USP Chapter 797 Standards require that on December 1, 2019 and after, 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**

**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.

**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.

**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.**

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