USP <797> Compliance: 
Personnel Training and Evaluation

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Objective

To identify the USP <797> requirements for the Training and Evaluation of preparers of Compounded Sterile Products (CSPs)
Section References to Personnel Training and Evaluation within Chapter <797>

- RESPONSIBILITY OF COMPOUNDING PERSONNEL
- PERSONNEL TRAINING AND EVALUATION IN ASEPTIC MANIPULATION SKILLS
- ENVIRONMENTAL QUALITY AND CONTROL
- MAINTAINING STERILITY, PURITY, AND STABILITY OF ... CSPs
- APPENDICES

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Training and Evaluation References to Other USP Chapters

- USP <71> Sterility Tests
- USP <795> Pharmaceutical Compounding-Nonsterile Preparations
- USP <1075> Good Compounding Practices
- USP <1116> Microbial Evaluation of Clean Rooms and Other Controlled Environments
Who is responsible for Training and Evaluating compounding personnel?

“Qualified licensed healthcare professionals who supervise....”
Who must be Trained and Evaluated?

“Personnel who prepare CSPs shall be trained...”

– Includes those who prepare doses, not just those who prepare kits.
What are the sources of Training and Evaluation?

What are the specific methods of Training and Evaluation?

- Didactic training
- Written competence assessments
- Skill assessment
- Media-fill testing
In case of Evaluation failure?

Compounding personnel who fail ...

“... Shall be immediately re-instructed and re-evaluated ... to ensure correction of all aseptic deficiencies.”
What are the specific subjects of Training and Evaluation?

Compounding personnel shall be trained on the theoretical principles and practical skills of:

- Garbing procedures
- Aseptic work practices
- Cleaning and disinfection procedures
Garbing Procedure Training and Evaluation

• Garbing Training
  – Specific procedure detailed under heading Personnel Cleansing and Garbing

• Garbing Evaluation
  – Appendix III. Sample form for Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel
  – Will include gloved fingertip sampling
Cleaning and disinfection procedure
Training and Evaluation

• Cleaning/disinfection Training
  – Specific procedures detailed under heading Cleaning and Disinfecting the Compounding Area

• Cleaning/disinfecting evaluation
  – Appendix V. Sample Form for Assessing Cleaning and Disinfection Procedures
Aseptic Work Practices/Aseptic Manipulation Skills/Aseptic Work Skills/Aseptic Technique/Aseptic Manipulative Skills

• Aseptic Training
  – Didactic review
  – Written test

• Aseptic Evaluation
  – Appendix IV. Sample form for Assessing Aseptic Technique and Related Practices of Compounding Personnel
  – Media-fill testing
Media-fill Testing

• Used to assess the quality of the aseptic skill of compounding personnel.

• Should represent the most challenging conditions encountered.
Media-fill Testing

• USP <71> gives detailed instructions for preparation of media to be used.

• Media must pass “suitability” tests for sterility and for growth promotion.
Media-fill Testing

- USP <71> permits “ready-to-use”, commercially available media to be used for sterility tests provided they pass the suitability tests.

Valiteq RL-2 Validation Kit from Lab Safety Corporation
Media-fill Testing

- USP <71> permits “ready-to-use”, commercially available media to be used for sterility tests provided they pass the suitability tests.
Media-fill Testing

• Users should obtain and retain suitability test documentation from vendor.

• For GroMed products, available on QI Medical website.
Media-fill Testing

- Test procedure should incorporate all the most typical manipulations performed.

- Commercial kits contain instructions for appropriate risk levels for non-radioactive CSPs, but not for radiopharmaceuticals.
Media-fill Testing

Standard instructions should be modified to simulate unique manipulations of nuclear pharmacy.

Include use of all syringe/needle size combinations used routinely

Include transfers from and into routinely-used shielded vials of appropriate sizes

Include manipulations with and without use of syringe shield

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Media-fill Testing

USP <797> provides for options in incubation of samples:

1. 14 days at 20 to 25 degrees C, or
2. 14 days at 30 to 35 degrees C, or
3. 7 days at 20 to 25 degrees C followed by 7 days at 30 to 35 degrees C.
Media-fill Testing

14 day incubation is required, not 7-10 days as suggested by literature in some commercially available kits.

Personnel failure indicated by visible turbidity in the medium on or before 14 days.
SUMMARY

USP <797> contains specific and detailed information about the Training and Evaluation of Personnel Compounding CSPs, including:

- Responsibility
- Applicability
- Sources
- Methods
- Subjects

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