set.
- If present, walls, doors, and door frames within the AECA perimeter must be cleaned and disinfected monthly and when surface contamination is known or suspected.
- Ceilings within the perimeter of the AECA must be cleaned and disinfected when visibly soiled and when surface contamination is known or suspected.
- Vial stoppers on packages of conventionally manufactured sterile ingredients must be wiped with sterile 70% IPA 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 daily and when surface contamination is known or suspected. Apply sterile 70% IPA to the horizontal work surface between each prescription set.
- The horizontal work surface must be disinfected between each prescription set.
- Vial stoppers on packages of conventionally manufactured sterile ingredients must be wiped with sterile 70% IPA to ensure that the critical sites are wet and allowed to dry before they are used to compound allergenic extracts prescription sets.

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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.