

The following information is excerpted from the final USP (797) Chapter on Pharmaceutical Compounding—Sterile Preparations that take effect November 1, 2023. These are the minimum standards for allergy practice; individual states may enact more stringent requirements.

Dedicated Allergenic Extract Compounding Area (AECA) or ISO Class 5 PEC Hood—Which Will You Choose?

Allergy practices can opt to use an ISO Class 5 PEC hood, or construct a dedicated allergenic extract compounding area (AECA).

BOTH the PEC and AECA must meet the following requirements:

- 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 meter away from sinks
- Impact of activities around or adjacent to PEC or AECA must be considered



	Dedicated AECA	ISO Class 5 PEC Hood
Additional requirements	<ul style="list-style-type: none"> • Needs visible perimeter • No carpeting • While compounding, access must be restricted to authorized personnel • During compounding activities, no other activity is permitted in the area • Surfaces of walls, floors, fixtures, shelving, counters and cabinets in the AECA must be cleanable • Surfaces should be resistant to damage by cleaning and disinfecting agents <ul style="list-style-type: none"> - Standard drywall/paint can be damaged by cleaning agents - Epoxy paint, and vinyl or fiberglass panels affixed to a wall are cost-effective options • Surfaces upon which allergen extract prescription sets are prepared must be smooth, impervious, free from cracks and crevices, and non-shedding for optimal cleaning • Minimize dust-collecting overhangs (utility pipes, ledges, windowsills) and when present must be cleanable • Well-lighted environment with temperature and humidity controls 	<ul style="list-style-type: none"> • Must be certified every 6 months
Cleaning procedures/ requirements	<ul style="list-style-type: none"> • All work surfaces where direct compounding occurs must be cleaned and disinfected at the beginning and end of each compounding shift, when spills occur, and when surface contamination is known or suspected • Apply sterile 70% IPA to the horizontal work surface 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 • Clean and disinfect walls, doors and door frames within the AECA perimeter monthly, and when surface contamination is known or suspected • Clean and disinfect ceilings within the AECA perimeter when visibly soiled and when surface contamination is known or suspected 	<ul style="list-style-type: none"> • All interior surfaces of the PEC must be cleaned and disinfected at the beginning and end of each compounding shift, when spills occur, and when surface contamination is known or suspected • Apply sterile 70% IPA to the horizontal work surface 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

If you have questions, contact practicemanagement@aaaai.org