

Appendix I. Principal Competencies, Conditions, Practices, and Quality Assurances That Are Required († “shall”) and Recommended (‡ “should”) in USP Chapter (797) (continued)

PATIENT OR CAREGIVER TRAINING

† Multiple component formal training program to ensure patients and caregivers understand the proper storage, handling, use, and disposal of CSPs.

PATIENT MONITORING AND ADVERSE EVENTS REPORTING

† Written standard procedures describe means for patients to ask questions and report concerns and adverse events with CSPs, and for compounding supervisors to correct and prevent future problems.

‡ Adverse events and defects with CSPs reported to FDA’s MedWatch and USP’s MEDMARX programs.

GLOSSARY

† Twenty-eight terms are defined and integral to complying with USP (797).

Appendix II. Common Disinfectants Used in Health Care for Inanimate Surfaces and Noncritical Devices, and Their Microbial Activity and Properties¹

Chemical Category of Disinfectant							
	Isopropyl alcohol	Accelerated hydrogen peroxide	Quaternary Ammonium (e.g., dodecyl dimethyl ammonium chloride)	Phenolics	Chlorine (e.g., sodium hypochlorite)	Iodophors (e.g., povidone-iodine)	
Concentration Used	60–95%	0.5% ³	0.4–1.6% aq	0.4–1.6% aq	100–5000 ppm	30–50 ppm	
Microbial Inactivation ²	Bacteria	+	+	+	+	+	
	Lipophilic viruses	+	+	+	+	+	
	Hydrophilic viruses	±	+	±	±	±	
	M.tuberculosis	+	+	±	+	±	
	Mycotic agents (fungi)	+	+	+	+	±	
	Bacterial Spores	–	–	–	–	+	–
Important Chemical & Physical Properties	Shelf life >1 week	+	+	+	+	+	
	Corrosive or deleterious effects	±	–	–	–	±	
	Non-evaporable residue	–	–	+	+	–	+
	Inactivated by organic matter	+	±	+	±	+	+
	Skin irritant	±	–	+	+	+	±
	Eye irritant	+	–	+	+	+	+
	Respiratory irritant	–	–	–	–	+	–
Systemic toxicity	+	–	+	+	+	+	

Key to abbreviation and symbols: aq = diluted with water; ppm = parts per million; + = yes; – = no; ± = variable results.

¹ Modified from World Health Organization, Laboratory Bio Safety Manual 1983 and Rutala WA, “Antisepsis, disinfection and sterilization in the hospital and related institutions,” *Manual of Clinical Microbiology*, American Society for Microbiology, Washington, DC, 1995, pages 227-245.

² Inactivation of the most common microorganisms (i.e., bacteria) occurs with a contact time of ≤1 minute; inactivation of spores requires longer contact times (e.g., 5-10 minutes for 5,000 ppm chlorine solution against *C. difficile* spores). Reference: Perez J, Springthorpe VS, Sattar SA, “Activity of selected oxidizing microbicides against the spores of *Clostridium difficile*: Relevance to environmental control,” *American Journal of Infection Control*, August 2005, pages 320-325.

³ Accelerated hydrogen peroxide is a new generation of hydrogen peroxide-based germicides in which the potency and performance of the active ingredient have been enhanced and accelerated through the use of appropriate acids and detergents.

Appendix III. Sample Form for Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel

Printed name and position/title of person assessed: _____

Name of facility or location: _____

Appendix III. Sample Form for Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel

(continued)

Hand Hygiene and Garbing Practices: The qualified evaluator will check each space for which the person being assessed has acceptably completed the described activity, prints N/A if the activity is not applicable to the assessment session or N/O if the activity was not observed.*

_____	Presents in a clean appropriate attire and manner.
_____	Wears no cosmetics or jewelry (watches, rings, earrings, etc. piercing jewelry included) upon entry into ante-areas.
_____	Brings no food or drinks into or stored in the ante-areas or buffer areas.
_____	Is aware of the line of demarcation separating clean and dirty sides and observes required activities.
_____	Dons shoe covers or designated clean-area shoes one at a time, placing the covered or designated shoe on clean side of the line of demarcation, as appropriate.
_____	Dons beard cover if necessary.
_____	Dons head cover assuring that all hair is covered.
_____	Dons face mask to cover bridge of nose down to include chin.
_____	Performs hand hygiene procedure by wetting hands and forearms and washing using soap and warm water for at least 30 seconds.
_____	Dries hands and forearms using lint-free towel or hand dryer.
_____	Selects the appropriate sized gown examining for any holes, tears, or other defects.
_____	Dons gown and ensures full closure.
_____	Disinfects hands again using a waterless alcohol-based surgical hand scrub with persistent activity and allows hands to dry thoroughly before donning sterile gloves.
_____	Dons appropriate sized sterile gloves ensuring that there is a tight fit with no excess glove material at the fingertips.
_____	Examines gloves ensuring that there are no defects, holes, or tears.
_____	While engaging in sterile compounding activities, routinely disinfects gloves with sterile 70% IPA prior to work in the direct compounding area (DCA) and after touching items or surfaces that may contaminate gloves.
_____	Removes PPE on the clean side of the ante-area.
_____	Removes gloves and performs hand hygiene.
_____	Removes gown and discards it, or hangs it on hook if it is to be reused within the same work day.
_____	Removes and discards mask, head cover, and beard cover (if used).
_____	Removes shoe covers or shoes one at a time, ensuring that uncovered foot is placed on the dirty side of the line of demarcation and performs hand hygiene again. (Removes and discards shoe covers every time the compounding area is exited).

*The person assessed is immediately informed of all unacceptable activities (i.e., spaces lacking check marks, N/A, or N/O) and shown and informed of specific corrections.

_____	Signature of Person Assessed	_____	Printed Name	_____	Date
-------	------------------------------	-------	--------------	-------	------

_____	Signature of Qualified Evaluator	_____	Printed Name	_____	Date
-------	----------------------------------	-------	--------------	-------	------

Appendix IV. Sample Form for Assessing Aseptic Technique and Related Practices of Compounding Personnel

Printed name and position/title of person assessed: _____

Name of facility or location: _____

Aseptic Technique, Safety, and Quality Assurance Practices: The qualified evaluator checks each space for which the person being assessed has acceptably completed the described activity, prints N/A if the activity is not applicable to the assessment session or N/O if the activity was not observed.*

_____	Completes the Hand Hygiene and Garbing Competency Assessment Form.
_____	Performs proper hand hygiene, garbing, and gloving procedures according to SOPs.
_____	Disinfects ISO Class 5 device surfaces with an appropriate agent.
_____	Disinfects components/vials with an appropriate agent prior to placing into ISO Class 5 work area.
_____	Introduces only essential materials in a proper arrangement in the ISO Class 5 work area.
_____	Does not interrupt, impede, or divert flow of first-air to critical sites.

Appendix IV. Sample Form for Assessing Aseptic Technique and Related Practices of Compounding Personnel (continued)

_____	Ensures syringes, needles, and tubing remain in their individual packaging and are only opened in ISO Class 5 work area.
_____	Performs manipulations only in the appropriate DCA of the ISO Class 5 device.
_____	Does not expose critical sites to contact contamination or worse than ISO Class 5 air.
_____	Disinfects stoppers, injection ports, and ampul necks by wiping with sterile 70% IPA and allows sufficient time to dry.
_____	Affixes needles to syringes without contact contamination.
_____	Punctures vial stoppers and spikes infusion ports without contact contamination.
_____	Labels preparation(s) correctly.
_____	Disinfects sterile gloves routinely by wiping with sterile 70% IPA during prolonged compounding manipulations.
_____	Cleans, sets up, and calibrates automated compounding device (e.g., "TPN compounder") according to manufacturer's instructions.
_____	Disposes of sharps and waste according to institutional policy or recognized guidelines.

*The person assessed is immediately informed of all unacceptable activities (i.e., spaces lacking check marks, N/A, or N/O) and shown and informed of specific corrections.

Signature of Person Assessed	Printed Name	Date
Signature of Qualified Evaluator	Printed Name	Date

Appendix V. Sample Form for Assessing Cleaning and Disinfection Procedures

Printed name and position/title of person assessed: _____
Name of facility or location: _____

Cleaning and Disinfection Practices: The qualified evaluator will check each space for which the person being assessed has acceptably completed the described activity, prints N/A if the activity is not applicable to the assessment session or N/O if the activity was not observed.*

Daily Tasks:

_____	Prepares correct concentration of disinfectant solution according to manufacturer's instructions.
_____	Uses appropriately labeled container for the type of surface to be cleaned (floor, wall, production bins, etc.).
_____	Documents disinfectant solution preparation.
_____	Follows garbing procedures when performing any cleaning activities.
_____	At the beginning of each shift, cleans all ISO Class 5 devices prior to compounding in the following order: walls, IV bar, automated compounders, and work surface.
_____	Uses a lint free wipe soaked with sterile 70% IPA or other approved disinfectant solution and allows to dry completely.
_____	Removes all compounder components and cleans all ISO Class 5 areas as stated above at the end of each shift.
_____	Cleans all counters and easily cleanable work surfaces.
_____	Mops floors, using the mop labeled "floors," starting at the wall opposite the room entry door; mops floor surface in even strokes toward the operator. Moves carts as needed to clean entire floor surface. Use of a microfiber cleaning system is an acceptable alternative to mops.
_____	In the ante-area, cleans sink and all contact surfaces; cleans floor with a disinfectant solution or uses microfiber cleaning system.

Monthly Tasks:

_____	Performs monthly cleaning on a designated day. Prepares a disinfectant solution as stated in daily tasks that is appropriate for the surfaces to be cleaned.
_____	Cleans buffer area and ante-area ceiling, walls, and storage shelving with a disinfectant solution and a mop or uses a microfiber cleaning system.
_____	Once ISO Class 5 area is clean, cleans compounding room ceiling, followed by walls and ending with the floor. Uses appropriate labeled mops or microfiber cleaning system.
_____	Cleans all buffer area totes and storage shelves by removing contents and using a germicidal detergent soaked lint free wipe, cleans the inside surfaces of the tote and then the entire exterior surfaces of the tote. Allows totes to dry. Prior to replacing contents into tote, wipes tote with sterile 70% IPA to remove disinfectant residue. Uses new wipe as needed.
_____	Cleans all buffer area carts by removing contents and using germicidal detergent soaked lint free wipe, cleans all carts starting with the top shelf and top of post, working down to wheels. Cleans the under side of shelves in a similar manner. Uses a new wipe for each cart. Allows to dry. Wipes carts with sterile 70% IPA wetted lint-free wipe to remove any disinfectant residue. Uses new wipe as needed.

Appendix V. Sample Form for Assessing Cleaning and Disinfection Procedures *(continued)*

Cleans buffer area chairs, the interior and exterior of trash bins, and storage bins using disinfectant solution soaked lint free wipe.

Documents all cleaning activities as to who performed such activities with date and time noted.

*The person assessed is immediately informed of all unacceptable activities (i.e., spaces lacking check marks, N/A, or N/O) and shown and informed of specific corrections.

Signature of Person Assessed

Printed Name

Date

Signature of Qualified Evaluator

Printed Name

Date