

Pharmacy Quality Assurance Commission
Sterile Compounding Assessment Tool Development

Workshop #1 Agenda

February 2, 2016
11am – 3pm
Washington State Department of Health
20425 72nd Avenue S, Building 2, Suite 310, Rm. 309
Kent, WA 98032

Introductions

Pharmacy Quality Assurance Commission-Sterile Compounding Assessment Tool Development
Workgroup Members include: Tim Lynch, Maureen Sparks, Cheryl Adams, Elizabeth Jensen, and
Chris Barry

Today's Schedule

Why are we here?

Develop a common ground document to be in compliance with the statute and USP 797.

**RCW 18.64.270 Responsibility for drug purity—Compounding—Adulteration—
Penalty.**

(2) Any medicinal products that are compounded for patient administration or
distribution to a licensed practitioner for patient use or administration shall, at a
minimum, meet the standards of the official United States pharmacopeia as it applies to
nonsterile products and sterile administered products.

Purpose of tool in Washington State

What are your thoughts about the purpose of a sterile compounding assessment tool?



ALABAMA STATE BOARD OF PHARMACY

Sterile Compounding Pharmacy

USP <797> COMPLIANCE SELF-ASSESSMENT FORM

Code of Alabama 1975

§34-23-9. Purity of Drugs Dispensed

Supervising Pharmacist: License Number:
Pharmacy Name: Permit Number:
Address:
City: State: Zip Code: Phone Number:

For each standard, mark "X" in the COMPLIANT box if your facility is 100% compliant with that standard

If facility NEVER compounds under a specific requirement mark "X" in the N/A box

If not COMPLIANT, complete the "USP <797> Action Plan, Exception & Compliance Form" attached

USP <797> states, "The use of technologies, techniques, materials, and procedures other than those described in this chapter is not prohibited so long as they have been proven to be equivalent or superior with statistical significance to those described herein." Therefore, if you are compliant with an item, but not in the exact manner stated due to an exception described above, please place the letters "EX" for "Exception" in the compliant box. Then provide an explanation on the USP <797> Action Plan, Exception & Compliance Form

Table with 3 columns: Requirement, Compliant, N/A. Includes sections for Standard Operating Procedures, Compounding Personnel, CSP Microbial Contamination Risk Levels, and Low-risk Level CSPs with 12-Hour or Less Beyond Use Date (BUD).

USP <797> REQUIREMENTS		Compliant	N/A
18	Sinks are not located adjacent to the ISO Class 5 PEC; sinks are separated from the immediate area of the ISO Class 5 PEC device		
19	Quality assurance practices include routine disinfection and air quality testing, visual confirmation that personnel are appropriately garbing, review of all orders for correct identity and strength, and visual inspection of CSPs		
20	Media-fill test procedure or equivalent test is performed at least annually by personnel		
Medium-Risk Level CSPs			
21	Product considered medium risk if multiple individual or small doses of sterile products are combined or pooled to prepare a CSP that will be administered either to multiple patients or to one patient on multiple occasions		
22	Products considered medium-risk if the compounding process includes complex aseptic manipulations or unusually long duration		
23	In the absence of sterility tests, storage is not more than 30 hours at controlled room temperature, 9 days at cold temperature, and 45 days in a frozen state of -25° to -10°		
24	Products considered medium-risk if aseptic manipulations within an ISO Class 5 environment use prolonged and complex mixing and transfer, more than 3 sterile products and two entries into any container, and pooling ingredients from multiple sterile products to prepare multiple CSPs		
25	Quality assurance practices include routine disinfection and air quality testing, visual confirmation that personnel are appropriately garbed, review of all orders for correct identity and strength, visual inspection of CSPs, as well as a more challenging media-fill test performed annually		
26	If compounding personnel are improperly garbed and gloved, this makes CSP high-risk		
High-Risk Level CSPs			
27	Product considered high-risk if any nonsterile ingredients or devices are used		
28	Product considered high-risk if CSP is exposed to air quality worse than ISO Class 5 for > 1 hour		
29	Product considered high-risk if Nonsterile water-containing preparations are stored for more than 6 hours before being sterilized		
30	Sterilization methods are verified to achieve sterility for the quantity and type of containers		
31	Allowable limits for bacterial endotoxins are met		
32	All high-risk CSP solutions subjected to terminal sterilization by filtration are appropriately prefiltered and terminally filtered in ISO Class 5 air		
33	CSP maintains acceptable strength, purity and integrity of containers after sterilization		
34	In the absence of sterility tests, storage is not more than 24 hours at controlled room temperature, 3 days at cold temperature, and 45 days in a solid frozen state of -25° to -10°		
35	Media-fill test procedure or equivalent test is performed at least semi-annually by personnel		
36	Quality assurance practices include routine disinfection, air quality testing, visual confirmation of appropriate personnel garbing, review of all orders for correct identity and strength, and visual inspection of CSPs		
37	Sterility tests are performed for autoclaved CSPs if they are prepared in batches > 25 units		
Personnel Training and Evaluation in Aseptic Manipulation Skills			
38	Before beginning to prepare CSPs, personnel are trained by expert personnel, audio-video instructional sources, professional publications in the theoretical principles, practical skills of aseptic manipulations and in achieving and maintaining ISO Class 5 environmental conditions		
39	Personnel perform didactic review and pass written and media-fill testing of aseptic manipulative skills initially, then at least annually thereafter for low- and medium-risk level compounding		
40	Personnel perform didactic review and pass written and media-fill testing of aseptic manipulative skills initially, and at least semi-annually for high-risk compounding		
41	Personnel who fail written tests or whose media-fill test vials result in cross microbial colonization are immediately re-instructed and re-evaluated prior to resuming compounding		
Immediate Use CSPs			
42	Immediate-use CSPs are used only when there is a need for emergency or immediate patient administration of a CSP, where administration can begin with 1 hour of compounding		
43	Product considered immediate-use only if the compounding process involves simple transfer of not more than 3 commercially manufactured packages of sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers and not more than 2 entries into any one container or package of sterile infusion solution or administration container/device		
44	Unless required for preparation, compounding is a continuous process not to exceed 1 hour		
45	Aseptic technique is followed and if not immediately administered, CSP is continually supervised		
46	Administration begins not later than 1 hour following the start of the preparation of the CSP		

USP <797> REQUIREMENTS		Compliant	N/A
47	Unless the person who prepares the CSP immediately witnesses or completely administers it, the CSP is labeled with patient identifier, names and amounts of all ingredients, initials of the compounding, and the exact 1-hour BUD and time		
48	If administration has not begun within 1 hour of being compounded, CSP is discarded		
Single Dose and Multiple Dose Containers			
49	Single-dose containers entered in worse than ISO Class 5 air quality are used within 1 hour of entry		
50	Single-dose containers entered in ISO Class 5 or cleaner air are used within 6 hours of entry		
51	Opened single-dose ampoules are not stored		
52	Closure sealed multiple-dose containers are used within 28 days after initial opening or entry, unless specified otherwise by the manufacturer		
Hazardous Drugs as CSPs			
53	Hazardous drugs are prepared for administration only under conditions that protect the healthcare workers and other personnel in the preparation and storage areas		
54	Hazardous drugs are stored separately from other inventory		
55	Hazardous drugs are handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparation for administration and disposal		
56	Hazardous drugs are prepared in an ISO Class 5 environment with protective engineering controls in place and follows aseptic practices specified for the appropriate contamination risk levels		
57	Access is limited to areas where hazardous drugs are stored and prepared		
58	All hazardous drugs are prepared in a BSC or a CACI that meets or exceeds standards		
59	The ISO Class 5 BSC or CACI is placed in an ISO Class 7 area, physically separated and optimally has not less than 0.01-inch water column negative pressure to adjacent positive pressure ISO Class 7 or better ante-areas. Certain exceptions allowed if CACI meets 797 requirements (pages 14,23).		
60	A pressure indicator is installed that can be readily monitored for correct room pressurization		
61	If closed-system vial-transfer devices are used, they are used within the ISO Class 5 environment of a BSC or CACI		
62	Personnel protective equipment is worn when compounding		
63	Personnel who compound hazardous drugs are trained in storage, handling and disposal of drugs prior to preparing or handling hazardous CSPs		
64	Effectiveness of training is verified by testing specific hazardous drug preparations techniques and is documented for each person at least annually		
65	Compounding personnel of reproductive capability confirm in writing that they understand the risks of hazardous drug handling.		
66	Disposal of hazardous waste complies with all applicable federal and state regulations		
67	Personnel who perform routine custodial waste removal and cleaning activities for hazardous drugs are trained in appropriate procedures to protect themselves and prevent contamination		
Radiopharmaceuticals as CSPs			
68	Radiopharmaceuticals are compounded using appropriately shielded vials and syringes in a properly functioning and certified ISO Class 5 PEC located in the ISO Class 8 or cleaner air environment		
69	Radiopharmaceutical vials designed for multi-use, compounded with technetium-99m, exposed to ISO Class 5 environment, and punctured by needles with no direct contact contamination are used by the time indicated by the manufacturers' recommendations		
70	Technetium-99m/molybdenum-99 generator systems are stored and operated under conditions recommended by manufacturers and applicable state and federal regulations; such generator systems are operated in an ISO Class 8 or cleaner air environment		
71	Direct visual inspection of radiopharmaceutical CSPs containing high concentrations of doses of radioactivity are conducted in accordance with ALARA		
72	Radiopharmaceuticals prepared as low-risk level CSPs with 12-hour or less BUD are prepared in a segregated compounding area; a line of demarcation is established		
73	Materials and garb exposed in patient care and treatment do not cross the line of demarcation		
Allergen Extracts as CSPs			
74	Compounding is performed only with simple transfers using sterile ingredients and supplies		
75	Allergen extracts contain appropriate concentrations of preservatives		
76	Before compounding, personnel appropriately wash hands with soap and water, apply alcohol-based scrub with persistent activity, don hair covers, facial hair covers, gowns, face masks and gloves		
77	Sterile gloves are intermittently disinfected with sterile 70% IPA		
78	Vial/ampule critical sites are wet with 70% IPA for 10 seconds and allowed to dry before use		

USP <797> REQUIREMENTS		Compliant	N/A
79	Compounding manipulations are performed to minimize contact contamination of critical sites		
80	Vials are labeled with patient's name, BUD and storage information based on manufacturers' recommendations or peer-reviewed literature		

USP <797> REQUIREMENTS		Compliant	N/A
Verification of Compounding Accuracy and Sterility (High-risk Compounding)			
81	Packaged and labeled CSPs are visually inspected for physical integrity and expected appearance		
82	The accuracy of identities, concentrations, amounts and purities of ingredients in CSPs are confirmed by reviewing labels on packages, observing and documenting correct measurements with approved and correctly standardized devices, and reviewing information in labeling with certificates of analysis provided by suppliers		
83	The licensed healthcare professional is responsible for determining that the selected sterilization method both sterilizes and maintains the strength, purity, quality and packaging integrity of CSPs.		
84	Commercially available sterile filters are approved for human-use applications in sterilizing pharmaceutical fluids		
85	Sterile filters used to sterilize CSPs are pyrogen free with a nominal porosity of 0.2 or 0.22 micrometers		
86	Sterile filters used are certified by the manufacturer to retain at least 10 ⁷ microorganisms of a strain of <i>Brevundimonas diminuta</i> on each square centimeter of upstream filter surface area		
87	The compounding supervisor ensures that the filters are chemically and physically stable at the pressure and temperature conditions to be used, that they have enough capacity to filter the required volumes, and that they will achieve sterility and maintain prefiltration pharmaceutical quality		
88	The filter dimensions and liquid material to be sterile-filtered permit the sterilization process to be completed rapidly, without replacement of the filter during the process		
89	When CSPs are known to contain excessive particulate matter, a prefilter of larger-porosity membrane is placed upstream from the sterilizing filter to remove gross particulate contaminants.		
90	Filter units used are subjected to manufacturers' recommended integrity test		
91	Personnel must know that filters will achieve sterilization of the particular CSPs being sterilized		
92	The description of steam sterilization conditions and duration for specific CSPs are included in written documentation in the compounding facility		
93	The effectiveness of steam sterilization is verified using appropriate Bis of <i>Bacillus stearothermophilus</i> and other confirmation methods		
94	Heated filtered air is evenly distributed throughout the chamber by a blower device; the oven is equipped with a system for controlling temperature and exposure period		
95	Dry heat is used only for those materials that cannot be sterilized by steam		
96	During sterilization, sufficient space is left between materials to allow for good air circulation		
97	The description of dry heat sterilization conditions and duration for specific CSPs are included in written documentation in the compounding facility		
98	The effectiveness of dry heat sterilization is verified using appropriate BIs of <i>Bacillus subtilis</i> and other confirmation methods		
99	The description of dry heat depyrogenation cycle conditions and duration for specific CSPs are included in written documentation in the compounding facility		
100	The effectiveness of the dry heat depyrogenation cycle is verified using endotoxin challenge vials (ECVs); the bacterial endotoxin test is performed on the ECVs to verify that the cycle is capable of achieving a 3-log reduction in endotoxin		
Environmental Quality and Control			
Facility Design and Environmental Controls			
101	Critical sites are only exposed to ISO Class 5 or cleaner air		
102	Compounding facility provides a comfortable and well-lighted working environment		
103	PECs maintain ISO Class 5 and meet airflow requirements		
104	Policies and procedures for PEC area are written and followed; determined by the scope and risk levels of aseptic compounding activities utilized during the preparation of the CSPs		
105	The buffer area maintains ISO Class 7 conditions		
106	A minimum differential positive pressure of 0.02- to 0.05-inch water column is used for rooms providing a physical separation through the use of walls, doors and pass-through		
107	Displacement airflow is employed for buffer areas not physically separated from the ante-areas		
108	Adequate HEPA-filtered airflow is supplied to the buffer area and ante-area		
109	ISO Class 7 buffer and ante-area supplied with HEPA-filtered air receive an ACPH of not less than 30		
110	If the area has an ISO Class 5 recirculating device, a minimum of 15 ACPHs through the area supply HEPA filters is adequate, providing the combined ACPH not less than 30		

USP <797> REQUIREMENTS		Compliant	N/A
111	Only the furniture, equipment, supplies and other material required for the compounding activities are brought into the area and they are nonpermeable, nonshedding, cleanable, and resistant to disinfectants; before such items are brought into the area, they are cleaned and disinfected		
112	The surfaces of ceilings, walls, floors, fixtures, shelving, counters and cabinets in the buffer area are smooth, impervious, free from cracks and crevices and nonshedding; the surfaces are resistant to damage by disinfectant agents		
113	Junctures of ceilings to walls are coved or caulked		
114	If ceilings consist of inlaid panels, the panels are impregnated with a polymer to render them impervious and hydrophobic; they are caulked around each perimeter		
115	The exterior lens surface of the ceiling lighting fixtures are smooth, mounted flush and sealed; any other penetrations through the ceiling or walls are sealed		
116	The buffer area does not contain sources of water (sinks) or floor drains		
117	Works surfaces are constructed of smooth, impervious materials		
118	Carts are stainless steel wire, nonporous plastic or sheet metal with cleanable casters		
119	Storage shelving, counters and cabinets are smooth, impervious, free from cracks and crevices, nonshedding, cleanable and disinfectable; their number, design and manner of installation promotes effective cleaning and disinfection		
Placement of Primary Engineering Controls			
120	PECs are located within a restricted access ISO Class 7 buffer area unless an exception met		
121	When isolators are used for sterile compounding, the recovery time to achieve ISO Class 5 air quality is documented and internal procedures are developed		
122	Certification that each ISO classified area is within established guidelines is performed no less than every 6 months and each time the LAFW, BSC, CAI or CACI is relocated or the physical structure of the buffer area or anti-area has been altered		
123	A pressure gauge or velocity meter is installed to monitor the pressure differential or air-flow between the buffer area and the ante-area and between the ante-area and the general environment outside the compounding area; results are reviewed and documented in a log at least every work shift (minimum daily) or by a continuous recording device		
124	The pressure between the ISO Class 7 and the general pharmacy area is not less than 5 Pa (0.02 inch water column)		
125	In facilities where low- and medium-risk level CSPs are prepared, differential airflow is maintained at a minimum velocity of 0.2 meters/second (40 feet per minute) between buffer area and ante-area		
126	Media that supports the growth of fungi is used in high-risk level environments		
127	For low-risk level CSPs with 12-hour or less BUD prepared in a PEC that maintains an ISO Class 5 sampling, air sampling is performed at locations inside the ISO Class 5 environment and other areas that are in close proximity to the ISO Class 5 during the certification of the PEC		
128	A sufficient volume of air (400 to 1000 liters) is tested at each location where compounding takes place, performed at least semi-annually		
Additional Personnel Requirements			
129	Foods, drinks and materials exposed in patient care and treatment areas do not enter ante-areas, buffer areas or segregated compounding areas		
Cleaning and Disinfecting the Compounding Area			
130	When compounding activities require the manipulation of blood-derived or other biological material, the manipulations are clearly separated from routine material-handling procedures and equipment used in CSP preparation and are controlled by specific SOPs to avoid any cross-contamination		
131	When possible, packaged compounding supplies and components are uncartoned and wiped down with a disinfectant that does not leave a residue in an ante-area ISO Class 8 air quality, before being passed into buffer areas; Supplies are allowed to dry before compounding		
Personnel Cleansing and Garbing			
132	Personal hand hygiene and garb procedures are performed in ante-areas		
133	For ISO Class 5, all cleaning and disinfecting practices and policies for the compounding of CSPs are included in written SOPs and are followed by all compounding personnel		
134	LAFWs, BSCs, CAIs, and/or CACIs are cleaned and disinfected frequently, including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods, when spills occur and when surface contamination is known or suspected		
135	Work surfaces in ISO Class 7 buffer areas, ISO Class 8 ante-areas and segregated compounding areas are cleaned and disinfected at least daily, and dust and debris are removed when necessary from storage sites		

USP <797> REQUIREMENTS		Compliant	N/A
136	Floors in ISO Class 7 and 8 areas are cleaned daily when no compounding occurs; mopping is performed by trained personnel using approved agents and written procedures		
137	In the buffer or clean area, ante-area and segregated compounding area, walls, ceilings, and shelving are cleaned and disinfected monthly		
138	All cleaning materials are nonshedding and dedicated to use in the buffer or clean area, ante-area, and segregated areas and are not removed from these areas except for disposal		
139	If cleaning materials are reused, SOPs ensure that the effectiveness of the cleaning device is maintained and repeated use does not add to the bioburden of the area being cleaned		
140	Sterile 70% IPA swabs do not contact any object before contacting the site to be cleaned		
141	No particle-generating material is used to disinfect the sterile entry points of packages and devices		
142	No shipping cartons are taken into the buffer area, clean area or segregated compounding area		
143	Personnel with rashes, sunburn, weeping sores, conjunctivitis, active respiratory infection or cosmetics are prohibited from preparing CSPs		
144	Personnel remove personal outer garments, cosmetics, artificial nails, hand- wrist- or body-jewelry that can interfere with the fit of gowns and gloves, and visible body piercing above the neck; natural nails are kept neat and trimmed		
145	Garb and cleansing in ante-area as follows: shoes or shoe covers, head and facial hair covers, face mask, fingernail cleansing, hand and forearm washing and drying, nonshedding gown		
146	Cleansing and gloving in buffer room or area as follows: hand cleansing with an alcohol-based product with persistent activity, allow hands to dry, don sterile gloves		
147	Gloves are routinely disinfected with sterile 70% IPA after contacting nonsterile objects		
148	Gloves are inspected for holes and replaced when breaches are detected		
Personnel Training and Competency			
149	Prior to compounding, personnel are trained in garbing procedures, aseptic work practices, achieving and maintaining ISO Class 5 conditions and cleaning and disinfections procedures		
150	Media-fill testing of aseptic work skills are performed initially before beginning to prepare CSPs and at least annually thereafter for low- and medium-risk level; and semi-annually for high-risk level		
151	Personnel who fail written tests, observational audits, or whose media-fill test vials have one or more units showing contamination are re-instructed and re-evaluated to ensure correction of all aseptic work practice deficiencies; personnel pass all evaluations prior to resuming compounding		
152	Personnel demonstrate proficiency of proper hand hygiene, garbing and consistent cleaning procedures in addition to didactic evaluation of aseptic media fill and glove tip testing		
153	Personnel are visually observed during the process of performing hand hygiene and garbing procedures and appropriately documented and maintained to provide a permanent record		
154	Personnel successfully complete an initial competency evaluation and gloved fingertip/thumb sampling procedure no less than 3 times before initially being allowed to compound CSPs; which must be repeated at least annually for low- and medium-risk, and twice annually for high-risk compounding		
155	All compounding personnel have technique and competency evaluated initially during the Media-Fill Test Procedure and subsequent annual or semi-annual Media-Fill Test Procedures.		
Action Levels, Documentation and Data Evaluation			
156	Surface sampling is performed in all ISO classified areas on a periodic basis		
157	Microbial sampling data is collected and reviewed routinely		
158	When microbial sampling exceed action levels, procedures and practices are reviewed		
Elements of Quality Control			
159	A written description of specific training and performance evaluations for compounding personnel is developed for each site		
160	Facility follows procedures for physical inspection of all sterile drugs and devices		
161	If any nonsterile components, including containers and ingredients, are used to make a CSP, such CSPs must be high risk		
162	Bulk of unformulated drug substances and added substances or excipients are stored in tightly closed containers under temperature, humidity and lighting conditions that are either indicated in the official monographs or approved by suppliers		
163	The date of receipt of nonsterile components is clearly and indelibly marked on each package		
164	All devices used to compound a CSP operate properly within acceptable tolerance limits, as determined by the device's manufacturer or any regulations that govern the use of that device		
165	For all equipment, SOPs exist and are followed that state routine maintenance required and frequency of calibration, annual maintenance, monitoring for proper function, and procedures for use		

USP <797> REQUIREMENTS		Compliant	N/A
166	Personnel are appropriately trained to operate any equipment they use while compounding and are trained to determine if the device is operating properly or is malfunctioning.		
167	Results from equipment maintenance and calibration are kept for the lifetime of the equipment		
Verification of Automatic Compounding Devices for Parenteral Nutrition			
168	Testing procedures for accuracy are verified to meet the USP requirements stated in the individual monograph for the component being tested		
169	Compounding personnel keep a daily record of the accuracy assessments and the results are reviewed at least in weekly intervals		
Finished Preparation Release Checks and Tests			
170	All CSPs are visually inspected for being intact with no abnormal particulate matter, and prescriptions and written compounding procedures are reviewed to verify accuracy of correct ingredients and amounts, aseptic mixing, high-risk sterilization, packaging, labeling, and expected physical appearance before they are administered or dispensed.		
171	A double-check system is in place that meets state regulations that includes label accuracy and accuracy of the addition of all ingredients used		
172	High-risk level CSPs must be sterility tested if they are prepared in batches of > 25 identical containers, or exposed longer than 12 hours at 2 to 8 degrees and 6 hours at warmer than 8 degrees before being sterilized		
173	If high-risk level CSPs are dispensed before receiving the results of their sterility tests, there is a written procedure requiring daily observation of incubating test specimens		
174	High-risk level CSPs must be pyrogen tested, excluding those for inhalation or ophthalmic administration, if prepared in batches of > 25 identical containers, or exposed longer than 12 hours at 2 to 8 degrees and 6 hours at warmer than 8 degrees before being sterilized		
Storage and Beyond Use Dating			
175	Personnel who prepare, dispense and administer CSPs store them strictly in accordance with the conditions stated on the label of ingredient products and finished CSPs		
176	If CSPs are distributed to and administered in other than healthcare facilities, the effect of potentially uncontrolled and unmonitored temperature conditions is considered when assigning BUDs		
177	The controlled temperature areas are monitored at least once daily and results are documented		
178	Facilities have policies and procedures governing the determination of BUDs		
179	Compounding personnel verify the storage temperature when placing a product into or removing a product from the storage unit		
180	Temperature-sensitive mechanisms are placed to reflect true temperature in the controlled space and are not subject to significantly prolonged temperature fluctuations		
Maintaining Sterility, Purity and Stability of Dispensed and Distributed CSPs			
181	The facilities have written procedures for proper packaging, storage, and transportation conditions to maintain sterility, quality, purity and strength of CSPs		
182	Chemotoxic and other hazardous CSPs have safeguards to maintain the integrity of the CSP and minimize the exposure potential of these products to the environment and personnel		
183	Delivery and patient-care-setting personnel are properly trained to deliver the CSP to the appropriate storage location		
184	Outdated and unused CSPs are returned to the compounding facility for disposition as appropriate		
185	SOPs exist to ensure that the storage conditions in the patient-care setting are suitable for the CSP-specific storage requirements		
186	Returned CSPs are only redispensed if sterility, acceptable purity, strength and quality can be assured		
187	If redispensed CSPs are given a later BUD, sterility testing and quantitative assay of ingredients occur to support the extended BUD		
Patient or Caregiver Training			
188	A multiple component formal training program is in place to ensure that patients and caregivers understand proper storage, handling, use and disposal of CSPs		
Patient Monitoring and Adverse Events Reporting			
189	SOPs are available that describe the means for patients to ask questions, report concerns and adverse events with CSPs, and for compounding supervisors to correct and prevent future problems		
190	Reports of CSP adverse events are reviewed promptly and thoroughly by compounding supervisors		
Quality Assurance Program			
191	A formal quality assurance program is in place that monitors, evaluates, corrects and improves activities and processes		

USP <797> REQUIREMENTS

Compliant N/A

It is affirmed that all information provided herein is true and correct to the best of my knowledge and belief and it is recognized that providing information known to be false may result in disciplinary action.

Pharmacist's Signature _____ **License #** _____

Pharmacist's E-Mail Address: _____

Date Completed: _____

Supervising Pharmacist's Signature _____ **License #** _____

Supervising Pharmacist's Email Address: _____

Date Completed: _____

ATTENTION: Email completed document to Shirley Feagin at sfeagin@albop.com. For your records, copy yourself on the email transaction. Keep a copy as your working document.

Sterile Compounding Assessment Tool Input

The following include comments/ input the Sterile Compounding Assessment Tool (Pharmacy USP 797 Compliance Self Assessment_v1):

1

Please find a copy of the Addendum. I edited #14, 23, 28-29, 34, 49-50, 52, 59, 111-112, 119, 138, 145, 172, and 174, specific with specifications for Fahrenheit degrees and time stamp documentation, relating to all Compounded Sterile Products however more stringent rules for High Risk Compounds.

I feel the essence of the form is complete in auditing a licensed site, speaking from my past Pharmacist Investigator experience too.

2

For line 120-PECs are located within a restricted access ISO Class 7 buffer area unless an exception met

Have we defined what these exceptions are? Many Critical Access Hospitals are working with space constraints yet provide a hood for nursing to use when mixing immediate use CSP's. These hoods are not located within an ISO Class 7 buffer area. How will we address issues like this?

For line 116-The buffer area does not contain sources of water (sinks) or floor drains.

Again there is the issue of CAH's and there limited resources and space. If a LAFW is located within a restricted area but has a sink in the room, does this negate the use of the LAFW if the only compounding performed is low risk CSP's or the use of a closed system transfer device to mix a bag of cefazolin? What if the facility use a glove box instead? Does the location of a sink in the room negate the use of the glove box?

3

The checklist should start by defining the facility type, PEC type and sterile product risk levels prepared. Eliminate all sections that should be covered in adequate policies and procedures such as definitions of risk levels (example omit lines 11 through 52). Checklist sections should consist of USP 797 requirements (shalls). Do not include "shoulds" on the checklist. Avoid statements that cannot be assessed by the investigator and are components of a policy.

1. Facility type:
 - a. Segregated compounding area – complete checklist sections XX (create a checklist that covers segregated compounding area requirements)
 - i. LAFW –

- ii. CAI- (create a checklist for CAI requirements to comply with chapter to permit compounding all risk levels in segregated compounding area)
 - b. Clean room suite – complete checklist section XX
 - c. Hazardous drug compounding
 - i. BSC – complete checklist section XX
 - ii. CACI- complete checklist section XX
 - 2. Risk level of CSP prepared
 - a. Low
 - b. Medium
- High – complete checklist section XX

4

I like this tool. I did have a comment on item 146- for workflow purposes, we don't use sterile gloves in the ante room (entry into the buffer room is hands free). I have found support for this from Eric Kastango on his Simplifi797 blog. I also wondered how the tool will be used- I assume this is something we will discuss in the group? I noticed that it does not include all the requirements that I have seen in the new WA sterile compounding law, and also USP 800, so is it just for baseline assessment of 797 compliance? Or will the tool be edited to encompass these requirements once they are law?

5

I've attached some comments on the proposed self-inspection form. Many are due to the way that USP797 is written. Unfortunately, there are many requirements in USP797 that are convoluted or unintended/unworkable. I'm hopeful that the next version will be written in a more logical and cohesive manner. My interpretations are based on my own experience as well as that of experts in the field. Perhaps Washington's self-inspection form can help to remove some of this confusion.

6

Could many of the "if" statements be stricken? It is difficult to be compliant with an "if" statement.

7

A second option for organizing the checklist would be to have several ones based on these criteria:

1. Enclosed buffer room, ante room vs. segregated compounded area.
 - A. If Segregated compounded area only, it would make it automatically 12 h BUD therefore only those requirements would be in the check list.
 - B. If enclosed clean room does the facility perform low/medium risk compounding or high risk?

- i. If High Risk additional requirements would apply. (sterilization etc.)

Sections on Cleaning, Personnel Training etc would remain the same.

A third option would be to organize the checklist based on Appendix I of current USP 797: Principal Competencies, Conditions, Practices, and Quality Assurances that are Required (“shall”) and (“should”) in USP Chapter <797>

The rest of the document is pretty much an outline of all current USP 797 requirements as organized in the chapter. No changes needed.

8

I think this document is too long for most people and could be more effective if we had one form for those that only do low and medium risk compounding with additional forms for those that do high risk/radiopharmaceuticals/allergens. It would make the document more useful for 90% of the pharmacists who do compounding.

9

Might I suggest that PQAC simply state that all sterile compounding must comply with current USP guidelines as published by USP. This document would only be current until USP makes a new version. Once a new version exists, Washington State would run the risk of holding pharmacists (pharmacies) accountable to different, and possibly conflicting, guidelines/laws. In addition, this would add a significant cost burden, both in time and money, to PQAC. This would be an incredible hardship as it appears that PQAC is currently significantly behind on inspections and licensing.

10

My input might be little different from others.

As we are licensed in 44 other states and PCAB accredited since 2008, we have several different regulatory bodies inspect us annually for sterile and non-sterile compounding practice such as NABP, PCAB now ACHC, California State, etc. They all use USP as their guideline and utilize a tool like you attached on this email.

Two years ago when we first hold the stakeholders meeting around compounding practice it was clearly expressed that we (Washington state) should use USP rather than reinventing the wheel. But for some reason, the members of the board seemed to have some issues with that and began to develop something unique. Well two years later we still don't have anything and restarting and trying to follow the USP.

To me the attachment is acceptable and effective. We can use that for now. But it should be upgraded when USP comes up with upgraded version like what they are doing now.

I believe it is not that we don't have the guideline. We have USP and it is a living guideline and standard. It will come up with a new one every couple of years, which is OK.

What we are struggling is how to implement it in reality and live by that daily. That is where everyone needs help. That is why we joined PCAB in 2007, the first one to get certified in Washington State. And it takes time, a lot of efforts, resources, and training to implement.

I really sense PQAC should focus on how to help members implement the practice. I would be more than happy to contribute to develop that process based on our experience. In fact I would love to develop with PQAC a certification program to certify compounding technicians and pharmacists as a first step. Please share with me your thoughts.

11

Thank you for the opportunity to provide comment on the draft USP 797 gap analysis tool. We have used the Alabama tool to conduct gap analysis at several of our sites and have found it useful. The Washington version is similar and improved in some areas. Please consider our comments on specific areas (typos or grammar) and general suggestions. Primarily, we think it would be useful to have all personnel requirements in one section, rather than in multiple sections. Secondly, while hazardous drugs are addressed in the current version of USP 797, there are additional state WACs that cover hazardous drugs. Consider removing these checks, as compliance may be misleading if not all areas in the WACs are addressed in the gap analysis.

12

Just my humble opinion...the tool is too specific and too cumbersome.

Good luck finding a balance that promotes safety without making the tool impossible to use.

USP<797> REQUIREMENTS	Compliant	N/A	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
GREEN CELLS indicate comments received for item																	
Permit Number:																	
USP <797> states, "The use of technologies, techniques, materials, and procedures other than those described in this chapter is not prohibited so long as they have been proven to be equivalent or superior with statistical significance to those described herein." Therefore, if you are compliant with an item, but not in the exact manner stated due to an exception described above, please place the letters "EX" for "Exception" in the compliant box. Then provide an explanation on the USP <797> Action Plan, Exception & Compliance Form									Incomplete instruction in this box. No text appears after the phrase, "Then provide an"	This list should be tailored to the requirements for the levels of sterile compounding: emergent, low, medium, high. Throughout – there are several high-risk steps inserted throughout even those steps that apply to low/medium. It has also been confusing when "low risk sterile preparation/immediate use" vs "sterile preparation/immediate use" – some clarity there		Should this be pharmacy license number?		"Permit Number" eludes to increased licensing, paperwork and finances. This is something PQAC and our state cannot afford. Pharmacies should not be required to file additional permitting to perform skill sets that are deemed a normal part of our profession. This eluded to, added fee would increase the overall costs of medications and would be further limiting access to medications that are necessary for patients.	We request that the Commission strike this upper section – tool is for self-assessment, yet requesting this information implies that the tool will be used for reporting purposes.		What is permit number?
Standard Operating Procedures																	
The permitted pharmacy listed above shall have a written, properly approved, Standard Operating Procedures Manual (or Policy and Procedure Manual) with detailed instructions that describe how, when (frequency), and by whom all requirements in USP <797> are to be met.												Not sure what the language of the WAC will be but at this point "permitted" is not relevant. "Properly approved" – by who? Requirements for 797 should be met at all times - the "when" is not needed.		Properly approved by whom? It appears we already have inconsistencies when inspectors are asked to interpret or approve methods of action.	"Whom" is not always applicable as it is not always a necessary requirement; we request that this word be stricken.		What is the meaning of "properly approved" SOPs?
Compounding Personnel																	
Documentation is on file for EACH person who compounds sterile products that they are adequately skilled, educated, instructed, and trained to correctly perform and document the following activities:									Put steps 2 through 10 in order of performance.					According to USP 797 guidelines, it is the supervisor of the sterile compounding at the site that is responsible for these tasks. It is not listed in USP 797 that the state regulatory agency is responsible for this.			Eliminate this section (Compounding Personnel) since Personnel Training is addressed below (38) or combine two sections.
2 Perform aseptic hand cleansing								Move to line 4	3								
3 Perform disinfection of compounding surfaces								Move to line 3	4								
4 Select and appropriately don protective garb									2								
5 Maintain or achieve sterility of CSPs								Should be separate section	6								If this section remains change to "Annual completion of Media-fill test."
6 Protect personnel and compounding environment from contamination by hazardous drugs									7								
7 Identify, weigh and measure ingredients									5				N/A for weight	"Weigh" is normally only applicable to high risk compounding or use of TPN compounding. Add: "as applicable to the CSPs prepared by the pharmacy" to solve this issue.			
8 Manipulate sterile products aseptically									8								
9 Sterilize high-risk CSPs									9					This wouldn't apply to all pharmacies performing sterile compounding.			
# Label and quality inspect CSPs									10								
CSP Microbial Contamination Risk Levels																	
Low-risk Level CSPs																	
# The CSPs are compounded with aseptic manipulations entirely within ISO Class 5 or better quality air using only sterile ingredients, products, components and devices																	
# Compounding involves only transfer, measuring and mixing manipulations using not more than 3 commercially manufactured sterile products and not more than 2 entries into any container																	
13 Manipulations are limited to aseptically opening ampoules, penetrating disinfected stoppers on vials with sterile needles and syringes and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile products, and containers for storage and dispensing																	
# In the absence of sterility tests, storage is not more than 48 hours at controlled room temperature, 14 days at cold temperature, and 45 days in a solid frozen state of -25° to -10° Fahrenheit																	Need units for temp (C vs. F) for all sections that mention temps
# If compounding personnel are improperly garbed and gloved, CSP treated as a high-risk compound																	
Low-risk Level CSPs with 12-Hour or Less Beyond Use Date (BUD)																	
# PECs are certified, maintained ISO Class 5 and located in a segregated compounding area restricted to sterile compounding activities																	AKA Segregated Compounding Areas
17 The segregated compounding area is not in a location that has unsealed windows or doors that connect to the outdoors or high traffic flow, or in a location that is adjacent to construction sites, warehouse or food preparation								We assume the intent is that the windows and doors are not to be adjacent to warehouses or eating areas.									
18 Sinks are not located adjacent to the ISO Class 5 PEC; sinks are separated from the immediate area of the ISO Class 5 PEC device															Please specify that separated sinks are N/A if using CACI		Consider move to facility design (101)

19	Quality assurance practices include routine disinfection and air quality testing, visual confirmation that personnel are appropriately garbed, review of all orders for correct identity and strength, and visual inspection of CSPs													frequency testing? (underlined routine)		This is the same as for all risk levels; consider combining them in to one quality assurance section for ease of use of this tool in the field.		Redundant—requirement is same for all compounding personnel. Suggest Remove: "visual confirmation that personnel are appropriately garbed, review of all orders for correct identity and strength, and visual inspection of CSPs"; address under Personnel Training (38)	
#	Media-fill test procedure or equivalent test is performed at least annually by personnel								Every 3 months/ min 6 months						This should apply to Low-Risk Level as well not just <12 hours.	We recommend that this criteria be combined into one section for personnel training and competencies for ease of use in the field (for high-risk; media fills should be done semi-annually, otherwise: annually)		Remove, place under Personnel Training (38) or under 5 if Compounding Personnel section is to remain	
Medium-Risk Level CSPs																			
21	Product considered medium risk if multiple individual or small doses of sterile products are combined or pooled to prepare a CSP that will be administered either to multiple patients or to one patient on multiple occasions															This appears to be a statement related to all medium-risk level CSPs, rather than a question; consider moving this language to the grey area with the title of the section, so that it is clear that it is defining information for medium-risk level CSPs.			
#	Products considered medium-risk if the compounding process includes complex aseptic manipulations or unusually long duration																		See comment 21 – again move to the grey area containing the title of this section. "Complex" and "duration" are undefined terms; please clarify.
23	In the absence of sterility tests, storage is not more than 30 hours at controlled room temperature, 9 days at cold temperature, and 45 days in a frozen state of -25° to -10°																		Define cold temperature
24	Products considered medium-risk if aseptic manipulations within an ISO Class 5 environment use prolonged and complex mixing and transfer, more than 3 sterile products and two entries into any container, and pooling ingredients from multiple sterile products to prepare multiple CSPs																		See comment 21 – again move to the grey area containing the title of this section.
25	Quality assurance practices include routine disinfection and air quality testing, visual confirmation that personnel are appropriately garbed, review of all orders for correct identity and strength, visual inspection of CSPs, as well as a more challenging media-fill test performed annually																		Redundant as above. Remove, "visual confirmation that personnel are appropriately garbed, review of all orders for correct identity and strength, visual inspection of CSPs, as well as a more challenging media-fill test performed annually" place under Personnel Training (38).
#	If compounding personnel are improperly garbed and gloved, this makes CSP high-risk																		See comment for item 15, above; change to question of whether compounding personnel are properly garbed and gloved.
High-Risk Level CSPs																			
#	Product considered high-risk if any nonsterile ingredients or devices are used																		Same comment as for item #21: move to the grey area containing the title of this section.
#	Product considered high-risk if CSP is exposed to air quality worse than ISO Class 5 for > 1 hour																		Same comment as for item #21: move to the grey area containing the title of this section.
29	Product considered high-risk if Nonsterile water-containing preparations are stored for more than 6 hours before being sterilized																		Same comment as for item #21: move to the grey area containing the title of this section.
#	Sterilization methods are verified to achieve sterility for the quantity and type of containers																		N/A
#	Allowable limits for bacterial endotoxins are met																		N/A
32	All high-risk CSP solutions subjected to terminal sterilization by filtration are appropriately prefiltered and terminally filtered in ISO Class 5 air																		N/A
#	CSP maintains acceptable strength, purity and integrity of containers after sterilization																		Broad statement – lacking details on compliance. Please clarify the question to be more specific. Consider referencing language from the most recent USP chapters 1, 7, 71, 788, 797, 1163, 1191, 1207, 1209, and 1222 to determine acceptable testing methods and assays.
#	In the absence of sterility tests, storage is not more than 24 hours at controlled room temperature, 3 days at cold temperature, and 45 days in a solid frozen state of -25° to -10°																		Fahrenheit
#	Media-fill test procedure or equivalent test is performed at least semi-annually by personnel																		Propose deletion of strike-through text and addition of highlighted (underlined) text. Media-fill test procedure or equivalent test that represents high risk compounding is performed at least semi-annually by personnel.
36	Quality assurance practices include routine disinfection, air quality testing, visual confirmation of appropriate personnel garbing, review of all orders for correct identity and strength, and visual inspection of CSPs																		Again combine into one section called Employee Training and Aseptic Manipulation Skills/Competencies.
#	Sterility tests are performed for autoclaved CSPs if they are prepared in batches > 25 units																		Redundant, combine with personnel training and evaluation.
Personnel Training and Evaluation in Aseptic Manipulation																			
38	Before beginning to prepare CSPs, personnel are trained by expert personnel, audio-video instructional sources, professional publications in the theoretical principles, practical skills of aseptic manipulations and in achieving and maintaining ISO Class 5 environmental conditions																		This is very specific wording. Could the wording similar to #63 be incorporated here?
39	Personnel perform didactic review and pass written and media-fill testing of aseptic manipulative skills initially, then at least annually thereafter for low- and medium-risk level compounding																		Repeating comments on items 20 and 25: We recommend that this criteria be combined into one section for personnel training and competencies for ease of use in the field, and that the structure could be easier to follow if all quality assurance items were contained in one section; consider moving this item to a section on quality assurance.

Personnel Cleansing and Garbing																		
132	Personal hand hygiene and garb procedures are performed in ante-areas											Change highlighted "Personal hand hygiene" verbiage to "Hand washing" so it is not confused with antiseptic hand cleansing and donning of gloves that should be done in the buffer room.		Please clarify that this criteria is not applicable if using CAI				
133	For ISO Class 5, all cleaning and disinfecting practices and policies for the compounding of CSPs are included in written SOPs and are followed by all compounding personnel																	
134	LAFWs, BSCs, CAIs, and/or CACIs are cleaned and disinfected frequently, including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods, when spills occur and when surface contamination is known or suspected											This should go under Cleaning and Disinfecting the Compounding Area Section.		We believe that cleaning CACI is not necessary if it is not used during a shift, but that the intent here is to ensure that these listed are cleaned prior to use. Can fix this issue by adding "or prior to use".				
135	Work surfaces in ISO Class 7 buffer areas, ISO Class 8 ante-areas and segregated compounding areas are cleaned and disinfected at least daily, and dust and debris are removed when necessary from storage sites											Cleaned daily, when in use.		Please clarify that this criteria is not applicable if using CAI				
136	Floors in ISO Class 7 and 8 areas are cleaned daily when no compounding occurs; mopping is performed by trained personnel using approved agents and written procedures											When used; if facility is closed no cleaning is obviously necessary.	Should be "daily while no compounding is occurring"	Please clarify that this criteria is not applicable if using CAI	Change to "Floors in the buffer or clean area, ante-area and segregated compounding are cleaned daily" . . .			
137	In the buffer or clean area, ante-area and segregated compounding area, walls, ceilings, and shelving are cleaned and disinfected monthly													Please clarify that this criteria is not applicable if using CAI				
138	All cleaning materials are nonshedding and dedicated to use in the buffer or clean area, ante-area, and segregated areas and are not removed from these areas except for disposal														Consider hyphenation: "non-shedding"			
139	If cleaning materials are reused, SOPs ensure that the effectiveness of the cleaning device is maintained and repeated use does not add to the bioburden of the area being cleaned																	
140	Sterile 70% IPA swabs do not contact any object before contacting the site to be cleaned																	
141	No particle-generating material is used to disinfect the sterile entry points of packages and devices																	
142	No shipping cartons are taken into the buffer area, clean area or segregated compounding area																	
143	Personnel with rashes, sunburn, weeping sores, conjunctivitis, active respiratory infection or cosmetics are prohibited from preparing CSPs											USP 797 states "severe" sunburn/fr ashes		Current standards do not exclude cosmetic use if using a CAI or CACI and following mfg recommendations; please clarify this here for consistency with current guidelines.				
144	Personnel remove personal outer garments, cosmetics, artificial nails, hand- wrist- or body-jewelry that can interfere with the fit of gowns and gloves, and visible body piercing above the neck; natural nails are kept neat and trimmed																	
145	Garb and cleansing in ante-area as follows: shoes or shoe covers, head and facial hair covers, face mask, fingernail cleansing, hand and forearm washing and drying, nonshedding gown											Introducing water into a clean room setting increases the potential of microbial or fungal issues. A cleanroom with a single-plenum system, for example, would mean air from the ante room would mix with the rest of the cleanroom.		This is not clear – is this items needed or sequencing of cleaning?	Please clarify that this is not applicable if using CAI – CAI follow mfr requirements gown is required per NuAire	Consider hyphenation: "non-shedding"		
146	Cleansing and gloving in buffer room or area as follows: hand cleansing with an alcohol-based product with persistent activity, allow hands to dry, don sterile gloves											for workflow purposes, we don sterile gloves in the ante room (entry into the buffer room is hands free). I have found support for this from Eric Kastango on his Simplifi797 blog.			NA if using CAI – Cleansing and gloving is required prior to compounding just not in buffer room; we urge the Commission to clarify this here. In addition, we believe this is not applicable if using a CAI.			
147	Gloves are routinely disinfected with sterile 70% IPA after contacting nonsterile objects													This is during compounding process, otherwise should be removed/replaced				
148	Gloves are inspected for holes and replaced when breaches are detected													Recommend adding the requirement for disposing of everything but the gown upon exit from the buffer area.				
Personnel Training and Competency																		
149	Prior to compounding, personnel are trained in garbing procedures, aseptic work practices, achieving and maintaining ISO Class 5 conditions and cleaning and disinfections procedures											Delete the "s" in disinfections		This section and the first section could be linked/combined.	Some of this is a repeat on Personal training and Evaluation on Aseptic Manipulation Skills.	Combine personnel issues that show up in other sections in to this section for consistency and ease of use – see comments next to specific items	Only one section on Personnel Training and Competency should be in the form. See Personnel Training (38) above.	
150	Media-fill testing of aseptic work skills are performed initially before beginning to prepare CSPs and at least annually thereafter for low- and medium-risk level; and semi-annually for high-risk level															Combine personnel issues that show up in other sections in to this section for consistency and ease of use – see comments next to specific items	Only one section on Personnel Training and Competency should be in the form. See Personnel Training (39) above.	
151	Personnel who fail written tests, observational audits, or whose media-fill test vials have one or more units showing contamination are re-instructed and re-evaluated to ensure correction of all aseptic work practice deficiencies; personnel pass all evaluations prior to resuming compounding															Combine personnel issues that show up in other sections in to this section for consistency and ease of use – see comments next to specific items	Only one section on Personnel Training and Competency should be in the form. See Personnel Training (41) above.	
152	Personnel demonstrate proficiency of proper hand hygiene, garbing and consistent cleaning procedures in addition to didactic evaluation of aseptic media fill and glove tip testing															Combine personnel issues that show up in other sections in to this section for consistency and ease of use – see comments next to specific items	Only one section on Personnel Training and Competency should be in the form. Add hand hygiene/garbing to Personnel Training (38-41)	
153	Personnel are visually observed during the process of performing hand hygiene and garbing procedures and appropriately documented and maintained to provide a permanent record															Combine personnel issues that show up in other sections in to this section for consistency and ease of use – see comments next to specific items	Eliminate, same as 152 above.	
154	Personnel successfully complete an initial competency evaluation and gloved fingertip/thumb sampling procedure no less than 3 times before initially being allowed to compound CSPs; which must be repeated at least annually for low- and medium-risk, and twice annually for high-risk compounding															Combine personnel issues that show up in other sections in to this section for consistency and ease of use – see comments next to specific items	Only one section on Personnel Training and Competency should be in the form. Add Gloved Fingertip Testing to Personnel Training (38-41)	
155	All compounding personnel have technique and competency evaluated initially during the Media-Fill Test Procedure and subsequent annual or semi-annual Media-Fill Test Procedures.															Combine personnel issues that show up in other sections in to this section for consistency and ease of use – see comments next to specific items	Repeat, eliminate this line.	
Action Levels, Documentation and Data Evaluation																		
156	Surface sampling is performed in all ISO classified areas on a periodic basis													Minimum frequency requirement?	Add a requirement to specify "Periodic" whatever it may be for the facility monthly, every three months, every six months.	Combine into Quality Assurance section		
157	Microbial sampling data is collected and reviewed routinely													Minimum frequency requirement?	Add requirement for genus identification no matter what the action level.	Combine into Quality Assurance section		
158	When microbial sampling exceed action levels, procedures and practices are reviewed													Add "s" in exceed	Needs clarity	Combine into Quality Assurance section		
Elements of Quality Control																		
159	A written description of specific training and performance evaluations for compounding personnel is developed for each site															Standard Operating Procedures from USP 797 are not included.	Combine into Training and Competencies section	
160	Facility follows procedures for physical inspection of all sterile drugs and devices																Quality Control Section	

<p>It is affirmed that all information provided herein is true and correct to the best of my knowledge and belief and it is recognized that providing information known to be false may result in disciplinary action.</p>															<p>We request that this section be stricken, as it appears to be an attestation section that would lead this document to be used outside the scope of a self-assessment. Requesting this information implies forced reporting rather than self-use. If these sections are kept, we request that the Commission clarify the purpose of this section if this tool is for purposes outside of self-evaluation.</p>		
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January 15, 2016

Lisa Hodgson, Office Director
Department of Health
Health Professions and Facilities
PO BOX 47852
Olympia, WA 98504-7852
Lisa.hodgson@doh.wa.gov

Dear Ms. Hodgson:

I appreciate the opportunity to provide stakeholder comments regarding the proposed sterile compounding assessment tool. The following includes Confluence Health's response to the specific questions outlined in the email from Brett Lorentson on December 22, 2015. In addition, we've outlined some additional comments that may be helpful if PQAC determines it necessary to move forward with the assessment tool. Attached is an edited Pharmacy USP797 Compliance Self-Assessment tool with high-level recommendations.

- Does this item need to be included on the checklist?
Overall, the assessment tool is too detailed. The inspection process in Washington State differs significantly from the process in Alabama. Most significantly, a detailed USP 797 assessment tool may be needed in Alabama as a result of NOT having pharmacist investigators. Since Washington State utilizes pharmacist investigators, a scaled down assessment tool should be considered. We believe an assessment tool including 20 to 30 elements of assessment would be more than adequate. In addition, the development of such a detailed assessment tool is premature given that the national USP 797 guidelines are under revision and many of the elements in this tool may later become irrelevant. Conversely, a shorter assessment tool will likely require less future revision.
- Can we remove any elements?
See attached. Most of the assessment tool should be eliminated in favor of a shortened, 20 to 30 elements of assessment to be performed by the licensed institution for review by the investigator during routine licensing inspections.
- Are any items or areas not applicable to all settings?
See attached.
- What do we need to have for this tool to be accurate and useful?
If the self-assessment tool remains as detailed as the current draft, I recommend delaying the development and implementation of the assessment tool until after the updated national USP

797 guidelines are finalized. But, in the interim while the national USP 797 guidelines are being finalized, I would support moving ahead with a more general self-assessment tool used to educate pharmacy staff of sterile compounding expectations. In addition, I encourage the Commission to utilize outside consultants in the development of a tool. I understand the Commission has utilized CriticalPoint in the past. I am concerned that this company may not be able to remain unbiased due to its relationship with a key member on the national committee developing the USP 797 Guidelines. Attached you will find contact information for Lou Diorio with LDT Health Solutions, Inc who has worked with other State Boards to develop sterile compounding rules. LDT's past experience with State Boards would be valuable in this process.

***Lou Diorio, RPh, FAPhA
Principal
LDT Health Solutions, Inc
201-738-9125
LSDiorio@LDTRx.com***

- What should we communicate to reflect what we need to do?
The Commission should invest significant time and resources in educating the pharmacy community and pharmacist inspectors on the specific elements of USP 797 that they see as priority. The pharmacy community has been unable to comply with the inconsistent inspection process of current. It would be valuable to have the Commission set expectations for the pharmacist inspectors related to USP 797 compliance. In addition, the PQAC Newsletter and ListServ can be better utilized to communicate changes and updates prior to the implementation of new inspection practices. I appreciated the recommendations set forth in the Pharmacy Commission Communication Plan dated July 2015. Many of the elements present in the communication plan would be useful in developing expectations for sterile compounding.

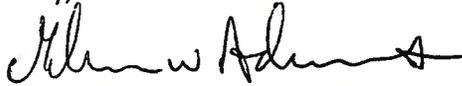
If PQAC proceeds with the development of an assessment tool for sterile compounding, I strongly encourage the Commission to implement a SELF-assessment tool. An abbreviated assessment tool that a licensed institution completes on an annual basis could be valuable in many ways:

- Gap Analysis: A self-assessment tool that is completed annually, would help an organization identify areas of deficiency and compliance (including areas that are not applicable to the institution).
- Corrective Action Plan: An annual self-assessment tool supports the Commissions vision of a "corrective action" plan for the pharmacy inspection process. Institutions could utilize a self-assessment tool to track corrective action plans for areas of noncompliance.
- Education: A completed self-assessment tool could be presented to the investigators during a routine licensing inspection. The tool could be used to educate the inspectors about the institution and it would be a useful discussion for improving practice.

I encourage the Commission to review the inspection process in the state of Oregon. Oregon uses a similar "self-assessment" process for their routine pharmacy inspection process.

I appreciate your attention to these comments and look forward to your response. I am hopeful for future opportunities to provide additional clarification and/or recommendations to proposed sterile compounding guidance documents and rules. I can be reached at 509-665-6012 or glenn.adams@confluencehealth.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Glenn Adams". The signature is fluid and cursive, with a long horizontal stroke at the end.

Glenn Adams, PharmD

Senior Vice President of Ancillary Services

Glenn.adams@confluencehealth.org

(509) 665-6012

Cc: Tim Lynch
Doreen Beebe
Timothy Farrell
Jennifer Moore

Pharmacy Quality Assurance Commission		Input/ Comments/Questions/Comments/ Action Plan		
Sterile Compounding Pharmacy				
USP <797> COMPLIANCE SELF-ASSESSMENT FORM				
Pharmacist Completing Assessment:	Date:			
Supervising Pharmacist In Charge:	License Number:			
Pharmacy Name:	Permit Number:			
Address:				
City:	State:		Zip Code:	Phone Number:
For each standard, mark "X" in the COMPLIANT, NONCOMPLIANT, or N/A box if your facility is 100% compliant If facility NEVER compounds under a specific requirement mark "X" in the N/A box				
If not COMPLIANT or N/A, complete the Comments/Action Plan section "USP <797> Action Plan, Exception &				
USP <797> states, "The use of technologies, techniques, materials, and procedures other than those described in this chapter is not prohibited so long as they have been proven to be equivalent or superior with statistical significance to those described herein." Therefore, if you are compliant with an item, but not in the exact manner stated due to an exception described above, please place the letters "EX" for "Exception" in the compliant box. Then provide an explanation on the USP <797> Action Plan, Exception & Compliance Form				
<u>Provide brief description of sterile compounding practices at this institution:</u>				

Commented [AG1]: Additional items/details could be added to the self-inspection form if trends in non-compliance are identified through the routine inspection process.

Formatted Table

USP <797> REQUIREMENTS	Compliant	N/A	Input/ Comments/Questions
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USP <797> REQUIREMENTS	Compliant	Noncompliant	N/A	
Standard Operating Procedures				
1 The permitted pharmacy listed above shall have a written, properly approved , Standard Operating Procedures Manual (or Policy and Procedure Manual) with detailed instructions that describe how, when (frequency), and by whom all requirements in USP <797> are to be met.				
Compounding Personnel				
Documentation is on file for EACH each person who compounds sterile products that they are adequately skilled, educated, instructed, and trained to correctly perform and document				
2 Perform aseptic hand cleansing				
3 Perform disinfection of compounding surfaces				
4 Select and appropriately don protective garb				
5 Maintain or achieve sterility of CSPs				
6 Protect personnel and compounding environment from contamination by hazardous drugs				
7 Identify, weigh and measure ingredients				
8 Manipulate sterile products aseptically				
9 Sterilize high-risk CSPs				
10 Label and quality inspect CSPs				
CSP Microbial Contamination Risk Levels				
Low-risk Level CSPs				
11 The CSPs are compounded with aseptic manipulations entirely within ISO Class 5 or better quality air				
12 Compounding involves only transfer, measuring and mixing manipulations using not more than 3 commercially manufactured sterile products and not more than 2 entries into any container				
13 Manipulations are limited to aseptically opening ampoules, penetrating disinfected stoppers on vials with sterile needles and syringes and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile products, and containers for storage				
14 In the absence of sterility tests, storage is not more than 48 hours at controlled room temperature. The pharmacy compounds low-risk level CSPs.				
15 if compounding personnel are improperly garbed and gloved, CSP treated as a high-risk compound. The pharmacy is compliant with low-risk level CSP compounding practices.				
Low-risk Level CSPs with 12-Hour or Less Beyond Use Date (BUD)				
16 PECs are certified, maintained ISO Class 5 and located in a segregated compounding area restricted to				
17 The segregated compounding area is not in a location that has unsealed windows or doors that connect to the outdoors or high traffic flow, or in a location that is adjacent to construction sites, warehouse-				
18 Sinks are not located adjacent to the ISO-Class 5 PEC; sinks are separated from the immediate area of				

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USP <797> REQUIREMENTS		Compliant	N/A	Input/ Comments/Questions
19	Quality assurance practices include routine disinfection and air quality testing, visual confirmation that personnel are appropriately garbing, review of all orders for correct identity and strength, and visual inspection of CSPs. The pharmacy compounds low-risk level CSPs with 12-hour or less beyond use date (BUD).			
20	Media-fill test procedure or equivalent test is performed at least annually by personnel. The pharmacy is compliant with low-risk level CSPs with 12 hour or less beyond use date compounding practices.			
Medium-Risk Level CSPs				
21	Product considered medium-risk if multiple individual or small doses of sterile products are combined or pooled to prepare a CSP that will be administered either to multiple patients or to one patient on.			
22	Products considered medium-risk if the compounding process includes complex aseptic manipulations or			
23	In the absence of sterility tests, storage is not more than 30 hours at controlled room temperature, 9 days			
24	Products considered medium-risk if aseptic manipulations within an ISO-Class 5 environment use prolonged and complex mixing and transfer, more than 3 sterile products and two entries into any container, and pooling ingredients from multiple sterile products to prepare.			
25	Quality assurance practices include routine disinfection and air quality testing, visual confirmation that personnel are appropriately garbed, review of all orders for correct identity and strength, visual inspection of CSPs, as well as a more challenging media-fill test performed annually. The pharmacy compounds medium-risk level CSPs.			
26	if compounding personnel are improperly garbed and gloved, this makes CSP high-risk. The pharmacy is compliant with medium-risk level CSPs compounding practices.			
High-Risk Level CSPs				
27	Product considered high-risk if any nonsterile ingredients or devices are used.			
28	Product considered high-risk if CSP is exposed to air quality worse than ISO Class 5 for > 1 hour.			
29	Product considered high-risk if Nonsterile water-containing preparations are stored for more than 6 hours.			
30	Sterilization methods are verified to achieve sterility for the quantity and type of containers.			
31	Allowable limits for bacterial endotoxins are met.			
32	All high-risk CSP solutions subjected to terminal sterilization by filtration are appropriately prefiltered and.			
33	CSP maintains acceptable strength, purity and integrity of containers after sterilization.			
34	In the absence of sterility tests, storage is not more than 24 hours at controlled room temperature, 3 days			
35	Media-fill test procedure or equivalent test is performed at least semi-annually by personnel.			

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USP <797> REQUIREMENTS		Compliant	N/A	Input/ Comments/Questions
36	Quality assurance practices include routine disinfection, air quality testing, visual confirmation of appropriate personnel garbing, review of all orders for correct identity and strength, and visual inspection of CSPs <u>The pharmacy compounds high risk level CSPs</u>			
37	Sterility tests are performed for autoclaved CSPs if they are prepared in batches > 25 units <u>The pharmacy is compliant with risk level CSPs compounding practices</u>			
Personnel Training and Evaluation in Aseptic Manipulation Skills				
38	Before beginning to prepare CSPs, personnel are trained by expert personnel, audio-video instructional sources, professional publications in the theoretical principles, practical skills of aseptic			
39	Personnel perform didactic review and pass written and media-fill testing of aseptic manipulative skills			
40	Personnel perform didactic review and pass written and media-fill testing of aseptic manipulative skills			
41	Personnel who fail written tests or whose media-fill test vials result in cross microbial colonization are <u>Documentation on personnel training and evaluation is complete for each employee compounding sterile products. Documents are available for review by outside surveyors upon request.</u> immediately re-instructed and re-evaluated prior to resuming compounding			
Immediate Use CSPs				
42	Immediate-use CSPs are used only when there is a need for emergency or immediate patient administration of a CSP, where administration can begin with 1 hour of compounding			
43	Product considered immediate-use only if the compounding process involves simple transfer of not more than 3 commercially manufactured packages of sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers and not more than 2 entries into any one container or package of sterile infusion solution or administration			
44	Unless required for preparation, compounding is a continuous process not to exceed 1 hour			
45	Aseptic technique is followed and if not immediately administered, CSP is continually supervised			
46	Administration begins not later than 1 hour following the start of the preparation of the CSP			
47	<u>The pharmacy and/or organization compounds immediate use CSPs</u> Unless the person who prepares the CSP immediately witnesses or completely administers it, the CSP is labeled with patient identifier, names and amounts of all ingredients, initials of the compounder, and the exact 1-hour BUD and time			
48	<u>The pharmacy is compliant with immediate use CSPs compounding practices</u> If administration has not begun within 1 hour of being compounded, CSP is discarded			
Single Dose and Multiple Dose Containers				
49	Single-dose containers entered in worse than ISO Class 5 air quality are used within 1 hour of entry			
50	Single-dose containers entered in ISO Class 5 or cleaner air are used within 6 hours of entry			
51	Opened single-dose ampoules are not stored			

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USP <797> REQUIREMENTS		Compliant	N/A	Input/ Comments/Questions
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52	Closure sealed multiple-dose containers are used within 28 days after initial opening or entry, unless the organization has a policy on the appropriate use of single dose and multidose vials.			
Hazardous Drugs as CSPs				
53	Hazardous drugs are prepared for administration only under conditions that protect the healthcare workers and other personnel in the preparation and storage areas			
54	Hazardous drugs are stored separately from other inventory			
55	Hazardous drugs are handled with caution at all times using appropriate chemotherapy gloves during			
56	Hazardous drugs are prepared in an ISO Class 5 environment with protective engineering controls in			
57	Access is limited to areas where hazardous drugs are stored and prepared			
58	All hazardous drugs are prepared in a BSC or a CACI that meets or exceeds standards			
59	The ISO Class 5 BSC or CACI is placed in an ISO Class 7 area, physically separated and optimally has not less than 0.01-inch water column negative pressure to adjacent positive pressure ISO Class 7 or better ante-areas. Certain exceptions allowed if CACI meets 797.			
60	A pressure indicator is installed that can be readily monitored for correct room pressurization			
61	If closed-system vial transfer devices are used, they are used within the ISO Class 5 environment of a			
62	Personnel protective equipment is worn when compounding			
63	Personnel who compound hazardous drugs are trained in storage, handling and disposal of drugs prior to			
64	Effectiveness of training is verified by testing specific hazardous drug preparations techniques and is			
65	Compounding personnel of reproductive capability confirm in writing that they understand the risks of			
66	Disposal of hazardous waste complies with all applicable federal and state regulations			
67	Personnel who perform routine custodial waste removal and cleaning activities for hazardous drugs are			
Radiopharmaceuticals as CSPs				
68	Radiopharmaceuticals are compounded using appropriately shielded vials and syringes in a properly functioning and certified ISO Class 5 PEC located in the ISO Class 8 or cleaner air			
69	Radiopharmaceutical vials designed for multi-use, compounded with technetium-99m, exposed to ISO Class 5 environment, and punctured by needles with no direct contact contamination are used by			
70	Technetium-99m/molybdenum-99 generator systems are stored and operated under conditions recommended by manufacturers and applicable state and federal regulations; such generator systems are operated in an ISO Class 8 or cleaner air environment			
71	Direct visual inspection of radiopharmaceutical CSPs containing high concentrations of doses of radioactivity are conducted in accordance with ALARA			

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USP <797> REQUIREMENTS		Compliant	N/A	Input/ Comments/Questions
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72	Radiopharmaceuticals prepared as low-risk level CSPs with 12-hour or less-BUD are prepared in a segregated compounding area; a line of demarcation is established <u>The pharmacy compounds radiopharmaceutical CSPs</u>			
73	<u>The pharmacy is compliant with radiopharmaceutical CSPs compounding practices</u> Materials and garb exposed in patient care and treatment do not cross the line of demarcation			

Allergen Extracts as CSPs

74	Compounding is performed only with simple transfers using sterile ingredients and supplies			
75	Allergen extracts contain appropriate concentrations of preservatives			
76	Before compounding, personnel appropriately wash hands with soap and water, apply alcohol-based			
77	Sterile gloves are intermittently disinfected with sterile 70% IPA			
78	Vial/ampule critical sites are wet with 70% IPA for 10 seconds and allowed to dry before use			
79	Compounding manipulations are performed to minimize contact contamination of critical sites <u>The pharmacy/organization compounds allergen extract CSPs.</u>			
80	Vials are labeled with patient's name, BUD and storage information based on manufacturers' recommendations or peer-reviewed literature <u>The pharmacy/organization is compliant with allergen extract CSP compounding practices.</u>			

Verification of Compounding Accuracy and Sterility (High-risk Compounding)

81	Packaged and labeled CSPs are visually inspected for physical integrity and expected appearance			
82	The accuracy of identities, concentrations, amounts and purities of ingredients in CSPs are confirmed by reviewing labels on packages, observing and documenting correct measurements with approved and correctly standardized devices, and reviewing information in labeling with certificates of			
83	The licensed healthcare professional is responsible for determining that the selected sterilization method			
84	Commercially available sterile filters are approved for human-use applications in sterilizing pharmaceutical			
85	Sterile filters used to sterilize CSPs are pyrogen free with a nominal porosity of 0.2 or 0.22			
86	Sterile filters used are certified by the manufacturer to retain at least 10 ⁷ microorganisms of a strain of			
87	The compounding supervisor ensures that the filters are chemically and physically stable at the pressure and temperature conditions to be used, that they have enough capacity to filter the required volumes, and that they will achieve sterility and maintain prefiltration pharmaceutical			
88	The filter dimensions and liquid material to be sterile-filtered permit the sterilization process to be completed rapidly, without replacement of the filter during the process			
89	When CSPs are known to contain excessive particulate matter, a prefilter of larger porosity membrane is			

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USP <797> REQUIREMENTS		Compliant	N/A	Input/ Comments/Questions
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90	Filter units used are subjected to manufacturers' recommended integrity test			
91	Personnel must know that filters will achieve sterilization of the particular CSPs being sterilized			
92	The description of steam sterilization conditions and duration for specific CSPs are included in written			
93	The effectiveness of steam sterilization is verified using appropriate Bis of Bacillus stearothermophilus			
94	Heated filtered air is evenly distributed throughout the chamber by a blower device; the oven is equipped			
95	Dry heat is used only for those materials that cannot be sterilized by steam			
96	During sterilization, sufficient space is left between materials to allow for good air circulation			
97	The description of dry heat sterilization conditions and duration for specific CSPs are included in written			
98	The effectiveness of dry heat sterilization is verified using appropriate BIs of Bacillus subtilis and other			
99	The description of dry heat depyrogenation cycle conditions and duration for specific CSPs are included in			
100	The effectiveness of the dry heat depyrogenation cycle is verified using endotoxin challenge vials (ECVs); the bacterial endotoxin test is performed on the ECVs to verify that the cycle is capable of			

Environmental Quality and Control				
Facility Design and Environmental Controls				

101	Critical sites are only exposed to ISO Class 5 or cleaner air			
102	Compounding facility provides a comfortable and well-lighted working environment			
103	PECs maintain ISO Class 5 and meet airflow requirements			
104	Policies and procedures for PEC area are written and followed; determined by the scope and risk levels of			
105	The buffer area maintains ISO Class 7 conditions			
106	A minimum differential positive pressure of 0.02- to 0.05-inch water column is used for rooms providing a			
107	Displacement airflow is employed for buffer areas not physically separated from the ante-areas			
108	Adequate HEPA-filtered airflow is supplied to the buffer area and ante-area			
109	ISO Class 7 buffer and ante-area supplied with HEPA-filtered air receive an ACPH of not less than			

110	If the area has an ISO Class 5 recirculating device, a minimum of 15 ACPHs through the area supply HEPA filters is adequate, providing the combined ACPH not less than 30. The institution utilizes an outside certifier for USP 797 requirements.			
	Documents from the outsider certifier are readily available for review by outside surveyors.			

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USP <797> REQUIREMENTS		Compliant	N/A	Input/ Comments/Questions
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USP <797> REQUIREMENTS		Compliant	N/A	
111	Only the furniture, equipment, supplies and other material required for the compounding activities are brought into the area and they are nonpermeable, nonshedding, cleanable, and resistant to			
112	The surfaces of ceilings, walls, floors, fixtures, shelving, counters and cabinets in the buffer area are smooth, impervious, free from cracks and crevices and nonshedding; the surfaces are			
113	Junctures of ceilings to walls are covered or caulked			
114	If ceilings consist of inlaid panels, the panels are impregnated with a polymer to render them impervious			
115	The exterior lens surface of the ceiling lighting fixtures are smooth, mounted flush and sealed; any other			
116	The buffer area does not contain sources of water (sinks) or floor drains			
117	Work surfaces are constructed of smooth, impervious materials			
118	Carts are stainless steel wire, nonporous plastic or sheet metal with cleanable casters			
119	Storage shelving, counters and cabinets are smooth, impervious, free from cracks and crevices, nonshedding, cleanable and disinfectable; their number, design and manner of installation promotes effective cleaning and disinfection			
Placement of Primary Engineering Controls				
120	PECs are located within a restricted access ISO Class 7 buffer area unless an exception met			
124	When isolators are used for sterile compounding, the recovery time to achieve ISO Class 5 air quality is			
122	Certification that each ISO-classified area is within established guidelines is performed no less than every 6 months and each time the LAFW, BSC, CAI or CACI is relocated or the physical structure of			
123	A pressure gauge or velocity meter is installed to monitor the pressure differential or air flow between the buffer area and the ante-area and between the ante-area and the general environment outside the compounding area; results are reviewed and documented in a log at least every			
124	The pressure between the ISO Class 7 and the general pharmacy area is not less than 5 Pa (0.02 inch			
125	In facilities where low and medium risk level CSPs are prepared, differential airflow is maintained at a			
126	Media that supports the growth of fungi is used in high risk level environments			
127	For low risk level CSPs with 12-hour or less BUD prepared in a PEC that maintains an ISO Class 5 sampling, air sampling is performed at locations inside the ISO Class 5 environment and other areas that are in close proximity to the ISO Class 5 during the certification of the PEC			
128	A sufficient volume of air (400 to 1000 liters) is tested at each location where compounding takes place,			
Additional Personnel Requirements				

USP <797> REQUIREMENTS		Compliant	N/A	Input/ Comments/Questions
129	Foods, drinks and materials exposed in patient care and treatment areas do not enter ante-areas, buffer			
Cleaning and Disinfecting the Compounding Area				
130	When compounding activities require the manipulation of blood-derived or other biological material, the manipulations are clearly separated from routine material handling procedures and equipment			
131	When possible, packaged compounding supplies and components are uncartoned and wiped down with a disinfectant that does not leave a residue in an ante-area ISO Class 8 air quality, before being			
Personnel Cleansing and Garbing				
132	Personal hand hygiene and garb procedures are performed in ante-areas			
133	For ISO Class 5, all cleaning and disinfecting practices and policies for the compounding of CSPs are			
134	LAFWs, BSCs, CAIs, and/or CACIs are cleaned and disinfected frequently, including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods, when spills occur and when surface contamination is known			
135	Work surfaces in ISO Class 7 buffer areas, ISO Class 8 ante-areas and segregated compounding areas are cleaned and disinfected at least daily, and dust and debris are removed when necessary from			
136	Floors in ISO Class 7 and 8 areas are cleaned daily when no compounding occurs; mopping is performed			
137	In the buffer or clean area, ante-area and segregated compounding area, walls, ceilings, and shelving are			
138	All cleaning materials are nonshedding and dedicated to use in the buffer or clean area, ante-area, and			
139	If cleaning materials are reused, SOPs ensure that the effectiveness of the cleaning device is maintained			
140	Sterile 70% IPA swabs do not contact any object before contacting the site to be cleaned			
141	No particle-generating material is used to disinfect the sterile entry points of packages and devices			
142	No shipping cartons are taken into the buffer area, clean area or segregated compounding area			
143	Personnel with rashes, sunburn, weeping sores, conjunctivitis, active respiratory infection or cosmetics			
144	Personnel remove personal outer garments, cosmetics, artificial nails, hand-wrist or body jewelry that can interfere with the fit of gowns and gloves, and visible body piercing above the neck; natural			
145	Garb and cleansing in ante-area as follows: shoes or shoe covers, head and facial hair covers, face mask, fingernail cleansing, hand and forearm washing and drying, nonshedding gown			
146	Cleansing and gloving in buffer room or area as follows: hand cleansing with an alcohol-based product			
147	Gloves are routinely disinfected with sterile 70% IPA after contacting nonsterile objects			
148	Gloves are inspected for holes and replaced when breaches are detected			
Personnel Training and Competency				

USP <797> REQUIREMENTS		Compliant	N/A	Input/ Comments/Questions
149	Prior to compounding, personnel are trained in garbing procedures, aseptic work practices, achieving and			
150	Media-fill testing of aseptic work skills are performed initially before beginning to prepare CSPs and at			
151	Personnel who fail written tests, observational audits, or whose media-fill test vials have one or more units showing contamination are re-instructed and re-evaluated to ensure correction of all aseptic work-			
152	Personnel demonstrate proficiency of proper hand hygiene, garbing and consistent cleaning procedures in			
153	Personnel are visually observed during the process of performing hand hygiene and garbing procedures			
154	Personnel successfully complete an initial competency evaluation and gloved fingertip/thumb sampling procedure no less than 3 times before initially being allowed to compound CSPs; which must be			
155	All compounding personnel have technique and competency evaluated initially during the Media-Fill Test			
Action Levels, Documentation and Data Evaluation				
156	Surface sampling is performed in all ISO classified areas on a periodic basis			
157	Microbial sampling data is collected and reviewed routinely			
158	When microbial sampling exceed action levels, procedures and practices are reviewed			
Elements of Quality Control				
159	A written description of specific training and performance evaluations for compounding personnel is developed for each site			
160	Facility follows procedures for physical inspection of all sterile drugs and devices			
161	If any nonsterile components, including containers and ingredients, are used to make a CSP, such CSPs			
162	Bulk of unformulated drug substances and added substances or excipients are stored in tightly closed containers under temperature, humidity and lighting conditions that are either indicated in-			
163	The date of receipt of nonsterile components is clearly and indelibly marked on each package			
164	All devices used to compound a CSP operate properly within acceptable tolerance limits, as determined			
165	For all equipment, SOPs exist and are followed that state routine maintenance required and frequency of			
166	Personnel are appropriately trained to operate any equipment they use while compounding and are trained to determine if the device is operating properly or is malfunctioning.			
167	Results from equipment maintenance and calibration are kept for the lifetime of the equipment			
Verification of Automatic Compounding Devices for Parenteral Nutrition				
168	Testing procedures for accuracy are verified to meet the USP requirements stated in the individual monograph for the component being tested			
169	Compounding personnel keep a daily record of the accuracy assessments and the results are reviewed at			

USP <797> REQUIREMENTS		Compliant	N/A	Input/ Comments/Questions
Finished Preparation Release Checks and Tests				
170	All CSPs are visually inspected for being intact with no abnormal particulate matter, and prescriptions and written compounding procedures are reviewed to verify accuracy of correct ingredients and amounts, aseptic mixing, high-risk sterilization, packaging, labeling, and expected physical			
171	A double-check system is in place that meets state regulations that includes label accuracy and accuracy			
172	High-risk level CSPs must be sterility tested if they are prepared in batches of > 25 identical containers, or exposed longer than 12 hours at 2 to 8 degrees and 6 hours at warmer than 8 degrees			
173	If high-risk level CSPs are dispensed before receiving the results of their sterility tests, there is a written			
174	High-risk level CSPs must be pyrogen tested, excluding those for inhalation or ophthalmic administration, if prepared in batches of > 25 identical containers, or exposed longer than 12 hours at 2 to 8			
Storage and Beyond Use Dating				
175	Personnel who prepare, dispense and administer CSPs store them strictly in accordance with the conditions stated on the label of ingredient products and finished CSPs			
176	If CSPs are distributed to and administered in other than healthcare facilities, the effect of potentially			
177	The controlled temperature areas are monitored at least once daily and results are documented			
178	Facilities have policies and procedures governing the determination of BUDs			
179	Compounding personnel verify the storage temperature when placing a product into or removing a product from the storage unit			
180	Temperature-sensitive mechanisms are placed to reflect true temperature in the controlled space and are			
Maintaining Sterility, Purity and Stability of Dispensed and Distributed CSPs				
181	The facilities have written procedures for proper packaging, storage, and transportation conditions to			
182	Chemotoxic and other hazardous CSPs have safeguards to maintain the integrity of the CSP and minimize the exposure potential of these products to the environment and personnel			
183	Delivery and patient-care setting personnel are properly trained to deliver the CSP to the appropriate			
184	Outdated and unused CSPs are returned to the compounding facility for disposition as appropriate			
185	SOPs exist to ensure that the storage conditions in the patient-care setting are suitable for the CSP-			
186	Returned CSPs are only redispensed if sterility, acceptable purity, strength and quality can be			
187	If redispensed CSPs are given a later BUD, sterility testing and quantitative assay of ingredients occur to			
Patient or Caregiver Training				
188	A multiple component formal training program is in place to ensure that patients and caregivers understand proper storage, handling, use and disposal of CSPs			

USP <797> REQUIREMENTS	Compliant	N/A	Input/ Comments/Questions
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Patient Monitoring and Adverse Events Reporting

189	SOPs are available that describe the means for patients to ask questions, report concerns and adverse			
190	Reports of CSP adverse events are reviewed promptly and thoroughly by compounding			

Quality Assurance Program

191	A formal quality assurance program is in place that monitors, evaluates, corrects and improves activities			
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USP <797> REQUIREMENTS

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It is affirmed that all information provided herein is true and correct to the best of my knowledge and belief and it is recognized that providing information known to be false may result in disciplinary action.

Pharmacist's Signature _____ License # _____

Pharmacist's E-Mail Address: _____

Date Completed: _____

Supervising Pharmacist's Signature _____ License # _____

Supervising Pharmacist's Email Address: _____

Date Completed: _____

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