WA Pharmacy Quality Assurance Commission 2021 Responsible Pharmacy Manager
Pharmacy Self-Inspection Worksheet

USP 797 – Sterile Compounding Addendum

Attention: Responsible Pharmacy Manager or Equivalent Manager

Washington law holds the responsible manager (or equivalent manager) and all pharmacists on duty responsible for ensuring pharmacy compliance with all state and federal laws governing the practice of pharmacy. Failure to complete this addendum within the month of March or within 30 days of becoming responsible manager (as required by WAC 246-945-005) may result in disciplinary action. The following addendum is required to be filled out and kept on file with the General Pharmacy Self-Inspection Worksheet. **Do not send to the commission office.**

The primary objective of this report, and your self-inspection, is to provide an opportunity to identify and correct areas of non-compliance with state and federal law. This worksheet does not replace U.S. Pharmacopeia (USP) <797> Pharmaceutical Compounding – Sterile Preparations. (**Note**: Neither the self-inspection nor a commission inspection evaluates your complete compliance with all laws and rules of the practice of pharmacy.)

By answering the questions and referencing the appropriate laws/rules/CFR provided, you can determine whether you are compliant with many of the rules and regulations. If you have corrected any deficiencies, please write corrected and the date of correction by the appropriate question.

If you are an early adopter of USP chapter 800 under PQAC Policy Statement #60 - Regulation of the Handling of Hazardous Drugs, Questions 43, 56, and 72 you may answer N/A to the USP <797> requirement. However, a requirement statement from USP <800> has been added in blue.

Date responsible manager/change of responsible manager inspection was performed: Click or tap to enter a date.

Signature of responsible pharmacy manager: Click or tap here to enter text.

Questions highlighted in **blue** are questions that will be focused on during routine pharmacy inspections.

General Rule Reference - Applies to all questions through worksheet.

RCW 18.64.270(2) "Any medicinal products that are compounded for patient administration or distribution to a licensed practitioner for patient use or administration shall, at a minimum, meet the standards of the official United States pharmacopeia as it applies to nonsterile products and sterile administered products."

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
Standard Operating Procedures						
☐	☐	☐	1	**The permitted pharmacy listed above shall have a written, properly approved, Standard Operating Procedures Manual (or Policy and Procedure Manual) with detailed instructions that describe how, when (frequency), and by whom all requirements in USP <797> are to be met.**	USP Chapter 797 - Suggested Standard Operating Procedures. "The compounding facility shall have written, properly approved SOPs designed to ensure the quality of the environment in which a CSP is prepared."	Click or tap here to enter text.
Compounding Personnel						
				Documentation is on file for EACH person who compounds sterile products that they are adequately skilled, educated, instructed, and trained to correctly perform and document the following activities:	USP Chapter 797 - "The dispenser shall, when appropriate and practicable, obtain and evaluate results of testing for identity, strength, purity, and sterility before a CSP is dispensed. Qualified licensed healthcare professionals who supervise compounding and dispensing of CSPs shall ensure that the following objectives are achieved: 1. Compounding personnel are adequately skilled, educated, instructed, and trained to correctly perform and document the following activities in their sterile compounding duties. a. perform antiseptic hand cleansing and disinfection of nonsterile compounding surfaces; b. select and appropriately don protective garb; c. maintain or achieve sterility of CSPs in ISO 5 PEC devices and protect personnel and compounding environments from contamination by radioactive, cytotoxic, and chemotoxic drugs (see Hazardous Drugs as CSPs and Radiopharmaceuticals as CSPs); d. identify, weigh, and measure ingredients; e. manipulate sterile products aseptically, sterilize high-risk level CSPs, and label and quality inspect CSPs."	Click or tap here to enter text.
☐	☐	☐	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.**		
Personnel Training and Competency						
☐	☐	☐	9	**Before beginning to prepare CSPs, personnel are trained by expert personnel, audio-video instructional sources, professional publications in**	USP Chapter - 797 Personnel Training and Evaluation in Aseptic Manipulation Skills - "Personnel who prepare CSPs shall be trained conscientiously and skillfully by expert personnel and through audio–video instructional sources and professional publications in the theoretical principles	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				the theoretical principles, practical skills of aseptic manipulations.	and practical skills of aseptic manipulations and in achieving and maintaining ISO Class 5 (see Table 1) environmental conditions before they begin to prepare CSPs."	
☐	☐	☐	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.**	USP Chapter 797 Environmental Quality and Control - Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures - "Personnel who prepare CSPs shall be trained conscientiously and skillfully by expert personnel and through multimedia instructional sources and professional publications in the theoretical principles and practical skills of garbing procedures, aseptic work practices, achieving and maintaining ISO Class 5 (see Table 1) environmental conditions, and cleaning and disinfection procedures. USP Chapter - 797 Personnel Training and Evaluation in Aseptic Manipulation Skills - "Personnel who prepare CSPs shall be trained conscientiously and skillfully by expert personnel and through audio–video instructional sources and professional publications in the theoretical principles and practical skills of aseptic manipulations and in achieving and maintaining ISO Class 5 (see Table 1) environmental conditions before they begin to prepare CSPs."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 - Personnel Training and Evaluation in Aseptic Manipulation Skills - "Compounding personnel shall perform didactic review and pass written and media-fill testing of aseptic manipulative skills initially, at least annually thereafter for low- and medium-risk level compounding, and semiannually for high-risk level compounding."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 - Personnel Training and Evaluation in Aseptic Manipulation Skills - "Compounding personnel who fail written tests or whose media-fill test vials result in gross microbial colonization shall be immediately reinstructed and reevaluated by expert compounding personnel to ensure correction of all aseptic practice deficiencies."	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	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.**	USP Chapter 797 Environmental Quality and Control - Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures - "In addition to didactic evaluation and aseptic media fill, compounding personnel must demonstrate proficiency of proper hand hygiene, garbing, and consistent cleaning procedures."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797- Environmental Quality and Control - Competency Evaluation of Garbing and Aseptic Work Practice - Garbing and Gloving Competency Evaluation - "Compounding personnel shall be visually observed during the process of performing hand hygiene and garbing procedures (see Personnel Cleansing and Garbing under Personnel Training and Evaluation in Aseptic Manipulation Skills above). The visual observation shall be documented on a form such as the Sample Form for Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel (see Appendix III) and maintained to provide a permanent record and long-term assessment of personnel competency."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 - Environmental Quality and Control - Competency Evaluation of Garbing and Aseptic Work Practice - Gloved Fingertip Sampling - "All compounding personnel shall successfully complete an initial competency evaluation and gloved fingertip/thumb sampling procedure (zero cfu) no less than three times before initially being allowed to compound CSPs for human use."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 - Environmental Quality and Control - Competency Evaluation of Garbing and Aseptic Work Practice - Aseptic Manipulation Competency Evaluation - "After successful completion of an initial Hand Hygiene and Garbing Competency Evaluation, all compounding personnel shall have their aseptic technique and related practice competency evaluated initially during the Media-Fill Test Procedure and subsequent annual or semi-annual Media-Fill Test Procedures."	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
CSP Microbial Contamination: Low-Risk Level CSPs						
☐	☐	☐	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.**	USP Chapter 797 - CSP Microbial Contamination Risk Levels - Low-Risk Conditions - "CSPs compounded under the following conditions are at a low risk of contamination. 1. The CSPs are compounded with aseptic manipulations entirely within ISO Class 5 or better air quality using only sterile ingredients, products, components, and devices."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 - CSP Microbial Contamination Risk Levels - Low-Risk Conditions - "CSPs compounded under the following conditions are at a low risk of contamination. 2. The compounding involves only transfer, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile products and not more than two entries into any one sterile container or package (e.g., bag, vial) of sterile product or administration container/device to prepare the CSP."	Click or tap here to enter text.
☐	☐	☐	19	**Manipulations are limited to aseptically opening ampules, 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.**	USP Chapter 797 - CSP Microbial Contamination Risk Levels - Low-Risk Conditions - "CSPs compounded under the following conditions are at a low risk of contamination. 3. Manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers or other sterile products, and containers for storage and dispensing."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 - CSP Microbial Contamination Risk Levels - Low-Risk Conditions - "CSPs compounded under the following conditions are at a low risk of contamination. 4. For a low-risk level preparation, in the absence of passing a sterility test (see Sterility Tests <71>), the storage periods cannot exceed the following time periods: before administration, the CSPs are properly stored and are exposed for not more than 48 hours at controlled room temperature (see General Notices and Requirements), for not more than 14 days at a cold temperature (see General Notices and Requirements), and for 45 days in solid frozen state between - 25° and -10°."	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
CSP Microbial Contamination: Low-Risk Level CSPs with 12-Hour or Less Beyond-Use Date (BUD)						
☐	☐	☐	21	**PECs are certified, maintained ISO Class 5 and located in a segregated compounding area restricted to sterile compounding activities.**	USP Chapter 797 - CSP Microbial Contamination Risk Levels - Low-Risk Level CSPs with 12-Hour or Less BUD - "1. PECs (LAFWs, BSCs, CAIs, CACIs) shall be certified and maintain ISO Class 5 as described in Facility Design and Environmental Controls for exposure of critical sites and shall be in a segregated compounding area restricted to sterile compounding activities that minimize the risk of CSP contamination."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 - CSP Microbial Contamination Risk Levels - Low-Risk Level CSPs with 12-Hour or Less BUD - "2. The segregated compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors or high traffic flow, or that is adjacent to construction sites, warehouses, or food preparation. Note that this list is not intended to be all inclusive."	Click or tap here to enter text.
☐	☐	☐	23	**Sinks are not located within one meter of the ISO Class 5 PEC.**	USP Chapter 797 - CSP Microbial Contamination Risk Levels - Low-Risk Level CSPs with 12-Hour or Less BUD - "3. Personnel shall follow the procedures described in Personnel Cleansing and Garbing and Additional Personnel Requirements prior to compounding. Sinks should not be located adjacent to the ISO Class 5 PEC. Sinks should be separated from the immediate area of the ISO Class 5 PEC device."	Click or tap here to enter text.
CSP Microbial Contamination: Medium-Risk Level CSPs						
☐	☐	☐	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.**	USP Chapter 797 - CSP Microbial Contamination Risk Levels - Medium Risk Conditions - "When CSPs are compounded aseptically under Low-Risk Conditions and one or more of the following conditions exists, such CSPs are at a medium risk of contamination. 1. 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."	Click or tap here to enter text.
☐	☐	☐	25	**Products considered medium-risk if the compounding process includes complex aseptic manipulations or unusually long duration.**	USP Chapter 797 - CSP Microbial Contamination Risk Levels - Medium Risk Conditions - "When CSPs are compounded aseptically under Low-Risk Conditions and one or more of the following conditions exists, such CSPs are at a medium	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
					risk of contamination. 2. The compounding process includes complex aseptic manipulations other than the single-volume transfer."	
☐	☐	☐	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.**	USP Chapter 797 - CSP Microbial Contamination Risk Levels - Medium Risk Conditions - "When CSPs are compounded aseptically under Low-Risk Conditions and one or more of the following conditions exists, such CSPs are at a medium risk of contamination. 4. In the absence of passing a sterility test (see Sterility Tests USP Chapter 71), the storage periods cannot exceed the following time periods: before administration, the CSPs are properly stored and are exposed for not more than 30 hours at controlled room temperature (see General Notices and Requirements), for not more than 9 days at a cold temperature (see General Notices and Requirements), and for 45 days in sold frozen state between -25° and -10°."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 Appendices - CSP Microbial Contamination Risk Levels - Medium-Risk Level CSPs - "Aseptic manipulations within an ISO Class 5 environment using prolonged and complex mixing and transfer, more than three sterile products and entries into any container, and pooling ingredients from multiple sterile products to prepare multiple CSPs."	Click or tap here to enter text.
Immediate Use CSPs						
☐	☐	☐	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 start of compounding.**	USP Chapter 797 Immediate-Use CSPs - "The immediate-use provision is intended only for those situations where there is a need for emergency or immediate patient administration of a CSP. … 4. Administration begins not later than 1 hour following the start of the preparation of the CSP."	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	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.**	USP Chapter 797 Immediate-Use CSPs - "Immediate-use CSPs are exempt from the requirements described for Low-Risk Level CSPs only when all of the following criteria are met: 1. The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile-nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers and not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration con-trainer/device. For example, anti neoplastics shall not be prepared as immediate-use CSPs because they are hazardous drugs."	Click or tap here to enter text.
☐	☐	☐	30	**Aseptic technique is followed and if not immediately administered, CSP is continually supervised.**	USP Chapter 797 Immediate-Use CSPs - "Immediate-use CSPs are exempt from the requirements described for Low-Risk Level CSPs only when all of the following criteria are met: 3. During preparation, aseptic technique is followed and, if not immediately administered, the finished CSP is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other CSPs, and direct contact of outside surfaces."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 Immediate-Use CSPs - "Immediate-use CSPs are exempt from the requirements described for Low-Risk Level CSPs only when all of the following criteria are met: 5. Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour BUD and time."	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	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.**	USP Chapter 797 Immediate-Use CSPs - "Immediate-use CSPs are exempt from the requirements described for Low- Risk Level CSPs only when all of the following criteria are met: 5. Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1 hour BUD and time."	Click or tap here to enter text.
Single-Dose and Multiple-Dose Containers						
☐	☐	☐	33	**Single-dose containers are used within 1 hour of entry when opened or removed in worse than ISO Class 5 air quality.**	USP Chapter 797 - Single-Dose and Multiple-Does Containers - "Opened or needle-punctured single-dose containers, such as bags, bottles, syringes, and vials of sterile products and CSPs shall be used within 1 hour if opened in worse than ISO Class 5 (see Table 1) air quality (see Immediate-Use CSPs), and any remaining contents must be discarded."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 - Single-Dose and Multiple-Does Containers - "Single-dose vials exposed to ISO Class 5 (see Table 1) or cleaner air may be used up to 6 hours after initial needle puncture."	Click or tap here to enter text.
☐	☐	☐	35	**Opened single-dose ampules are not stored.**	USP Chapter 797 - Single-Dose and Multiple-Does Containers - "Opened single-dose ampules shall not be stored for any time period."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 - Single-Dose and Multiple-Does Containers - "Multiple-dose containers (e.g., vials) are formulated for removal of portions on multiple occasions because they usually contain antimicrobial preservatives. The BUD after initially entering or opening (e.g., needle-punctured) multiple-dose containers is 28 days (see Antimicrobial Effectiveness Testing USP Chapter 51) unless otherwise specified by the manufacturer."	Click or tap here to enter text.
Hazardous Drugs as CSPs						
☐	☐	☐	37	**Hazardous drugs are prepared for administration only under conditions**	USP Chapter 797 - Hazardous Drugs as CSPs - "Hazardous drugs shall be prepared for administration only under	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				that protect the healthcare workers and other personnel in the preparation and storage areas.	conditions that protect the healthcare workers and other personnel in the preparation and storage areas."	
☐	☐	☐	38	**Hazardous drugs are stored separately from other inventory.**	USP Chapter 797 - Hazardous Drugs as CSPs - "Hazardous drugs shall be stored separately from other inventory in a manner to prevent contamination and personnel exposure."	Click or tap here to enter text.
☐	☐	☐	39	**Hazardous drugs are handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparation for administration and disposal.**	USP Chapter 797 - Hazardous Drugs as CSPs - "Hazardous drugs shall be handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparation for administration, and disposal."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 - Hazardous Drugs as CSPs - "Hazardous drugs shall be prepared in an ISO Class 5 (see Table 1) environment with protective engineering controls in place and following aseptic practices specified for the appropriate contamination risk levels defined in this chapter."	Click or tap here to enter text.
☐	☐	☐	41	**Access is limited to areas where hazardous drugs are stored and prepared.**	USP Chapter 797 - Hazardous Drugs as CSPs - "Access shall be limited to areas where drugs are stored and prepared to protect persons not involved in drug preparation."	Click or tap here to enter text.
☐	☐	☐	42	**All hazardous drugs are prepared in a BSC or a CACI that meets or exceeds standards.**	USP Chapter 797 - Hazardous Drugs as CSPs - "All hazardous drugs shall be prepared in a BSC3 or a CACI that meets or exceeds the standards for CACI in this chapter."	Click or tap here to enter text.
Hazardous Drugs as CSPs						
☐	☐	☐	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.** **Early adopters of USP 800 pursuant to PQAC Policy #60: The ISO Class 5 C-PEC is placed in either an ISO Class 7 ante-room or an unclassified**	USP Chapter 797 - Hazardous Drugs as CSPs - "The ISO Class 5 (see Table 1) BSC or CACI shall be placed in an ISO Class 7 (see Table 1) area that is physically separated (i.e., a different area from other preparation areas) and optimally has not less than 0.01-inch water column negative pressure to adjacent positive pressure ISO Class 7 (see Table 1) or better ante-areas, thus providing inward airflow to contain any airborne drug."	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				containment segregated compounding area (C-SCA). If using a C- SCA, the C-PEC and C-SCA must be externally vented, maintain at least 12 ACPH with negative pressure between 0.01 and 0.03 inches of water column relative to adjacent areas, and BUDs must be adjusted accordingly.		
☐	☐	☐	44	**A pressure indicator is installed that can be readily monitored for correct room pressurization.**	USP Chapter 797 - Hazardous Drugs as CSPs - "A pressure indicator shall be installed that can be readily monitored for correct room pressurization."	Click or tap here to enter text.
☐	☐	☐	45	**If closed-system vial-transfer devices are used, they are used within the ISO Class 5 environment of a BSC or CACI.**	USP Chapter 797 - Hazardous Drugs as CSPs - "When closed-system vial-transfer devices (CSTDs) (i.e., vial-transfer systems that allow no venting or exposure of hazardous substance to the environment) are used, they shall be used within the ISO Class 5 (see Table 1) environment of a BSC or CACI."	Click or tap here to enter text.
☐	☐	☐	46	**Personal protective equipment is worn when compounding.**	USP Chapter 797 - Hazardous Drugs as CSPs - "Appropriate personnel protective equipment (PPE) shall be worn when compounding in a BSC or CACI and when using CSTD devices."	Click or tap here to enter text.
☐	☐	☐	47	**Personnel who compound hazardous drugs are trained in storage, handling and disposal of drugs prior to preparing or handling hazardous CSPs.**	USP Chapter 797 - Hazardous Drugs as CSPs - "All personnel who compound hazardous drugs shall be fully trained in the storage, handling, and disposal of these drugs."	Click or tap here to enter text.
☐	☐	☐	48	**Effectiveness of training is verified by testing specific hazardous drug preparations techniques and is documented for each person at least annually.**	USP Chapter 797 - Hazardous Drugs as CSPs - "This training shall occur prior to preparing or handling hazardous CSPs, and its effectiveness shall be verified by testing specific hazardous drugs preparation techniques. Such verification shall be documented for each person at least annually."	Click or tap here to enter text.
☐	☐	☐	49	**Compounding personnel of reproductive capability confirm in writing that they understand the risks of hazardous drug handling.**	USP Chapter 797 - Hazardous Drugs as CSPs - "Compounding personnel of reproductive capability shall confirm in writing that they understand the risks of handling hazardous drugs."	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	50	**Disposal of hazardous waste complies with all applicable federal and state regulations.**	USP Chapter 797 - Hazardous Drugs as CSPs - "Disposal of all hazardous drug wastes shall comply with all applicable federal and state regulations."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 - Hazardous Drugs as CSPs - "All personnel who per-form routine custodial waste removal and cleaning activities in storage and preparation areas for hazardous drugs shall be trained in appropriate procedures to protect themselves and prevent contamination."	Click or tap here to enter text.
Environmental Quality and Control						
Facility Design and Environmental Controls						
☐	☐	☐	52	**Critical sites are only exposed to ISO Class 5 or cleaner air.**	USP Chapter 797 - Environmental Quality and Control - Exposure of Critical Sites - "Protection of critical sites by precluding physical contact and airborne contamination shall be given the highest priority in sterile compounding practice. Airborne contaminants, especially those generated by sterile compounding personnel, are much more likely to reach critical sites than are contaminants that are adhering to the floor or other surfaces below the work level. Furthermore, large and high-density particles that are generated and introduced by compounding manipulations and personnel have the potential to settle on critical sites even when those critical sites are exposed within ISO Class 5 (see Table 1) air."	Click or tap here to enter text.
☐	☐	☐	53	**Compounding facility provides a comfortable and well- lighted working environment.**	USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls - "Compounding facilities are physically designed and environmentally controlled to minimize airborne contamination from contacting critical sites. These facilities shall also provide a comfortable and well-lighted working environment, …"	Click or tap here to enter text.
☐	☐	☐	54	**Facility has current certification documenting that PECs maintain ISO Class 5 and meet airflow requirements.**	USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls - Engineering Control Performance Verification - "Certification procedures such as those outlined in Certification Guide for Sterile Compounding Facilities (CAG-003-2006)[7] shall be performed by a qualified individual no less than every 6 months and	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
					whenever the device or room is relocated or altered or major service to the facility is performed."	
☐	☐	☐	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.**	USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls - "Policies and procedures for maintaining and working within the PEC area shall be written and followed. The policies and procedures will be determined by the scope and risk levels of the aseptic compounding activities utilized during the preparation of the CSPs."	Click or tap here to enter text.
☐	☐	☐	56	**Facility has current certification documenting that the buffer area maintains ISO Class 7 conditions with an ACPH of not less than 30.** **Early adopters of USP 800 pursuant to PQAC Policy #60: If using an unclassified containment segregated compounding area (C-SCA), the C-PEC and C-SCA must be externally vented, maintain at least 12 ACPH with negative pressure between 0.01 and 0.03 inches of water column relative to adjacent areas, and BUDs must be adjusted accordingly.**	USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls - "An ISO Class 7 (see Table 1) buffer area and ante-area supplied with HEPA-filtered air shall receive an ACPH of not less than 30."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls - "For rooms providing a physical separation through the use of walls, doors, and pass-through, a minimum differential positive pressure of 0.02- to 0.05-inch water column is required."	Click or tap here to enter text.
☐	☐	☐	58	**Displacement airflow is employed for buffer areas not physically separated from the ante-areas.**	USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls - "For buffer areas not physically separated from the ante-areas, the principle of displacement air-flow shall be employed."	Click or tap here to enter text.
☐	☐	☐	59	**Adeqate HEPA-filtered airflow is supplied to the buffer area and ante-area.**	USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls - "Adequate HEPA-filtered airflow supplied to the buffer area and ante-area is required to maintain cleanliness classification during operational activity through the number of ACPHs."	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	60	**Facility has current certification documenting that ante- area maintains ISO Class 8 conditions with an ACPH of not less than 30.**	USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls - "Buffer areas are designed to maintain at least ISO Class 7 (see Table 1) conditions for 0.5-mm particles under dynamic conditions and ISO Class 8 (see Table 1) conditions for 0.5-mm and larger particles under dynamic conditions for the ante-areas." USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls - Engineering Control Performance Verification - "Certification procedures such as those outlined in Certification Guide for Sterile Compounding Facilities (CAG-003-2006)[7] shall be performed by a qualified individual no less than every 6 months and whenever the device or room is relocated or altered or major service to the facility is performed." USP Chapter 797 - Environmental Quality and Control - Viable and Nonviable Environmental Sampling (ES) Testing - Environmental Quality and Control - Environmental Nonviable Airborne Particle Testing Program - Total Particle Counts - "ISO Class 8: not more than 3,520,000 particles or 0.5 mm size and larger per cubic meter of air for any ante-area."	Click or tap here to enter text.
☐	☐	☐	61	**For nuclear buffer areas, facility has current certification documenting that the buffer area maintains ISO Class 8 conditions.**	USP Chapter 797 - Radiopharmaceuticals as CSPs - "These radiopharmaceuticals shall be compounded using appropriately shielded vials and syringes in a properly functioning and certified ISO Class 5 (see Table 1) PEC located in an ISO Class 8 (see Table 1) or cleaner air environment to permit compliance with special handling, shielding, and negative air flow requirements." USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls - Engineering Control Performance Verification - "Certification procedures such as those outlined in Certification Guide for Sterile Compounding Facilities (CAG-003-2006)[7] shall be performed by a qualified individual no less than every 6 months and whenever the device or room is relocated or altered or major service to the facility is performed."	Click or tap here to enter text.
☐	☐	☐	62	**If the area has an ISO Class 5 recirculating device, a minimum of 15 ACPHs through the area supply HEPA**	USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls - "If the area has an ISO Class 5 (see Table 1) recirculating device, a minimum	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				filters is adequate, providing the combined ACPH not less than 30.	of 15 ACPHs through the area supply HEPA filters is adequate, providing the combined ACPH is 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.**	USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls - Only the furniture, equipment, supplies, and other material required for the compounding activities to be performed shall be brought into the area, and they shall be nonpermeable, nonshedding, cleanable, and resistant to disinfectants.	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls - "The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area shall be smooth, impervious, free from cracks and crevices, and nonshedding, thereby promoting cleanability and minimizing spaces in which microorganisms and other contaminants may accumulate. The surfaces shall be resistant to damage by disinfectant agents."	Click or tap here to enter text.
☐	☐	☐	65	**Junctures of ceilings to walls are coved or caulked.**	USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls - "Junctures of ceilings to walls shall be coved or caulked to avoid cracks and crevices where dirt can accumulate."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls - "If ceilings consist of inlaid panels, the panels shall be impregnated with a polymer to render them impervious and hydrophobic, and they shall be caulked around each perimeter to seal them to the support frame."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls - "The exterior lens surface of ceiling lighting fixtures should be smooth, mounted flush, and sealed. Any other penetrations through the ceiling or walls shall be sealed."	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	68	**The buffer area does not contain sources of water (sinks) or floor drains.**	USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls - The buffer area shall not contain sources of water (sinks) or floor drains.	Click or tap here to enter text.
☐	☐	☐	69	**Works surfaces are constructed of smooth, impervious materials**	USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls - "Work surfaces shall be constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that they are easily cleaned and disinfected."	Click or tap here to enter text.
☐	☐	☐	70	**Carts are stainless steel wire, nonporous plastic or sheet metal with cleanable casters.**	USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls - "Carts should be of stainless steel wire, nonporous plastic, or sheet metal construction with good quality, cleanable casters to promote mobility."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 - Environmental Quality and Control - Facility Design and Environmental Controls - "Storage shelving, counters, and cabinets shall be smooth, impervious, free from cracks and crevices, nonshedding, cleanable, and disinfectable; their number, design, and manner of installation shall promote effective cleaning and disinfection."	Click or tap here to enter text.
Placement of Primary Engineering Controls						
☐	☐	☐	72	**PECs are located within a restricted access ISO Class 7 buffer area unless an exception met. Exceptions:** • **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.**	USP Chapter 797 - Environmental Quality and Control - Placement of Primary Engineering Controls - "PECs (LAFWs, BSCs, CAIs, and CACIs) shall be located within a restricted access ISO Class 7 (see Table 1) buffer area (see Figure 1), with the following CAI/CACI exceptions below: Only authorized personnel and materials required for compounding and cleaning shall be permitted in the buffer area. Presterilization procedures for high-risk level CSPs, such as weighing and mixing, shall be completed in no worse than an ISO Class 8 (see Table 1) environment. PECs shall be located out of traffic patterns and away from room air currents that could disrupt the intended airflow patterns."	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				Early adopters of USP 800 pursuant to PQAC Policy #60: If using an unclassified containment segregated compounding area that complies with USP 800.		
☐	☐	☐	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.**	USP Chapter 797 - Environmental Quality and Control - Placement of Primary Engineering Controls - "When isolators are used for sterile compounding, the recovery time to achieve ISO Class 5 (see Table 1) air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 - Environmental Quality and Control - Pressure Differential Monitoring - "A pressure gauge or velocity meter shall be installed to monitor the pressure differential or airflow between the buffer area and the ante- area and between the ante-area and the general environment outside the compounding area. The results shall be reviewed and documented on a log at least every work shift (minimum frequency shall be at least daily) or by a continuous recording device."	Click or tap here to enter text.
☐	☐	☐	75	**The pressure between the ISO Class 7 and the general pharmacy area is not less than 5 Pa -0.02 inch water column.**	USP Chapter 797 - Environmental Quality and Control - Pressure Differential Monitoring - "The pressure between the ISO Class 7 (see Table 1) and the general pharmacy area shall not be less than 5 Pa (0.02 inch water column)."	Click or tap here to enter text.
☐	☐	☐	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, when buffer area is not physically separated from ante-areas.**	USP Chapter 797 - Environmental Quality and Control - Pressure Differential Monitoring - In facilities where low- and medium-risk level CSPs are prepared, differential airflow shall maintain a minimum velocity of 0.2 meters per second (40 feet per minute) between buffer area and ante-area.	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
Additional Personnel Requirements						
☐	☐	☐	77	**Foods, drinks and materials exposed in patient care and treatment areas do not enter ante-areas, buffer areas or segregated compounding areas.**	USP Chapter 797 - Environmental Quality and Control - Additional Personnel Requirements - "Food, drinks, and materials exposed in patient care and treatment areas shall not enter ante-areas, buffer areas, or segregated compounding areas where components and ingredients of CSPs are present."	Click or tap here to enter text.
Cleaning and Disinfecting the Compounding Area						
☐	☐	☐	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.**	USP Chapter 797 - Environmental Quality and Control - Additional Personnel Requirements - "When compounding activities require the manipulation of a patient's blood-derived or other biological material (e.g., radiolabeling a patient's or donor's white blood cells), the manipulations shall be clearly separated from routine material-handling procedures and equipment used in CSP preparation activities, and they shall be controlled by specific SOPs in order to avoid any cross- contamination."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 - Environmental Quality and Control - Additional Personnel Requirements - "Packaged compounding supplies and components, such as needles, syringes, tubing sets, and small- and large-volume parenterals, should be uncartoned and wiped down with a disinfectant that does not leave a residue (e.g., sterile 70% IPA), when possible in an ante-area of ISO Class 8 (see Table 1) air quality, before being passed into the buffer areas."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 - Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area - The cleaning and disinfecting practices and frequencies in this section apply to ISO Class 5 (see Table 1) compounding areas for exposure of critical sites as well as buffer areas, ante areas, and segregated compounding areas All cleaning and disinfecting practices and policies for the compounding of CSPs shall be included in written SOPs and shall be followed by all compounding personnel.	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	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.**	USP Chapter 797 - Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area - "Cleaning and disinfecting surfaces in the LAFWs, BSCs, CAIs, and CACIs are the most critical practices before the preparation of CSPs. Consequently, such surfaces shall be 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 of individual CSPs, when there are spills, and when surface contamination is known or suspected from procedural breaches."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 - Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area - "Work surfaces in the ISO Class 7 (see Table 1) buffer areas and ISO Class 8 (see Table 1) ante-areas as well as segregated compounding areas shall be cleaned and disinfected at least daily, and dust and debris shall be removed when necessary from storage sites for compounding ingredients and supplies using a method that does not degrade the ISO Class 7 or 8 (see Table 1) air quality."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 - Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area - "Floors in the buffer or clean area, ante-area, and segregated compounding area are cleaned by mopping with a cleaning and disinfecting agent once daily at a time when no aseptic operations are in progress. Mopping shall be performed by trained personnel using approved agents and procedures described in the written SOPs."	Click or tap here to enter text.
☐	☐	☐	84	**In the buffer or clean area, ante-area and segregated compounding area, walls, ceilings, and shelving are cleaned and disinfected monthly.**	USP Chapter 797 - Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area - "In the buffer or clean area, ante-area, and segregated compounding area, walls, ceilings, and shelving shall be cleaned and disinfected monthly."	Click or tap here to enter text.
☐	☐	☐	85	**All cleaning materials are nonshedding and dedicated to use in the buffer or clean area, ante-area, and segregated areas and are not**	USP Chapter 797 - Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area - "All cleaning materials, such as wipers, sponges, and mops, shall be nonshedding, preferably composed of synthetic micro fibers, and dedicated to use in the buffer or clean area,	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				removed from these areas except for disposal.	ante- area, and segregated compounding areas and shall not be re- moved 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.**	USP Chapter 797 - Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area - "If cleaning materials (e.g., mops) are reused, procedures shall be developed (based on manufacturers' recommendations) that ensure that the effectiveness of the cleaning device is maintained and that repeated use does not add to the bioburden of the area being cleaned."	Click or tap here to enter text.
☐	☐	☐	87	**Sterile 70% IPA swabs do not contact any object before contacting the site to be cleaned.**	USP Chapter 797 - Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area - "The surface of the sterile 70% IPA swabs used for disinfecting entry points of sterile packages and devices shall not contact any other object before contacting the surface of the entry point."	Click or tap here to enter text.
☐	☐	☐	88	**No particle-generating material is used to disinfect the sterile entry points of packages and devices.**	USP Chapter 797 - Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area - "Sterile 70% IPA wetted gauze pads or other particle- generating material shall not be used to disinfect the sterile entry points of packages and devices."	Click or tap here to enter text.
☐	☐	☐	89	**No shipping cartons are taken into the buffer area, clean area or segregated compounding area.**	USP Chapter 797 - Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area - "No shipping or other external cartons may be taken into the buffer or clean area or segregated compounding area."	Click or tap here to enter text.
Personnel Cleansing and Garbing						
☐	☐	☐	90	**Personal hand hygiene and garb procedures are performed in ante-areas.**	USP Chapter 797 - Environmental Quality and Control - Personnel Cleansing and Garbing - "The careful cleansing of hands and arms and the correct donning of PPE by compounding personnel constitute the first major step in preventing microbial contamination in CSPs. … Before entering the buffer area or segregated compounding area (see Low-Risk Level CSPs with 12-Hour or Less BUD), com-pounding personnel shall remove personal outer garments (e.g., bandannas, coats, hats, jackets, scarves, sweaters, vests); all cosmetics, because they shed flakes and particles; and all hand, wrist, and other visible jewelry or piercings (e.g., earrings, lip or eyebrow piercings) that can interfere with the	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
					effectiveness of PPE (e.g., fit of gloves and cuffs of sleeves). The wearing of artificial nails or extenders is prohibited while working in the sterile compounding environment. Natural nails shall be kept neat and trimmed."	
☐	☐	☐	91	**Personnel with rashes, sunburn, weeping sores, conjunctivitis, active respiratory infection or cosmetics are prohibited from preparing CSPs.**	USP Chapter 797 - Environmental Quality and Control - Personnel Cleansing and Garbing - "When individuals are experiencing rashes, sunburn, weeping sores, conjunctivitis, active respiratory infection, as well as when they wear cosmetics, they shed these particles at even higher rates. Particles shed from compounding personnel pose an increased risk of microbial contamination of critical sites of CSPs. Therefore, compounding personnel with such conditions as mentioned above shall be excluded from working in ISO Class 5 (see Table 1) and ISO Class 7 (see Table 1) compounding areas until their conditions are remedied."	Click or tap here to enter text.
☐	☐	☐	92	**Don shoe covers one at a time placing covered shoe on clean side line of demarcation.** ***This is considered a best practice.***		Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 - Environmental Quality and Control - Personnel Cleansing and Garbing - "Personnel shall don the following PPE in an order that proceeds from those activities considered the dirtiest to those considered the cleanest. Garbing activities considered the dirtiest include donning of dedicated shoes or shoe covers, head and facial hair covers (e.g., beard covers in addition to face masks), and face masks/eye shields."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 - Environmental Quality and Control - Personnel Cleansing and Garbing - "Once inside the buffer area or segregated compounding area (see Low-Risk Level CSPs with 12-Hour or Less BUD), and prior to donning sterile powder-free gloves, antiseptic hand cleansing shall be performed using a waterless alcohol-based surgical hand scrub with persistent activity following manufacturers' recommendations."	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	95	**Gloves are routinely disinfected with sterile 70% IPA after contacting nonsterile objects.**	USP Chapter 797 - Environmental Quality and Control - Personnel Cleansing and Garbing - "Routine application of sterile 70%IPA shall occur throughout the compounding process and whenever nonsterile surfaces (e.g. vials, counter tops, chairs, carts) are touched."	Click or tap here to enter text.
☐	☐	☐	96	**Gloves are inspected for holes and replaced when breaches are detected.**	USP Chapter 797 - Environmental Quality and Control - Personnel Cleansing and Garbing - "Gloves on hands shall also be routinely inspected for holes, punctures, or tears and replaced immediately if such are detected."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 - Environmental Quality and Control - Personnel Cleansing and Garbing - "When compounding personnel exit the compounding area during a work shift, the exterior gown may be removed and retained in the compounding area if not visibly soiled, to be redonned during that same work shift only."	Click or tap here to enter text.
Elements of Quality Control						
☐	☐	☐	98	**A written description of specific training and performance evaluations for compounding personnel is developed for each site.**	USP Chapter 797 - Environmental Quality and Control - "A written description of specific training and performance evaluation program for individuals involved in the use of aseptic techniques for the preparation of sterile products shall be developed for each site."	Click or tap here to enter text.
☐	☐	☐	99	**Facility follows procedures for physical inspection of all sterile drugs and devices**		Click or tap here to enter text.
☐	☐	☐	100	**If any nonsterile components, including containers and ingredients, are used to make a CSP, such CSPs must be high risk.**	USP Chapter 797 - Environmental Quality and Control - Ingredients and Devices - Nonsterile Ingredients and Devices - "If any nonsterile components, including containers and ingredients, are used to make a CSP, such CSPs must be high risk."	Click or tap here to enter text.
☐	☐	☐	101	**Bulk or unformulated drug substances and added substances or excipients are stored in tightly closed containers under temperature, humidity and**	USP Chapter 797 - Environmental Quality and Control - Ingredients and Devices - Nonsterile Ingredients and Devices - "Bulk or unformulated drug substances and added substances or excipients shall be stored in tightly closed	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				lighting conditions that are either indicated in the official monographs or approved by suppliers.	containers under temperature, humidity, and lighting conditions that are either indicated in 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.**	USP Chapter 797 - Environmental Quality and Control - Equipment - "It is necessary that equipment, apparatus, and devices used to compound a CSP be consistently capable of operating properly and within acceptable tolerance limits."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 - Environmental Quality and Control - Equipment - "Written procedures outlining required equipment calibration, annual maintenance, monitoring for proper function, and controlled procedures for use of the equipment and specified time frames for these activities are established and followed. Routine maintenance and frequencies shall be outlined in these SOPs."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 - Environmental Quality and Control - Equipment - "Personnel are prepared through an appropriate combination of specific training and experience to operate or manipulate any piece of equipment, apparatus, or device they may use when preparing CSPs. Training includes gaining the ability to determine whether any item of equipment is operating properly or is malfunctioning."	Click or tap here to enter text.
☐	☐	☐	105	**Results from equipment maintenance and calibration are kept for the lifetime of the equipment.**	USP Chapter 797 - Environmental Quality and Control - Equipment - "Results from the equipment calibration, annual maintenance reports, and routine maintenance are kept on file for the lifetime of the equipment."	Click or tap here to enter text.
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.**	USP Chapter 797 - Environmental Quality and Control - Environmental Viable Airborne Particle Testing Program - Viable Air Sampling - "For low-risk level CSPs with 12-hour or less BUD prepared in a PEC (LAFWs, BSCs, CAIs) that maintains an ISO Class 5 (see Table 1), air sampling shall be performed at locations inside the ISO Class 5 (see Table 1) environment and other areas that are in close proximity to	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
					the ISO Class 5 (see Table 1) environment during the certification of the PEC."	
☐	☐	☐	107	**A sufficient volume of air (400 to 1000 liters) is tested at each location where compounding takes place, performed at least semi-annually.**	USP Chapter 797 - Environmental Quality and Control - Environmental Viable Airborne Particle Testing Program - Air Sampling Devices - "Sufficient volume of air (400 to 1000 liters) shall be tested at each location in order to maximize sensitivity."	Click or tap here to enter text.
☐	☐	☐	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)**	USP Chapter 797 - Environmental Quality and Control - Viable and Nonviable Environmental Sampling (ES) Testing - Environmental Nonviable Airborne Particle Testing Program - Engineering Control Performance Verification - "PECs (LAFWs, BSCs, CAIs, and CACIs) and secondary engineering controls (buffer and ante-areas) are essential components of the overall contamination control strategy for aseptic compounding. As such, it is imperative that they perform as designed and that the resulting levels of contamination be within acceptable limits. Certification procedures such as those outlined in Certification Guide for Sterile Compounding Facilities (CAG-003-2006)[7] shall be performed by a qualified individual no less than every 6 months and whenever the device or room is relocated or altered or major service to the facility is performed."	Click or tap here to enter text.
☐	☐	☐	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)**	USP Chapter 797 - Environmental Quality and Control - Viable and Nonviable Environmental Sampling (ES) Testing - Environmental Nonviable Airborne Particle Testing Program - Total Particle Counts - "Certification that each ISO classified area, for example, ISO Class 5, 7, and 8 (see Table 1), is within established guidelines shall be performed 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."	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	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.**	USP Chapter 797 - Environmental Quality and Control - Viable and Nonviable Environmental Sampling (ES) Testing - Environmental Viable Airborne Particle Testing Program - Sampling Plan - "An appropriate environmental sampling plan shall be developed for airborne viable particles based on a risk assessment of compounding activities performed. Selected sampling sites shall include locations within each ISO Class 5 environment and in the ISO Class 7 and 8 areas and in the segregated compounding areas at greatest risk of contamination (e.g., work areas near the ISO Class 5 environment, counters near doors, pass-through boxes)."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 - Environmental Quality and Control - Viable and Nonviable Environmental Sampling (ES) Testing - Environmental Viable Airborne Particle Testing Program - Sampling Plan - "The plan shall include sample location, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels."	Click or tap here to enter text.
☐	☐	☐	112	**A general microbiological growth medium supplemented with additives to neutralize the effects of disinfecting agents is used to support the growth of bacteria.**	USP Chapter 797 - Environmental Quality and Control - Viable and Nonviable Environmental Sampling (ES) Testing - Environmental Viable Airborne Particle Testing Program - Growth Medium - "A general microbiological growth medium such as Soybean–Casein Digest Medium shall be used to support the growth of bacteria."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 - Environmental Quality and Control - Surface Cleaning and Disinfection Sampling and Assessment - "Surface sampling shall be performed in all ISO classified areas on a periodic basis."	Click or tap here to enter text.
☐	☐	☐	114	**Sampling data is collected and reviewed on a routine basis as a means of evaluating overall control of the compounding environment.**	USP Chapter 797 - Environmental Quality and Control - Action Levels, Documentation, and Data Evaluation - "Sampling data shall be collected and reviewed on a routine basis as a means of evaluating the overall control of the compounding environment."	Click or tap here to enter text.
☐	☐	☐	115	**When microbial sampling exceeds action levels, procedures and practices are reviewed.**	USP Chapter 797 - Environmental Quality and Control - Action Levels, Documentation, and Data Evaluation - "Any cfu count that exceeds its respective action level (see Table	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
					4) should prompt a reevaluation of the adequacy of personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency within the aseptic compounding location. An investigation into the source of the contamination shall be conducted."	
☐	☐	☐	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.**	USP Chapter 797 - Environmental Quality and Control - Viable and Nonviable Environmental Sampling (ES) Testing - Environmental Viable Airborne Particle Testing Program - Action Levels, Documentation, and Data Evaluation - "Counts of cfu are to be used as an approximate measure of the environmental microbial bioburden. Action levels are deter-mined on the basis of cfu data gathered at each sampling location and trended over time. The numbers in Table 2 should be used only as guidelines. Regardless of the number of cfu identified in the pharmacy, further corrective actions will be dictated by the identification of microorganisms recovered (at least the genus level) by an appropriate credentialed laboratory of any microbial bioburden captured as a cfu using an impaction air sampler."	Click or tap here to enter text.
☐	☐	☐	117	**In high risk environments, growth media also supports the growth of fungi.**	USP Chapter 797 - Environmental Quality and Control - Viable and Nonviable Environmental Sampling (ES) Testing - Environmental Viable Airborne Particle Testing Program - Growth Medium - "Malt extractagar or some other media that supports the growth of fungi shall be used in high- risk level compounding environments."	Click or tap here to enter text.
Verification of Automated Compounding Devices for Parenteral Nutrition						
☐	☐	☐	118	**Testing procedures for accuracy are verified to meet the USP requirements stated in the individual monograph for the component being tested.**	USP Chapter 797 - Verification of Automated Compounding Devices (ACDs) for Parenteral Nutrition Compounding - Accuracy - "Thus, their testing procedures shall be verified to meet the USP requirements stated in the individual monograph for the component being tested."	Click or tap here to enter text.
☐	☐	☐	119	**Compounding personnel keep a daily record of the accuracy assessments and the results are reviewed at least in weekly intervals.**	USP Chapter 797 - Verification of Automated Compounding Devices (ACDs) for Parenteral Nutrition Compounding - Precision - "Thus, compounding personnel shall keep a daily record of the above-described accuracy assessments and review the results over time. This review shall occur at least	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
					at weekly intervals to avoid potentially clinically significant cumulative errors over time."	
Finished Preparation Release Checks and Tests						
☐	☐	☐	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.**	USP Chapter 797 - Finished Preparation Release Checks and Tests - Inspection of Solution Dosage Forms and Review of Compounding Procedures - "All CSPs that are intended to be solutions shall be visually examined for the presence of particulate matter and not administered or dispensed when such matter is observed. The prescription orders, written compounding procedure, preparation records, and expended materials used to make CSPs at all contamination risk levels are inspected for accuracy of correct identities and amounts of ingredients, aseptic mixing and sterilization, packaging, labeling, and expected physical appearance before they are administered or dispensed."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 - Finished Preparation Release Checks and Tests - Compounding Accuracy Checks - "Written procedures for double-checking compounding accuracy shall be followed for every CSP during preparation and immediately prior to release."	Click or tap here to enter text.
Storage and Beyond-Use Dating						
☐	☐	☐	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.**	USP Chapter 797 Storage and Beyond-Use Dating - "Personnel who prepare, dispense, and administer CSPs shall store them strictly in accordance with the conditions stated on the label of ingredient products and finished CSPs."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 Storage and Beyond-Use Dating - Determining Beyond-Use Dates - "When CSPs will be distributed to and administered in residential locations other than healthcare facilities, the effect of potentially uncontrolled and unmonitored temperature conditions shall be considered when assigning BUDs."	Click or tap here to enter text.
☐	☐	☐	124	**The controlled temperature areas are monitored at least once daily and results are documented.**	USP Chapter 797 Storage and Beyond-Use Dating - Monitoring Controlled Storage Areas - "A controlled temperature area shall be monitored at least once daily and the results documented on a temperature log."	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	125	**Facilities have policies and procedures governing the determination of BUDs.**	USP Chapter 797 Storage and Beyond-Use Dating - Determining Beyond-Use Dates - "To ensure consistent practices in determining and assigning BUDs, the compounding facility should have written policies and procedures governing the determination of the BUDs for all compounded products."	Click or tap here to enter text.
☐	☐	☐	126	**Compounding personnel verify the storage temperature when placing a product into or removing a product from the storage unit.**	USP Chapter 797 Storage and Beyond-Use Dating - Monitoring Controlled Storage Areas - "Additionally, compounding personnel shall note the storage temperature when placing the product into or removing the product from the storage unit in order to monitor any temperature aberrations."	Click or tap here to enter text.
☐	☐	☐	127	**Temperature-sensitive mechanisms are placed to reflect true temperature in the controlled space and are not subject to significantly prolonged temperature fluctuations.**	USP Chapter 797 Storage and Beyond-Use Dating - Monitoring Controlled Storage Areas - "The temperature-sensing mechanisms shall be suitably placed in the controlled temperature storage space to reflect accurately its true temperature. In addition, the compounding facility shall adhere to appropriate procedures of all controlled storage spaces to ensure that such spaces are not subject to significantly prolonged temperature fluctuations as may occur, for example, by leaving a refrigerator door open too long."	Click or tap here to enter text.
Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs						
☐	☐	☐	128	**The facilities have written procedures for proper packaging, storage, and transportation conditions to maintain sterility, quality, purity and strength of CSPs.**	USP Chapter 797 Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs - "Establishing, maintaining, and ensuring compliance with comprehensive written policies and procedures encompassing these responsibilities is a further responsibility of the compounding facility."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs - Packaging, Handling, and Transport - "Chemotoxic and other hazardous CSPs require safeguards to maintain the integrity of the CSP and to minimize the exposure potential of these products to the environment and to personnel who may come in contact with them."	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	130	**Delivery and patient-care-setting personnel are properly trained to deliver the CSP to the appropriate storage location.**	USP Chapter 797 Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs - Use and Storage - "Delivery and patient-care-setting personnel shall be properly trained to deliver the CSP to the appropriate storage location."	Click or tap here to enter text.
☐	☐	☐	131	**Outdated and unused CSPs are appropriately disposed.**	USP Chapter 797 Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs - Use and Storage - "Outdated and unused CSPs shall be returned to the compounding facility for disposition."	Click or tap here to enter text.
☐	☐	☐	132	**SOPs exist to ensure that the storage conditions in the patient-care setting are suitable for the CSP-specific storage requirements.**	USP Chapter 797 Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs - Use and Storage - "SOPs must exist to ensure that storage conditions in the patient care setting are suitable for the CSP specific storage requirements."	Click or tap here to enter text.
☐	☐	☐	133	**Returned CSPs are only redispensed if sterility, acceptable purity, strength and quality can be assured.**	USP Chapter 797 Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs - Redispensed CSPs - "The compounding facility shall have the sole authority to determine when unopened, returned CSPs may be redispensed. Returned CSPs may be redispensed only when personnel responsible for sterile compounding can ensure that such CSPs are sterile, pure, and stable (contain labeled strength of ingredients)."	Click or tap here to enter text.
☐	☐	☐	134	**If redispensed CSPs are given a later BUD, sterility testing and quantitative assay of ingredients occur to support the extended BUD.**	USP Chapter 797 Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs - Redispensed CSPs - "Assignment of new storage times and BUDs that exceed the original dates for returned CSPs is permitted only when there is supporting evidence from sterility testing and quantitative assay of ingredients."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 - Patient or Caregiver Training - "A formal training program is provided as a means to ensure understanding and compliance with the many special and complex responsibilities placed on the patient or caregiver for the storage, handling, and administration of CSPs."	Click or tap here to enter text.
Patient Monitoring and Adverse Events Reporting						
☐	☐	☐	136	**SOPs are available that describe the means for patients or other recipients**	USP Chapter 797 - Patient Monitoring and Adverse Events Reporting - "The SOP manuals of compounding facilities	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				to ask questions, report concerns and adverse events with CSPs, and for compounding supervisors to correct and prevent future problems.	shall describe specific instructions for receiving, acknowledging, and dating receipts, and for recording, or filing, and evaluating reports of adverse events and of the quality of preparation claimed to be associated with CSPs."	
☐	☐	☐	137	**Reports of CSP adverse events are reviewed promptly and thoroughly by compounding supervisors.**	USP Chapter 797 - Patient Monitoring and Adverse Events Reporting - "Reports of adverse events with CSPs shall be reviewed promptly and thoroughly by compounding supervisors to correct and prevent future occurrences."	Click or tap here to enter text.
Quality Assurance Program						
☐	☐	☐	138	**Media-fill test procedure with appropriate risk level prepared or equivalent test is performed at least annually by personnel.**	USP Chapter 797 Environmental Quality and Control - Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures - "Media-fill testing of aseptic work skills shall be performed initially before beginning to prepare CSPs and at least annually thereafter for low- and medium-risk level compounding and semiannually for high-risk level compounding."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 - CSP Microbial Contamination Risk Levels - Low-Risk Level CSPS - Quality Assurance - "Quality assurance practices include, but are not limited to the following: Routine disinfection and air quality testing of the direct compounding environment to minimize microbial surface contamination and maintain ISO Class 5 air quality. Visual confirmation that compounding personnel are properly donning and wearing appropriate items and types of protective garments, including eye protection and face masks. Review of all orders and packages of ingredients to ensure that the correct identity and amounts of ingredients were compounded. Visual inspection of CSPs to ensure the absence of particulate matter in solutions, the absence of leakage from vials and bags, and the accuracy and thoroughness of labeling."	Click or tap here to enter text.
☐	☐	☐	140		USP Chapter 797 - Quality Assurance (QA) Program - "A provider of CSPs shall have in place a formal QA program	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				A formal quality assurance program is in place that monitors, evaluates, corrects and improves activities and processes.	intended to provide a mechanism for monitoring, evaluating, correcting, and improving the activities and processes described in this chapter."	
CSP Microbial Contamination: High-Risk Level CSPs						
☐	☐	☐	141	**Sterilize high-risk CSPs.**	USP Chapter 797 - CSP Microbial Contamination Risk Levels - "High-risk level CSPs must be sterilized before being administered to patients."	Click or tap here to enter text.
☐	☐	☐	142	**If compounding personnel are improperly garbed and gloved, CSP treated as a high-risk compound.**	USP Chapter 797 CSP Microbial Contamination Risk Levels - High Risk Conditions - "CSPs compounded under any of the following conditions are either contaminated or at a high risk to become contaminated. 3. Compounding personnel are improperly garbed and gloved (see Personnel Cleansing and Use of Barrier Protective Equipment)."	Click or tap here to enter text.
☐	☐	☐	143	**Product considered high-risk if any nonsterile ingredients or devices are used.**	USP Chapter 797 - CSP Microbial Contamination Risk Levels - High Risk Conditions - "CSPs compounded under any of the following conditions are either contaminated or at a high risk to become contaminated. 1. Nonsterile ingredients, including manufactured products not intended for sterile routes of administration (e.g., oral), are incorporated or a nonsterile device is employed before terminal sterilization."	Click or tap here to enter text.
☐	☐	☐	144	**Product considered high-risk if CSP is exposed to air quality worse than ISO Class 5 for > 1 hour.**	USP Chapter 797 - CSP Microbial Contamination Risk Levels - High Risk Conditions - "CSPs compounded under any of the following conditions are either contaminated or at a high risk to become contaminated. 2. Any of the following are exposed to air quality worse than ISO Class 5 for more than 1 hour (see Immediate-Use CSPs): sterile contents of commercially manufactured products, CSPs that lack effective antimicrobial preservatives, and sterile surfaces of devices and containers for the preparation, transfer, sterilization, and packaging of CSPs."	Click or tap here to enter text.
☐	☐	☐	145	**Product considered high-risk if Nonsterile water- containing preparations are stored for more than 6 hours before being sterilized.**	USP Chapter 797 - CSP Microbial Contamination Risk Levels - High Risk Conditions - "CSPs compounded under any of the following conditions are either contaminated or at a high risk to become contaminated. 4. Nonsterile water-	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
					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.**	USP Chapter 797 - Elements of Quality Control - Ingredients and Devices - Nonsterile Ingredients and Devices - "The date of receipt by the compounding facility shall be clearly and indelibly marked on each package of ingredient."	Click or tap here to enter text.
☐	☐	☐	147	**Sterilization methods are verified to achieve sterility for the quantity and type of containers.**	USP Chapter 797 - Responsibility of Compounding Personnel - "The dispenser shall, when appropriate and practicable, obtain and evaluate results of testing for identity, strength, purity, and sterility before a CSP is dispensed. Qualified licensed healthcare professionals who supervise compounding and dispensing of CSPs shall ensure that the following objectives are achieved: 5. Sterilization methods achieve sterility of CSPs while maintaining the labeled strength of active ingredients and the physical integrity of packaging."	Click or tap here to enter text.
☐	☐	☐	148	**Media-fill test procedure or equivalent test is performed at least semi-annually by personnel.**	USP Chapter 797 - CSP Microbial Contamination Risk Levels - High Risk Level CSPs - Quality Assurance - "In addition, a media-fill test that represents high-risk level compounding is performed semiannually by each person authorized to compound high-risk level CSPs."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 - CSP Microbial Contamination Risk Levels - High Risk Level CSPs - Quality Assurance - "Quality Assurance procedures for high-risk level CSPs include all those for low-risk level CSPs." USP Chapter 797 - CSP Microbial Contamination Risk Levels - Low-Risk Level CSPs - Quality Assurance - "Quality assurance practices include, but are not limited to the following: Routine disinfection and air quality testing of the direct compounding environment to minimize microbial surface contamination and maintain ISO Class 5 air quality. Visual confirmation that compounding personnel are properly donning and wearing appropriate items and types of protective garments, including eye protection and face masks.	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
					Review of all orders and packages of ingredients to ensure that the correct identity and amounts of ingredients were compounded. Visual inspection of CSPs to ensure the absence of particulate matter in solutions, the absence of leakage from vials and bags, and the accuracy and thoroughness of labeling."	
☐	☐	☐	150	**Allowable limits for bacterial endotoxins are met.**	USP Chapter 797 - Finished Preparation Release Checks and Tests - Bacterial Endotoxin (Pyrogen) Testing - "In the absence of a bacterial endotoxins limit in the official monograph or other CSP formula source, the CSP shall not exceed the amount of USP Endotoxin Units (per hour per kilogram of body weight or square meters of body surface area) specified in Bacterial Endotoxins Test <85> referenced above for the appropriate route of administration."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 - Finished Preparation Release Checks and Tests - Sterility Testing - "All high-risk level CSPs that are prepared in groups of more than 25 identical individual single-dose packages (e.g., ampules, bags, syringes, vials) or in multiple-dose vials (MDVs) for administration to multiple patients or that are exposed longer than 12 hours at 2° to 8° and longer than 6 hours at warmer than 8° before they are sterilized shall meet the sterility test (see Sterility Tests <71>) before they are dispensed or administered."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 - Finished Preparation Release Checks and Tests - Sterility Testing - "When high-risk level CSPs are dispensed before receiving the results of their sterility tests, there shall be a written procedure requiring daily observation of the incubating test specimens and immediate recall of the dispensed CSPs when there is any evidence of microbial growth in the test specimens."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 - Finished Preparation Release Checks and Tests - Bacterial Endotoxin (Pyrogen) Testing - "All high-risk level CSPs, except those for inhalation and ophthalmic administration, that are prepared in groups of more than 25 identical individual single-dose packages (e.g., ampules, bags, syringes, vials) or in MDVs for administration to multiple patients or that are exposed longer than 12 hours at 2° to 8° and longer than 6 hours at warmer than 8°	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
					before they are sterilized shall be tested to ensure that they do not contain excessive bacterial endotoxins (see USP Chapter 85 - Bacterial Endotoxins Test and USP Chapter 151 - Pyrogen Test)."	
☐	☐	☐	154	**All high-risk CSP solutions subjected to terminal sterilization by filtration are appropriately prefiltered and terminally filtered in ISO Class 5 air.**	USP Chapter 797 - CSP Microbial Contamination Risk Levels - High Risk Level CSPs - "All high-risk level CSP solutions subjected to terminal sterilization are prefiltered by passing through a filter with a nominal pore size not larger than 1.2. µm preceding or during filing into their final containers to remove particulate matter. Sterilization of high- risk level CSPs by filtration shall be performed with a sterile 0.2-µm or 0.22-µm nominal pore size filter entirely within an ISO Class 5 or superior air quality environment."	Click or tap here to enter text.
☐	☐	☐	155	**CSP maintains acceptable strength, purity and integrity of containers after sterilization.**	USP Chapter 797 Appendices - CSP Microbial Contamination Risk Levels - High Risk Level CSPs - "Maintain acceptable strength and purity of ingredients and integrity of containers after sterilization."	Click or tap here to enter text.
☐	☐	☐	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°.**	USP Chapter 797 - CSP Microbial Contamination Risk Levels - High Risk Level CSPs - "For sterilized high-risk level preparation, in the absence of passing a sterility test, the storage periods cannot exceed the following time periods: before administration, the CSPs are properly stored and are exposed for not more than 24 hours at controlled room temperature (see General Notices and Requirements), for not more than 3 days at a cold temperature (see General Notices and Requirements), and for 45 days in sold frozen state between -25° and -10°."	Click or tap here to enter text.
☐	☐	☐	157	**Sterility tests are performed for autoclaved CSPs if they are prepared in batches > 25 units.**	USP Chapter 797 - CSP Microbial Contamination Risk Levels - High Risk Level CSPs - "[NOTE—Sterility tests for autoclaved CSPs are not required unless they are prepared in batches of more than 25 units.]"	Click or tap here to enter text.
Verification of Compounding Accuracy and Sterility (High-Risk Compounding)						
☐	☐	☐	158	**Packaged and labeled CSPs are visually inspected for physical integrity and expected appearance.**	USP Chapter 797 - Verification of Compounding Accuracy and Sterility - "Packaged and labeled CSPs shall be visually inspected for physical integrity and expected appearance, including final fill amount."	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	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.**	USP Chapter 797 - Verification of Compounding Accuracy and Sterility - "The accuracy of identities, concentrations, amounts, and purities of ingredients in CSPs shall be confirmed by reviewing labels on packages, observing and documenting correct measurements with approved and correctly standardized devices, and reviewing information in labeling and certificates of analysis provided by suppliers."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - "The licensed healthcare professionals who supervise compounding shall be responsible for determining that the selected sterilization method (see Methods of Sterilization under USP Chapter 1211 - Sterilization and Sterility Assurance of Compendial Articles) both sterilizes and maintains the strength, purity, quality, and packaging integrity of CSPs."	Click or tap here to enter text.
☐	☐	☐	161	**Commercially available sterile filters are approved for human-use applications in sterilizing pharmaceutical fluids.**	USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High-Risk Level CSPs by Filtration - "Commercially available sterile filters shall be approved for human-use applications in sterilizing pharmaceutical fluids."	Click or tap here to enter text.
☐	☐	☐	162	**Sterile filters used to sterilize CSPs are pyrogen free with a nominal porosity of 0.2 or 0.22 micrometers.**	USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High-Risk Level CSPs by Filtration - "Sterile filters used to sterilize CSPs shall be pyrogen free and have a nominal pore size of 0.2 or 0.22 µm."	Click or tap here to enter text.
☐	☐	☐	163	**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.**	USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High-Risk Level CSPs by Filtration - "They shall be certified by the manufacturer to retain at least 10^7 microorganisms of a strain of Brevundimonas (Pseudomonas) diminuta on each square centimeter of upstream filter surface area under conditions similar to those in which the CSPs will be sterilized (see High-Risk Conditions in High-Risk Level CSPs)."	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	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.**	USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High-Risk Level CSPs by Filtration - "The compounding supervisor shall ensure, directly or from appropriate documentation, 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, including strength of ingredients of the specific CSP."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High-Risk Level CSPs by Filtration - "The filter dimensions and liquid material to be sterile-filtered shall permit the sterilization process to be completed rapidly, without the replacement of the filter during the process."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High-Risk Level CSPs by Filtration - "When CSPs are known to contain excessive particulate matter, a prefilter of larger nominal pore size membrane is placed upstream from the sterilizing filter to remove gross particulate contaminants in order to maximize the efficiency of the sterilizing filter."	Click or tap here to enter text.
☐	☐	☐	167	**Filter units used are subjected to manufacturers' recommended integrity test.**	USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High-Risk Level CSPs by Filtration - "Filter units used to sterilize CSPs shall also be subjected to manufacturers' recommended integrity test, such as the bubble point test."	Click or tap here to enter text.
☐	☐	☐	168	**Personnel must know that filters will achieve sterilization of the particular CSPs being sterilized.**	USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High-Risk Level CSPs by Filtration - "Compounding personnel shall ascertain that selected filters will achieve sterilization of the particular CSPs being sterilized."	Click or tap here to enter text.
☐	☐	☐	169	**The description of steam sterilization conditions and duration for specific CSPs are included in written documentation in the compounding facility.**	USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High- Risk Level CSPs by Steam - "The description of steam sterilization conditions and duration for specific CSPs shall be included in written documentation in the compounding facility."	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	170	**The effectiveness of steam sterilization is verified using appropriate BIs of Bacillus stearothermophilus and other confirmation methods.**	USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High-Risk Level CSPs by Steam - "The effectiveness of steam sterilization shall be verified using appropriate BIs of Bacillus stearothermophilus (see USP Chapter 1229.5 - Biological Indicators for Sterilization) and other confirmation methods such as temperature-sensing devices (see USP Chapter 1211 - Sterilization and Sterility Assurance of Compendial Articles and USP Chapter 71 - Sterility Tests)."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High-Risk Level CSPs by Heat - "Heated filtered air shall be evenly distributed throughout the chamber by a blower device."	Click or tap here to enter text.
☐	☐	☐	172	**Dry heat is used only for those materials that cannot be sterilized by steam.**	USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High-Risk Level CSPs by Heat - "Dry heat shall be used only for those materials that cannot be sterilized by steam, when either the moisture would damage the material or the material is impermeable."	Click or tap here to enter text.
☐	☐	☐	173	**During sterilization, sufficient space is left between materials to allow for good air circulation.**	USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High-Risk Level CSPs by Heat - "During sterilization, sufficient space shall be left between materials to allow for good circulation of the hot air."	Click or tap here to enter text.
☐	☐	☐	174	**The description of dry heat sterilization conditions and duration for specific CSPs are included in written documentation in the compounding facility.**	USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High-Risk Level CSPs by Heat - "The description of dry heat sterilization conditions and duration for specific CSPs shall be included in written documentation in the compounding facility."	Click or tap here to enter text.
☐	☐	☐	175	**The effectiveness of dry heat sterilization is verified using appropriate BIs of Bacillus subtilis and other confirmation methods.**	USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Sterilization Methods - Sterilization of High-Risk Level CSPs by Heat - "The effectiveness of dry heat sterilization shall be verified using appropriate BIs of Bacillus subtilis (see USP Chapter 1229.5 - Biological	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
					Indicators for Sterilization) and other confirmation methods such as temperature-sensing devices (see USP Chapter 1211 - Sterilization and Sterility Assurance of Compendial Articles and USP Chapter 71 - Sterility Tests)."	
☐	☐	☐	176	**The description of dry heat depyrogenation cycle conditions and duration for specific CSPs are included in written documentation in the compounding facility.**	USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Depyrogenation by Dry Heat - "The description of the dry heat depyrogenation cycle and duration for specific load items shall be included in written documentation in the compounding facility."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 - Verification of Compounding Accuracy and Sterility - Depyrogenation by Dry Heat - "The effectiveness of the dry heat depyrogenation cycle shall be verified using endotoxin challenge vials (ECVs). The bacterial endotoxin test should be performed on the ECVs to verify that the cycle is capable of achieving a 3-log reduction in endotoxin (see USP Chapter 1211 - Sterilization and Sterility Assurance of Compendial Articles and USP Chapter 85 - Bacterial Endotoxins Test)."	Click or tap here to enter text.
Radiopharmaceuticals as CSPs						
☐	☐	☐	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.**	USP Chapter 797 - Radiopharmaceuticals as CSPs - "These radiopharmaceuticals shall be compounded using appropriately shielded vials and syringes in a properly functioning and certified ISO Class 5 (see Table 1) PEC located in an ISO Class 8 (see Table 1) or cleaner air environment to permit compliance with special handling, shielding, and negative air flow requirements."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 - Radiopharmaceuticals as CSPs - "Radiopharmaceutical vials designed for multi-use, compounded with technetium-99m, exposed to ISO Class 5 (see Table 1) environment, and punctured by needles with no direct contact contamination may be used up to the time indicated by manufacturers' recommendations."	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	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.**	USP Chapter 797 - Radiopharmaceuticals as CSPs - "Technetium-99m/molybdenum-99 generator systems shall be stored and eluted (operated) under conditions recommended by manufacturers and applicable state and federal regulations. Such generator systems shall be eluted in an ISO Class 8 (see Table 1) or cleaner air environment to permit special handling, shielding, and air flow requirements."	Click or tap here to enter text.
☐	☐	☐	181	**Direct visual inspection of radiopharmaceutical CSPs containing high concentrations of doses of radioactivity are conducted in accordance with ALARA.**	USP Chapter 797 - Radiopharmaceuticals as CSPs - "To limit acute and chronic radiation exposure of inspecting personnel to a level that is as low as reasonably achievable (ALARA), direct visual inspection of radiopharmaceutical CSPs containing high concentrations of doses of radioactivity shall be conducted in accordance with ALARA."	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 - Radiopharmaceuticals as CSPs - "Radiopharmaceuticals prepared as Low-Risk Level CSPs with 12-Hour or Less BUD shall be prepared in a segregated compounding area. A line of demarcation defining the segregated compounding area shall be established."	Click or tap here to enter text.
☐	☐	☐	183	**Materials and garb exposed in patient care and treatment do not cross the line of demarcation.**	USP Chapter 797 - Radiopharmaceuticals as CSPs - "Materials and garb exposed in a patient care and treatment area shall not cross a line of demarcation into the segregated compounding area."	Click or tap here to enter text.
Allergen Extracts as CSPs						
☐	☐	☐	184	**Compounding is performed only with simple transfers using sterile ingredients and supplies.**	USP Chapter 797 - Allergen Extracts as CSPs - "Allergen extracts as CSPs are single-dose and multiple-dose intradermal or subcutaneous injections that are prepared by specially trained physicians and personnel under their direct supervision. Allergen extracts as CSPs are not subject to the personnel, environmental, and storage requirements for all CSP Microbial Contamination Risk Levels in this chapter only when all of the following criteria are met: 1. The compounding process involves simple transfer via sterile needles and syringes of commercial sterile allergen products and appropriate sterile added substances (e.g., glycerin, phenol in sodium chloride injection)."	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	185	**Allergen extracts contain appropriate concentrations of preservatives.**	USP Chapter 797 - Allergen Extracts as CSPs – Allergen extracts as CSPs are single-dose and multiple-dose intradermal or subcutaneous injections that are prepared by specially trained physicians and personnel under their direct supervision. Allergen extracts as CSPs are not subject to the personnel, environmental, and storage requirements for all CSP Microbial Contamination Risk Levels in this chapter only when all of the following criteria are met: 2. All allergen extracts as CSPs shall contain appropriate substances in effective concentrations to prevent the growth of microorganisms. Nonpreserved allergen extracts shall comply with the appropriate CSP risk level requirements in the chapter.	Click or tap here to enter text.
☐	☐	☐	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.**	USP Chapter 797 - Allergen Extracts as CSPs - "Allergen extracts as CSPs are single-dose and multiple-dose intradermal or subcutaneous injections that are prepared by specially trained physicians and personnel under their direct supervision. Allergen extracts as CSPs are not subject to the personnel, environmental, and storage requirements for all CSP Microbial Contamination Risk Levels in this chapter only when all of the following criteria are met: 3. Before beginning compounding activities, personnel perform a thorough hand- cleansing procedure by removing debris from under fingernails using a nail cleaner under running warm water followed by vigorous hand and arm washing to the elbows for at least 30 seconds with either nonantimicrobial or antimicrobial soap and water."	Click or tap here to enter text.
☐	☐	☐	187	**Sterile gloves are intermittently disinfected with sterile 70% IPA.**	USP Chapter 797 - Allergen Extracts as CSPs - "Allergen extracts as CSPs are single-dose and multiple-dose intradermal or subcutaneous injections that are prepared by specially trained physicians and personnel under their direct supervision. Allergen extracts as CSPs are not subject to the personnel, environmental, and storage requirements for all CSP Microbial Contamination Risk Levels in this chapter only when all of the following criteria are met: 7. Compounding personnel disinfect their gloves intermittently with sterile 70% IPA when preparing multiple allergen ex-tracts as CSPs."	Click or tap here to enter text.

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	188	**Vial/ampule critical sites are wet with 70% IPA for 10 seconds and allowed to dry before use.**	USP Chapter 797 - Allergen Extracts as CSPs - "Allergen extracts as CSPs are single-dose and multiple-dose intradermal or subcutaneous injections that are prepared by specially trained physicians and personnel under their direct supervision. Allergen extracts as CSPs are not subject to the personnel, environmental, and storage requirements for all CSP Microbial Contamination Risk Levels in this chapter only when all of the following criteria are met: 8. Ampule necks and vial stoppers on packages of manufactured sterile ingredients are disinfected by careful wiping with sterile 70% IPA swabs to ensure that the critical sites are wet for at least 10 seconds and allowed to dry before they are used to compound allergen extracts as CSPs."	Click or tap here to enter text.
☐	☐	☐	189	**Compounding manipulations are performed to minimize contact contamination of critical sites.**	USP Chapter 797 - Allergen Extracts as CSPs - "Allergen extracts as CSPs are single-dose and multiple-dose intradermal or subcutaneous injections that are prepared by specially trained physicians and personnel under their direct supervision. Allergen extracts as CSPs are not subject to the personnel, environmental, and storage requirements for all CSP Microbial Contamination Risk Levels in this chapter only when all of the following criteria are met: 9. The aseptic compounding manipulations minimize direct contact contamination (e.g., from glove fingertips, blood, nasal and oral secretions, shed skin and cosmetics, other nonsterile materials) of critical sites (e.g., needles, opened ampules, vial stoppers)."	Click or tap here to enter text.
☐	☐	☐	190	**Vials are labeled with patient's name, BUD and storage information based on manufacturers' recommendations or peer-reviewed literature.**	USP Chapter 797 - Allergen Extracts as CSPs - "Allergen extracts as CSPs are single-dose and multiple-dose intradermal or subcutaneous injections that are prepared by specially trained physicians and personnel under their direct supervision. Allergen extracts as CSPs are not subject to the personnel, environmental, and storage requirements for all CSP Microbial Contamination Risk Levels in this chapter only when all of the following criteria are met: 10. The label of each multiple-dose vial (MDV) of allergen extracts as CSPs lists the name of one specific patient and a BUD and storage temperature range that is assigned based on manufacturers' recommendations or peer-reviewed publications."	Click or tap here to enter text.