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

Introduction: (introduction added)

- This checklist includes the reported "principal competencies, conditions, practices, and quality assurance that are required" ("shalls") in U.S. Pharmacopeial (USP) <797>.
- This checklist is designed to be a tool to guide and aid you to assess your compliance with USP <797>.
- At the end of the checklist, there is a section specifically addresses isolators which includes USP <797> requirements and <800> recommendations.
- The language provided in this checklist, at times, does not include all of the specific language communicated in USP <797>, if there is a need for further understanding of requirement language, please refer to USP <797> for additional language.
- Department of Health Office of Inspection and Investigations is available to assist you with interpreting these requirements, and assist your understanding the compliance with USP <797>.
- The Pharmacy Quality Assurance Commission recognizes that USP <797> and <800> are currently being revised, and recommends your pharmacy to keep abreast of the any developments and proposals with the revision, specifically if remodeling your facility. For this information, please visit the U.S. Pharmacopeial (USP) website- http://www.usp.org/usp-healthcare-professionals/compounding

Notes Key:

- Identified changes in comparison of template document-*Alabama State Board of Pharmacy USP <797> Compliance Self-Assessment Form*- (deletions/additions/moved items), research, or questions
- Items that need to be reviewed

Self-Assessment Contents: Contents section Added

Section Name	Requirement numbers	Page numbers
Standard Operating Procedures		
Compounding Personnel		
Personnel Training and Evaluation in Aseptic Manipulation Skills		
Personnel Training and Competency		
CSP Microbial Contamination Risk Levels: Low-risk Level CSPS		
CSP Microbial Contamination Risk Levels: Low-risk Level CSPs with 12-hour or Less Beyond Use Date (BUD)		
CSP Microbial Contamination Risk Levels: Medium-risk Level CSPs		
Immediate Use CSPs		
Single Dose and Multiple Dose Containers		
Hazardous Drugs as CSPs		
Environmental Quality and Control: Facility Design and Environmental Controls		
Placement of Primary Engineering Controls		
Additional Personnel Requirements		
Cleaning and Disinfecting the Compounding Area		
Personnel Cleansing and Garbing		
Action Levels, Documentation and Data Evaluation		
Elements of Quality Control		
Viable and Non-Viable Environmental Sampling		
Verification of Automatic Compounding Devices for Parenteral Nutrition		
Finished Preparation Release Checks and Tests		
Storage and Beyond Use Dating		
Maintaining Sterility, Purity and Stability of Dispensed and Distributed CSPs		
Patient or Caregiver Training		
Patient Monitoring and Adverse Events Reporting		
Quality Assurance Program		
CSP Microbial Contamination Risk Levels: High-risk Level CSPs		
Verification of Compounding Accuracy and Sterility (High-risk Compounding)		
Radiopharmaceuticals as CSPs		
Allergen Extracts as CSPs		
Isolators: USP <797> Requirements and <800> Recommendations		

DRAFT

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

Revised affirmation section

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

Old #	New #	For each requirement mark "X" the appropriate box: (added/updated language) • Compliant = your facility is 100% compliant with the requirement • Non-Compliant = your facility is not currently 100% compliant with the requirement • 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.	Compliant	Non-Compliant	Non-Applicable (N/A)	NOTES Added: Non-compliant
		Standard Operating Procedures				
1	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.				
		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	2.	Perform aseptic hand cleansing				
3	3.	Perform disinfection of compounding surfaces				
4	4.	Select and appropriately don protective garb				
5	5.	Maintain or achieve sterility of CSPs				
7	6.	Identify, weigh and measure ingredients				
8	7.	Manipulate sterile products aseptically				
10	8.	Label and quality inspect CSPs				

Old #	New #		Compliant	Non-Compliant	Non-Applicable (N/A)	Notes
		Personnel Training and Evaluation in Aseptic Manipulation Skills				Moved section: Personnel related
38	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 and in achieving and maintaining ISO Class 5 environmental conditions				
39	10.	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	11.	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	12.	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				
		Personnel Training and Competency				Moved section: Personnel related
149	13.	Prior to compounding, personnel are trained in garbing procedures, aseptic work practices, achieving and maintaining ISO Class 5 conditions and cleaning and disinfections procedures				Need to review language
150	14.	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				Need to review language
151	15.	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				Need to review language
152	16.	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				Need to review language
153	17.	Personnel are visually observed during the process of performing hand hygiene and garbing procedures and appropriately documented and maintained to provide a permanent record				Need to review language
154	18.	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;				Need to

Old #	New #		Compliant	Non-Compliant	Non-Applicable (N/A)	Notes
		which must be repeated at least annually for low- and medium-risk, and twice annually for high-risk compounding				review language
155	19.	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.				Need to review language
		CSP Microbial Contamination : *Low-risk Level CSPs*				
11	20.	The CSPs are compounded with aseptic manipulations entirely within ISO Class 5 or better quality air using only sterile ingredients, products, components and devices				
12	21.	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	22.	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				
14	23.	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°				
		CSP Microbial Contamination: Low-risk Level CSPs with 12-Hour or Less Beyond Use Date (BUD)				
16	24.	PECs are certified, maintained ISO Class 5 and located in a segregated compounding area restricted to sterile compounding activities				
17	25.	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				
18	26.	Sinks are not located within one meter of the ISO Class 5 PEC; sinks are separated from the immediate area of the ISO Class 5 PEC device				Added language: "within one meter of". Language in proposed 797, provides guidance of

Old #	New #		Compliant	Non-Compliant	Non-Applicable (N/A)	Notes
						distance.
		CSP Microbial Contamination: Medium-Risk Level CSPs				
21	27.	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	28.	Products considered medium-risk if the compounding process includes complex aseptic manipulations or unusually long duration				
23	29.	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	30.	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				
		Immediate Use CSPs				Removed #44: Unless required for preparation, compounding is a continuous process not to exceed 1 hour
42	31.	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	32.	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				
45	33.	Aseptic technique is followed and if not immediately administered, CSP is continually supervised				
47	34.	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				
46 &	35.	Administration begins not later than 1 hour following the start of the preparation of the CSP;				Combined

Old #	New #		Compliant	Non-Compliant	Non-Applicable (N/A)	Notes
48		If administration has not begun within 1 hour of being compounded, CSP is discarded				46 & 48
		Single Dose and Multiple Dose Containers				
49	36.	Single-dose containers entered in worse than ISO Class 5 air quality are used within 1 hour of entry				
50	37.	Single-dose containers entered in ISO Class 5 or cleaner air are used within 6 hours of entry				Research: vials / syringes
51	38.	Opened single-dose ampoules are not stored				
52	39.	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				
6	40.	Protect personnel and compounding environment from contamination by hazardous drugs				Moved to Hazardous
53	41.	Hazardous drugs are prepared for administration only under conditions that protect the healthcare workers and other personnel in the preparation and storage areas				
54	42.	Hazardous drugs are stored separately from other inventory				
55	43.	Hazardous drugs are handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparation for administration and disposal				
56	44.	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	45.	Access is limited to areas where hazardous drugs are stored and prepared				
58	46.	All hazardous drugs are prepared in a BSC or a CACI that meets or exceeds standards				
59	47.	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				List exceptions/ what are the exceptions?
60	48.	A pressure indicator is installed that can be readily monitored for correct room pressurization				
61	49.	If closed-system vial-transfer devices are used, they are used within the ISO Class 5 environment of a BSC or CACI				
62	50.	Personnel protective equipment is worn when compounding				
63	51.	Personnel who compound hazardous drugs are trained in storage, handling and disposal of drugs prior to preparing or handling hazardous CSPs				

Old #	New #		Compliant	Non-Compliant	Non-Applicable (N/A)	Notes
64	52.	Effectiveness of training is verified by testing specific hazardous drug preparations techniques and is documented for each person at least annually				
65	53.	Compounding personnel of reproductive capability confirm in writing that they understand the risks of hazardous drug handling.				
66	54.	Disposal of hazardous waste complies with all applicable federal and state regulations				
67	55.	Personnel who perform routine custodial waste removal and cleaning activities for hazardous drugs are trained in appropriate procedures to protect themselves and prevent contamination				
		Environmental Quality and Control				
		Facility Design and Environmental Controls				
101	56.	Critical sites are only exposed to ISO Class 5 or cleaner air *(Included in Isolator section)*				Isolator
102	57.	Compounding facility provides a comfortable and well-lighted working environment *(Included in Isolator section)*				Isolator
103	58.	Facility has current certification documenting that PECs maintain ISO Class 5 and meet airflow requirements *(Included in Isolator section with additional language)*				Isolator / Added language: Facility has current certification documentin g that..
104	59.	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 *(Included in Isolator section)*				Isolator
105	60.	Facility has current certification documenting that the buffer area maintains ISO Class 7 conditions				Isolator Research/ Added language: Facility has current certification documentin g that..
106	61.	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				Isolator Research
107	62.	Displacement airflow is employed for buffer areas not physically separated from the ante-				Isolator /

Old #	New #		Compliant	Non-Compliant	Non-Applicable (N/A)	Notes
		areas				Added: able to select N/A (due to ante room)
108	63.	Adequate HEPA-filtered airflow is supplied to the buffer area and ante-area *(Included in Isolator section with additional language)*				Isolator
109	64.	Facility has current certification documenting that ante-area and ISO Class 7 buffer area are supplied with HEPA-filtered air receive an ACPH of not less than 30 *(Included in Isolator section with additional language)*				Isolator / Added language: Facility has current certification documentin g that..
110	65.	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 *(Included in Isolator section)*				Isolator Research/ Added: able to select N/A (due to ante room)
111	66.	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 *(Included in Isolator section)*				Isolator
112	67.	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 *(Included in Isolator section with additional language)*				Isolator
113	68.	Junctures of ceilings to walls are coved or caulked *(Included in Isolator section)*				Isolator
114	69.	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 *(Included in Isolator section)*				Isolator
115	70.	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 *(Included in Isolator section)*				Isolator
116	71.	The buffer area does not contain sources of water (sinks) or floor drains *(Included in Isolator section with additional language)*				Isolator

Old #	New #		Compliant	Non-Compliant	Non-Applicable (N/A)	Notes
117	72.	Works surfaces are constructed of smooth, impervious materials *(Included in Isolator section)*				Isolator
118	73.	Carts are stainless steel wire, nonporous plastic or sheet metal with cleanable casters *(Included in Isolator section)*				Isolator
119	74.	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 *(Included in Isolator section)*				Isolator
		Placement of Primary Engineering Controls				Deleted #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 (covered in viable/non-viable
120	75.	PECs are located within a restricted access ISO Class 7 buffer area unless an exception met Exceptions:				Added:

Old #	New #		Compliant	Non-Compliant	Non-Applicable (N/A)	Notes
		• Only authorized personnel and materials required for compounding and cleaning shall be permitted in buffer area • Presterilization procedures for high-risk level CSPs, such as weighing and mixing, shall be completed in no worse than Class 8 environment. • PECS shall be located out of traffic patterns and away from room air currents that could disrupt the intended airflow patterns.				Exception language from USP797
121	76.	When isolators are used for sterile compounding, the recovery time to achieve ISO Class 5 air quality is documented and internal procedures are developed				Isolator
123	77.	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 *(Included in Isolator section)*				Isolator
124	78.	The pressure between the ISO Class 7 and the general pharmacy area is not less than 5 Pa - 0.02 inch water column *(Included in Isolator section with additional language)*				Isolator
125	79.	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				Isolator
		Additional Personnel Requirements				
129	80.	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	81.	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			N/A?	Added: patient's to language-from USP797. Able to select N/A? Examples of when to apply: include/exclude?
131	82.	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,				Isolator

Old #	New #		Compliant	Non-Compliant	Non-Applicable (N/A)	Notes
		before being passed into buffer areas; Supplies are allowed to dry before compounding *(Included in Isolator section)*				
133	83.	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				Moved from Personnel Cleansing & Garbing
134	84.	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				Moved from Personnel Cleansing & Garbing
135	85.	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 *(Included in Isolator section with additional language)*				Isolator/ moved from Personnel Cleansing & Garbing
136	86.	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 *(Included in Isolator section with additional language)*				Isolator/ moved from Personnel Cleansing & Garbing
137	87.	In the buffer or clean area, ante-area and segregated compounding area, walls, ceilings, and shelving are cleaned and disinfected monthly *(Included in Isolator section with additional language)*				Isolator/ Moved from Personnel Moved from Cleansing & Garbing
138	88.	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				Moved from Cleansing & Garbing
139	89.	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				Moved from Cleansing & Garbing
140	90.	Sterile 70% IPA swabs do not contact any object before contacting the site to be cleaned				Moved from

Old #	New #		Compliant	Non-Compliant	Non-Applicable (N/A)	Notes
						Cleansing & Garbing
141	91.	No particle-generating material is used to disinfect the sterile entry points of packages and devices				Moved from Cleansing & Garbing
142	92.	No shipping cartons are taken into the buffer area, clean area or segregated compounding area				Moved from Cleansing & Garbing
		Personnel Cleansing and Garbing				
132	93.	Personal hand hygiene and garb procedures are performed in ante-areas				
143	94.	Personnel with rashes, sunburn, weeping sores, conjunctivitis, active respiratory infection or cosmetics are prohibited from preparing CSPs				
No #, New	95.	Don shoe covers one at a time placing covered shoe on clean side line of demarcation				
144 & 145	96.	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 *(Included in Isolator section)*				Isolator / combined 144 & 145/ organized dirtiest to cleanest
146	97.	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 and apply 70% IPA *(Included in Isolator section with additional language)*				Isolator / Added language: don sterile gloves and apply 70% IPA
147	98.	Gloves are routinely disinfected with sterile 70% IPA after contacting nonsterile objects				
148	99.	Gloves are inspected for holes and replaced when breaches are detected				
No #, New	100.	Only exterior gown used for non-hazardous compounding maybe removed and redoned in the ante area during the work shift if not visibly soiled. It is suggested that gowns be redones only if they are removed and retained on the clean side of the line of demarcation in the ante area				Added new requirement

Old #	New #		Compliant	Non-Compliant	Non-Applicable (N/A)	Notes
		Action Levels, Documentation and Data Evaluation				
156	101.	Surface sampling is performed in all ISO classified areas on a periodic basis				Need to review language
157	102.	Microbial sampling data is collected and reviewed routinely				Need to review language
158	103.	When microbial sampling exceed action levels, procedures and practices are reviewed				Need to review language
		Elements of Quality Control				
159	104.	A written description of specific training and performance evaluations for compounding personnel is developed for each site				Need to review language
160	105.	Facility follows procedures for physical inspection of all sterile drugs and devices				Need to review language
161	106.	If any nonsterile components, including containers and ingredients, are used to make a CSP, such CSPs must be high risk				Need to review language
162	107.	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				Need to review language
163	108.	The date of receipt of nonsterile components is clearly and indelibly marked on each package				Need to review language
164	109.	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				Need to review language
165	110.	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				Need to review language

Old #	New #		Compliant	Non-Compliant	Non-Applicable (N/A)	Notes
166	111.	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.				Need to review language
167	112.	Results from equipment maintenance and calibration are kept for the lifetime of the equipment				Need to review language
		Viable and Non-Viable Environmental Sampling				Added Section
127	113.	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				After Class 5….Deleted: during the certification of the PEC
128	114.	A sufficient volume of air (400 to 1000 liters) is tested at each location where compounding takes place, performed at least semi-annually				
No #, New	115.	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)				Added New requirement
No #, New	116.	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)				Added New requirement
No #, New	117.	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				Added New requirement
No #, New	118.	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				Added New requirement
No #, New	119.	A general microbiological growth medium supplemented with additives to neutralize the effects of disinfecting agents is used to support the growth of bacteria.				Added New requirement
No #, New	120.	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				Added New requirement
No #, New	121.	Sampling data is collected and reviewed on a routine basis as a means of evaluating overall control of the compounding environment				Added New requirement

Old #	New #		Compliant	Non-Compliant	Non-Applicable (N/A)	Notes
No #, New	122.	When microbial sampling exceeds action levels, procedures and practices are reviewed				Added New requirement
No #, New	123.	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				Added New requirement
		Verification of Automatic Compounding Devices for Parenteral Nutrition				
168	124.	Testing procedures for accuracy are verified to meet the USP requirements stated in the individual monograph for the component being tested				Need to review language
169	125.	Compounding personnel keep a daily record of the accuracy assessments and the results are reviewed at least in weekly intervals				Need to review language
		Finished Preparation Release Checks and Tests				
170	126.	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.				Need to review language
171	127.	A double-check system is in place that meets state regulations that includes label accuracy and accuracy of the addition of all ingredients used				Need to review language
172	128.	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				Need to review language
173	129.	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				Need to review language
174	130.	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				Need to review language
		Storage and Beyond Use Dating				
175	131.	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				Need to review language
176	132.	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				Need to

Old #	New #		Compliant	Non-Compliant	Non-Applicable (N/A)	Notes
		BUDs				review language
177	133.	The controlled temperature areas are monitored at least once daily and results are documented				Need to review language
178	134.	Facilities have policies and procedures governing the determination of BUDs				Need to review language
179	135.	Compounding personnel verify the storage temperature when placing a product into or removing a product from the storage unit				Need to review language
180	136.	Temperature-sensitive mechanisms are placed to reflect true temperature in the controlled space and are not subject to significantly prolonged temperature fluctuations				Need to review language
		Maintaining Sterility, Purity and Stability of Dispensed and Distributed CSPs				
181	137.	The facilities have written procedures for proper packaging, storage, and transportation conditions to maintain sterility, quality, purity and strength of CSPs				Need to review language
182	138.	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				Need to review language
183	139.	Delivery and patient-care-setting personnel are properly trained to deliver the CSP to the appropriate storage location				Need to review language
184	140.	Outdated and unused CSPs are returned to the compounding facility for disposition as appropriate				Need to review language
185	141.	SOPs exist to ensure that the storage conditions in the patient-care setting are suitable for the CSP-specific storage requirements				Need to review language
186	142.	Returned CSPs are only redispensed if sterility, acceptable purity, strength and quality can be assured				Need to review

Old #	New #		Compliant	Non-Compliant	Non-Applicable (N/A)	Notes
						language
187	143.	If redispensed CSPs are given a later BUD, sterility testing and quantitative assay of ingredients occur to support the extended BUD				Need to review language
		Patient or Caregiver Training				
188	144.	A multiple component formal training program is in place to ensure that patients and caregivers understand proper storage, handling, use and disposal of CSPs				Need to review language
		Patient Monitoring and Adverse Events Reporting				
189	145.	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				Need to review language
190	146.	Reports of CSP adverse events are reviewed promptly and thoroughly by compounding supervisors				Need to review language
		Quality Assurance Program				
19	147.	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				Moved from Low –risk level CSPs with 12hr
20	148.	Media-fill test procedure or equivalent test is performed at least annually by personnel				Moved from Low –risk level CSPs with 12hr
25	149.	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				Moved from Medium-risk
35	150.	Media-fill test procedure or equivalent test is performed at least semi-annually by personnel				Moved from high-risk
36	151.	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				Moved from high-risk
191	152.	A formal quality assurance program is in place that monitors, evaluates, corrects and				Need to

Old #	New #		Compliant	Non-Compliant	Non-Applicable (N/A)	Notes
		improves activities and processes				review language
		CSP Microbial Contamination : High-Risk Level CSPs				Moved section to end of document
9	153.	Sterilize high-risk CSPs				Moved from compounding personnel
26	154.	If compounding personnel are improperly garbed and gloved, this makes CSP high-risk				Moved from medium risk
15	155.	If compounding personnel are improperly garbed and gloved, CSP treated as a high-risk compound				Moved from low risk
126	156.	Media that supports the growth of fungi is used in high-risk level environments				Moved from Placement of Primary Engineering Controls
27	157.	Product considered high-risk if any nonsterile ingredients or devices are used				
28	158.	Product considered high-risk if CSP is exposed to air quality worse than ISO Class 5 for > 1 hour				
29	159.	Product considered high-risk if Nonsterile water-containing preparations are stored for more than 6 hours before being sterilized				
30	160.	Sterilization methods are verified to achieve sterility for the quantity and type of containers				
31	161.	Allowable limits for bacterial endotoxins are met				
32	162.	All high-risk CSP solutions subjected to terminal sterilization by filtration are appropriately prefiltered and terminally filtered in ISO Class 5 air				
33	163.	CSP maintains acceptable strength, purity and integrity of containers after sterilization				
34	164.	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°				
37	165.	Sterility tests are performed for autoclaved CSPs if they are prepared in batches > 25 units				
		Verification of Compounding Accuracy and Sterility (High-risk Compounding)				Moved

Old #	New #		Compliant	Non-Compliant	Non-Applicable (N/A)	Notes
						section to end of document
81	166.	Packaged and labeled CSPs are visually inspected for physical integrity and expected appearance				
82	167.	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	168.	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	169.	Commercially available sterile filters are approved for human-use applications in sterilizing pharmaceutical fluids				
85	170.	Sterile filters used to sterilize CSPs are pyrogen free with a nominal porosity of 0.2 or 0.22 micrometers				
86	171.	Sterile filters used are certified by the manufacturer to retain at least 10^7 microorganisms of a strain of Brevundimonas diminuta on each square centimeter of upstream filter surface area				
87	172.	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	173.	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	174.	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	175.	Filter units used are subjected to manufacturers' recommended integrity test				
91	176.	Personnel must know that filters will achieve sterilization of the particular CSPs being sterilized				
92	177.	The description of steam sterilization conditions and duration for specific CSPs are included in written documentation in the compounding facility				
93	178.	The effectiveness of steam sterilization is verified using appropriate Bis of Bacillus stearothermophilus and other confirmation methods				
94	179.	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				

Old #	New #		Compliant	Non-Compliant	Non-Applicable (N/A)	Notes
95	180.	Dry heat is used only for those materials that cannot be sterilized by steam				
96	181.	During sterilization, sufficient space is left between materials to allow for good air circulation				
97	182.	The description of dry heat sterilization conditions and duration for specific CSPs are included in written documentation in the compounding facility				
98	183.	The effectiveness of dry heat sterilization is verified using appropriate BIs of Bacillus subtilis and other confirmation methods				
99	184.	The description of dry heat depyrogenation cycle conditions and duration for specific CSPs are included in written documentation in the compounding facility				
100	185.	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				
		Radiopharmaceuticals as CSPs				Moved section to end
68	186.	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	187.	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	188.	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	189.	Direct visual inspection of radiopharmaceutical CSPs containing high concentrations of doses of radioactivity are conducted in accordance with ALARA				
72	190.	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	191.	Materials and garb exposed in patient care and treatment do not cross the line of demarcation				
		Allergen Extracts as CSPs				Moved section to end
74	192.	Compounding is performed only with simple transfers using sterile ingredients and supplies				
75	193.	Allergen extracts contain appropriate concentrations of preservatives				
76	194.	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				

Old #	New #		Compliant	Non-Compliant	Non-Applicable (N/A)	Notes
77	195.	Sterile gloves are intermittently disinfected with sterile 70% IPA				
78	196.	Vial/ampule critical sites are wet with 70% IPA for 10 seconds and allowed to dry before use				
79	197.	Compounding manipulations are performed to minimize contact contamination of critical sites				
80	198.	Vials are labeled with patient's name, BUD and storage information based on manufacturers' recommendations or peer-reviewed literature				

Isolators

USP <797> Requirements and <800> Recommendations

- The following section focuses on Isolators. The contents include USP<797> requirements ("shalls") and <800> recommendations.
- Isolator USP <797> requirements will be noted in each item with the following: *[USP <797> requirement]*
- Information for <800> was obtained by interpreting the proposed General Chapter <800> Hazardous Drugs-Handling in Healthcare Settings *PF* 40(3) [May–Jun.2013], (CMP: J. Sun.) Correspondence Number-C139868. Location of document-http://www.usp.org/usp-nf/notices/general-chapter-hazardous-drugs-handling-healthcare-settings

Corresponding number indicates that the item is located in the checklist. The language maybe the same or additional language has been added.

New		**Isolators**				Added section
New or corresponding #		**General**	Compliant	Non-Compliant	Non-Applicable (N/A)	Added section
New	A1	Placement in a restricted access ISO Class 7 buffer area required ***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)*** • 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 • Particle counts sampled approximately 6 to 12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations • Not more than 3520 particles (0.5 um and larger) per m^3 shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing the transfer				Added recommendation/ Need to review language

Old #	New #		Compliant	Non-Compliant	Non-Applicable (N/A)	Notes
New	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 CSP's with 12-hour or less BUD can be prepared				Added recommendation/ Need to review language
New	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.				Added recommendation/ Need to review language
101	A4	Critical sites are only exposed to ISO Class 5 or cleaner air *[USP <797> requirement]*				Same language as <797> Checklist item 101; from Facility Design and Environmental Controls
102	A5	Compounding facility provides a comfortable and well-lighted working environment *[USP <797> requirement]*				Same language as <797> Checklist item 102; from Facility Design and Environme

Old #	New #		Compliant	Non-Compliant	Non-Applicable (N/A)	Notes
						ntal Controls
103	A6	Facility has current certification according to the Controlled Environment Testing Association (CETA) Application Guides documenting that PECs maintain ISO Class 5 and meet airflow requirements *[USP <797> requirement]*				Similar language as <797> Checklist item 103; from Facility Design and Environmental Controls
104	A7	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 *[USP <797> requirement]*				Same language as <797> Checklist item 104; from Facility Design and Environmental Controls
108	A8	Adequate ceiling delivered HEPA-filtered airflow is supplied to the buffer area and ante-area *[USP <797> requirement]*				Similar language as <797> Checklist item 108; from Facility Design and

Old #	New #		Compliant	Non-Compliant	Non-Applicable (N/A)	Notes
						Environmental Controls
109	A9	Facility has current certification according to the CETA Application Guides documenting that the ante-area and ISO Class 7 buffer area are supplied with HEPA-filtered air receive an ACPH of not less than 30 *[USP <797> requirement]*				Similar language as <797> Checklist item 109; from Facility Design and Environmental Controls
110	A10	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> requirement]*				Same language as <797> Checklist item 110; from Facility Design and Environmental Controls
111	A11	Only the furniture, equipment, supplies and other material required for the compounding activities are brought into the area and are non-permeable, non-shedding, cleanable, and resistant to disinfectants; before such items are brought into the area, they are cleaned and disinfected *[USP <797> requirement]*				Same language as <797> Checklist item 111; from Facility

Old #	New #		Compliant	Non-Compliant	Non-Applicable (N/A)	Notes
						Design and Environmental Controls
112	A12	The surfaces of ceilings, walls, floors, fixtures, shelving, counters and cabinets in the compounding areas are smooth, impervious, free from cracks and crevices and non-shedding; the surfaces are resistant to damage by disinfectant agents *[USP <797> requirement]*				Similar language as <797> Checklist item 112; from Facility Design and Environmental Controls
113	A13	Junctures of ceilings to walls are covered or caulked *[USP <797> requirement]*				Same language as <797> Checklist item 113; from Facility Design and Environmental Controls
114	A14	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*[USP <797> requirement]*				Same language as <797> Checklist item 114; from

Old #	New #		Compliant	Non-Compliant	Non-Applicable (N/A)	Notes
						Facility Design and Environmental Controls
115	A15	The exterior lens surface of the ceiling lighting are smooth, mounted flush and sealed; any other penetrations through the ceiling or walls are sealed *[USP <797> requirement]*				Same language as <797> Checklist item 115; from Facility Design and Environmental Controls
116	A16	The buffer area does not contain sources of water (sinks) or floor drains, <u>but sinks are permitted in a Segregated Compounding Area when located at least 1 meter or 3 feet away from the PEC</u> *[USP <797> requirement]*				Similar language as <797> Checklist item 116; from Facility Design and Environmental Controls
117	A17	Work surfaces are constructed of smooth, impervious materials *[USP <797> requirement]*				Same language as <797> Checklist item 117;

Old #	New #		Compliant	Non-Compliant	Non-Applicable (N/A)	Notes
						from Facility Design and Environmental Controls
118	A18	Carts are stainless steel wire, non-porous plastic or sheet metal with cleanable casters *[USP <797> requirement]*				Same language as <797> Checklist item 118; from Facility Design and Environmental Controls
119	A19	Storage shelving, counters and cabinets are smooth, impervious, free from cracks and crevices, non-shedding, cleanable and disinfectable; their number, design and manner of installation promotes effective cleaning and disinfection *[USP <797> requirement]*				Same language as <797> Checklist item 119; from Facility Design and Environmental Controls
123	A20	A pressure gauge is installed to monitor the pressure differential 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*[USP <797> requirement]*				Same language as <797> Checklist

Old #	New #		Compliant	Non-Compliant	Non-Applicable (N/A)	Notes
						item 123; from Placement of Primary Engineering Controls
124	A21	The pressure between the ISO Class 7 and the general pharmacy area is not less than 5 Pa (0.02 inch water column). <u>If using a cascading pressure differential, this value should be 0.04". 0.02 from buffer room to anteroom and 0.02" from the anteroom to the general pharmacy</u> *[USP <797> requirement]*				Similar language as <797> Checklist item 124; from Placement of Primary Engineering Controls
131	A22	All 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 *[USP <797> requirement]*				Same language as <797> Checklist item 131; from Cleaning and Disinfecting the Compounding Area
135	A23	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. <u>This cleaning is clearly documented (paper or electronically)</u> *[USP <797> requirement]*				Similar language as <797> Checklist

Old #	New #		Compliant	Non-Compliant	Non-Applicable (N/A)	Notes
						item 135; from Cleaning and Disinfecting the Compounding Area
136	A24	Floors in ISO Class 7 and 8 areas and segregated compounding areas are cleaned daily with a germicidal detergent and water when no compounding occurs; mopping is performed by trained personnel using approved agents and written procedures *[USP <797> requirement]*				Similar language as <797> Checklist item 136; from Cleaning and Disinfecting the Compounding Area
137	A25	In the buffer or clean area, ante-area and segregated compounding area, walls, ceilings, and shelving are cleaned and disinfected monthly and cleaning is clearly and properly documented *[USP <797> requirement]*				Similar language as <797> Checklist item 137; from Cleaning and Disinfecting the Compounding Area

Old #	New #		Compliant	Non-Compliant	Non-Applicable (N/A)	Notes
144 & 145	A26	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 – sequence is not absolute), hand hygiene (fingernail cleansing, hand and forearm washing and drying) is done after donning head, face and feet, clean garb non-shedding gown. *[USP <797> requirement]*				Same language as <797> Checklist items 144 & 145; from Personnel Cleansing and Garbing
146	A27	Cleansing and gloving in buffer room or segregated area as follows: hand cleansing with an alcohol-based product with persistent activity, allow hands to dry, don sterile gloves and apply 70% IPA *[USP <797> requirement]*				Similar language as <797> Checklist item 146; from Personnel Cleansing and Garbing
New		**Nonhazardous Compounding**				Added section
New	A28	Placement in an ISO classified room (Restricted access ISO Class 7 buffer area required ***UNLESS* all 3 Exceptions are met**-Refer to "General" section)				Added recommendation/ Need to review language
New	A29	Full beyond use dating can be assigned even with the isolator in a regular room				Added recommendation/

Old #	New #		Compliant	Non-Compliant	Non-Applicable (N/A)	Notes
						Need to review language
New	A30	Room must be cleanable and accommodations for hand washing must be available				Added recommendation/ Need to review language
New	A31	Must be unidirectional airflow				Added recommendation/ Need to review language
New	A32	Should be certified in accordance with CETA CAG-002 (as referenced in CAG-003 and <797>)				Added recommendation/ Need to review language
110	A33	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> requirement]*				Same language as <797> Checklist item 110; from Facility Design and Environmental Controls.

Old #	New #		Compliant	Non-Compliant	Non-Applicable (N/A)	Notes
New	A34	Garbing same as those in **Personal Cleansing and Garbing** , unless manufacturer can provide written documentation based on validated environmental testing that any component(s) of PPE or personal cleansing is not required				Added recommendation/ Need to review language
New		**Hazardous Compounding**				Added section
New	A35	For Nonsterile- Containment Ventilated Enclosure (CVE) or Class I Biological Safety Cabinet (BSC) (**Class II BSCs or Compounding Aseptic Containment Isolators (CACIs) may be used for nonsterile compounding if they are dedicated for nonsterile compounding; if they are used for occasional nonsterile compounding, Class II BSCs or CACIs must undergo thorough cleaning and disinfection before being used for sterile compounding)				Added recommendation/ Need to review language
New	A36	For Sterile- Class II BSC or CACI				Added recommendation/ Need to review language
New	A37	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.				Added recommendation/ Need to review language
New	A38	C-SCA must be cleanable (all of the architectural elements of a cleanroom; walls, floors, ceilings) and have accommodations for hand washing				Added recommendation/ Need to review language

Old #	New #		Compliant	Non-Compliant	Non-Applicable (N/A)	Notes
New	A39	Hazardous drugs (HDs) shall not be stored, unpacked, compounded, or otherwise manipulated in an area that is positive pressure relative to the surrounding area.				Added recommendation/ Need to review language
New	A40	Low- and medium-risk CSPs may be prepared in a BSC located in a C-SCA, provided the beyond-use date of the CSP does not exceed 12 hours				Added recommendation/ Need to review language
New	A41	CACI that meets the requirements in <797> may be used for hazardous drug compounding if it is placed in a C-SCA				Added recommendation/ Need to review language
New	A42	Access to areas where HDs are stored and prepared shall be restricted to authorized staff				Added recommendation/ Need to review language
New	A43	Location of the HD compounding area shall be located away from break rooms and refreshment areas. Signage designating the hazard shall be prominently displayed before entry into the HD area				Added recommendation/ Need to review language
New	A44	BSC or 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				Added recommen

Old #	New #		Compliant	Non-Compliant	Non-Applicable (N/A)	Notes
		the Containment Primary Engineering Control (C-PEC) and is labeled to require PPE handling precautions				dation/ Need to review language
New	A45	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				Added recommendation/ Need to review language
New	A46	Containment Secondary Engineering Controls (C-SECs) – Shall be vented to the outside air through HEPA filtration				Added recommendation/ Need to review language
New	A47	For both Sterile and Nonsterile HD compounding, a sink shall be available for hand washing. It shall not be within an ISO Class 7 buffer area.				Added recommendation/ Need to review language
New	A48	For Nonsterile Compounding – Shall be performed in a C-PEC that provides personnel and environmental protection (i.e., Class I BSC or CVE). The C-PEC shall be externally vented. (Unidirectional airflow within the C-PEC is not required)				Added recommendation/ Need to review language
New	A49	For Nonsterile Compounding – The C-PEC shall be placed in a room that is physically separated (i.e., a different room from other preparation areas) but does not need to be ISO 7 nor have HEPA-filtered air (Minimum of 12 ACPH, maintained at a negative pressure of at least 0.01 inches of water column and all the architectural finish requirements prescribed in				Added recommendation/ Need to

Old #	New #		Compliant	Non-Compliant	Non-Applicable (N/A)	Notes
		<797>				review language
New	A50	For Sterile Compounding – Shall be performed in a C-PEC that provides an ISO Class 5 critical area and shall be used in conjunction with aseptic practices specified for the appropriate risk levels (i.e., Class II and III BSCs and CACIs). The airflow shall be unidirectional (laminar flow) and the "first air" at the face of the filter is free from airborne particulate contamination				Added recommendation/ Need to review language
New	A51	For Sterile Compounding – C-PEC placement in a C-SEC that meets ISO Class 7 is preferred, but if a C-PEC is placed in a room with air quality worse than ISO Class 7, the BUD of all CSOs prepared in that area may need to be limited to 12 h, depending on the type of C-PEC used				Added recommendation/ Need to review language
New	A52	Garbing and gloving requirements shall be used for compounding and HD (nonsterile and sterile) in any setting and when using any and all C-PECs				Added recommendation/ Need to review language
New	A53	Gloves used shall be labeled as ASTM-tested chemotherapy gloves, be power-free and free of physical defects				Added recommendation/ Need to review language
New	A54	Wearing two pairs of gloves is required when compounding, administering, managing a spill and disposing of HDs. For sterile preparations, the outer glove shall be sterile. Change gloves every 30 minutes or when torn, punctured or contaminated				Added recommendation/ Need to review language

Old #	New #		Compliant	Non-Compliant	Non-Applicable (N/A)	Notes
New	A55	When working within a CACI, the outer glove (over the isolator glove) shall be a sterile, powder free, ASTM-tested chemotherapy glove				Added recommendation/ Need to review language
New	A56	Hand hygiene shall be performed before donning gloves and immediately after removal of gloves				Added recommendation/ Need to review language
New	A57	Disposable gowns that protect from spills and splashes of HDs and waste material, that have been tested to resist permeability by HDs, shall be worn when handling HDs (Absorbent materials are not appropriate outer wear when handling HDs)				Added recommendation/ Need to review language
New	A58	Head, hair and shoe covers shall be worn in HD compounding areas. Shoe covers are not worn outside the HD compounding area in order to avoid spreading drug contamination to other areas				Added recommendation/ Need to review language
New	A59	Consider all PPE worn when handling HDs as being contaminated with trace quantities of HDs and worn PPE should not be placed into red bag or red sharps containers, but disposed of accordingly				Added recommendation/ Need to review language
New	A60	HDs should be received from the supplier sealed in impervious plastic and should be immediately delivered to the C-SEC. HDs shall only be stored in areas with appropriate				Added / Need to

Old #	New #		Compliant	Non-Compliant	Non-Applicable (N/A)	Notes
		ventilation controls and handled with ASTM-tested, powder-free chemotherapy gloves				review language
New	A61	C-PECs used for compounding HDs shall be disinfected at the beginning of the workday, between batches of compounding medications, at the beginning of each subsequent shift (if compounding takes place over an extended period of time), routinely during compounding, and after anytime the C-PEC has been powered off				Added recommendation/ Need to review language
New	A62	For BSCs and 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)				Added recommendation/ Need to review language
New	A63	Each entity shall have a compounding supervisor or designated individual responsible for developing and implementing appropriate procedures, overseeing facility compliance with applicable laws, regulations and standards; ensuring competency of personnel and assuring environmental control of the compounding areas				Added recommendation/ Need to review language