Facilities that prepare CSPs must develop SOPs for the compounding process and other support activities.

- A designated person must ensure that SOPs are appropriate and are implemented, which includes ensuring that personnel demonstrate competency in performing every procedure that relates to their job function.
- A designated person must follow up to ensure that corrective actions are taken if problems, deviations, failures, or errors are identified.
- The corrective action must be documented.
All personnel who perform or oversee compounding or support activities must be trained in the SOPs. All compounding personnel must:

1) Be able to recognize potential
   - problems,
   - deviations,
   - failures, or
   - errors
   associated with preparing a CSP (e.g., those related to
   - equipment,
   - facilities,
   - materials,
   - personnel,
   - the compounding process, or
   - testing)
   that could potentially result in contamination or other adverse impact on CSP quality

2) Report any problems, deviations, failures or errors to the designated person(s).

• SOPs must be **reviewed at least every 12 months** by the designated person(s) to ensure that they reflect current practices, and the review must be documented.

• Any **changes or alterations** to an SOP must be **made only by a designated person** and must be documented.

• Revisions to SOPs must be **communicated to all personnel** involved in these processes and procedures, and personnel should document acknowledgment of the communication.

Does not seem to specify training or proficiency testing for SOP changes.
What are Standard Operating Procedures?

- Itemized instructions that describe
  - How a task will be performed – the procedure
  - Who will perform the task (including eligibility to perform the task)
  - Why the task is necessary
  - Any limitations in performing the task
  - What action to take when unacceptable deviations or discrepancies occur.

**Benefits of an SOP**

Ideally, an SOP

- Establishes and maintains a standard of practice
- Ensures consistency
- Allows delegation of tasks
- Sets out clear lines of accountability
- Provides useful template for training new staff
### Areas which should have SOPs

- Beyond-Use dating
- Chemical and physical stability
- Cleaning and disinfecting
- Component quality evaluation
- Compounding methods
- Dispensing
- Documentation
- Environmental quality and maintenance
- Equipment maintenance, calibration, and operation
- Formulation development
- Labeling
- Materials and final compounded preparation handling and storage
- Measuring and weighing
- Packaging and repackaging
- Patient monitoring, complaints, and adverse event reporting
- Patient or caregiver education and training
- Personnel cleanliness and garb
- Purchasing
- Quality Assurance and Continuous Quality Monitoring
- Safety
- Shipping
- Testing
- Training and retraining

Per USP<1163> Quality Assurance in Pharmaceutical Compounding

### Components of an SOP:

- Title
- SOP number
- Author(s)
- Date effective
- Authorization signature
- Responsibility
- Purpose of the procedure
- Equipment and supplies required
- Procedure
  - detailed step-by-step explanation that can be easily followed by different individuals with the same results. The instructions should be concise to minimize any required interpretation.
- References
- Documentation form—easily accessible written record or log and where to find it
- Revision date

ASHP Guidelines on Compounding Sterile Preparations (2014)
Distinguish the following documents:

- **Policy** – overarching document
- **Standard Operating Procedure** – from the policy, but more specific
- **Training Document(s)** – more explanatory and detailed; include testing
- **Check list** – for use to remember steps or order of steps
- **Documentation logbooks or electronic logs**

All five documents must match.

Changes to one document should accompany review of the corresponding documents.
Questions to Consider

How to develop an SOP?

• From the bottom up – development by the people doing the procedure on a regular basis
• Upper level dictate – the word comes down from on high (corporate).
• Committee – everybody gets a say

How are SOPs and changes communicated?

• By email → please read and sign that you understand
• Training program
• Word of mouth