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.

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

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