

## Pharmacy Quality Assurance Commission Sterile Compounding [USP <797>] Self-Assessment Compliance Checklist

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### Introduction:

- The main goal of the Pharmacy Commission with this sterile compounding checklist is to promote access to safe and effective pharmaceutical services that require sterile compounding.
- The United States Pharmacopeia (USP) <797> is the national standard written into Washington state law, [RCW 18.64.270 \(2\)](#), to require safe and appropriate pharmacy compounding services.
- This checklist is designed to be a tool to guide and aid you in evaluating your compliance with USP <797>, and does not replace *U.S. Pharmacopeia (USP) <797> Pharmaceutical Compounding-Sterile Preparations*.
- This checklist includes the “shalls” in *U.S. Pharmacopeia (USP) <797> Pharmaceutical Compounding-Sterile Preparations*.
- The checklist includes a section at the end that specifically addresses isolators, including two USP <797> requirements and best practice recommendations.
- Investigators will not use the checklist to measure compliance, but may use it as a reference document.
- The Pharmacy Commission investigators can help you understand these requirements, and how to comply with USP <797>.
- The Pharmacy Commission recognizes that USP <797> is currently being revised. The Commission recommends that your pharmacy stay informed of the developments and proposals related to upcoming revisions, specifically if you are remodeling your facility. For this information, please see the U.S. Pharmacopeia (USP) website- <http://www.usp.org/usp-healthcare-professionals/compounding>.

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Date Self-Assessment Completed:	Date Self-Assessment Completed:
Self-Assessment Conducted by:	Self-Assessment Conducted by:
Title:	Title:

Item Number	For each requirement mark "X" the appropriate box: <ul style="list-style-type: none"> <li>• Compliant = your facility is 100% compliant with the requirement</li> <li>• Non-Compliant = your facility is not currently 100% compliant with the requirement</li> <li>• Non-Applicable (N/A) = your facility never compounds and does not need to meet requirement. If N/A is filled, you "shall" comply with the requirement.</li> </ul>	Compliant	Non-Compliant	Non-Applicable (N/A)	NOTES
<b>Standard Operating Procedures</b>					
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.				
<b>Compounding Personnel</b>					
	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:				
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.	Identify, weigh and measure ingredients				
7.	Manipulate sterile products aseptically				
8.	Label and quality inspect CSPs				

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<b>Personnel Training and Competency</b>			
9.	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		
10.	Prior to compounding, personnel are trained in garbing procedures, aseptic work practices, achieving and maintaining ISO Class 5 conditions and cleaning and disinfections procedures		
11.	Personnel perform didactic review, pass written and media-fill testing of aseptic work skills initially before beginning to prepare CSPs and at least annually thereafter for low- and medium-risk level; and semi-annually for high-risk level		
12.	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		
13.	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		
14.	Personnel are visually observed during the process of performing hand hygiene and garbing procedures and appropriately documented and maintained to provide a permanent record		
15.	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		
16.	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.		
<b>CSP Microbial Contamination: Low-risk Level CSPs</b>			
17.	The CSPs are compounded with aseptic manipulations entirely within ISO Class 5 or better quality air using only sterile ingredients, products, components and devices		
18.	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		
19.	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		
20.	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°, or per manufacturer guidelines		

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<b>CSP Microbial Contamination: Low-risk Level CSPs with 12-Hour or Less Beyond Use Date (BUD)</b>			
21.	PECs are certified, maintained ISO Class 5 and located in a segregated compounding area restricted to sterile compounding activities		
22.	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		
23.	Sinks are not located within one meter of the ISO Class 5 PEC		
<b>CSP Microbial Contamination: Medium-Risk Level CSPs</b>			
24.	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		
25.	Products considered medium-risk if the compounding process includes complex aseptic manipulations or unusually long duration		
26.	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°, or per manufacturer guidelines		
27.	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		
<b>Immediate Use CSPs</b>			
28.	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		
29.	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		
30.	Aseptic technique is followed and if not immediately administered, CSP is continually supervised		
31.	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		
32.	Administration begins not later than 1 hour following the start of the preparation of the CSP; If administration has not begun within 1 hour of being compounded, CSP is discarded		

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Single Dose and Multiple Dose Containers			
33.	Single-dose containers entered in worse than or removed from ISO Class 5 air quality are used within 1 hour of entry		
34.	Single-dose containers entered in ISO Class 5 or cleaner air are used within 6 hours of entry, if vial is kept inside the PEC		
35.	Opened single-dose ampuls are not stored		
36.	Closure sealed multiple-dose containers are used within 28 days after initial opening or entry, or as specified by the manufacturer, whichever is less		
Hazardous Drugs as CSPs			
37.	Hazardous drugs are prepared for administration only under conditions that protect the healthcare workers and other personnel in the preparation and storage areas		
38.	Hazardous drugs are stored separately from other inventory		
39.	Hazardous drugs are handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparation for administration and disposal		
40.	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		
41.	Access is limited to areas where hazardous drugs are stored and prepared		
42.	All hazardous drugs are prepared in a BSC or a CACI that meets or exceeds standards		
43.	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 are allowed if CACI meets <797> requirements, see Isolators item A1 **		
44.	A pressure indicator is installed that can be readily monitored for correct room pressurization		
45.	If closed-system vial-transfer devices are used, they are used within the ISO Class 5 environment of a BSC or CACI		
46.	Personnel protective equipment is worn when compounding		
47.	Personnel who compound hazardous drugs are trained in storage, handling and disposal of drugs prior to preparing or handling hazardous CSPs		
48.	Effectiveness of training is verified by testing specific hazardous drug preparations techniques and is documented for each person at least annually		
49.	Compounding personnel of reproductive capability confirm in writing that they understand the risks of hazardous drug handling.		
50.	Disposal of hazardous waste complies with all applicable federal and state regulations		
51.	Personnel who perform routine custodial waste removal and cleaning activities for hazardous drugs are trained in appropriate procedures to protect themselves and prevent contamination		

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Environmental Quality and Control			
Facility Design and Environmental Controls			
52.	Critical sites are only exposed to ISO Class 5 or cleaner air		
53.	Compounding facility provides a comfortable and well-lighted working environment		
54.	Facility has current certification documenting that PECs maintain ISO Class 5 and meet airflow requirements		
55.	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		
56.	Facility has current certification documenting that the buffer area maintains ISO Class 7 conditions with an ACPH of not less than 30.		
57.	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		
58.	Displacement airflow is employed for buffer areas not physically separated from the ante-areas		
59.	Adequate HEPA-filtered airflow is supplied to the buffer area and ante-area		
60.	Facility has current certification documenting that ante-area maintains ISO Class 8 conditions with an ACPH of not less than 30		
61.	For nuclear buffer areas, facility has current certification documenting that the buffer area maintains ISO Class 8 conditions		
62.	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		
63.	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		
64.	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		
65.	Junctures of ceilings to walls are covered or caulked		
66.	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		
67.	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		
68.	The buffer area does not contain sources of water (sinks) or floor drains		
69.	Works surfaces are constructed of smooth, impervious materials		
70.	Carts are stainless steel wire, nonporous plastic or sheet metal with cleanable casters		

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71.	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				
<b>Placement of Primary Engineering Controls</b>					
72.	PECs are located within a restricted access ISO Class 7 buffer area unless an exception met Exceptions: <ul style="list-style-type: none"> <li>Only authorized personnel and materials required for compounding and cleaning shall be permitted in buffer area</li> <li>Presterilization procedures for high-risk level CSPs, such as weighing and mixing, shall be completed in no worse than Class 8 environment.</li> <li>PECS shall be located out of traffic patterns and away from room air currents that could disrupt the intended airflow patterns.</li> </ul>				
73.	When isolators are used for sterile compounding, the recovery time to achieve ISO Class 5 air quality is documented and internal procedures are developed				
74.	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				
75.	The pressure between the ISO Class 7 and the general pharmacy area is not less than 5 Pa -0.02 inch water column ( <i>Included in Isolator section with additional language</i> )				
76.	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				
<b>Additional Personnel Requirements</b>					
77.	Foods, drinks and materials exposed in patient care and treatment areas do not enter ante-areas, buffer areas or segregated compounding areas				
<b>Cleaning and Disinfecting the Compounding Area</b>					
78.	When compounding activities require the manipulation of patient's 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				
79.	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				
80.	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				
81.	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				

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82.	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			
83.	Floors in ISO Class 7 and 8 areas are cleaned daily while you are not actively compounding; mopping is performed by trained personnel using approved agents and written procedures			
84.	In the buffer or clean area, ante-area and segregated compounding area, walls, ceilings, and shelving are cleaned and disinfected monthly			
85.	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			
86.	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			
87.	Sterile 70% IPA swabs do not contact any object before contacting the site to be cleaned			
88.	No particle-generating material is used to disinfect the sterile entry points of packages and devices			
89.	No shipping cartons are taken into the buffer area, clean area or segregated compounding area			
<b>Personnel Cleansing and Garbing</b>				
90.	Personal hand hygiene and garb procedures are performed in ante-areas			
91.	Personnel with rashes, sunburn, weeping sores, conjunctivitis, active respiratory infection or cosmetics are prohibited from preparing CSPs			
92.	Don shoe covers one at a time placing covered shoe on clean side line of demarcation			
93.	PPE is donned in an order that proceeds from activities considered dirtiest to cleanest: Garb and cleansing in ante-area as follows: Dirty garb (shoes or shoe covers, head and facial hair covers, face mask) Hand hygiene (fingernail cleansing, hand and forearm washing and drying), Clean garb nonshedding gown			
94.	Cleansing and gloving in buffer room or area as follows: hand cleansing with a surgical alcohol-based product with persistent activity, allow hands to dry, don sterile gloves and apply sterile 70% IPA			
95.	Gloves are routinely disinfected with sterile 70% IPA after contacting nonsterile objects			
96.	Gloves are inspected for holes and replaced when breaches are detected			
97.	Only exterior gown used for non-hazardous compounding maybe removed and redonned in the ante area during the work shift if not visibly soiled. It is suggested that gowns be redonned only if they are removed and retained on the clean side of the line of demarcation in the ante area			

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Elements of Quality Control			
98.	A written description of specific training and performance evaluations for compounding personnel is developed for each site		
99.	Facility follows procedures for physical inspection of all sterile drugs and devices		
100.	If any nonsterile components, including containers and ingredients, are used to make a CSP, such CSPs must be high risk		
101.	Bulk or 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		
102.	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		
103.	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		
104.	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.		
105.	Results from equipment maintenance and calibration are kept for the lifetime of the equipment		
Viable and Non-Viable Environmental Sampling			
106.	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		
107.	A sufficient volume of air (400 to 1000 liters) is tested at each location where compounding takes place, performed at least semi-annually		
108.	Engineering control performance verification is performed by a qualified individual no less than every 6 months and whenever the device or room is relocated, altered or major service to the facility is performed. (Nonviable)		
109.	Total particle counts are performed by a qualified operator using state-of-the-art electronic equipment and are within established guidelines in each ISO classified area no less than every 6 months and whenever the LAFW, BSC, CAI, or CACI is relocated or the physical structure of the buffer area or ante-area has been altered. (Nonviable)		
110.	An appropriate environmental sampling plan is in place for airborne viable particles, is performed at least every 6 months, and includes locations within each ISO class 5 environments and in the ISO class 7 and 8 areas		
111.	The sampling plan for airborne particles includes sample location, method of collection, frequency of sampling, volume of air sampled, time of day as related to activity in the compounding area and action levels		
112.	A general microbiological growth medium supplemented with additives to neutralize the effects of disinfecting agents is used to support the growth of bacteria.		

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113.	Surface sampling is performed in all ISO classified areas on a periodic basis to evaluate cleaning and disinfecting procedures and employee competency in work practices				
114.	Sampling data is collected and reviewed on a routine basis as a means of evaluating overall control of the compounding environment				
115.	When microbial sampling exceeds action levels, procedures and practices are reviewed				
116.	Regardless of the number of cfu identified in each sample, microorganisms recovered must be identified at least by genus level by an appropriate credentialed laboratory				
117.	High risk media only that supports the growth of fungi is used in high-risk level compounding environments				
<b>Verification of Automatic Compounding Devices for Parenteral Nutrition</b>					
118.	Testing procedures for accuracy are verified to meet the USP requirements stated in the individual monograph for the component being tested				
119.	Compounding personnel keep a daily record of the accuracy assessments and the results are reviewed at least in weekly intervals				
<b>Finished Preparation Release Checks and Tests</b>					
120.	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.				
121.	A double-check system is in place that meets state regulations that includes label accuracy and accuracy of the addition of all ingredients used				
<b>Storage and Beyond Use Dating</b>					
122.	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				
123.	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				
124.	The controlled temperature areas are monitored at least once daily and results are documented				
125.	Facilities have policies and procedures governing the determination of BUDs				
126.	Compounding personnel verify the storage temperature when placing a product into or removing a product from the storage unit				
127.	Temperature-sensitive mechanisms are placed to reflect true temperature in the controlled space and are not subject to significantly prolonged temperature fluctuations				

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<b>Maintaining Sterility, Purity and Stability of Dispensed and Distributed CSPs</b>			
128.	The facilities have written procedures for proper packaging, storage, and transportation conditions to maintain sterility, quality, purity and strength of CSPs		
129.	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		
130.	Delivery and patient-care-setting personnel are properly trained to deliver the CSP to the appropriate storage location		
131.	Outdated and unused CSPs are appropriately disposed		
132.	SOPs exist to ensure that the storage conditions in the patient-care setting are suitable for the CSP-specific storage requirements		
133.	Returned CSPs are only redispensed if sterility, acceptable purity, strength and quality can be assured		
134.	If redispensed CSPs are given a later BUD, sterility testing and quantitative assay of ingredients occur to support the extended BUD		
<b>Patient or Caregiver Training</b>			
135.	A multiple component formal training program is in place to ensure that patients and caregivers understand proper storage, handling, use and disposal of CSPs		
<b>Patient Monitoring and Adverse Events Reporting</b>			
136.	SOPs are available that describe the means for patients or other recipients to ask questions, report concerns and adverse events with CSPs, and for compounding supervisors to correct and prevent future problems		
137.	Reports of CSP adverse events are reviewed promptly and thoroughly by compounding supervisors		
<b>Quality Assurance Program</b>			
138.	Media-fill test procedure with appropriate risk level prepared or equivalent test is performed at least annually by personnel		
139.	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		
140.	A formal quality assurance program is in place that monitors, evaluates, corrects and improves activities and processes		

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<b>CSP Microbial Contamination : High-Risk Level CSPs</b>			
141.	Sterilize high-risk CSPs		
142.	If compounding personnel are improperly garbed and gloved, CSP treated as a high-risk compound		
143.	Product considered high-risk if any nonsterile ingredients or devices are used		
144.	Product considered high-risk if CSP is exposed to air quality worse than ISO Class 5 for > 1 hour		
145.	Product considered high-risk if Nonsterile water-containing preparations are stored for more than 6 hours before being sterilized		
146.	The date of receipt of nonsterile components is clearly and indelibly marked on each package		
147.	Sterilization methods are verified to achieve sterility for the quantity and type of containers		
148.	Media-fill test procedure or equivalent test is performed at least semi-annually by personnel		
149.	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		
150.	Allowable limits for bacterial endotoxins are met		
151.	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		
152.	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		
153.	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		
154.	All high-risk CSP solutions subjected to terminal sterilization by filtration are appropriately prefiltered and terminally filtered in ISO Class 5 air		
155.	CSP maintains acceptable strength, purity and integrity of containers after sterilization		
156.	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°		
157.	Sterility tests are performed for autoclaved CSPs if they are prepared in batches > 25 units		
<b>Verification of Compounding Accuracy and Sterility (High-risk Compounding)</b>			
158.	Packaged and labeled CSPs are visually inspected for physical integrity and expected appearance		
159.	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		
160.	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.		

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161.	Commercially available sterile filters are approved for human-use applications in sterilizing pharmaceutical fluids			
162.	Sterile filters used to sterilize CSPs are pyrogen free with a nominal porosity of 0.2 or 0.22 micrometers			
163.	Sterile filters used are certified by the manufacturer to retain at least 10 <sup>7</sup> microorganisms of a strain of <i>Brevundimonas diminuta</i> on each square centimeter of upstream filter surface area			
164.	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			
165.	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			
166.	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.			
167.	Filter units used are subjected to manufacturers' recommended integrity test			
168.	Personnel must know that filters will achieve sterilization of the particular CSPs being sterilized			
169.	The description of steam sterilization conditions and duration for specific CSPs are included in written documentation in the compounding facility			
170.	The effectiveness of steam sterilization is verified using appropriate Bis of <i>Bacillus stearothermophilus</i> and other confirmation methods			
171.	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			
172.	Dry heat is used only for those materials that cannot be sterilized by steam			
173.	During sterilization, sufficient space is left between materials to allow for good air circulation			
174.	The description of dry heat sterilization conditions and duration for specific CSPs are included in written documentation in the compounding facility			
175.	The effectiveness of dry heat sterilization is verified using appropriate BIs of <i>Bacillus subtilis</i> and other confirmation methods			
176.	The description of dry heat depyrogenation cycle conditions and duration for specific CSPs are included in written documentation in the compounding facility			
177.	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			

Sterile Compounding [USP <797>] Self-Assessment Compliance Checklist

Compliant	Non-Compliant	Non-Applicable (N/A)	Notes
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<b>Radiopharmaceuticals as CSPs</b>			
178.	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		
179.	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		
180.	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		
181.	Direct visual inspection of radiopharmaceutical CSPs containing high concentrations of doses of radioactivity are conducted in accordance with ALARA		
182.	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		
183.	Materials and garb exposed in patient care and treatment do not cross the line of demarcation		
<b>Allergen Extracts as CSPs</b>			
184.	Compounding is performed only with simple transfers using sterile ingredients and supplies		
185.	Allergen extracts contain appropriate concentrations of preservatives		
186.	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		
187.	Sterile gloves are intermittently disinfected with sterile 70% IPA		
188.	Vial/ampule critical sites are wet with 70% IPA for 10 seconds and allowed to dry before use		
189.	Compounding manipulations are performed to minimize contact contamination of critical sites		
190.	Vials are labeled with patient's name, BUD and storage information based on manufacturers' recommendations or peer-reviewed literature		



## Isolators

### Best Practice Recommendations

**The following are best practice recommendations (unless otherwise noted \*\*) according to Pharmacy Quality Assurance Commission and expert opinion, and are advisory only.**

Item Number	For each requirement mark "X" the appropriate box: <ul style="list-style-type: none"> <li>• Compliant = your facility is 100% compliant with the requirement</li> <li>• Non-Compliant = your facility is not currently 100% compliant with the requirement</li> <li>• Non-Applicable (N/A) = your facility never compounds and does not need to meet requirement.</li> </ul>	Compliant	Non-Compliant	Non-Applicable (N/A)	NOTES
<b>Isolators</b>					
<b>General</b>					
A1	Placement in a restricted access ISO Class 7 buffer area required <b><i>Exceptions where isolators may be placed in an air quality worse than ISO Class 7 (only applies if all of the following conditions are met)</i></b> <ul style="list-style-type: none"> <li>• The isolator shall provide isolation from the room and maintain ISO Class 5 during dynamic operating conditions, including transferring ingredients, components, and devices into and out of the isolator and during preparation of CSP's</li> <li>• Particle counts sampled approximately 6 to 12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations</li> <li>• Not more than 3520 particles (0.5 um and larger) per m<sup>3</sup> shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing the transfer</li> </ul> If don't meet A1, must meet A2. <span style="float: right;">**[USP &lt;797&gt; requirement]</span>				

Isolators: Best Practice Recommendations

Compliant	Non-Compliant	Non-Applicable (N/A)	Notes
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A2	If placement cannot be located in a ISO Class 7 buffer area and all exception conditions cannot be met, then the PEC (Primary Engineering Control) is considered a PEC located in a segregated compounding area and only low-risk non-hazardous CSP's with 12-hour or less BUD can be prepared <i>** [USP &lt;797&gt; requirement]</i>				
A3	Sterile gloves are required for sterile compounding and should be replaced regularly. A sterile glove should be placed over the top of the glove mounted to the isolator and should be replaced at the same interval as is appropriate for any other sterile compounding process. The glove mounted to the sleeve (gauntlet) does not need to be sterile and should be replaced daily or between operators.				
A4	If CACI is used for occasionally nonsterile compounding, then CACI must undergo thorough cleaning and disinfection before being used for sterile compounding.				
<b>Isolator Nonhazardous Compounding</b>					
A5	Room must be cleanable and accommodations for hand washing must be available				
A6	Must be unidirectional airflow				
A7	Should be certified in accordance with CETA CAG-002 (as referenced in CAG-003 Sterile Environments and <797>)				
A8	Garbing same as those in <b>Personal Cleansing and Garbing</b> , unless manufacturer can provide written documentation based on validated environmental testing that any component(s) of PPE or personal cleansing is not required				
<b>Isolator Hazardous Compounding</b>					
A9	For sterile hazardous compounding a CACI must be used.				
A10	All compounding shall be done in a separate area designated for hazardous drug compounding. A separate, negative pressure room or Containment Segregated Compounding Area (C-SCA) is allowed if it has at least 12 ACPH.				
A11	C-SCA must be cleanable (all of the architectural elements of a cleanroom; walls, floors, ceilings) and have accommodations for hand washing				
A12	CACI that meets the requirements in <797> may be used for hazardous drug compounding if it is placed in a C-SCA				

Isolators: Best Practice Recommendations

Compliant	Non-Compliant	Non-Applicable (N/A)	Notes
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A13	CACI used for the preparation of HDs shall not be used for the preparation of a non-HD unless the non-HD preparation is placed into a protective outer wrapper before removal from the Containment Primary Engineering Control (C-PEC) and is labeled to require PPE handling precautions				
A14	Containment Primary Engineering Controls (C-PECs) – Shall be externally vented and placed in a restricted access segregated room which has a minimum negative pressure of 0.01 inches of water column				
A15	Gloves used shall be labeled as ASTM D6978-tested chemotherapy gloves, be powder-free and free of physical defects				
A16	When working within a CACI, the outer glove (over the isolator glove) shall be a sterile, powder free, ASTM D6978-tested chemotherapy glove				
A17	CACIs, the area under the work tray shall be cleaned at least monthly to reduce the contamination level (when cleaning a CACI, donning a respirator when opening the front of the cabinet is necessary)				