USP Chapter 797 Proposed Requirements

Because **Practice Matters!** to the AAAAI

Personnel Hygiene and Garbing

All personnel who perform compounding procedures must follow specific hygiene and garbing requirements, including the following:

- Hand washing procedures as outlined below
- Wear the following garb:
  - Powder-free sterile gloves
  - Non-cotton, low-lint garment with sleeves that fit snugly around the wrists and that is enclosed at the neck
  - Face mask
  - Low-lint, disposable cover for head and if applicable, disposable cover for facial hair

Hand Hygiene Procedure

To appropriately wash hands before compounding, follow these steps:

1. Remove debris from underneath fingernails under warm running water using a disposable nail cleaner. Wash hands and forearms up to the elbows with soap and water for at least 30 seconds.
2. Dry hands and forearms to the elbows completely with low-lint disposable towels or wipes.
3. Apply an alcohol-based hand rub with persistent antimicrobial activity to dry skin, following the manufacturer's instructions for application times, and use a sufficient amount of product to keep the hands wet for the duration of the application time.
4. Allow hands to dry thoroughly before donning sterile gloves.

Documentation

Compounding Records must include at least the following information:

- Name, concentration, volume, vendor or manufacturer, lot number, and expiration date for each ingredient
- Date and time of preparation of the allergenic extract
- Assigned internal identification number
- Identity of all individuals involved in each step
- Total quantity compounded
- Assign Beyond Use Date (BUD): no later than the earliest expiration date of any allergenic extract or any diluent that is part of the prescription set, AND must not exceed 1 year from the date the prescription set is mixed
- Documentation of results of quality control (QC) procedures (e.g visual inspection, second verification of quantities)

This information is based on a draft of USP Chapter 797 from 2018. The final version of Chapter 797 will be published on June 1, 2019. Each practice will be responsible for evaluating how to implement the final version, which becomes official as of December 2019. Visit aaaai.org and read Practice Matters! for important updates.

American Academy of Allergy Asthma & Immunology

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Personnel Qualifications

Before beginning to independently prepare allergen extracts, all compounding personnel must complete training and be able to demonstrate knowledge of theoretical principles and skills for sterile compounding. The following personnel training must be completed and documented prior to compounding allergen extracts, and must be reevaluated ANNUALLY:

- Pass a written exam
- Gloved fingertip and thumb sampling (3 times before beginning to prepare prescription sets, and then at least annually thereafter)
- Media-fill test (annual)
  ***Personnel who have not compounded an allergenic extract prescription set in more than 6 months must be reevaluated with a written exam, gloved fingertip and thumb sampling, and a media fill test before resuming compounding duties

Gloved Fingertip and Thumb Sampling Procedure

Perform evaluation after completing hand hygiene and garbing procedures

- Use one sampling device per hand (e.g., plates, paddles, or slides) containing general microbial growth agar supplemented with neutralizing additives to support both bacterial and fungal growth. Label each contact sampling device with a personnel identifier, the right or left hand, and the date and time of sampling.
- Put on gloves. Do not disinfect gloves immediately before touching the sampling device as this could cause a false-negative result.
- Using a separate sampling device for each hand, collect a gloved fingertip and thumb sample from both hands by rolling finger pads and thumb pad over the agar surface.
- Incubate the sampling device at a temperature of 30°–35° for no less than 48 hours and then at 20°–25° for no less than 5 additional days. If using plates or slides, invert them during incubation to prevent condensate from dropping onto the agar and affecting the accuracy of the colony-forming unit (CFU) reading.
- Record the number of CFU per hand (left hand, right hand).
- Determine whether the CFU action level is exceeded by counting the total number of CFU on both hands.

Media-Fill Testing Procedure

- Use sterile or non-sterile soybean casein digest media to stimulate compounding techniques. If all the starting components are sterile, use sterile soybean-casein digest media and if some starting components are non-sterile, use a non-sterile soybean-casein digest. Do not further dilute the media unless specified by the manufacturer.
- Once the compounding simulation is completed and the final containers are filled with the test media, incubate them in an incubator for 7 days at 20°–25° followed by 7 days at 30°–35° to detect a broad spectrum of microorganisms. Failure is indicated by visible turbidity or other visual manifestations of growth in the media in one or more container–closure unit(s) on or before 14 days.

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