Hot Off the Press: Final Standards for Allergen Extract Compounding under USP Chapter 797

Under the new standards, to continue in-office compounding of individual treatment sets for allergen immunotherapy, otolaryngic allergy practices will, beginning Dec. 1, need to comply with the following:

1. Personnel Qualifications

- Designate one person to oversee and evaluate compounding personnel.
- Provide training and testing on principles and procedures for new staff and annual evaluation for others for sterile compounding, garbing, hygiene, gloved fingertip and thumb sampling and media fill tests.
- Ensure that compounding personnel wear powder-free sterile gloves; non-cotton, low-lint sleeved garments that gather at the wrist and close at the neck; face mask and disposable cover for head and facial hair.

2. Facilities

- Compounding must occur in either (1) an ISO Class 5 Primary Engineering Control (PEC) OR (2) in a dedicated Allergenic Extracts Compounding Area (AECA), either of which must not be within one meter from a sink and can't be near unsealed windows, doors to the outside, or high traffic or other areas that present environmental control challenges such as bathrooms or kitchens.
- If used, a PEC must be certified every 6 months, and cleaned and disinfected before and after each compounding, and surface must be disinfected between each prescription set.
- An AECA must have a visible perimeter and meet the following conditions:
  - o Access restricted to authorized personnel.
  - o No other activity permitted during compounding.
  - o All surfaces must be cleanable and kept clean.
  - o No carpet is allowed.
  - o No surfaces that can be damaged by cleaning and sanitizing agents.
  - o Surfaces must be smooth, impervious, non-shedding, and free of cracks or crevices.
  - o Overhangs should be avoided or must be easily cleaned.
  - o Well lit, and temperature and humidity controlled for comfort of compounding personnel.
  - o Work surface must be cleaned and disinfected before and after each compounding session, and disinfected between each new set, as well as at the time of any spill or contamination.
- Vial stoppers on packages of conventionally manufactured sterile ingredients must be disinfected with 70% IPA wipes before each use.
- Walls, doors, and door frames within and AECA must be disinfected monthly and when contamination is suspected.
- Ceilings in the AECA must be cleaned and disinfected when visibly soiled.

3. Documentation

- Labels on prescription sets must include patient name, type and fractional dilution with corresponding vial number, beyond use date, and required storage conditions.
- Standard Operating Procedures manuals describing required compounding process.
- Training, assessment results, evaluations, and qualification records for all compounding personnel, including any corrective actions following assessments and evaluations.
- Certification reports for PEC, if used.
- Temperature logs for refrigeration.
- Compounding records for individual extract prescription sets.
- Information on any complaints and adverse events.
- Investigations and corrective actions following any complaints and adverse events.

To download a copy of USP 797 go to: **https://www.usp.org/compounding**

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Glossary *

- **Allergenic extract prescription set:** Combinations of licensed allergenic extracts which would be mixed and diluted to provide subcutaneous immunotherapy to an individual patient, even though these allergenic extract combinations are not specified in the approved BLAs for the licensed biological products.
- **Allergenic extracts:** Biological substances used for the diagnosis and/or treatment of allergic diseases such as allergic rhinitis, allergic sinusitis, allergic conjunctivitis, bee venom allergy, and food allergy.
- **Allergenic extracts compounding area (AECA):** A designated, unclassified space, area, or room with a visible perimeter that is suitable for preparation of allergenic extract prescription sets.
- **Aseptic processing:** A method by which separate, sterile components (e.g., drugs, containers, or closures) are brought together under conditions that maintain their sterility. The components can either be purchased as sterile or, when starting with nonsterile components, can be separately sterilized prior to combining (e.g., by membrane filtration, autoclave).
- **Aseptic technique:** A set of methods used to keep objects and areas free of microorganisms and thereby minimize infection risk to the patient. It is accomplished through practices that maintain the microbe count at an irreducible minimum.
- **Compounding:** The process of combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug or bulk drug substance to create a sterile medication.
- **Garb:** Items such as gloves, garments (e.g., gowns, coveralls), shoe covers, head and facial hair covers, masks, and other items designed to reduce particle-shedding from personnel and minimize the risk of contamination of CSP(s).
- **Gloved fingertip and thumb sampling:** Process to evaluate a compounder's competency in correctly performing hand hygiene and garbing.
- **Media-fill test:** A simulation used to qualify processes and personnel engaged in sterile compounding to ensure that the processes and personnel are able to prepare CSPs without contamination.

* Glossary descriptions extracted from the 2019 release of the USP General Chapter <797> Pharmaceutical Compounding -Sterile Preparations. Download a copy of USP 797: https://www.usp.org/compounding

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USP 797 Compliance Training and Media Fill Test Workshop at the 2019 AAOA Annual Meeting

Join us at the 2019 AAOA Annual Meeting in New Orleans, September 13, 2019 for an optional paid workshop on USP 797 Compliance Training and Media Fill Test!

The USP guidelines are due to go in effect by the end of the year. Take advantage of this opportunity to have your staff review compliance training (note: laptop/tablet required) and check that box for the year. The AAOA is rolling out its new online compliance training module to help you and your staff ahead of the curve and make sure everyone is practicing within the new USP 797 protocol. In addition to USP compliance, we are offering a media fill kit to complete the compounding training.

When: September 13, 2019 - 3:45 PM - 5:45 PM
Where: 2019 AAOA Annual Meeting
Hilton New Orleans Riverside
New Orleans, LA

Cost: $125 per AAOA member
$300 per non member