COMPLIANCE - Sterile Compounding[1],[2]

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Bureau of Health Professions Licensure

Board of Registration in Pharmacy
250 Washington Street, Boston, MA 02108-4619
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DATE(S) OF INSPECTION:			INSPECTION #:	ISP-							
PHARMACY DBA NAME:											
STREET ADDRESS:											
CITY / STATE / ZIP:											
TELEPHONE:											
FAX:											
EMAIL:											
PHARMACY LIC. NUMBERS:											
PHARMACY LIC. EXPIRATION:											
DEA REG. NUMBER:											
DEA REG. EXPIRATION:											
PURPOSE OF INSPECTION:	☐ NEW STORE		☐ RELOCATION		☐ COMPLIANCE						
MANAGER OF RECORD (MOR):											
MOR REG. NUMBER:											
PHARMACY HOURS:	MON		TUE		WED		THU		FRI		
	SAT				SUN						
PRACTICE SETTING:	☐ COMMUNITY CHAIN		☐ COMMUNITY INDEPENENT		☐ LONG TERM CARE						
DAILY PHARMACY VOLUME (RXs):	☐ LESS THAN 100		☐ 100 TO 500		☐ ABOVE 500						
PROCEDURAL:	☐ PATIENT SPECIFIC ☐ ANTICIPATORY		☐ HAZARDOUS ☐ ROBOTICS ☐ ALLERGEN EXTRACTS		☐ HIGH RISK ☐ INVESTIGATIONAL DRUGS ☐ RADIOPHARMACEUTICALS						
SECURITY CAMERAS:	☐ YES ☐ NO										
OUT OF STATE LICENSE(S)?	☐ YES ☐ NO										

	White – Compliance Statement	**USP <797> Standards**	Question #s: 1.00 - 86.00
	Blue – Compliance Criteria	**USP <800> Standards**	Questions #s: HD 1.00 – HD 89.00
	Gray – Recommended "Best Practices"		

[1] MA Board of Registration in Pharmacy: Sterile Compounding Pharmacy Practice Resources - https://www.mass.gov/lists/pharmacy-practice-resources (last accessed 11.29.23)

[2] 247 CMR 17.00 – Sterile compounding DRAFT regulations approved by Board of Registration in Pharmacy. Pharmacy to assess current operations with draft regulations. https://www.mass.gov/lists/draft-regulations-for-the-board-of-registration-in-pharmacy (last accessed 12/20/2023)

Item#	Requirement	Yes/No/N/A	Comment
A	**Standard Operating Procedures (SOPs) for Compounded Sterile Preparations (CSPs)**		
1.0	Does the pharmacy have a designated person(s) who meets the requirements in compliance with USP <797> standards? ***Inspector note: Per USP, "The compounding facility must designate one or more individuals (i.e., the designated person(s)) to be responsible and accountable for the performance and operation of the facility and personnel in the preparation of CSPs and for performing other functions."*** ***If no, go to compliance statements.***		
1.1	The designated person(s) (for the QA program) has the training, experience, responsibility, and authority to perform the duties required of them.		
1.2	The designated person(s) is responsible and accountable for the performance and operation of the facility. ***Per USP, "The designated person(s) is responsible for ensuring that each area related to CSP preparation meets the classified air quality standard appropriate for the activities conducted in that area. The designated person(s) must also ensure that the ISO Class 5 areas are located, operated, maintained, monitored, and certified to have appropriate air quality."***		
1.3	The designated person(s) is responsible for personnel performing sterile compounding or other related functions (e.g., quality checks and prescription dispensing of compounded preparations).		
1.4	The designated person(s) reviews facility SOPs at least every 12 months to ensure that they reflect current practice, and such review is documented.		
1.5	The designated person(s) ensures that SOP revisions are implemented.		
1.6	The designated person(s) communicates all SOP revisions to all impacted personnel. ***Inspector note: USP <797> recommends that personnel should also document acknowledgment and communication of SOP changes and revisions.***		
1.7	The designated person(s) ensures that personnel demonstrate competency in performing every procedure that relates to their job function.		
1.8	The designated person(s) ensures that corrective actions are taken if problems, deviations, out-of-range results, failures, or errors are identified. ***Inspector note: Per USP, "Data collected in response to corrective actions must be reviewed to confirm that the actions taken have been effective."***		

Item#	Requirement	Yes/No/N/A	Comment
A	**Standard Operating Procedures (SOPs) for Compounded Sterile Preparations (CSPs)**		
2.0	Has the pharmacy developed and implemented SOPs that describe sterile compounding processes and other support activities in compliance with USP <797> standards? ***Inspector note: For this to be answered yes, all topics must be addressed if applicable to their business practices.If no, go to compliance statements.***		
2.1	**Scope of Practice:** Types of CSPs that are prepared (e.g., immediate use, allergenic extracts, Category 1, Category 2, Category 3). Roles and responsibilities of the designated person(s).		
2.2	**Personnel Training and Evaluation:** Description of initial and ongoing training and competency for the designated person(s), compounding personnel, personnel with direct oversight of compounding personnel, and personnel who only perform restocking or cleaning, and disinfecting duties outside of the primary engineering control (PEC). Description of media-fill testing procedures, hand hygiene and garbing competency, and aseptic manipulation competency. Training and competency assessment of personnel on all sterilization methods and equipment used by the facility. Frequency of training is defined.		
2.3	**Personal Hygiene and Garbing:** Description of the required garb, manner of storage, and order of garbing, including disinfection procedures for reusing goggles, respirators, and other reusable equipment. ***Inspector note: Per USP, the RABS (or pharmaceutical isolator) sleeve and glove changes should (not required) be changed per the manufacturer's recommendations and defined in the facility's SOPs.***		
2.4	**Facility Design and Engineering Controls:** Description of design requirements to maintain air quality standards and procedures for evaluating, maintaining, and certifying the areas used for compounding.		
2.5	**Certification and Recertification:** Description of sampling sites and procedures.		
2.6	**Microbiological Air and Surface Monitoring[3]:** Description of the pharmacy's microbiological air and surface monitoring program which includes a diagram of the sampling locations, procedures for collecting samples, frequency of sampling, size of samples (e.g., surface area, volume of air), time of day of sampling in relation to activities in the compounding area, and action levels that will trigger corrective actions and documentation requirements.		
2.7	**Cleaning, Disinfection, and Application of Sporicidal Disinfectants and Sterile 70% IPA:** Description of procedures for cleaning, disinfecting, and applying sporicidal disinfectants and include the frequency, methods, locations of cleaning, and documentation requirements.		
2.8	**Equipment:** Description of procedures for the calibration, maintenance, cleaning, use of the equipment, and documentation requirements.		

[3] **Board Policy 2023:09**: Defines action level as being based on cumulative counts of CFUs identified and particle recovered from all sampling locations within a specific ISO Classified space. Adopted 10/5/2023.

Item#	Requirement	Yes/No/N/A	Comment
A	**Standard Operating Procedures (SOPs) for Compounded Sterile Preparations (CSPs)**		
2.9	**Components:** Description of procedures that address the selection, receipt, evaluation, handling, storage, and documentation of all CSP components, including all ingredients and container closures.		
2.10	**Master Formulation and Compounding Records:** Description of procedures for developing and maintaining MFRs and required information, documentation, and record-keeping requirements for MFRs and CRs.		
2.11	**Release Inspections and Testing:** Description of release testing procedures (e.g., visual inspections and/or sterility and endotoxin testing), out-of-specification procedures, corrective action procedures, and documentation requirements.		
2.12	**Labeling:** Procedures for labeling and label verification (confirming against the prescription or medication order, the MFR, and the CR) to prevent errors, CSP mix-ups, and required displayed information.		
2.13	**CSP handling, storage, packaging, shipping, and transport:** Processes and techniques for handling, storing, packaging, and transporting CSPs that include temperature monitoring, excursions, shipping containers, packaging requirements, and selected transportation modes.		
2.14	**Documentation:** Record keeping requirements and procedures for documentation maintenance and storage. ***Inspector note: USP requires readily retrievable records for two years; however, it is acknowledged that state or accreditation organizations may require records for a longer period.***		
2.15	**Sterilization and Depyrogenation:** Description of methods used for establishing and verifying the effectiveness of the terminal sterilization and depyrogenation methods selected, as well as the methods for maintaining and cleaning the sterilizing and depyrogenation equipment. ***If not applicable to their business practices, inspector should answer statement as N/A.***		
2.16	**Immediate Use CSPs:** Description of processes followed to meet all conditions of exemption from the requirements for Category 1, Category 2, and Category 3 CSPs. ***If not applicable to their business practices, inspector should answer statement as N/A.***		
2.17	**Blood/Biological Handling:** Description of processes used to avoid cross-contamination and meet applicable regulatory requirements. ***If not applicable to their business practices, inspector should answer statement as N/A.***		

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A	**Standard Operating Procedures (SOPs) for Compounded Sterile Preparations (CSPs)**		
2.18	**Allergenic Extracts:** Description of procedures for training, competency assessments, personnel hygiene and garbing, facility requirements, cleaning, and disinfecting, beyond use dates (BUDs), labeling, storage, shipping and transporting, and documentation. ***If applicable to their business practices, please complete the Allergenic Extracts module.*** ***If not applicable to their business practices, inspector should answer statement as N/A.***		
B	**CSPs - Immediate Use, Proprietary Vial/Bag Systems, and Blood-Derived**		
3.0	Does the pharmacy prepare and dispense compounded sterile preparations for direct and immediate use?		
4.0	Does the pharmacy meet all conditions specified in USP <797> for CSPs compounded for direct and immediate use? ***Inspector note: Per USP <797>, all conditions must be met to qualify for exemptions of the requirements for Category 1, Category 2, and Category 3 CSPs.If no, go to compliance statements.***		
4.1	Aseptic techniques, processes, and procedures are followed. ***Inspector note: Per USP <797>, facility SOPs must describe procedures followed "to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other conventionally manufactured products or CSPs."***		
4.2	Personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and the facility's SOPs. ***Review personnel records to verify.***		
4.3	Preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs. ***Inspector note: Examples of this include approved labeling and/or published or unpublished stability and compatibility studies.***		
4.4	Preparation involves not more than three (3) different sterile products (e.g., ingredients and/or components in a single container).		
4.5	Unused components from a single-use container are discarded after the preparation for one individual patient is complete (i.e., single-dose containers are not used for more than one patient).		
4.6	Administration begins within four hours of the start of the preparation, and if not, the preparation is discarded. ***If administration is not performed within the same facility/campus of the pharmacy and/or is outside the pharmacy's control, inspector should answer statement as N/A.***		

Item#	Requirement	Yes/No/N/A	Comment
B	**CSPs - Immediate Use, Proprietary Vial/Bag Systems, and Blood-Derived**		
4.7	Unless the person preparing the preparation is administering or witnessing administration, the preparation is labeled with names and amounts of all active ingredients, name or initials of preparer, and exact four-hour time in which administration must begin. ***If administration is not performed within the same facility/campus of the pharmacy and/or is outside the pharmacy's control, inspector should answer statement as N/A.***		
5.0	Does the pharmacy prepare proprietary bag and vial systems (ex. addEASE, ADD-Vantage, Mini Bag Plus, Vial2Bag) in compliance with USP <797> standards? ***Inspector note: Docking and activation of proprietary bag and vial systems for immediate administration to an individual patient is out of scope of USP <797> and may be performed outside of an ISO Class 5 environment.If no, go to the compliance statements.If the pharmacy does not stock, prepare, and/or dispense any proprietary vial and bag systems, inspector should answer statement as N/A.***		
5.1	Docking for *future activation* and administration is performed in an ISO Class 5 environment and in accordance with requirements of USP <797>, except for BUD assignment.		
5.2	BUD assignment is not longer than specified in the manufacturer's labeling.		
6.0	Does the pharmacy meet the conditions specified in USP <797> for CSPs to be prepared per approved labeling? ***Inspector note: Preparing a conventionally manufactured sterile product in accordance with the directions in the manufacturer's approved labeling is considered outside the scope of the USP chapter.If no, go to compliance statements.If the pharmacy only <u>compounds</u> sterile preparations (e.g., does <u>not</u> prepare sterile preparations that strictly adheres to the conventionally manufactured approved labeling for preparation), inspector should answer statement as N/A.***		
6.1	The product is prepared as a single dose for an individual patient.		
6.2	The approved labeling includes information for the diluent, the resultant strength, the container closure system, and the storage time.		
7.0	Does the pharmacy perform compounding activities that require the manipulation of a patient's blood-derived or other biological material (e.g., autologous serum)?		

Item#	Requirement	Yes/No/N/A	Comment
B	**CSPs - Immediate Use, Proprietary Vial/Bag Systems, and Blood-Derived**		
8.0	For compounding activities that require the manipulation of a patient's blood-derived or other biological material, does the pharmacy perform manipulations that are clearly separated from other compounding activities and equipment used in CSP preparation activities and are controlled by specific SOPs to avoid any cross-contamination? ***Inspector note: Per USP, a separate cart could be used for blood-derived or other biological materials (a separate area is not required by the chapter). Pharmacy should change garb. Pharmacy to have cleaning processes as part of SOPs to avoid cross-contamination.If the pharmacy does not compound with blood products or other biological materials, inspector should answer statement as N/A. If the inspector answers the compliance question as "no", please describe your observations.***		
C	**Facility Design and Engineering Controls**		
9.0	**Segregated Compounding Area (SCA):** Does the pharmacy use an SCA as an SEC in compliance with USP <797> standards for facility design and environmental control? ***Inspector note: Per USP, only Category 1 CSPs may be compounded in a SCA.*** ***If no, go to compliance statements.*** ***If pharmacy only uses a cleanroom suite for sterile compounding preparations, inspector should answer question as N/A.***		
9.1	The facility is designed to afford a well-lighted and comfortable working environment.		
9.2	Only Category 1 CSPS are prepared in a SCA. ***If pharmacy is compounding Category 2 or Category 3 CSPs in a SCA, inspector should answer this statement as no and collect photographs and copies of the MFR, CR, and provide a description of their observations in the Inspector Notes.***		
9.3	The SCA is located away from unsealed windows, doors that connect to outdoors, and traffic flow. ***Inspector note: Per USP, "strong air currents from opened doors, personnel traffic, or air streams from the HVAC system can disrupt the unidirectional airflow of an open-faced PEC."***		
9.4	The SCA is located away from environmental control challenges and separate from areas not related to compounding (i.e., restrooms, warehouses, food preparation areas).		
9.5	A visible perimeter establishes the boundaries of the SCA. ***Inspector note: Per USP, the SCA is defined as "a designated space, area, or room that is not required to be classified and is defined with a visible perimeter. The SCA must contain a PEC and is suitable for preparation of Category 1 CSPs only." USP further defines a perimeter as "a visible demarcation (such as a door, walls, or visible marking on the floor) that defines the SCA or AECA." The perimeter will be defined in the pharmacy's SOPs. Tape or an alternative method may be used to define this visible perimeter, since this is not a classified space.***		

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C	**Facility Design and Engineering Controls**		
9.6	Access to the SCA is restricted to authorized personnel. ***Inspector note: Per USP, authorized personnel includes personnel involved in compounding processes, maintenance, and cleaning.***		
9.7	Free-standing humidifiers/dehumidifiers and air conditioners are not located within the perimeter of the SCA.		
9.8	Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in the compounding area. ***Inspector note: Per USP, these items should be low-shedding, easily cleaned, and disinfected. This applies to items within the perimeter around the Primary Engineering Control (PEC).***		
9.9	Shipping cartons or other corrugated or uncoated cardboard are not allowed in the SCA.		
9.10	The SCA and all surfaces (walls, floors, counters, equipment) are clean, uncluttered, and dedicated to compounding.		
9.11	The sink is located inside the SCA or in proximity and is located at least one meter away from the PEC.		
9.12	The area within one meter of the PEC is dedicated only for sterile compounding (e.g., not storage, hand hygiene, donning and doffing garb, or other highly particle-generating activities, such as patient care).		
9.13	If overhangs or ledges are present in the SCA, are they easily cleanable? ***If no, describe observations in Inspector Notes.***		
10.0	Are surfaces smooth, impervious, free from cracks and crevices, and non-shedding so they can be cleaned and disinfected? ***Inspector note: this is a recommendation by USP.*** ***If no, describe in comments Inspector Notes (e.g., peeling of Formica countertops).***		
11.0	Are surfaces resistant to damage from cleaning, sanitizing, and sporicidal agents used? ***Inspector note: this is a recommendation by USP.*** ***If no, describe in comments inspector observations (i.e. observed rust on preparation cart or flaking of particle board on shelving).***		
12.0	**Cleanroom Suite:** Does the pharmacy use a Cleanroom Suite (ISO-classified anteroom and buffer room) as a SEC in compliance with USP <797> standards for facility design and environmental control? ***Inspector note: Per USP <797>, a cleanroom suite is required if compounding any Category 2 and Category 3 CSPs. If no, go to compliance statements.If pharmacy only uses an SCA for Category 1 CSPs, inspector should answer question as N/A.***		

Item#	Requirement	Yes/No/N/A	Comment
C	**Facility Design and Engineering Controls**		
12.1	Access to the cleanroom suite is restricted to authorized personnel. ***Inspector note: Per USP, authorized personnel includes personnel involved in compounding processes, maintenance, and cleaning. Some examples pharmacies may use to demonstrate compliance with this statement (but are not specifically required by the chapter) include posting a sign or creating a badge access point for authorized personnel to enter the cleanroom suite.***		
12.2	The facility is designed to afford a well-lit environment.		
12.3	The facility provides a comfortable working environment (e.g., temperature and humidity settings so appropriate garb can be donned).		
12.4	The anteroom and buffer room are separated from surrounding unclassified areas by fixed walls and doors.		
12.5	Controls are in place to minimize the flow of lower-quality air into the more-controlled areas. ***Inspector note: Per USP, "strong air currents from opened doors, personnel traffic, or air streams from the HVAC system can disrupt the unidirectional airflow of an open-faced PEC."***		
12.6	Anterooms providing access to only positive pressure buffer rooms meet at least ISO Class 8 specifications. ***If the pharmacy has a negative pressure room, inspector should answer statement as N/A.***		
12.7	The anteroom provides access to a negative pressure room and meets at least ISO Class 7 specifications. ***If the pharmacy does not compound hazardous drugs, inspector should answer statement as N/A.***		
12.8	The buffer room, where the PEC is placed, meets ISO Class 7 or better air quality specifications. ***Inspector note: If the PEC is a pharmaceutical isolator, the buffer room must be at least ISO Class 8 air quality or better and an anteroom is not required.*** ***Per USP <797>, a pharmaceutical isolator is defined as an enclosure that provides HEPA-filtered ISO Class 5 unidirectional air operated at a continuously higher pressure than its surrounding environment and is decontaminated using an automated system. It uses only decontaminated interfaces or rapid transfer ports for materials transfer. A CAI or CACI is not a pharmaceutical isolator.***		
12.9	Air supply to the anteroom and buffer room is introduced through HEPA filters in the ceiling.		
12.10	Air returns are located low on the wall. ***If the pharmacy has a visual smoke study (as described in the USP chapter and compliance statement below), inspector should answer statement as N/A.***		

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C	**Facility Design and Engineering Controls**		
12.11	A visual smoke study demonstrates an absence of stagnant air where particles can accumulate and is repeated if any equipment/placement changes when air returns are not located low on the wall. ***Inspector note: Per USP, "the smoke study, along with environmental monitoring, must be repeated whenever a change is made to the placement of equipment within the room or any other alteration is performed within the cleanroom suite that affects the quality of the air (e.g., HVAC alterations, chapter of HEPA filter units)."*** ***If air returns are low on the wall, inspector should answer statement as N/A.***		
12.12	The anteroom has a line of demarcation to separate the dirty side from the clean side or has two separate anterooms, a dirty anteroom, and a clean anteroom. ***Describe observations for the type of line of demarcation in the Inspector Notes.***		
12.13	Personnel enter the dirty side/room first from the unclassified area and the clean side/room is located closest to the buffer room.		
12.14	All surfaces (ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets) are smooth, impervious, free from cracks and crevices, and non-shedding.		
12.15	Junctures between ceilings and walls and between the walls and floors are sealed.		
12.16	If the ceiling consists of inlaid panels, the panels are caulked to seal them to the support frame. ***If the ceiling does not consist of inlaid panels, inspector should answer statement as N/A.***		
12.17	Walls are constructed of, or covered with, a durable material (e.g., epoxy paint, heavy gauge polymer) and integrity of surface maintained.		
12.18	Walls, if paneled, are joined together, and sealed to the support structure. ***If walls are not paneled, inspector should answer statement as N/A.***		
12.19	Floors include coving to the sidewall or the juncture between floor and wall is caulked.		
12.20	If overhangs or ledges are present, they are easily cleanable. ***If there are no overhangs, ledges, utility pipes, windowsills, etc., inspector should answer statement as N/A.***		
12.21	Exterior lens surfaces of the ceiling light fixtures are smooth, mounted flush, and sealed.		
12.22	All other penetrations through the ceiling or walls (e.g., camera domes) are sealed.		
12.23	The buffer room does not contain plumbed water sources (e.g., sinks, eyewashes, showers, or floor drains).		
12.24	The anteroom does not contain floor drains.		

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C	**Facility Design and Engineering Controls**		
13.0	Are **PECs** used to prepare CSPs located in the appropriate space (e.g., buffer room or SCA) for category types prepared in compliance with USP <797> standards? ***Inspector to review certification reports and observe compounding area(s) to evaluate.*** ***If no, go to compliance statements.***		
13.1	All compounded sterile preparations (that are not for immediate use) are compounded in a PEC.		
13.2	PEC is certified to maintain ISO 5 classification or better conditions during dynamic operating conditions. ***The inspector should only answer yes if the PEC has been certified within the past six months.***		
13.3	The PEC is located out of traffic patterns and away from room air currents that could disrupt the intended airflow patterns inside the PEC.***Review certification report.***		
13.4	Placement of the PEC allows for cleaning around the PEC.		
13.5	**Category 2 and Category 3**: PEC(s) are in a cleanroom suite. ***If pharmacy only compounds Category 1 CSPs, inspector should answer this statement as N/A.***		
14.0	Does the pharmacy have any CAIs/CACIs used for sterile compounded preparations?***If the pharmacy does not use any CAI/CACIs for compounding CSPs, inspector should answer question as N/A.***		
15.0	Are **CAIs/CACIs** (RABS) used for compounding sterile preparations operated in compliance with manufacturer specifications **and** USP <797> standards? ***If no, go to compliance statements.*** ***If the pharmacy does not use any CAI/CACIs for compounding CSPs, inspector should answer question as N/A.***		
15.1	The documented recovery time is followed opening the CAI/CACI transfer chamber to maintain ISO Class 5 air quality. ***Inspector note: The recovery time should come from the manufacturer of the CAI/CACI.***		
15.2	Staff ensures that adequate recovery time is allowed after closing the CAI/CACI during compounding operations. ***Inspector note: The recovery time should come from the manufacturer of the CAI/CACI.***		

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C	**Facility Design and Engineering Controls**		
15.3	Sterile gloves are worn over the gloves attached to the CAI/CACI sleeve. ***Inspector note: Per USP, if using a RABS (i.e., a CAI or CACI), disposable gloves should be (not required) worn inside the gloves attached to the RABS sleeves.***		
16.0	Are there controls in place to minimize the influx of contaminants from materials (supplies and equipment) and personnel as they move from areas of lower quality to those of higher quality in compliance with USP <797> standards? ***Inspector note: An example of material movement from lower quality air to higher quality air includes movement from a non-classified area to an ISO Class 8 anteroom, ISO Class 8 anteroom to an ISO Class 7 buffer room, or from an ISO Class 7 buffer room to an ISO Class 5 PEC.If no, go to compliance statements.***		
16.1	Before any item is introduced into the SEC, placed into the pass-through chamber, or brought into the SCA (providing that packaging integrity will not be compromised), it is wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% isopropyl alcohol (IPA) using low-lint wipers by personnel wearing gloves.		
16.2	Before any item is introduced into the PEC, it is wiped with sterile 70% IPA using sterile low-lint wipers and allowed to dry before use.		
17.0	Does the pharmacy have the appropriate facility design and controls (including the fixtures, types of equipment, materials, and supplies that are stored) in the classified areas in compliance with USP <797> standards? ***If no, go to compliance statements.***		
17.1	The sink used for hand hygiene, located outside of the anteroom, is placed in an appropriate area and clean space to minimize the risk of bringing contaminants into the anteroom. ***Inspector note: Inspector should evaluate the sink location in relation to the activities that occur where the sink is located as well as the distance between the sink and the entrance to the compounding suite/SCA. Examples that may not be considered appropriate include but are not limited to: sink is in the bathroom, an adjacent suite or property, or in an employee breakroom where food is prepared.If the sink is in the anteroom, inspector should answer statement as N/A.***		
17.2	The sink used for hand hygiene, located inside of the anteroom, is placed in an appropriate area to minimize the risk of bringing contaminants into the buffer room. ***Inspector note: Inspector should evaluate the sink location in relation to the doors and compounding activities. For example, the sink is where compounders perform hand hygiene close to where garb is stored (where it can easily get wet/splashed). If the sink is located outside the anteroom, inspector should answer statement as N/A.***		

Item#	Requirement	Yes/No/N/A	Comment
C	**Facility Design and Engineering Controls**		
17.3	The doors into the anteroom from the general pharmacy area and from the anteroom into the clean/buffer room are prevented from both being open at the same time (e.g., by interlocking, training of personnel, or signage).		
17.4	The inside and outside doors of a pass-through are prevented from both being open at the same time (e.g., by interlocking, training of personnel, or signage).		
17.5	Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in a classified area or SCA. ***Inspector note: Per USP, items necessary for performing compounding activities are low-shedding and can be easily cleaned and disinfected.*** ***If no, describe the types of items that are observed. If appropriate, submit a photograph with inspection report.***		
17.6	Tacky mats are not used in the classified areas. ***Inspector note: Per USP <797>, "Tacky mats must not be placed within ISO-classified areas."***		
17.7	Shipping cartons or other corrugated or uncoated cardboard are not permitted in the classified areas.		
17.8	Carts used to transport components or equipment into classified areas are constructed from nonporous materials with cleanable casters and wheels.		
17.9	Carts (including casters) are cleaned and disinfected prior to moving from the dirty side to the clean side of the anteroom.		
18.0	Does the pharmacy's facility design for maintaining (e.g., recording, monitoring, and controlling) temperature and humidity (e.g., HVAC) comply with USP <797> standards? ***Inspector note: Compounded preparations that are finished and stored will be addressed in the general pharmacy module. Inspector should be aware that USP cleanroom temperature recommendations may not be harmonized with USP, FDA, or manufacturer/supplier temperature requirements for drug storage.*** ***If no, go to compliance statements.***		
18.1	The compounding area temperature and humidity is maintained by a heating, ventilation, and air conditioning (HVAC) system. ***If inspector finds a free-standing air conditioner, humidifier, or dehumidifier within the classified area or the SCA, the inspector should answer statement as "No." Additionally, inspector should describe what they observed, where the equipment was located, and collect/submit photographs.***		
18.2	The pharmacy records the temperature of the cleanroom suite on days when sterile compounding occurs. ***If pharmacy does not use a continuous recording system, describe the frequency of temperature recording in the notes.***		

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C	**Facility Design and Engineering Controls**		
18.3	The pharmacy records the humidity of the cleanroom suite on days when sterile compounding occurs. ***If pharmacy does not use a continuous recording system, describe the frequency of humidity recording in the notes.***		
18.4	The pharmacy maintains records of temperature and humidity that are specific to the cleanroom suite. ***Temperature and humidity for drug storage areas will be documented in the general pharmacy module.*** ***If the pharmacy only uses an SCA, inspector should answer statement as N/A.***		
18.5	The pharmacy can readily retrieve temperature and humidity records. ***If the electronic monitoring system is only capable of providing text message alerts for excursions alone (e.g., a report cannot be generated for ongoing temperature conditions), inspector should answer statement as "No."***		
18.6	The pharmacy controls temperature and humidity to maintain appropriate working conditions if no overnight drug storage occurs and/or is following the most restrictive drug label. ***Inspector note: Per USP <797>, the cleanroom suite should be maintained at a temperature of 20°C or cooler and a relative humidity of 60% or below to minimize the risk of microbial proliferation and to provide comfortable conditions for compounding personnel attired in the required garb.*** ***CRT is defined as 20°C-25°C per USP <659>.***		
18.7	The placement of the HVAC unit does not cause cross contamination or interfere with the functioning of the classified area. ***Inspector note: Air streams from the HVAC system(s) can disrupt the unidirectional airflow of an open-faced PEC such as a laminar airflow workbench (LAFW).***		
18.8	Temperature monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. ***Inspector note: Monitoring devices are typically calibrated or replaced.***		
18.9	Humidity monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. ***Inspector note: Monitoring devices are typically calibrated or replaced.***		
19.0	Does the pharmacy store drugs in the cleanroom suite overnight and/or for long periods of time? ***Inspector note: Long periods of time is not defined as pre-compounding preparation right before compounding activities are commenced.***		***Not Allowable: MA DRAFT 247 CMR 17.04 (3)***
20.0	If the pharmacy is storing drugs inside the cleanroom suite overnight and/or long periods of time, are any of the drugs stored unable to tolerate temperature excursions?		***Not Allowable: MA DRAFT 247 CMR 17.04 (3)***

Item#	Requirement	Yes/No/N/A	Comment
C	**Facility Design and Engineering Controls**		
21.0	What is the current temperature of the cleanroom suite/SCA? ***Record in the Inspector Notes.***		
22.0	What is the current relative humidity percentage of the cleanroom suite/SCA?***Record in the Inspector Notes.***		
23.0	Is the humidity maintained at less than 60% relative humidity (RH) in the compounding area to minimize risk of microbial proliferation?		***Required: MA DRAFT 247 CMR 17.10 (2)***
24.0	Is differential positive pressure maintained in compliance with USP <797> standards? ***Inspector note: Per USP <797>, no pressure differential is required between the SCA and the surrounding area. If no, go to compliance statements. Inspector should view logs and status (while observing compounding) to verify. If the pharmacy uses an SCA for sterile compounding environment, inspector should answer statement as N/A.***		
24.1	The facility design creates room separation to allow positive pressure differentials between spaces (rooms) for movement of air from higher quality air to lower quality air. ***Inspector should review a graphic of the airflow contained in the certification report.***		
24.2	The facility has a system in place to continuously monitor pressure differentials (e.g., magnehelic gauge). ***Per USP, pressure differentials need to be monitored continuously, but personnel are not specifically required to visually monitor pressure during compounding activities.***		
24.3	The facility has a record system to record pressure differentials on days when compounding occurs. ***Inspector note: Per USP, the quantitative results from the pressure monitoring device must be reviewed and documented at least daily on the days when compounding is occurs.***		
24.4	The differential positive pressure between unclassified and the first space in the compounding suite is at least 0.020 inch water column. ***Inspector note: Per USP, certifiers should confirm (this is a USP recommendation) positive pressure around doorways, pass-throughs and any opening in the cleanroom suite with smoke testing (to confirm positive pressure is maintained) with initial certification of the cleanroom suite.*** ***If no, record the observed pressure differential between the two identified spaces (e.g., ISO Class 8 anteroom and the general pharmacy area).***		
24.5	The differential positive pressure between adjacent classified areas is at least 0.020-inch water column. ***If no, record the observed pressure differential between the two identified spaces (e.g., ISO Class 8 anteroom and the ISO Class 7 buffer room).***		

Item#	Requirement	Yes/No/N/A	Comment
C	**Facility Design and Engineering Controls**		
24.6	Pressure differential monitoring and quantitative results are reviewed and documented at least daily on days when compounding occurs.		
25.0	Does the pharmacy have a policy in place to cease compounding when the pharmacy is unable to maintain positive pressure differentials (outside of anticipated variations due to opening and closing of doors)?		
26.0	Are pressure differential monitoring procedures in place that include an alarm or alert when there is an excursion? ***Inspector note: USP <797> does not require there to be an alarm or an alert.***		
27.0	Does the facility perform both sterile and nonsterile compounding?		
28.0	If the pharmacy performs nonsterile compounding and sterile compounding, are the designated areas separate and distinct from each other?		
29.0	If PECs are placed into the same room that are used for both sterile and nonsterile compounding, is the pharmacy in compliance with USP <797> standards? ***Inspector note: Per USP <797>, PECs used for both sterile and nonsterile compounding may be placed in the same room only if the PECs are sufficiently effective that the room can continuously maintain ISO Class 7 classification.*** ***If no, go to compliance statements.*** ***If the pharmacy does not perform nonsterile compounding in the same room as sterile compounding, inspector should answer this question as N/A.***		
29.1	PECs used for nonsterile compounding are placed at least one meter away from PECs used for sterile compounding.		
29.2	Particle-generating activity must not be performed while sterile compounding is in process.		
29.3	PECs are sufficiently effective that the room can continuously maintain ISO Class 7 classification air quality during nonsterile compounding.		
30.0	Does the pharmacy prepare Category 2 and Category 3 CSPs from nonsterile components? ***Inspector note: Category 1 CSPs can be made from nonsterile components.*** ***If the pharmacy does not compound using nonsterile components, the inspector should answer question as N/A.***		
31.0	Does the pharmacy's presterilization procedures comply with USP <797> standards? ***If no, go to compliance statements.***		
31.1	Presterilization procedures, such as weighing and mixing, are completed in an ISO Class 8 or better environment (e.g., anteroom or buffer room). ***Inspector note: This statement only applies for Category 2 and Category 3.***		

Item#	Requirement	Yes/No/N/A	Comment
C	**Facility Design and Engineering Controls**		
31.2	Presterilization procedures, such as weighing and mixing, are performed in a single-use containment glove bag, CVE, BSC, or CACI to minimize the risk of airborne contamination. ***Inspector note: This statement only applies for Category 2 and Category 3. CVEs, BSCs, or CACIs used for presterilization procedures must be certified at least every six months.***		
D	**Certification of PECs and SECs[4]**		
32.0	Does the pharmacy ensure that each area related to CSP preparation is certified to meet the classified air quality standard appropriate for the activities conducted in that area in compliance with USP <797> standards? ***If no, go to compliance statements.*** ***Inspector is to review current certification reports.***		
32.1	The most recent PEC and SEC certification reports are available for review.		
32.2	Certification of all classified areas, including PECs, is performed at least every six months.		
32.3	Certification of all classified areas, including PECs, is performed whenever a device is relocated or a major service to the facility is performed. ***Inspector note: Classified areas must be recertified if there are changes to the area such as redesign, construction, replacement or relocation of any PEC, or alteration in the configuration of the room that could affect airflow or air quality.***		
32.4	Certification reports are reviewed by the designated person(s). ***Inspector note: If the designated person(s) review is not documented, describe how it is ensured that the review occurred.***		
32.5	All ISO Class 5 PECs (laminar airflow workbenches or areas, BSCs, CAIs, CACIs, pharmaceutical isolators, IVLFZ, and robotic enclosures) have been certified within the last six months. ***If no, record the date of the last certification and include a copy of the certification report with the inspection report.***		
32.6	All PECs meet ISO Class 5 air quality requirements with (total, nonviable) particle counts documented within the report. ***Inspector note: Per ISO definition, ISO Class 5 areas are certified as having less than 3,520 particles per cubic meter of air under dynamic operating conditions.*** ***If no, describe what occurred and the pharmacy's response to total airborne particle sampling results, data evaluation, and action level (e.g., pharmacy took PEC out of service, pharmacy ordered new HEPA filter, PEC was repaired and re-certified).***		

[4] **Disclosure of Failed Certification**: Every pharmacy licensed pursuant to M.G.L. c. 112, § 39 shall report the failure of certification of primary and / or secondary engineering controls in any sterile compounding or institutional sterile compounding pharmacy licensed by the Board, as applicable.

Item#	Requirement	Yes/No/N/A	Comment
D	**Certification of PECs and SECs**		
32.7	All ISO Class 7 and 8 SECs (clean/buffer rooms and anterooms) have been certified within the last six months. ***Inspector note: Per ISO definition, ISO Class 7 areas are certified as having less than 352,000 particles per cubic meter of air under dynamic operating conditions and ISO Class 8 areas are certified as having less than 3,520,000 particles per cubic meter of air under dynamic operating conditions.*** ***If no, record the date of the last certification and include a copy of the certification report with the inspection report.***		
32.8	All SECs meet ISO Class 7 air quality requirements and ISO Class 8 air quality requirements where permitted, with particle counts documented within the report.***If no, describe what occurred and the pharmacy's response (e.g., pharmacy reduced BUD, pharmacy used an alternative facility, pharmacy followed mitigation strategies, and/or disaster planning processes).***		
33.0	Does the certification report received by the pharmacy have all required elements documented for the pharmacy's designated person(s) to make an informed decision related to functionality of PEC and SEC environments in compliance with USP <797> standards? ***Inspector note: It is recommended that the designated person review the certification report in its entirety.*** ***If no, go to compliance statements.***		
33.1	The certification report includes information about the equipment used for performing each test including last calibration date (or date when next calibration is due). ***Inspector note: Per USP, "total particle count testing must be performed under dynamic operating conditions using calibrated electronic equipment" and "all impaction air samplers must be serviced and calibrated as recommended by the manufacturer."***		
33.2	The certification report includes the name of the certifier. ***Inspector note: Per USP <797>, a qualified certifier <u>may</u> have received training and education from professional organizations such as the American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) and Controlled Environment Testing Association (CETA). Both organizations provide certification (Registered Certification Professional – Sterile Compounding Facilities), education, and resources.***		
33.3	The certification report describes the "dynamic conditions" including the number of personnel in the cleanroom suite. ***Inspector note: Compounders can perform mock compounding activities and/or performing media-fill while the certifier is conducting testing. Number of personnel present in the SEC must be documented.***		

Item#	Requirement	Yes/No/N/A	Comment
D	**Certification of PECs and SECs**		
33.4	**SEC: Airflow testing** is performed and documented on the certification report to determine acceptability of the **air volume and room air exchange rate (ACPH)**. ***Inspector note: Per USP <797>, unclassified SCAs have no ACPH requirement. If pharmacy only compounds in an SCA, inspector should answer statement as N/A.***		
33.5	**SEC:** All the following ACPH required elements were documented on the certification report: the ACPH from HVAC, the ACPH contributed from the PEC, and the total ACPH.***If pharmacy only compounds in an SCA, inspector should answer statement as N/A.***		
33.6	**The ISO Class 8 anteroom** is certified and documented as having a minimum of 20 ACPH with at least 15 ACPH of the total air change rate coming from HVAC through HEPA filters located in the ceiling. ***If the pharmacy has an ISO Class 7 anteroom, inspector should mark as N/A.***		
33.7	**The ISO Class 7 buffer room and ISO Class 7 anteroom (if required)** is certified and documented as having a minimum of 30 ACPH with at least 15 ACPH of the total air change rate in a room coming from the HVAC through HEPA filters located in the ceiling. ***Inspector note: If the PEC is used to meet the minimum total ACPH requirements, the PEC must not be turned off, except for maintenance.***		
33.8	**SEC: Airflow testing** is performed and documented on the certification report to determine acceptability of the **room pressure differential** in doorways between adjacent rooms.		
33.9	**SEC:** The differential pressure measured was at least 0.020-inch water column positive from the cleanroom to the anteroom and between the anteroom and all adjacent spaces with the doors closed. ***Inspector note: No pressure differential is required between the SCA and the surrounding area.***		
33.10	**SEC:** All SEC HEPA filters were leak tested (to confirm **HEPA filter integrity**).		
33.11	**SEC:** All SEC HEPA filters with leaks were repaired. ***If leaks were not repaired, describe what actions pharmacy took (e.g., pharmacy implemented mitigation strategies such as reduced BUD or used alternative pharmacy location).*** ***If no repairs were needed, inspector should answer statement as N/A.***		
33.12	**PEC:** (**Dynamic airflow**) **Smoke pattern tests** are performed for each PEC during dynamic operating conditions to demonstrate unidirectional airflow and sweeping action over and away from the CSPs. ***Inspector note: Per USP, "HEPA-filtered air must be supplied by the PEC at a velocity sufficient to sweep particles away from critical sites and maintain unidirectional airflow during operations. Proper design, control, and use minimizes turbulence and creation of eddies or stagnant air in the PEC." Describe if smoke pattern testing of PEC was documented thoroughly in the report or through video.***		

Item#	Requirement	Yes/No/N/A	Comment
D	**Certification of PECs and SECs**		
33.13	**PEC: Dynamic airflow smoke pattern** confirms equipment and supplies necessary for performing compounding activities in the PEC do not disrupt unidirectional airflow. ***Inspector note: Per USP, "Proper placement of equipment in a PEC must be initially verified by a dynamic airflow smoke pattern test to demonstrate minimal disruption in airflow. The dynamic airflow smoke pattern test must be repeated if equipment is placed in a different location."***		
33.14	**PEC: Total (nonviable) particle count** testing was performed under dynamic operating conditions using calibrated electronic equipment. ***Inspector note: Per USP, "Measurements of total airborne particles must be taken in each PEC at locations where there is greatest risk to the exposed CSPs, containers, and closures...Measurements of total airborne particles in other classified areas, including the buffer room(s) and anteroom(s), should be taken at representative locations that reflect the quality of air in the room(s)."***		
33.15	**PEC:** All PEC HEPA filters were leak tested (to confirm **HEPA filter integrity**). ***Inspector note: The certification report for each PEC should show air velocities within the PEC.***		
33.16	**PEC:** All PEC HEPA filters with leaks identified were repaired. ***If leaks were not repaired, describe what actions pharmacy took (example: PEC taken out of service until HEPA filter could be replaced). If no repairs were needed, inspector should answer statement as N/A.***		
33.17	**PEC-IVLFZ**: Pharmacy's integrated vertical laminar flow zone (IVLFZ) meets design, functional requirements, and certification requirements under USP <797>. ***Inspector note: Per USP <797>, "Strategic location of air returns in addition to full coverage of HEPA-filters above the work surface is required. Both static and dynamic smoke studies of air returns in addition to full coverage of HEPA-filtered air void of turbulence, dead air zones, and refluxing from the HEPA filters to and across the entire work area and to the air returns must be documented (e.g., with video)."If pharmacy does not use an IVLFZ, inspector should answer statement as N/A.***		

Item#	Requirement	Yes/No/N/A	Comment
D	**Certification of PECs and SECs**		
33.18	If a **robotic enclosure is used as the PEC**, or placed within the PEC, a dynamic airflow smoke pattern test must be performed initially and at least every 6 months thereafter to ensure that: 1) it is properly integrated into the facility, 2) there is no turbulence or refluxing at any critical site(s), 3) room air does not enter the PEC where sterile products and/or preparations may be exposed, and 4) all processes can be performed without introducing contamination to the direct compounding area(s). ***If pharmacy does not use a robotic enclosure, inspector should answer statement as N/A.***		
34.0	Was smoke testing performed in SEC to confirm all particle generating equipment (e.g., computers, printers, refrigerators, PECs) do not disrupt airflow? ***Inspector note: This question will be N/A <u>unless</u> the pharmacy is new, has recently completed construction, or equipment has been moved within SEC since last certification.***		
E	**Environmental Monitoring**		
35.0	Does the pharmacy have an established environmental monitoring (e.g., microbiological air and surface monitoring) program in compliance with USP <797> standards? ***Inspector note: Per USP, "The goals of a microbiological air and surface monitoring program are to determine whether contamination is present at unacceptable levels and to assess whether proper personnel practices are being followed, cleaning and disinfecting agents are effective, and environmental quality is maintained."*** ***If no, go to compliance statements.***		
35.1	Environmental monitoring program (e.g., viable air and/or surface monitoring) is performed initially in the selected sampling sites to establish a baseline level of environmental quality for each classified area, i.e., each ISO Class 5 PEC, each ISO Class 7, and ISO Class 8 room.		
35.2	Environmental monitoring program (e.g., viable air and/or surface monitoring) is performed in conjunction with the certification of new facilities and equipment.		
35.3	Environmental monitoring program (e.g., viable air and/or surface monitoring) is performed after any servicing of facilities or equipment.		
35.4	Environmental monitoring program (e.g., viable air and/or surface monitoring) is performed in response to identified problems (e.g., growth in sterility tests of sterile compounded preparation).		
35.5	Environmental monitoring program (e.g., viable air and/or surface monitoring) is performed in response to identified trends (e.g., repeated positive gloved fingertip and thumb sampling results, failed media fill testing, or repeated observations of air or surface contamination).		

Item#	Requirement	Yes/No/N/A	Comment
E	**Environmental Monitoring**		
35.6	Results from the environmental monitoring program (e.g., viable air and/or surface monitoring) are reviewed in response to changes that could impact the sterile compounding environment (e.g., change in cleaning agents) and in conjunction with personnel data (i.e., training records, visual observations, competency assessments) to assess the state of control and to identify potential risks of contamination. ***Inspector note: Per USP, the program is reviewed to "assess risks for contamination, potential routes of contamination, and the adequacy of cleaning and disinfecting agents and procedures. Regular review of the sampling data must be performed to detect trends and the results of the review must be documented."***		
35.7	The pharmacy ensures that viable air and surface sampling is performed by a trained and competent individual who is familiar with the methods and procedures for air sampling and surface testing. ***If sampling is conducted by internal personnel, inspector should verify that documented training and competencies are in the employee file.***		
35.8	Environmental monitoring program (e.g., viable air and/or surface monitoring) describes/identifies corrective actions to minimize the risk of CSP contamination and that these corrective actions are documented.		
36.0	Is surface sampling performed at the end of a compounding activity or shift but before the area has been cleaned and disinfected (to obtain a sample that is representative of the typical compounding conditions at the pharmacy)? ***Inspector note: this is a USP recommendation.***		
37.0	Does the pharmacy send out all air quality for viable airborne samples to an external lab (third party) for incubation and processing? ***If pharmacy exclusively does internal incubation and results processing, inspector should answer statement as N/A.***		
38.0	Does the pharmacy send out all surfaces for viable particle samples to an external lab (third party) for incubation and processing? ***If pharmacy exclusively does internal incubation and results processing, inspector should answer statement as N/A.***		
39.0	For any samples that are sent to an external lab (third party), does the pharmacy receive a report from the third-party confirming incubation parameters meet USP <797> requirements (e.g., the correct temperature and the correct length of incubation time are documented in the report)? ***Inspector note: Incubation parameters are the same as seen in statements 40.6-40.7 and 41.4-41.5. This question applies for any air or surface sample sent to an external lab.If no, describe observations.***		

Item#	Requirement	Yes/No/N/A	Comment
E	**Environmental Monitoring**		
40.0	Are processes for sampling and monitoring **air quality for viable airborne** particles in compliance with USP <797> standards? ***Inspector note: Per USP <797>, facilities performing any Category 3 compounding must adhere to the increased environmental monitoring requirements for all classified areas where Category 3 CSPs are compounded and increased environmental monitoring requirements always apply regardless of whether Category 3 CSPs are being compounded on a given day.*** ***Review six months of air sampling data to verify. If no, go to the compliance statements.***		
40.1	All classified areas are sampled using a volumetric active air sampling device (impaction air sampler). ***Inspector note: This sampling must be performed during dynamic operating conditions (to obtain a sample that is representative of the typical compounding conditions at the pharmacy).***		
40.2	All classified areas are sampled at the **frequencies** specified by USP for volumetric active air sampling. ***Inspector note: Per USP <797>, Category 1 and Category 2 compounding frequency is every six months and Category 3 compounding frequency is monthly.*** ***For facilities compounding any Category 3 CSPs, this must be completed within 30 days prior to the commencement of any Category 3 compounding and at least monthly thereafter regardless of the frequency of compounding Category 3 CSPs.***		***MA DRAFT 247 CMR 17.12 (3): at least every 3 months, or monthly for qualifying CSPs. Monitoring includes Non-viable (Total) particle counts.***
40.3	At least one cubic meter (1000 L) of air is tested using the volumetric active air sampling device from each sample location.		
40.4	All impaction air samplers are serviced and calibrated as recommended by the manufacturer.		
40.5	The pharmacy uses an appropriate microbiological growth media for sampling. ***Inspector note: An appropriate microbiological growth media means a media that supports the growth of bacteria and fungi (e.g., TSA), accompanied by a COA that verifies that the media meets expected growth promotion, pH, and sterilization requirements.***		
40.6	The pharmacy incubates all air samples for time and temperature in compliance with USP <797> following the one media device method. ***Inspector notes: Per USP <797> (Box 5), when using the one media device method, sampling media is to be covered, inverted, and incubated at 30°C–35°C for no less than 48 hours. Then, after examination and recording of results, further incubated at 20°C–25°C for no less than five additional days. If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***		

Item#	Requirement	Yes/No/N/A	Comment
E	**Environmental Monitoring[5]**		
40.7	The pharmacy incubates all air samples for time and temperature in compliance with USP <797> following the alternative two media device method. ***Inspector note: Per USP <797> (Box 5), two samples may be collected for each sample location and incubated concurrently to shorten the overall incubation period. Both samples are TSA, or one sample is TSA and the other fungal media (e.g., malt extract agar [MEA] or sabouraud dextrose agar [SDA]). Each sample is incubated in a separate incubator, one sample at 30°C-35°C for no less than 48 hours the other sample at 20°C-25°C for no less than five days. If fungal media is used, incubate at 20°C-25°C for no less than five days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***		
40.8	Results for all plates are recorded for each sample and did not exceed USP <797> Table 7 action levels (or internal action levels if more restrictive).**ISO Class 5: >1 cfu/m^3/deviceISO Class 7: >10 cfu/m^3/deviceISO Class 8: > 100 cfu/m^3/device** ***Inspector note: Per USP <797>, if two sampling media devices are collected at a single location, all recovered growth on each must be documented and action levels applied to each sampling media separately.***		
40.9	For any air sample locations exceeding action levels, pharmacy works with the assistance of a microbiologist to identify any microorganisms recovered to the genus level. ***Inspector note: Per USP <797>, an attempt must be made (meaning the lab attempted to identify the microorganisms and was unsuccessful).***		
40.10	For any areas that exceed action levels, an investigation is conducted to attempt to determine the cause and a corrective action plan is implemented.		
41.0	Are processes for sampling and monitoring **surfaces for viable particles** in compliance with USP <797> standards? ***Review six months of surface sampling data to verify. If no, go to the compliance statements.***		
41.1	**Surfaces** and pass-through chambers in the cleanroom suite and SCA are sampled for microbial contamination for each classified area. ***Inspector note: Sampling locations must include work surfaces in each classified room, the interior of each ISO Class 5 PEC, and all pass-through chambers connecting to classified areas. USP recommends samples be taken from: equipment contained within the PEC, staging, or working area near the PEC, and frequently touched surfaces.***		

[5] **Board Policy No. 2023-09** – This policy requires Pharmacies conducting sterile compounding to adhere to heightened standards (above minimal standards in USP <797> for environmental monitoring and remedial actions.

Item#	Requirement	Yes/No/N/A	Comment
E	**Environmental Monitoring**		
41.2	**Surfaces** within the cleanroom suite and SCA are sampled at the **frequencies** specified by USP for viable particle surface sampling. ***Inspector note: Category 1 and Category 2 CSP surface sampling frequency is monthly and Category 3 compounding is weekly, regardless of the frequency of compounding Category 3 CSPs.*** ***Additionally, surface sampling is to be performed within the PEC used to prepare Category 3 CSPs, at the end of each batch, before cleaning and disinfection occurs unless a self-enclosed robot is used. If a self-enclosed robot is used, frequency is at least once daily at the end of compounding operations.*** ***For facilities compounding any Category 3 CSPs, a surface sampling must be completed prior to assigning BUDs longer than the limits established in Table 13.***		***MA DRAFT 247 CMR 17.12 (3): at lease monthly, or weekly for qualifying CSPs.***
41.3	The pharmacy uses an appropriate microbiological growth media for sampling. ***Inspector note: An appropriate microbiological growth media means a surface sampling device with a raised convex surface for sampling flat surfaces is used that contain general microbial growth media that supports the growth of bacteria and fungi (e.g., TSA supplemented with additives that neutralize effects of any disinfecting agent, e.g., lecithin and polysorbate 80), accompanied by a COA that verifies that the media meets expected growth promotion, pH, and sterilization requirements. Per USP, "sterile swabs wetted with sterile water or a sterile neutralizing buffer may be used when sampling irregular surfaces and difficult-to-reach locations such as crevices, corners, and spaces between surfaces."***		
41.4	The pharmacy incubates all surface samples in compliance with USP <797> following the one media device method. ***Inspector notes: Per USP <797>, when using the one media device method, sampling media is to be covered, inverted, and incubated at 30°C-35°C for no less than 48 hours. Then, after examination and recording of results, further incubated at 20°C-25°C for no less than five additional days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***		

Item#	Requirement	Yes/No/N/A	Comment
E	**Environmental Monitoring**		
41.5	The pharmacy incubates all surface samples in compliance with USP <797> following the alternative two media device method. ***Inspector note: Per USP <797>, two samples may be collected for each sample location and incubated concurrently to shorten the overall incubation period. Both samples are TSA, or one sample is TSA and the other fungal media (e.g., MEA or SDA). Media must be supplemented with neutralizing additives (e.g., lecithin and polysorbate 80). Each sample is incubated in a separate incubator, one sample at 30°C-35°C for no less than 48 hours the other sample at 20°C-25°C for no less than five days. If fungal media is used, incubate at 20°C-25°C for no less than five days.If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***		
41.6	Results for all plates are recorded for each sample and did not exceed USP <797> Table 8 action levels (or internal action levels if more restrictive). **ISO Class 5: >3 cfu/media device** **ISO Class 7: >5 cfu/media device** **ISO Class 8: > 50 cfu/media device** ***Inspector note: Per USP <797>, if two sampling media devices are collected at a single location, all recovered growth on each must be documented and action levels applied to each sampling media device separately.***		
41.7	For any surface sample locations exceeding action levels, pharmacy works with the assistance of a microbiologist to identify any microorganisms recovered to the genus level. ***Inspector note: Per USP <797>, an attempt must be made (meaning the lab attempted to identify the microorganisms and was unsuccessful).***		
41.8	For any areas that exceed action levels, an investigation is conducted to determine cause, and a corrective action plan is implemented.		
F	**Compounding Personal Hygiene and Garbing**		
42.0	Does the pharmacy have a process to ensure all personnel entering the compounding area adhere to restrictions intended to minimize the risk of contamination in compliance with USP <797> standards? ***If no, go to compliance statements.***		
42.1	Compounding personnel are required to report conditions that may contaminate the sterile preparation and environment to the designated person(s). ***Inspector note: Per USP <797>, examples of conditions that have a higher risk of contaminating the CSP and sterile environment includes rashes, recent tattoos, oozing sores, conjunctivitis, or active respiratory infections.***		

Item#	Requirement	Yes/No/N/A	Comment
F	**Compounding Personal Hygiene and Garbing**		
42.2	The designated person(s) is responsible for evaluating whether compounding personnel should be excluded from working in compounding areas before their conditions have been resolved. ***Inspector note: Per USP <797>, the designated person(s) may permit accommodations if the quality of the CSP and environment will not be affected.***		
42.3	Any accommodations permitted by the designated person(s) are documented.		
42.4	Food (including mints, gum, etc.) and drinks are not permitted in anterooms, buffer rooms, or segregated compounding areas.		
43.0	Does the pharmacy stock the necessary garb to ensure minimum garbing requirements are continuously met in compliance with USP <797> standards? ***If no, go to compliance statements.***		
43.1	The pharmacy stocks gowns and/or coveralls that are low lint with sleeves that fit snugly around the wrists and an enclosed neck.		
43.2	The pharmacy stocks shoe covers that are low lint.		
43.3	The pharmacy stocks head covers that are low lint and cover the hair and ears.		
43.4	The pharmacy stocks facial hair covers (not masks) that are low lint. ***If the pharmacy does not have personnel with beards, inspector should answer this statement as N/A.***		
43.5	The pharmacy stocks masks that are low lint.		
43.6	The pharmacy stocks sterile, powder-free gloves.		
43.7	**Category 1 and Category 2:** All non-disposable garb used to prepare Category 1 and Category 2 CSPs is laundered before reuse. ***If only disposable items are used, inspector should mark as N/A.***		
43.8	**Category 3 only:** The pharmacy stocks low lint face and neck coverings that ensure no skin is exposed. ***Inspector note: This is an additional garbing requirement for facilities preparing any Category 3 CSPs.*** ***If the pharmacy does not prepare Category 3 CSPs, inspector should answer statement as N/A.***		
43.9	**Category 3 only:** The pharmacy stocks sterile, low lint outer garb (including sterile sleeves over gauntlet sleeves when a RABS is used). ***Inspector note: This is an additional garbing requirement for facilities preparing any Category 3 CSPs. If the pharmacy does not prepare Category 3 CSPs, inspector should answer statement as N/A.***		

Item#	Requirement	Yes/No/N/A	Comment
F	**Compounding Personal Hygiene and Garbing**		
43.10	**Category 3 only:** All non-disposable garb used to prepare Category 3 CSPs is **laundered and resterilized** with a validated cycle before each use. ***Document whether laundering and sterilization is performed in-house or by an outside vendor.*** ***If only disposable items are used, inspector should answer statement as N/A.***		
G	**Media-Fill**		
44.0	Is the media-fill testing simulation performed by the pharmacy in compliance with USP <797> standards? ***Inspector note: Per USP, "When performing a media-fill test, simulate the most difficult and challenging aseptic compounding procedures encountered by the person replacing all the components used in the CSPs with soybean-casein digest media. The simulation must capture elements that could potentially affect the sterility of the CSP."*** ***If no, go to compliance statements.***		
44.1	The simulation captures factors associated with the length of the process that can pose contamination risk (e.g., operator fatigue, quality of equipment).		
44.2	The simulation captures number of aseptic additions or transfers.		
44.3	The simulation captures number, type, and complexity of manipulations.		
44.4	The simulation captures number of personnel in the buffer room or SCA.		
44.5	Does the facility define "the most difficult and challenging procedures" and the rationale for how they are the most challenging? ***Inspector note: Best practice is for this to be documented in an SOP. Inspectors may also find this information documented on a training/competency assessment checklist. For complex/variety of compounding practices, inspectors may find additional media fills are completed (more than what is required by the USP chapters).***		
45.0	Are the pharmacy's media-fill storage, review, and preparation processes in compliance with USP <797> standards? ***If no, go to compliance statements.***		
45.1	If pharmacy uses commercial sterile microbial growth media, a COA was obtained. ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***		
45.2	The COA for the commercial sterile microbial growth media includes statements from the supplier that the lot of the growth media will support the growth of microorganisms. ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***		

Item#	Requirement	Yes/No/N/A	Comment
G	**Media-Fill**		
45.3	Storage of commercial sterile microbial growth media is in accordance with manufacturer instructions. ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***		
45.4	Commercial sterile microbial growth media is stored and used before its expiration date. ***Inspector note: Media is to be inoculated by the expiration date, meaning that the test needs to be started (not that incubation needs to be completed before the expiration date).*** ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***		
45.5	Sterile-to-sterile media-fill testing microbial growth media (non-commercial) was prepared and growth promotion capability was demonstrated prior to use, following USP <71>. ***If pharmacy only uses commercial sterile microbial growth media, inspector should answer statement as N/A.***		
45.6	Nonsterile starting components (commercially available nonsterile soybean-casein digest powder) are dissolved to make a 3% nonsterile solution, manipulated in a manner that simulates nonsterile-to-sterile compounding activities, with a minimum of one positive control container. ***If pharmacy does not perform sterile compounding using nonsterile ingredients, inspector should answer statement as N/A.***		
H	**Cleaning and Disinfection**		
46.0	Is the pharmacy equipped with the necessary cleaning and disinfecting equipment and supplies that comply with USP <797> standards?***If no, go to compliance statements.***		
46.1	All cleaning and disinfecting supplies (e.g., wipers, sponges, pads, and mop heads), except for tool handles and holders, are low lint.		
46.2	Reusable cleaning tools are made of cleanable materials (no wood handles or any other porous material).		
46.3	Reusable cleaning tools are dedicated for use in the classified areas or SCA and are not removed from these areas except for disposal.		

Item#	Requirement	Yes/No/N/A	Comment
H	**Cleaning and Disinfection**		
46.4	The pharmacy has the appropriate cleaners **EPA-registered disinfecting agent(s)** to adequately perform cleaning and disinfection. ***Inspector note: Examples of EPA-registered disinfectants include, but are not limited to: phenolics; oxidizers, such as peroxyacetic acid and sodium hypochlorite; quaternary ammonium; and hydrogen peroxide. If the agent is EPA-registered, a registration number will be on the label. Compounding personnel should have access to SDS and information/knowledge on dwell times. Per USP, Box 7, the pharmacy is to ensure the contact time specified by the manufacturer is achieved. Per USP, Inspector should check to see if agent is effective against Clostridium difficile.***		
46.5	The pharmacy has the appropriate **EPA-registered sporicidal agent(s)** to adequately perform sporicidal disinfection. ***Inspector notes: Examples of EPA-registered agents include but are not limited to: oxidizers such as peroxyacetic acid, sodium hypochlorite, and hydrogen peroxide.Compounding personnel should have access to SDS and information/knowledge on dwell times. Per USP, Box 8, the pharmacy is to ensure the contact time specified by the manufacturer is achieved.***		
46.6	All cleaning and disinfectant agents are appropriately labeled including expiration dates. ***Inspector should verify that no expired agents are present.***		
46.7	When used in the PEC, any cleaning and disinfecting agents that are not "ready-to-use" formulations are diluted using sterile water. ***If only ready-to-use formulations are used, inspector should answer statement as N/A.***		
47.0	Does the pharmacy's documented **cleaning and disinfection** activities for surfaces in the classified areas and/or SCA comply with the **frequencies** specified in USP <797> Table 10? ***Review cleaning logs to verify. If no, go to compliance statements.***		
47.1	All interior surfaces of the PEC are cleaned and disinfected on days when compounding occurs.		
47.2	All interior surfaces of the PEC are cleaned and disinfected when surface contamination is known or suspected.		
47.3	The removable work tray inside the PEC is cleaned and disinfected on days when compounding occurs. ***If the PEC is not equipped with a removeable work tray, inspector should answer statement as N/A.***		
47.4	All equipment inside the PEC is cleaned and disinfected on days when compounding occurs.		

Item#	Requirement	Yes/No/N/A	Comment
H	**Cleaning and Disinfection**		
47.5	All work surfaces outside of the PEC (e.g., counters, worktables) are cleaned and disinfected on days when compounding occurs.		
47.6	All pass-through chambers are cleaned and disinfected on days when compounding occurs. ***If the pharmacy is not equipped with a pass-through chamber, inspector should answer statement as N/A.***		
47.7	Floors in the buffer room, anteroom, and/or SCA are cleaned and disinfected on days when compounding occurs.		
47.8	Sinks used for hand hygiene are cleaned and disinfected on each day of use.		
47.9	Walls, doors, and door frames are cleaned and disinfected monthly.		
47.10	Storage and shelving bins are cleaned and disinfected monthly.		
47.11	All equipment outside the PEC is cleaned and disinfected monthly. ***Inspector note: Equipment in the SEC/SCA may include, but is not limited to: carts, refrigerators, computers, barcode readers, and label printers.***		
47.12	Ceilings in the buffer room and anteroom are cleaned and disinfected monthly.***If the pharmacy performs compounding only in a SCA, inspector should answer statement as N/A.***		
47.13	Ceilings in the SCA are required to be cleaned and disinfected only when visibly soiled and when surface contamination is suspected. ***If the pharmacy performs compounding only in a cleanroom suite, inspector should answer statement as N/A.***		
47.14	The surface of the removable work tray and the area underneath the removable work tray of the PEC is cleaned and disinfected monthly. ***If the PEC is not equipped with a removable work tray, inspector should answer statement as N/A.***		
48.0	Does the pharmacy's documented application of **sporicidal disinfectant** on surfaces comply with the **frequencies** specified for each CSP category in USP <797> Table 10? ***Inspector note: Per USP <797>, if the pharmacy prepares any Category 3 CSPs, the cleaning requirements for Category 3 must be always followed regardless of whether a Category 3 CSPs is prepared on any given day.*** ***Review cleaning logs to verify. If no, go to compliance statements.***		
48.1	**Sporicidal disinfectant** is applied to all interior surfaces of the **PEC** at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.***		

Item#	Requirement	Yes/No/N/A	Comment
H	**Cleaning and Disinfection**		
48.2	Sporicidal disinfectant is applied to equipment inside the PEC at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.***		
48.3	Sporicidal disinfectant is applied to work surfaces outside the PEC (e.g., counters, worktables) at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, application frequency is monthly. For any Category 3 compounding, application frequency is weekly.***		
48.4	Sporicidal disinfectant is applied to surfaces in the pass-through chambers at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.If the facility is not equipped with a pass-through chamber, inspector should answer statement as N/A.***		
48.5	Sporicidal disinfectant is applied to the floors in the buffer room, anteroom, and SCA at least monthly. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.***		
48.6	Sporicidal disinfectant is applied to walls, doors, and door frames at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***		
48.7	Sporicidal disinfectant is applied to storage shelving and bins at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***		
48.8	Sporicidal disinfectant is applied to equipment stored outside the PEC at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***		
48.9	Sporicidal disinfectant is applied to ceilings in the buffer room, anteroom, and SCA at least monthly. ***Inspector note: Per USP <797>, Table 10, the application frequency is monthly for all category types. Per USP, ceilings of the SCA are required to be cleaned, disinfected, and applied with sporicidal disinfectant only when visibly soiled and when surface contamination is suspected. The SCA may not have an accessible ceiling.***		
48.10	Sporicidal disinfectant is applied to sinks used for hand hygiene at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***		

Item#	Requirement	Yes/No/N/A	Comment
H	**Cleaning and Disinfection**		
48.11	Sporicidal disinfectant is applied to the work surface of the removable tray in the PEC and area underneath the removable work tray at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.*** ***If the PEC is not equipped with a removable work tray, inspector should answer statement as N/A.***		
I	**Components**		
49.0	Does the pharmacy compound CSPs using active pharmaceutical ingredients (APIs) and non-API components? ***Inspector note: Per USP <797>, non-API components may include pharmaceutical excipients, sterile containers, and container closure systems.*** ***If the pharmacy does not compound using API or non-API components, inspector should answer this question as N/A.***		
50.0	Is the pharmacy's selection of active API and non-API components in compliance with USP <797> standards? ***Verify by selecting products from the shelf of different suppliers and ask to see the COAs for those products. If no, go to compliance statements.***		
50.1	**APIs**: APIs used are compliant with the criteria in the USP–NF monograph, if one exists. ***If pharmacy does not compound CSPs that have a USP monograph, inspector should answer this statement as N/A.***		
50.2	**APIs:** All APIs used have a COA that includes the specifications (e.g., compendial requirements for quality) and that test results for the component show that the API meets expected quality.		
50.3	**APIs:** All APIs used are manufactured by an FDA-registered facility. ***Inspector note: This is a Federal Food, Drug, and Cosmetic Act, Section 503A, requirement as well. If the API comes from a repackager, the pharmacy must be able to confirm the manufacturer of the API was registered as an Establishment with FDA.***		
50.4	All **non-API components** comply with the criteria in the USP–NF monograph, if one exists.		
50.5	All **non-API components** are accompanied by documentation (e.g., COA, labeling) that includes the specifications and test results and shows that the component meets the specifications.		

Item#	Requirement	Yes/No/N/A	Comment
I	**Components**		
50.6	All **non-API components** used are manufactured by an FDA-registered facility. ***Inspector note: Per USP <797>, "If a component cannot be obtained from an FDA-registered facility, the designated person(s) must select an acceptable and reliable source (see USP <1197> Good Distribution Practices for Bulk Pharmaceutical Excipients). The compounding facility must establish the identity, strength, purity, and quality of the ingredients obtained from that supplier by reasonable means. Reasonable means may include but are not limited to visual inspections, evaluation of a COA supplied by the manufacturer, and/or verification by analytically testing a sample to determine conformance with the COA or other specifications."***		
51.0	Does the pharmacy have processes in place to evaluate API and non-API components upon receipt and before use in compliance with USP <797> standards? ***Inspector note: Non-API components may be defined as excipients, containers, and container closure systems.If no, go to compliance statements.If the pharmacy does not compound with API or other non-API components, inspector should answer question as N/A.***		
51.1	APIs or other components have been evaluated for use in sterile drug preparation. ***Inspector note: Per USP <797>, "Components labeled with 'not for pharmaceutical use,' 'not for injectable use,' 'not for human use' or an equivalent statement must not be used to compound for these purposes."*** ***If no, photograph and describe in the note's column. Request copies of the invoices for products with these types of labels.***		
51.2	Upon receipt of each lot of a component, personnel verify the labeling and condition of each component and examine the external packaging for evidence of deterioration and other aspects of unacceptable quality (e.g., outer packaging is damaged, temperature-sensing indicators show that the component has been exposed to excessive temperatures).		
51.3	Each lot of commercially available sterile, depyrogenated containers and container-closure systems are accompanied by a COA or other documentation showing conformance with established specifications for sterility and depyrogenation requirements.		
51.4	The date of receipt by the pharmacy is clearly marked on each API or component package that lacks a vendor expiration date and are assigned and labeled with an expiration date not to exceed one year after receipt by the pharmacy.		

Item#	Requirement	Yes/No/N/A	Comment
I	**Components**		
51.5	All components are reinspected before use. ***Inspector note: Per USP <797>, all packages must be inspected to detect container breaks, looseness of the cap or closure, and deviation from the expected appearance, aroma, and/or texture of the contents that might have occurred during storage. Sterile container closures are visually reinspected to ensure that they are free from defects that could compromise sterility and that they are otherwise suitable for their intended use.***		
51.6	Any component found to be of unacceptable quality upon receipt or reinspection prior to use is promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.		
51.7	Any other lots of that component from that vendor are examined to determine whether other lots have the same defect.		
J	**Equipment and Supplies**		
52.0	Is the pharmacy equipped with the appropriate supplies and equipment used for compounding in compliance with USP <797> standards? ***If no, go to compliance statements.***		
52.1	Supplies (e.g., beakers, utensils, needles, syringes, filters, and tubing sets) that contact components are not reactive, additive, sorptive, and do not alter the quality of sterile compounded preparation. ***Inspector note: The appropriate supplies are available as applicable to the type of CSPs prepared (e.g., non-PVC, silicone-free, able to withstand high heat, able to be sterilized).***		
52.2	Any supplies that are in direct contact with CSPs are sterile and/or depyrogenated.		
52.3	The equipment must be able to be cleaned using the required agents and tools without damaging the equipment and/or contaminating the compounded preparation. ***Inspector note: Equipment used in compounding are of suitable composition and the surfaces that contact components are not reactive or sorptive.***		
52.4	When nonsterile ingredients, products, components, or devices (e.g., non-sterile APIs and nonsterile vials and closures) are used for compounding, the pharmacy has the appropriate equipment to sterilize the finished product. Per USP, "Injectable compounded preparations that contain nonsterile components or that come into contact with nonsterile devices (e.g., containers, tubing) during any phase of the compounding procedure must be sterilized within 6 hours after completing the preparation to minimize the generation of bacterial endotoxins in CSPs." ***If the pharmacy does not perform compounding that requires sterilization, inspector should answer statement as N/A.***		

Item#	Requirement	Yes/No/N/A	Comment
J	**Equipment and Supplies**		
53.0	Does the pharmacy operate and maintain records for all equipment used for compounding in accordance with manufacturer specifications and USP <797> standards? ***If no, go to compliance statements.***		
53.1	Automated, mechanical, or electronic equipment (monitoring equipment, autoclaves, ovens, etc.) are periodically inspected and calibrated yearly or in accordance with the equipment manufacturer guidelines.		
53.2	Automated compounding devices (ACDs) and other similar equipment (single channel or multi-channel) are assessed for accuracy and calibrated daily, prior to initial use, and a daily record is maintained. ***Inspector note: Per USP, "The precision of the equipment can be monitored based on an assessment of day-to-day variations in its accuracy measures. Compounding personnel must maintain a daily record of the accuracy measurements on the days the equipment is in use. Corrective actions must be implemented if accuracy measurements are outside the manufacturer's specification."***		
53.3	Incubators used for environmental, and personnel monitoring are placed in a location outside of the sterile compounding area and calibrated in accordance with manufacturer's instructions. ***If the pharmacy does not incubate samples and or/media-fills in-house, inspector should answer statement as N/A.***		
53.4	Incubators used for environmental, and personnel monitoring are monitored for temperature during incubation periods either manually or by use of a continuous recording device. ***Inspector note: Incubators store media at 20˚C-25˚C and 30˚C-35˚C. If the pharmacy has more than one incubator, review records for both incubators.*** ***View incubator temperature records to verify. Evaluate the size of the incubator and volume of media it can store. If the pharmacy does not incubate samples and/or media-fills in-house, inspector should answer statement as N/A.***		
K	**Aseptic Processing**		
54.0	**Personnel Preparation Observation:** Before entering the compounding area, do compounding personnel remove any items that are not easily cleanable or are not necessary for compounding in compliance with USP <797> standards? ***If no, go to compliance statements.***		
54.1	All outer garments such as hats, scarves, sweaters, bandanas, vests, coats, and jackets are removed.		

Item#	Requirement	Yes/No/N/A	Comment
K	**Aseptic Processing**		
54.2	Makeup and/or cosmetics are removed.		
54.3	All hand, wrist, and other exposed jewelry, including piercings such as earrings, lip, or eyebrow piercings, etc., are removed and any jewelry that cannot be removed is covered.		
54.4	Earbuds or headphones are removed.		
54.5	Electronic devices that are not necessary for compounding or other required tasks are prohibited from entering the compounding areas.		
54.6	Nails are kept clean and neatly trimmed.		
54.7	Any nail polish, artificial nails, or extenders are removed.		
54.8	If worn, eyeglasses are wiped. ***If none of the pharmacy staff wear glasses, inspector should answer statement as N/A.***		
54.9	Any accommodations permitted by the designated person(s) has been documented. ***Inspector note: Per USP <797>, accommodations may be permitted if the quality of the CSP and environment will not be affected.***		
55.0	**Hand Hygiene Observation:** Were compounding personnel entering the compounding area observed performing the appropriate hand washing procedures in compliance with USP <797> standards? ***If no, go to compliance statements.***		
55.1	All personnel entering the compounding area performed hand hygiene.		
55.2	The order of hand washing was performed in the appropriate sequence in relation to the placement of the sink. ***Inspector note: If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb.***		
55.3	Fingernails are cleaned under warm running water using a disposable nail cleaner (e.g., nail pick). ***Inspector note: During observations, inspect whether nail picks are available for use when performing hand hygiene.***		
55.4	Brushes are not used for hand hygiene.		
55.5	Hands and forearms are washed up to the elbows with soap and warm water for at least 30 seconds. ***Inspector note: Compounding personnel describe method for ensuring they have washed for 30 seconds (example: clock or timer is available near the sink).***		
55.6	Soap containers are not refilled or topped off.		

Item#	Requirement	Yes/No/N/A	Comment
K	**Aseptic Processing**		
55.7	Hands and forearms are completely dried up to the elbows with low-lint disposable towels or wipers.		
55.8	Hand dryers are not used for hand hygiene.		
56.0	**Garbing Observation:** Were compounding personnel observed following the appropriate garbing procedures in compliance with USP <797> standards? ***If no, go to compliance statements.***		
56.1	All personnel entering the compounding area are fully garbed (with the required garb as determined by the facility SOPs).		
56.2	Compounding personnel entering the cleanroom suite and/or SCA adhere to the minimum garbing requirements in USP <797>. ***Inspector note: Per USP <797>, additional garbing requirements must be continuously met in the buffer room where Category 3 CSPs are prepared, regardless of whether Category 3 CSPs are compounded on a given day.***		
56.3	Donning procedures are performed in an order that reduces the risk of contamination. ***Inspector note: USP recommends (not requires) the donning procedure to be performed in the anteroom.*** ***If no, inspector must describe in the note's column why a risk of contamination is a concern.***		
56.4	Doffing procedures are performed in an order that reduces the risk of contamination.		
56.5	The order of garbing was performed in the appropriate sequence in relation to the placement of the sink. ***Inspector note: If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb.***		
56.6	Sterile gloves are donned in a classified room or SCA.		
56.7	Skin is not exposed inside the ISO Class 5 PEC.		
56.8	Garb is replaced immediately if it becomes visibly soiled or if its integrity is compromised.		
56.9	**Category 1 and Category 2 only:** Upon exit of the compounding area, all garb (except for gowns) is discarded or laundered prior to reuse. ***Inspector note: Gowns (disposable and non-disposable) may be reused within the same shift by the same person only if stored appropriately.*** ***If the facility prepares any Category 3 CSPs, additional garbing requirements must be followed and gowns must not be reused, inspector should answer statement as N/A.***		

Item#	Requirement	Yes/No/N/A	Comment
K	**Aseptic Processing**		
56.10	**Category 1 and Category 2 only:** Gowns reused within the same shift and by the same person are maintained in a manner that prevents contamination. ***Inspector note: Per USP <797>, gowns stored for reuse must be maintained in a classified area or adjacent to or within the SCA in a manner that prevents contamination (e.g., away from sinks to avoid splashing).If the facility prepares any Category 3 CSPs, additional garbing requirements must be followed and gowns must not be reused; inspector should answer statement as N/A.***		
57.0	List the name(s) of the CSPs observed by the inspector as part of live compounding demonstration.		
58.0	**Compounding Observation:** Are compounding personnel observed using the appropriate aseptic technique that ensures the quality of the CSP and the environment is maintained in compliance with USP <797> standards? ***If no, go to compliance statements.***		
58.1	All sterile compounding is performed in a PEC with ISO Class 5 conditions or better. ***If the pharmacy only performs immediate use compounding, inspector should answer this statement as N/A.***		
58.2	**Category 2 and Category 3 only:** All PECs are placed in a cleanroom suite. ***Inspector note: Per USP, "If compounding only Category 1 CSPs, the PEC may be placed in an unclassified SCA."If the pharmacy only prepares Category 1 CSPs, inspector should answer this statement as N/A.***		
58.3	Compounding personnel ascertain before use that components are of the correct identity, appropriate quality, within the expiration date, and have been stored under the proper conditions.		
58.4	All items are wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% IPA prior to being introduced into the clean side of the anteroom, placed into a pass-through chamber, and/or brought into the SCA. ***Inspector note: The wiping procedure or agents used should not compromise the packaging integrity or render the product label unreadable. Disinfectant dwell time minimums, as specified by the manufacturer, are to be followed.***		
58.5	Before any item is introduced into the PEC, it is wiped with sterile 70% IPA using sterile low-lint wipers and allowed to dry before use. ***Inspector note: Per USP, "When sterile items are received in sealed containers designed to keep them sterile until opening, the sterile items may be removed from the covering as the supplies are introduced into the ISO Class 5 PEC without the need to wipe the individual sterile supply items with sterile 70% IPA. The wiping procedure must not render the product label unreadable."***		

Item#	Requirement	Yes/No/N/A	Comment
K	**Aseptic Processing**		
58.6	Aseptic processes and manipulations are performed in a manner intended to minimize the risk of contamination. ***Inspector note: Observe the compounder's technique to ensure proper aseptic technique is utilized such as: preparation occurs in the direct compounding area (DCA); the compounder does not interrupt first air during the compounding process; proper set up of equipment, supplies, and components that ensure first air is not interrupted; the compounder handles the syringe in a manner that does not introduce contaminates (touch contamination on the plunger rod); proper entry and exit of materials in ISO Class 5 PEC; and frequent sanitization of gloves.***		
58.7	All critical sites (e.g., vial stoppers, ampule necks, and IV bag septum's) are wiped with sterile 70% IPA in the PEC and allowed to dry before puncturing.		
58.8	Gloves are disinfected with sterile 70% IPA immediately before compounding and regularly throughout the compounding process. ***Inspector note: Per USP, best practice is to re-sanitize each time hands re-enter the PEC. This may not occur when compounder is staging the next batch.***		
58.9	Gloves are regularly inspected for holes, punctures, or tears, and are replaced immediately if such defects are detected.		
59.0	Do compounding personnel adhere to the USP established time limits for components after initial puncture or entry in compliance with USP <797> standards? ***Look at punctured, stored containers and confirm if puncture time or BUD is noted on the container and stored within time limits. If no, go to compliance statements.***		
59.1	Single dose containers (entered or punctured only in an ISO Class 5 air or cleaner air) are not used beyond 12 hours after initial puncture or entry or assigned BUD, whichever is shorter. ***Inspector note: This applies to conventionally manufactured single-dose vials, compounded single-dose CSPs used as components, and CSP stock solutions. The labeled storage requirements during that 12-hour period must be maintained. Additionally, per USP, "This time limit for entering or puncturing (a single-dose CSP or CSP stock solution) is not intended to restrict the BUD of the final CSP."***		
59.2	Multiple-use containers are not used for more than 28 days after initial puncture or entry, manufacturer specifications, or assigned BUD, whichever is shorter. ***Inspector note: This applies to conventionally manufactured multiple-dose vials and compounded multiple-dose CSPs used as components. Multiple-dose CSPs are required to meet the criteria for antimicrobial effectiveness testing (USP <51>) and must be stored under the conditions upon which its BUD is based (e.g., refrigerator or controlled room temperature).***		

Item#	Requirement	Yes/No/N/A	Comment
K	**Aseptic Processing**		
59.3	The remaining contents of opened single-dose ampules (or vials where container closure system has been removed) are discarded immediately. ***Inspector note: Ampules or vials where the container closure system has been removed must not be stored for any time.***		
59.4	Pharmacy bulk package containers of sterile drugs for parenteral use are only entered or punctured in an ISO Class 5 PEC. ***Inspector note: Per USP, the pharmacy bulk package system must be used according to the manufacturer's labeling.***		
60.0	**Inspect several different finished compounded sterile preparations.** Are all the finished compounded sterile preparations free from any evidence of particulates, filaments, floaters, or signs of contamination? ***Inspector note: Additionally, list the name(s) of the compounded preparation(s) observed; description of type of contamination suspected (e.g., filament or floater); number of preparations affected (e.g., two of the five vials on the shelf); lot or batch information; BUD assigned; and collect photographs, copy of MFR, and CR.***		
61.0	Are there procedures for in-process checks performed by a pharmacist? ***Inspector note: In-process checks are safety steps for complex, multi-step compounding processes or high-risk drugs or high-risk populations (e.g., neonates). These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists and visual inspection of product. Documentation of the compounding accuracy is recommended to be performed by someone other than the compounder to ensure proper measurement, reconstitution, and component usage. Some checks may be done retrospectively and with the assistance of technology.***		
62.0	**Cleaning and Disinfection Observation:** Does the pharmacy perform cleaning and disinfection activities in compliance with USP <797> standards? ***If inspector is unable to observe cleaning activities (due to timing of compounding activities observed), inspector should interview compounder(s) to have them walk through their normal process. If this occurs, inspector should record in notes column "process only."*** ***If no, go to compliance statements.***		
62.1	All cleaning and disinfection activities are performed by appropriately garbed personnel.		
62.2	Cleaning and disinfection are performed on all surfaces in the classified area and SCA.		
62.3	Cleaning is performed in the direction of clean to dirty areas.		
62.4	Reusable cleaning tools are disinfected prior to and after each use.		

Item#	Requirement	Yes/No/N/A	Comment
K	**Aseptic Processing**		
62.5	Only sterile cleaning, disinfecting, and sporicidal agents are permitted for use in the PEC. ***Inspector note: If pharmacy utilizes non-ready to use (RTU) agents, they must be diluted with sterile water. Per USP, "Once opened, sterile cleaning and disinfecting agents and supplies (e.g., closed containers of sterile wipers) and sterile 70% IPA may be reused for a time period specified as by the manufacturer and/or described in the facility written SOPs."***		
62.6	Only sterile supplies and equipment are permitted for use in the PEC. ***Inspector notes: Non-disposable cleaning tools or handles must be properly disinfected prior to entering the PEC and prior to use.***		
62.7	Compounding personnel are using the appropriate sterile cleaning, disinfecting, and sporicidal agents within the PEC.		
62.8	Compounding personnel are using the appropriate cleaning and disinfecting procedures and techniques within the PEC. ***Inspector note: Per USP, "All cleaning, disinfecting, and application of sporicidal disinfectants must be documented according to the facility's SOPs"; "Cleaning must be performed in the direction of clean to dirty areas"; and when 70% sterile IPA is used, it is used last and allowed to dry. There are differing opinions on the best order of cleaning.*** ***Procedure includes using a sterile low-lint wiper to all surfaces. Allow surfaces to dry completely before beginning compounding.***		
62.9	The manufacturer's directions or published data for the minimum contact time is followed for each of the cleaning, disinfecting, and sporicidal disinfectant used.***Per USP, contact times should be included in the SOP based on the agent used.***		
62.10	Sterile 70% IPA is applied to all surfaces in the ISO Class 5 PEC at the frequencies specified by USP during active compounding. ***Inspector note: Per USP <797>, sterile 70% IPA must be applied: immediately before initiating compounding procedures, to the work surface of the PEC at least every 30 minutes (if the compounding process takes 30 minutes or less), to the work surface of the PEC immediately after compounding (when the compounding process takes more than 30 minutes), after each batch or lot is completed, and after cleaning and disinfecting.***		
L	**Sterilization and Depyrogenation**		
63.0	Does the pharmacy compound preparations with any nonsterile starting components?		

Item#	Requirement	Yes/No/N/A	Comment
L	**Sterilization and Depyrogenation**		
64.0	Are injectable compounded preparations that contain nonsterile components or that come into contact with nonsterile devices (e.g., containers, tubing) during any phase of the compounding procedure, sterilized within six hours after completing the preparation? ***If no, describe observations and collect a copy of the master formulation record, a copy of the compounding record, and a copy of the process for sterilization.If the pharmacy does not compound with nonsterile components or devices, or they only compound sterile ophthalmic and/or sterile drugs administered by inhalation, inspector should answer question as N/A.***		
65.0	**Filter Sterilization:** Does the pharmacy use the appropriate type of sterilization method, equipment, documentation, and testing in compliance with USP <797> standards? ***View compounding records for CSPs sterilized by filtration to verify.*** ***Inspector note: The sterilization method used must sterilize the CSP without degrading its physical and chemical stability (e.g., affecting its strength, purity, or quality) or the packaging integrity.*** ***If no, go to compliance statements.*** ***If the pharmacy does not use this sterilization method, inspector should answer question as N/A.***		
65.1	Sterilization by filtration is performed in an ISO 5 environment.		
65.2	Filters used have enough capacity to filter the required volumes. ***Inspector note: Per USP, "The filter dimensions and the CSP to be sterilized by filtration should permit the sterilization process to be completed without the need for replacement of the filter during the process."***		
65.3	The 0.2-micron sterile micro-porous membrane filter used to sterilize CSP solutions is chemically and physically compatible with the CSP. ***Inspector note: Per USP <797>, sterilizing filters must be appropriate for pharmaceutical use. Sterilizing filters labeled "for laboratory use" or equivalent must not be used. "Sterilizing filters must be certified by the manufacturer to retain at least 10^7 microorganisms of a strain of Brevundimonas diminuta per square centimeter of upstream filter surface area under conditions similar to those in which the CSPs will be filtered (i.e., pressure, flow rate, and volume filtered)."***		
65.4	Confirmation of filter integrity (bubble testing) is performed and documented for each filter used with each batch sterilized by filtration. ***Inspector note: If multiple filters are required for the compounding process, each of the filters must be tested.*** ***If no, collect a copy of the master formulation record and compounding record.***		

Item#	Requirement	Yes/No/N/A	Comment
L	**Sterilization and Depyrogenation**		
65.5	A prefiltration step is performed for any CSPs that are known to contain excessive particulate matter. ***Inspector note: The prefiltration step consists of using a filter with a larger nominal pore size (e.g., 1.2 micron) or a separate filter of larger nominal pore size should be placed upstream of (i.e., prior to) the sterilizing filter to remove gross particulate contaminants before the CSP is passed through the sterilizing-grade filter.***		
65.6	CSPs that are prepared using a filter that failed integrity tests are either discarded or, after investigating the cause of the failure and selection of an appropriate filter, refiltered for sterilization not more than one additional time. ***If no, collect a copy of the master formulation record and compounding record.***		
65.7	Single-use filters are only used once.		
66.0	**Steam Sterilization:** Does the pharmacy use the appropriate type of sterilization method, equipment (autoclave), documentation, and testing in compliance with USP <797> standards? ***Inspector note: The sterilization method used must sterilize the CSP without degrading its physical and chemical stability (e.g., affecting its strength, purity, or quality) or the packaging integrity.View documentation on compounding records for CSPs sterilized by steam to confirm. If no, go to compliance statements.If the pharmacy does not use this sterilization method, inspector should answer question as N/A.***		
66.1	The pharmacy has evaluated if steam sterilization would cause degradation of the drug. ***Inspector note: Per USP, compounded preparations that are degraded by moisture, pressure, or temperatures used may not be sterilized by steam heat.***		
66.2	Steam supplied is free of contaminants and generated using water per manufacturer's specifications.		
66.3	Solutions are passed through a 1.2 micron or smaller filter into the final containers to remove particulates before sterilization.		
66.4	Items are placed in the autoclave in a manner that allows steam to reach them without entrapment of air. ***Inspector note: The pharmacy should have the autoclave cycle validated for the size of the batch, sterilization temperature, and sterilization time to ensure the load will be sterile.***		
66.5	Sealed containers used can generate steam internally (e.g., small amount of water in empty crimped vials).		

Item#	Requirement	Yes/No/N/A	Comment
L	**Sterilization and Depyrogenation**		
66.6	The appropriate biological indicators (USP <1229>) are used to verify the effectiveness of each sterilization run or load and documented in the compounding record. ***Inspector note: Per USP <797>, "The effectiveness of steam sterilization must be verified and documented with each sterilization run or load by using appropriate biological indicators, such as spores of Geobacillus stearothermophilus (ATCC 12980, ATCC 7953, or equivalent; see Biological Indicators for Sterilization USP <1229.5>), and other confirmation methods such as physicochemical indicators (see Physicochemical Integrators and Indicators for Sterilization USP <1229.9>). The date, run, and load numbers of the steam sterilizer used to sterilize a CSP is documented in the compounding record."***		
66.7	All items are directly exposed to steam under adequate pressure for the length of time necessary as determined by use of appropriate biological indicators to render the items sterile. ***Inspector note: Per USP <797>, the duration of the exposure period must include sufficient time for the entire contents of the CSP and other items to reach the sterilizing temperature. The CSP and other items must remain at the sterilizing temperature for the duration of the sterilization period (an example provided in the chapter is 20-60 minutes at 121°C saturated steam under a pressure of 15 psi, depending on the volume or size of the CSP being sterilized). Any parameters for the autoclave must be set through validation.***		
66.8	A calibrated data recorder or chart is used to monitor each cycle and to examine for cycle irregularities (e.g., deviations in temperature or pressure) and results documented on the CR.		
67.0	**Dry Heat Sterilization:** Does the pharmacy use the appropriate type of sterilization method, equipment, documentation, and testing in compliance with USP <797> standards? ***Inspector note: The sterilization method used must sterilize the CSP without degrading its physical and chemical stability (e.g., affecting its strength, purity, or quality) or the packaging integrity. USP <1229.8> also applies.View documentation on compounding records for CSPs sterilized by dry heat to confirm. If no, go to compliance statements.If the pharmacy does not use this sterilization method, inspector should answer question as N/A.***		
67.1	The pharmacy has the appropriate dry heat sterilization equipment. ***Inspector note: Dry heat sterilization is usually performed in an oven designed for sterilization at 160°C or higher. The dry heat oven should be able to get to the appropriate temperature and pressure, for example, not be a toaster oven.***		
67.2	Solutions are passed through a 1.2 micron or smaller filter into the final containers to remove particulates before sterilization.		

Item#	Requirement	Yes/No/N/A	Comment
L	**Sterilization and Depyrogenation**		
67.3	During sterilization, sufficient space is left between materials to allow for circulation of hot air.		
67.4	CSPs and other items are exposed to dry heat for the length of time necessary for all items to reach sterilizing temperature of 160°C or higher. ***Inspector note: Per USP <797>, if lower temperatures are used, they are validated by biological indicators (see USP <1229.8>, Validation of Dry Heat Sterilization, Biological Indicators). The calibrated oven must be equipped with temperature controls and a timer.***		
67.5	The appropriate biological indicators are used to verify the effectiveness of each sterilization run or load and documented in the compounding record. ***Inspector note: Per USP <797>, "The effectiveness of dry heat sterilization must be verified and documented with each sterilization run or load by using appropriate biological indicators, such as spores of Bacillus atrophaeus (ATCC 9372; see Biological Indicators for Sterilization USP <1229.5>) and other confirmation methods (e.g., temperature-sensing devices). The date, run, and load numbers of the dry heat oven used to sterilize a CSP must be documented in the CR."***		
67.6	A calibrated data recorder or chart is used to monitor each cycle and the data is reviewed to identify cycle irregularities (e.g., deviations in temperature or exposure time) and results documented on the CR.		
68.0	**Dry Heat Depyrogenation:** Is the appropriate depyrogenation method used and documented in compliance with USP <797> standards? ***View documentation records of items depyrogenated to confirm.If the pharmacy does not use this method, inspector should answer question as N/A.***		
68.1	Glassware, metal, and other thermostable containers are exposed to dry heat for the length of time necessary for all items to be rendered pyrogen free.		
68.2	The effectiveness of the dry heat depyrogenation cycle is established and documented. ***Inspector note: Per USP <797>, this must be done initially, re-established any time there are changes made to the cycle (e.g., load conditions, duration, temperature), and verified at least annually by using endotoxin challenge vials (ECVs) to demonstrate that the cycle is capable of achieving a ≥ 3-log reduction in endotoxins (see Bacterial Endotoxins Test USP <85>). The verification must be documented.***		
68.3	Items that are not thermostable are depyrogenated by multiple rinses with sterile, nonpyrogenic water (e.g., sterile water for injection or sterile water for irrigation) and then thoroughly drained or dried immediately before use in compounding. ***Inspector note: USP <1228.4> Depyrogenation by Rinsing also applies.***		

Item#	Requirement	Yes/No/N/A	Comment
M	**Master Formulation and Compounding Records**		
69.0	Are **Master Formulation Records (MFRs)** created and maintained in compliance with USP <797> standards?		
69.1	The pharmacy creates and maintains MFRs for CSPs that are prepared for more than one patient.		
69.2	MFR changes and alterations are approved and documented according to the pharmacy's SOPs.		
69.3	The pharmacy creates and maintains MFRs for CSPs that are prepared from nonsterile ingredients.		
69.4	The MFR includes the name, strength or activity, and dosage form of the sterile compounded preparation.		
69.5	The MFR includes the identities and amounts of all ingredients.		
69.6	The MFR includes the type and size of container closure.		
69.7	The MFR includes complete instructions for preparing the sterile compounded preparation, including equipment, supplies, a description of the compounding steps, and any special precautions.		
69.8	The MFR includes a physical description of the final CSP.		
69.9	The MFR includes the BUD and storage requirements.		
69.10	The MFR includes the reference source to support the stability of the CSP.		
69.11	The MFR includes quality control procedures (e.g., pH testing, filter integrity testing).		
69.12	The MFR includes other information as needed to describe the compounding process and ensure repeatability (e.g., adjusting pH and tonicity, sterilization method).		
69.13	The MFR includes all required release tests, and if applicable, sterility test methods, process, number and endotoxin test and limits.		
70.0	Are **Compounding Records (CR)**[6] created and maintained in compliance with USP <797> standards? ***Inspector note: Per USP, a prescription or medication order or label may serve as the CR. Also, a copy of the MFR can be made that contains spaces for recording the information needed to complete the CR (e.g., both the MFR and CR are on the same document/form). A CR may be kept electronically, if readily retrievable, if it contains all required information.If no, go to compliance statements.***		

[6] **Compounding Records** - Each time it prepares a CSP, a pharmacy shall complete and maintain a compounding record that includes all elements as specified in the most recent version of USP and in M.G.L. c. 112, § 39D for "accountability documentation."

Item#	Requirement	Yes/No/N/A	Comment
M	**Master Formulation and Compounding Records**		
70.1	The pharmacy creates and maintains CRs for all for immediate-use CSPs prepared for more than one patient. ***Inspector note: if pharmacy does not prepare any CSPs for immediate-use, inspector should answer compliance statement as N/A.***		
70.2	The pharmacy creates and maintains CRs for all Category 1, Category 2, and Category 3 CSPs.		
70.3	The CR includes the name, strength or activity, dosage form of the CSP, and (if applicable) the MFR reference.		
70.4	The CR includes the date and time of preparation.		
70.5	The CR includes an assigned internal identification number (e.g., prescription, order, or lot number).		
70.6	The CR includes the identity of the individual(s) involved in the compounding process.		
70.7	The CR includes identity of the individual(s) verifying the final CSP.		
70.8	The CR includes the name of each component.		
70.9	The CR includes the vendor/manufacturer, lot number, and expiration date for each component. ***Inspector note: this is required for CSPs prepared for more than one patient and for CSPs prepared from nonsterile ingredient(s).***		
70.10	The CR includes the weight or volume of each component.		
70.11	The CR includes the strength or activity of each component.		
70.12	The CR includes the total quantity compounded.		
70.13	The CR includes the final yield (e.g., quantity, containers, number of units).		
70.14	The CR includes the assigned BUD and storage requirements.		
70.15	The CR includes results of quality-control procedures (e.g., visual inspection, filter integrity testing, pH testing).		
70.16	The CR includes calculations made to determine and verify quantities and/or concentrations of components. ***Inspector note: Per USP, "If applicable, the CR must also include…Calculations."***		
70.17	The CR is verified by the pharmacist for appropriateness and accuracy with in-process and final checks. ***Inspector note: "Documentation must comply with all laws and regulations of the applicable regulatory jurisdiction."***		

Item#	Requirement	Yes/No/N/A	Comment
N	**Labeling**		
71.0	Are the pharmacy's labels for CSPs in compliance with USP <797> standards and display all required information? ***If no, go to compliance statements.***		
71.1	Information on the label is prominently and legibly displayed. ***Inspector note: Definition of labeling includes other accompanying materials with the CSP, which includes, "written, printed, or graphic matter on the immediate container or on or inside any package or wrapper in which it is enclosed." The shipping container is not included in the definition of the "label."***		
71.2	Labeling meets any state or federal regulatory requirements.		
71.3	Labeling on the immediate container includes an assigned internal identification number (e.g., barcode, prescription, order, or lot number).		
71.4	Labeling on the immediate container includes the active ingredients and their amounts, activity, or concentration.		
71.5	Labeling on the immediate container includes the storage conditions, if other than controlled room temperature.		
71.6	Labeling on the immediate container includes the BUD. Per USP, "Each CSP label must state the date, or the hour and date, beyond which the preparation must not be used and must be discarded (i.e., the BUD)."		
71.7	The compounded CSP label does not use the term "expiration date" or equivalent.		
71.8	Labeling on the immediate container includes the dosage form.		
71.9	Labeling on the immediate container includes the total amount or volume when not obvious from the container.		
71.10	Labeling on the immediate container states that the CSP is a single-dose container (when space permits).		
71.11	Labeling on the immediate container states that the CSP is a multiple-dose container.		
71.12	Labeling includes the route of administration, as applicable.		
71.13	Labeling includes any special handling instructions and/or warning statements, as applicable.		
71.14	Labeling includes the compounding facility name and contact information if the CSP is to be sent outside of the facility or health care system in which it was compounded.		
72.0	Does the label contain information identifying the CSP is a compounded preparation? ***Inspector note: Per USP, this is a recommendation/should.***[7]		***Required: MA M.G.L. c94c s21***

[7] **M.G.L c94c s21. Labeling Requirement -** All drug preparations compounded, made or formulated by a pharmacy licensed by the board of registration in pharmacy shall have affixed to their container by the compounding pharmacy a label notifying prescribed users and practitioners that the drug is a sterile compounded drug preparation. Phone number of compounding pharmacy must be on label.

Item#	Requirement	Yes/No/N/A	Comment
O	**Establishing BUDs**		
73.0	**Category 1 and Category 2 CSPs:** Does the pharmacy assign BUDs for Category 1 and Category 2 CSPs in compliance with USP <797> standards? ***If no, go to compliance statements.***		
73.1	The assigned BUD does not exceed the shortest expiration date of any of the individual commercially available starting components.		
73.2	When assigning BUDs, the pharmacy ensures that the CSP formulation remains chemically and physically stable and that its packaging maintains its integrity for the duration of the assigned BUD.		
73.3	**Category 1 CSPs:** BUDs for **Category 1 CSPs** prepared in an SCA do not exceed the limits established in Table 12. ***Inspector note: Per USP <797> Table 12, BUD maximum limits for Category 1 CSPs are defined as 12 hours at controlled room temperature (CRT 20°C-25°C) or 24 hours refrigerated (2°C-8°C).*** ***If no Category 1 CSPs are prepared, inspector should answer statement as N/A.***		
73.4	**Category 2 CSPs:** BUDs for **aseptically processed (by filtration) Category 2 CSPs** that **do not** undergo sterility testing do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for aseptically processed Category 2 CSPs using one or more nonsterile starting components are defined as: one day CRT; four days refrigerator; and 45 days freezer. Aseptically processed Category 2 CSPs using only sterile starting components are defined as: four days CRT; 10 days refrigerator; and 45 days freezer.*** ***If no aseptically processed Category 2 CSPs are prepared, inspector should answer statement as N/A.***		
73.5	**Category 2 CSPs:** BUDs for **aseptically processed (by filtration) Category 2 CSPs** where **sterility testing and endotoxin testing (if applicable) are performed** and passed do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for aseptically processed Category 2 CSPs, that were sterility tested and passed, regardless of starting components being sterile or nonsterile, are defined as: 30 days CRT; 45 days refrigerator; and 60 days freezer.If no aseptically processed Category 2 CSPs are prepared, inspector should answer statement as N/A.***		

Item#	Requirement	Yes/No/N/A	Comment
O	**Establishing BUDs**		
73.6	**Category 2 CSPs:** BUDs for **terminally sterilized Category 2 CSPs** that **do not** undergo sterility testing do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for terminally sterilized to probability of nonsterile unit (PNSU) of 10^{-6} (e.g., dry heat, steam, irradiation) Category 2 CSPs are defined as: 14 days CRT; 28 days refrigerator; and 45 days freezer.*** ***If no terminally sterilized Category 2 CSPs are prepared, inspector should answer statement as N/A.***		
73.7	**Category 2 CSPs:** BUDs for **terminally sterilized Category 2 CSPs** where **sterility testing and endotoxin testing (if applicable) are performed** and passed do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for terminally sterilized to PNSU of 10^{-6} (e.g., dry heat, steam, irradiation) Category 2 CSPs are defined as: 45 days CRT; 60 days refrigerator; and 90 days freezer. Endotoxin testing is required for Category 2 injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility testing. USP <797> recommends that all injectable Category 2 CSPs made from one or more nonsterile components are also endotoxin tested.If no terminally sterilized Category 2 CSPs are prepared, inspector should answer statement as N/A.***		
74.0	Does the pharmacy ensure the assigned BUD does not exceed the shortest beyond use date of any individual compounded components? ***Inspector note: Per USP, "the BUD should generally not exceed the shortest BUD of any of the individual compounded components. However, there may be acceptable instances when the BUD of the final CSP exceeds the BUD assigned to compounded components (e.g., pH-altering solutions). If the assigned BUD of the final CSP exceeds the BUD of the compounded components, the physical, chemical, and microbiological quality of the final CSP must not be negatively impacted." Other examples where this may occur: formula within a formula, preservative-free compounded component used in a preserved final CSP, "in-use" times for pharmacy bulk packages, and cyclosporine ophthalmic stock solution.If no, inspector should describe the observations, including the name of the component whose BUD was shorter than the assigned BUD of the final CSP.***		
75.0	Are BUDs for **Category 3 CSPs** assigned in compliance with all conditions outlined in USP <797> standards and do not exceed the maximum limits established in Table 14? ***Inspector note: If all of the conditions described for Category 3 CSPs are not met, the applicable BUD must not exceed the established maximum limits in Table 13 for Category 2 CSPs.If no, go to compliance statements.If the pharmacy does not prepare Category 3 CSPs, inspector should answer question as N/A.***		

Item#	Requirement	Yes/No/N/A	Comment
O	**Establishing BUDs**		
75.1	The assigned BUD does not exceed the shortest expiration date of any of the individual starting components.		
75.2	When assigning BUDs, the pharmacy ensures that the CSP formulation remains chemically and physically stable and its packaging maintains its integrity for the duration of the assigned BUD.		
75.3	BUDs for **Category 3 CSPs** do not exceed the maximum limits for aseptically processed (e.g., filtered) established in Table 14. ***Inspector note: Per USP <797> Table 14, BUD maximum limits for aseptically processed Category 3 CSPs where sterility testing (and endotoxin testing, if applicable) had been performed and passed are defined as: 60 days CRT; 90 days refrigerator; and 120 days frozen.***		
75.4	BUDs for **Category 3 CSPs** do not exceed the maximum limits for terminally sterilized established in Table 14. ***Inspector note: Per USP <797> Table 14, BUD maximum limits terminally sterilized Category 3 CSPs where sterility testing (and endotoxin testing, if applicable) had been performed and passed are defined as: 90 days CRT; 120 days refrigerator; and 180 days frozen.***		
75.5	**Category 3 CSPs** are supported by stability data obtained using methods described in USP <1225> or a validated noninferior stability-indicating analytical method. ***Inspector note: Per USP <797>, Category 3 CSPs must prepared according to the EXACT formulation (API and other ingredients of identical grade and procedures) from which the stability data is derived. Category 3 CSPs must be packaged and stored in container closure of the same materials of composition as used in study and the facility must have documentation of the stability study.*** ***View records to verify the preparation exactly matches the preparation cited in the documentation including concentration of all active ingredients, excipients, etc.***		
75.6	**Category 3 CSPs** undergo sterility testing. ***Inspector note: Sterility testing is performed on all Category 3 CSPs.***		
75.7	**Category 3 CSPs** undergo bacterial endotoxin testing. ***If all compounds prepared are ophthalmics and/or drug administered by inhalation, bacterial endotoxin is not required, inspector should answer statement as N/A.***		
75.8	**Category 3 CSPs** undergo particulate matter testing. ***Inspector note: If the Category 3 CSP is an injection or an ophthalmic solution, particulate matter testing is also conducted once per formulation with acceptable results (See USP <788> Particulate Matter in Injections and USP <789> Particulate Matter in Ophthalmic Solutions).***		

Item#	Requirement	Yes/No/N/A	Comment
O	**Establishing BUDs**		
75.9	**Category 3 CSPs** undergo an evaluation for the container closure system. ***Inspector note: The container closure system used is evaluated for and conforms to container closure integrity to the end of the BUD (see USP <1207> Package Integrity Evaluation— Sterile Products). Evaluation must be done once for each formulation and for each container closure system in which it will be packaged.***		
76.0	Are **multiple-dose CSPs prepared** in compliance with USP <797> standards? ***If no, go to compliance statements.*** ***If the pharmacy does not prepare multiple-dose CSPs, inspector should answer question as N/A.***		
76.1	Multiple-dose CSPs are prepared as a Category 2 or Category 3 CSP only.		
76.2	When preservatives are used, they are appropriate for the CSP formulation and the route of administration. **Inspector note: Per USP <797>, "The preservative must not be inactivated by any ingredients in the CSP, and some preservatives are not always appropriate for the patient (e.g., neonates) or route of administration (e.g., intrathecal or ophthalmic injection)."**		
76.3	Aqueous multiple-dose CSPs pass antimicrobial effectiveness testing in accordance with USP <51>. ***Inspector note: Per USP <797>, a test can be one test done for each formulation in the particular container-closure system in which it will be packaged, or test results provided by an FDA-registered facility or in appropriate peer-reviewed literature,, provided the sterile compounded preparation formulation and container-closure system used are exactly the same as those tested, unless a bracketing study is performed. The concentration of all other ingredients (including preservatives) must be the same throughout the bracketing study.*** ***Additionally, multiple-dose, non-preserved, aqueous topical, and topical ophthalmic CSPs prepared as a Category 2 or Category 3 CSP are not required to pass antimicrobial effectiveness testing if the preparation is: For use by a single patient, labeled (in the label or labeling) to indicate that, once opened, it must be discarded after 24 hours when stored at controlled room temperature and/or that, once opened, it must be discarded after 72 hours when stored under refrigeration.***		

Item#	Requirement	Yes/No/N/A	Comment
O	**Establishing BUDs**		
76.4	Multiple-dose CSPs are labeled to indicate the beyond use date of the CSP once it is opened or punctured. ***Inspector note: Labeling on the CSP should indicate that once the CSP container is entered or punctured, it must not be used for longer than the assigned BUD or 28 days (if supported by antimicrobial effectiveness testing results), whichever is shorter.Inspector should review the CR or final compounded preparation to verify the label contains this information.***		
76.5	Container-closure systems used are evaluated for maintaining integrity (USP <1207>) for each formulation and fill volume. ***Inspector note: Per USP <797>, the container closure integrity test needs to be conducted only once on each formulation and on fill volume in the container closure system in which the multiple-dose CSP will be packaged.***		
P	**Finished Preparation Release Checks and Tests**		
77.0	Are all CSPs visually inspected for quality prior to release or dispensing in compliance with USP <797> standards? ***If no, go to compliance statements.***		
77.1	The CSP label is visually inspected to confirm that the CSP and its labeling match the prescription or medication order.		
77.2	CSPs are visually inspected for quality characteristics such as discoloration, visible particulates, or cloudiness.		
77.3	CSPs are visually inspected to verify container closure integrity (e.g., checking for leakage, cracks in the container, or improper seals).		
77.4	A visual inspection is also repeated prior to release or dispense for CSPs that have been stored in the pharmacy and not released or dispensed on the day of preparation.		
77.5	Any CSPs found to be of unacceptable quality (e.g., observed defects) are promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.		
78.0	For any CSPs assigned beyond use dates that require sterility testing, does the pharmacy ensure that all testing is performed, evaluated, and documented in accordance with USP <71> or a validated alternative method that is noninferior to USP <71> testing and USP <797> standards? ***Inspector note: Alternative testing methods may not be accepted in all regulatory jurisdictions that the pharmacy conducts business. If no, go to compliance statements.If the pharmacy does not prepare any CSPs that require sterility testing, inspector should mark as N/A.***		

Item#	Requirement	Yes/No/N/A	Comment
P	**Finished Preparation Release Checks and Tests**		
78.1	The required number of sterile compounded preparation units, as described in USP <71> and USP <797>, are tested. ***Inspector note: Per USP <71> Table 3, the minimum number of items to be tested for each medium is:Parenterals**Not more than 100 containers = 10% or four containers, whichever is greater**More than 100, but not more than 250 containers = 10 containers*** ***Large volume parenterals**2% or 10 containers, whichever is less* ***Non-parenterals (eye drops, inhalation, pellets, etc.)**Not more than 200 containers = 5% or two containers, whichever is greater More than 200, but not more than 250 containers = 10 containers Per USP <797>, if the number of CSPs compounded in a single batch is less than what is needed for testing as specified in USP <71> Table 3, additional units must be compounded to be able to perform testing as follows:*If 1-39 CSPs are compounded in a single batch, the sterility testing must be performed on a number of units equal to 10% of the number of CSPs prepared, rounded up to the next whole number. *If more than 40 CSPs are prepared in a single batch, the sample sizes specified in USP <71> Table 3 must be used.***		
78.2	Batch sizes of sterile CSPs do not exceed 250. ***Inspector Note: Per USP <797>, the maximum batch size for all sterile compounded preparation requiring sterility testing is limited to 250 final yield units.***		
78.3	Pharmacy is utilizing an alternative method for sterility assurance testing (other than USP <71>). ***Inspector note: Per USP, "If an alternative method is used for sterility testing, the method must be validated (see USP <1223>) and demonstrated to be suitable for that CSP formulation."*** ***If an alternative method is used, describe the method used and how the pharmacy ensures they are compliant with state-specific regulations.***		
78.4	When sterility testing identifies a failure, the pharmacy has processes to investigate and identify any contributing factors. ***Inspector note: Per USP, "Sterility tests resulting in failures must prompt an investigation into the possible causes and must include identification of the microorganism, as well as an evaluation of the sterility testing procedure, compounding facility, process, and/or personnel that may have contributed to the failure. The source(s) of the contamination, if identified, must be corrected, and the facility must determine whether the conditions causing the sterility failure affect other CSPs. The investigation and resulting corrective actions must be documented."Additionally, some rapid sterility test methods do not allow for the identification of the recovered microorganisms. If one of these methods is used, the pharmacy is not in compliance with the chapter, as the investigation must include identification of the recovered microorganism.***		

Item#	Requirement	Yes/No/N/A	Comment
P	**Finished Preparation Release Checks and Tests**		
79.0	For any CSPs assigned BUDs that require **bacterial endotoxin testing**, does the pharmacy ensure that all testing is performed and documented in compliance with USP <85> and USP <797> standards? ***Inspector note: Endotoxin limits reflect limits in an official monograph, or calculated as described in USP Chapter <85> for the route of administration for humans, and for animals based on weight.Although USP <797> refers to USP <85> Bacterial Endotoxins Test for calculating endotoxin limits for the appropriate route of administration, it does not address products administered epidurally or administered directly into the central nervous system. CSPs administered epidurally should have the same endotoxin limit as that of intrathecally administered CSPs.If no, go to compliance statements.If the pharmacy does not prepare CSPs that require bacterial endotoxin testing, inspector should answer question as N/A.***		
79.1	The pharmacy has an appropriate procedure for calculating/determining endotoxin limits. ***Per USP, there are endotoxin limits listed in USP product and compounded preparation monographs. The laboratory may be performing the calculation rather than the pharmacy; however, if done in house, this should be included in the pharmacy SOPs.*** ***If the dosage form does not require, inspector should answer statement as N/A.***		
79.2	The pharmacy collects patient weight to make bacterial endotoxin calculation for an animal patient. ***If the dosage form does not require or the pharmacy does not compound sterile preparations for animals, inspector should answer statement as N/A.***		
79.3	Bacterial endotoxins testing (USP <85>) is performed on all **injectable Category 2 CSPs** compounded from one or more nonsterile components that are assigned a BUD requiring sterility testing per Table 13. ***Inspector note: USP <797> recommends that all injectable Category 2 CSPs made from one or more nonsterile components is also endotoxin tested.***		
79.4	Bacterial endotoxins testing (USP <85>) is performed on all **injectable Category 3 CSPs** compounded from one or more nonsterile components.		
79.5	Any CSPs with failed endotoxin testing are quarantined, not further released, and action is taken for any product released prior to receipt of failed test results. ***View testing records and note any products with failed results and actions taken.***		
Q	**CSP Packaging, Shipping and Transport**		
80.0	Are processes and techniques for packaging and transporting CSPs in compliance with USP <797> standards?***If no, go to compliance statements.***		
80.1	The pharmacy uses the appropriate shipping containers and packaging materials (e.g., coolers and light-resistant packaging) based on the product specifications.		

Item#	Requirement	Yes/No/N/A	Comment
Q	**CSP Packaging, Shipping and Transport**		
80.2	CSPs are appropriately packaged to protect against damage, leakage, contamination, degradation, and adsorption during storage and transport. ***Inspector should look at packaging materials used to ensure cushioning to prevent breakage of glass vials and ensure that container is generally clean without non-microbial growth that would come in direct contact with CSPs.***		
80.3	Specific handling instructions when applicable, are included on the exterior of the container.		
80.4	The pharmacy selects transport modes that ensure CSPs are delivered properly in undamaged, sterile, and stable conditions (e.g., no undue exposure to heat, cold, or light). ***Inspector note: Transport modes include pneumatic tube transport systems and should not be used if the CSP is sensitive to shaking.***		
R	**Quality Assurance and Quality Control**[8]		
81.0	**Quality Assurance and Quality Control (QA/QC):** Does the pharmacy's SOP on quality assurance and quality control meet the requirements in compliance with USP <797> standards? ***If no, go to compliance statements.***		
81.1	Description of procedures for complaint handling, adverse events, and recalls that include corrective action, investigation, reporting, and documentation requirements.		
81.2	**QA/QC Out-Of-Specification (OOS) SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to determine the severity of the problem and the urgency for implementation and completion of the recall.		
81.3	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to determine the distribution of any affected CSP, including the date and quantity of distribution.		
81.4	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to identify patients who have received the CSP.		
81.5	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process for the disposal and documentation of the recalled CSP.		
81.6	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to investigate and document the reason for failure.		
82.0	Does the pharmacy ensure that QA and QC programs are conducted in compliance with USP <797> standards? ***If no, go to compliance statements.***		

[8] **Defective Drug Preparation Log:** Per M.G.L. c. 112, § 39D(e), a pharmacy that is licensed with the Board has a legal responsibility to recall a compounded drug preparation if it knows or should have reason to know that a compounded drug preparation dispensed or distributed into, within, or from Massachusetts by the pharmacy is or may be defective in any way.

Item#	Requirement	Yes/No/N/A	Comment
R	**Quality Assurance and Quality Control**		
82.1	The pharmacy has a formal QA/QC program with documented activities. ***Inspector note: Per USP, "Designated person(s) must ensure that the facility has formal, written QA and QC programs that establish a system of: adherence to procedures; prevention and detection of errors and other quality problems; evaluation of complaints and adverse events; and appropriate investigations and corrective actions."***		
82.2	The pharmacy's QA/QC program is reviewed at least once every 12 months by the designated person(s) and the results of the review are documented.		
82.3	The designated person(s) reviews all complaints to determine whether the complaint indicates a potential quality problem with the CSP.		
82.4	All complaints and adverse events are thoroughly investigated. ***Inspector note: Per USP <797>, the timeframe is specified in the facility SOP. Additionally, USP states, "The investigation must consider whether the quality problem extends to other CSPs."If facility SOP permits a long investigation period, include in the inspector notes the SOP's expected time frame to complete an investigation. State may have a more aggressive time frame to complete an investigation and report quality events to the state.***		
82.5	The record of each complaint is maintained by the pharmacy regardless of the source of the complaint (e.g., email, telephone, or mail) and includes the minimum required information. ***Inspector note: Per USP <797>, the complaint record must contain the following information:-Name of the complainant or other unique identifier;-Date the complaint was received;-Nature of the complaint;-The response to the complaint; and-Results of any investigation and any follow-up. In addition, to the extent that the information is known, the following should be recorded:-The name and strength of the CSP and the assigned internal identification number (e.g., prescription, order, or lot number).If no, inspector should document what is missing in the notes column.***		
82.6	The pharmacy's QA/QC program includes documentation of steps necessary for completing a recall, including reporting the recall to appropriate regulatory agencies. ***Inspector note: Per USP, "The recall must be reported to appropriate regulatory bodies as required by laws and regulations of the applicable regulatory jurisdiction."***		
83.0	If a CSP is dispensed or administered **before the results of release testing are known**, does the pharmacy ensure procedures for recalls and out-of-specification notifications are conducted and documented in compliance with USP <797> standards? ***Inspector note: Per USP <797>, if a CSP is dispensed or administered before the results of release testing are known, the facility must have procedures in place to notify, recall, and investigate.If no, go to compliance statements.***		

Item#	Requirement	Yes/No/N/A	Comment
R	**Quality Assurance and Quality Control**		
83.1	The pharmacy has a process in place to immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (e.g., sterility, strength, purity, bacterial endotoxin, or other quality attributes).		
83.2	The pharmacy has a process in place to recall any unused dispensed CSPs and quarantine any stock remaining in the pharmacy.		
83.3	The pharmacy has a process in place to investigate if other lots are affected and recall if necessary.		
S	**Personnel Training and Evaluation**		
84.0	Is the pharmacy's documented hand hygiene and garbing competency evaluations compliant with USP <797> standards? ***Inspector note: Only "No" or "Missing" documents would cause this question to be answered no.If no, refer to the records review worksheet (columns G-J) for details.***		
85.0	Is the pharmacy's documented aseptic manipulation competency evaluation compliant with USP <797> standards? ***Inspector note: Only "No" or "Missing" documents would cause this question to be answered no.*** ***If no, refer to the records review worksheet (columns K-O) for details.***		
86.0	Is the pharmacy's documented training program and ongoing competency evaluation compliant with USP <797> standards? ***Inspector note: Only "No" or "Missing" documents would cause this question to be answered no.*** ***If no, refer to the records review worksheet (columns P-S) for details.***		

797 Comments:

Item #	Requirement	Yes/No/N/A	Comment
AA	**General Information[9]**		
HD 1.00	Does the pharmacy handle any drugs on the National Institute for Occupational Safety and Health (NIOSH) list that require all the containment requirements of USP?		
HD 1.01	Does the pharmacy handle any hazardous drug active pharmaceutical ingredients (HD API)? If yes, please list.		
HD 1.02	Does the pharmacy handle any antineoplastic requiring manipulations (which can produce particles, aerosols, or gases)? If yes, please list.		
HD 2.00	Does the pharmacy handle any drugs on the NIOSH list that do not require all containment requirements of?		
HD 2.01	Does the pharmacy handle any final dosage forms of HDs (either compounded or manufactured unless required by the manufacturer) that do not require further manipulation other than counting and repackaging? If yes, please list.		
HD 2.02	Does the pharmacy handle any dosage forms of other HDs that are handled in full compliance with containment requirements of? If yes, please list.		
HD 2.03	Does the pharmacy handle any dosage forms of other HDs that are not handled using all containment requirements of? If yes, please list.		
HD 3.00	The pharmacy maintains a list of any items it handles that are included on the current NIOSH list of antineoplastic and other HDs.		
HD 4.00	The pharmacy reviews this list at least every 12 months for additions, deletions, or other changes and documents the review.		
HD 5.00	The pharmacy reviews this list whenever the pharmacy adds a new agent or dosage form to the items it handles.		
HD 6.00	The pharmacy has a system in place for the evaluation of new drugs (purchased, stored, handled, and/or dispensed) to determine whether they are considered HD.		
HD 6.01	Pharmacy evaluates the drugs against the current version of the NIOSH list.		
HD 6.02	In the absence of information, the pharmacy treats any new drug as an HD.		
HD 7.00	If the pharmacy handles any HDs not using all containment requirements of, an assessment of risk was performed for each drug and dosage form individually to determine alternative containment strategies, if needed, and work practices for each. Review documentation of assessment and SOPs related to work practices/alternative containment.		

[9] 247 CMR 17.03 (8)– Sterile compounding DRAFT regulations approved by Board of Registration in Pharmacy. A pharmacy may not compound non-sterile preparations in any Primary Engineering Control (PEC) or Secondary Engineering Control (SEC) used for sterile compounding. Pharmacy to assess current operations with draft regulations. https://www.mass.gov/lists/draft-regulations-for-the-board-of-registration-in-pharmacy (last accessed 12/20/2023)

Item #	Requirement	Yes/No/N/A	Comment
AA	**General Information**		
HD 8.00	The assessment of risk evaluation performed by the pharmacy's organization includes all required information, for each drug and dosage form. The first five (5) items below must be included in the evaluation to be compliant.		
HD 8.01	Type of HD (e.g., antineoplastic, non-antineoplastic, reproductive risk only);		
HD 8.02	Dosage form;		
HD 8.03	Risk of exposure;		
HD 8.04	Packaging;		
HD 8.05	Manipulation; and		
HD 8.06	If applicable, Table II and III drugs have alternative containment strategies and/or work practices to minimize occupational exposure.		
HD 8.07	The assessment of risk is reviewed at least every 12 months, and the review is documented. Enter date of last review in the notes.		
HD 9.00	The pharmacy has a designated person(s) to oversee the handling of HDs who is qualified and trained for development of standard operating procedures (SOPs); overseeing compliance with standards, laws, and rules; ensuring competency of personnel; and ensuring environmental control.		
HD 9.01	The designated person oversees the monitoring of the facility, including testing/sampling programs, maintaining, and documentation, and acting on results.		
HD 10.00	The assessment of risk and SOPs for handling HDs addresses all potential types of exposure, including all activities occurring within the operation that present an opportunity for exposure:		
HD 10.01	Receiving: Contacting HD residues on packaging, work surfaces, floors		
HD 10.02	Dispensing: Counting or packaging tablets and capsules		
HD 10.03	Compounding/other manipulations: Crushing/splitting tablets, opening capsules, pouring liquids, weighing, or mixing, constituting/reconstituting powdered/lyophilized HDs, expelling air from HD syringes, HD residue on personal protective equipment (PPE), cleaning activities of HD areas, and HD equipment maintenance.		
HD 10.04	Administration and other patient care activities (if applicable).		
HD 10.05	Spills: Spill generation, management, and disposal.		
HD 10.06	Transport		
HD 10.07	Waste: Collection and disposal of HD waste and trace contaminated waste		

Item #	Requirement	Yes/No/N/A	Comment
BB	**Standard Operating Procedures**		
HD 11.00	SOPs are reviewed at least every 12 months by the designated person, and the review is documented		
HD 12.00	SOPs are readily available to all who may need to handle HD or respond to a spill (pharmacy employees, housekeeping, nursing personnel, delivery personnel, etc.). Describe whether P&Ps are available electronically, by paper, or both.		
HD 13.00	SOPs address at a minimum:		
HD 13.02	Competent personnel		
HD 13.03	Occupational safety program		
HD 13.04	Designation of HD areas		
HD 13.05	Receiving HDs, including handling of damaged shipping containers/breakages		
HD 13.06	A list of HDs		
HD 13.07	Storage of HDs		
HD 13.08	Compounding of HDs		
HD 13.09	Use and maintenance of proper engineering controls (e.g., containment primary engineering control [C-PECs], containment secondary engineering control [C-SECs], and closed system drug transfer device [CSTDs]) to include SOPs for repairs, loss of power, moving, etc.		
HD 13.10	Hand hygiene and proper use of appropriate PPE based on activity (e.g., receipt, transport, compounding, administration, spill, disposal).		
HD 13.11	Deactivation, decontamination, cleaning, disinfection SOPs include all the following		
HD 13.11.01	Agents used		
HD 13.11.02	Dilutions, if used		
HD 13.11.03	Frequency		
HD 13.11.04	PPE to be worn (appropriate PPE resistant to the agents used, two pairs of chemotherapy gloves, impermeable disposable gowns, and eye, face, and respiratory protection if warranted--addressed in SOPs)		
HD 13.11.05	Documentation requirements		
HD 13.12	Receiving SOPs to include communications with suppliers about packaging and visual/other inspection of shipping containers for signs of damage and how to handle damaged containers.		
HD 13.13	If a shipping container appears damaged and does not need to be opened:		
HD 13.13.01	It is sealed without opening and wrapped in impervious plastic;		
HD 13.13.02	Labeled as "hazardous"; and		
HD 13.03.03	Returned to the supplier after contacting the supplier or disposed of as hazardous waste if supplier declines return.		
HD 13.14	If a damaged shipping container must be opened:		

Item #	Requirement	Yes/No/N/A	Comment
BB	**Standard Operating Procedures**		
HD 13.14.01	Container is sealed in plastic or an impervious container		
HD 13.14.02	It is transported to the C-PEC before opening, preferably nonsterile compounding C-PEC, if available;		
HD 13.14.03	container is placed on a plastic-backed preparation mat;		
HD 13.14.04	It is opened and undamaged items are removed and wiped down with a disposable wipe;		
HD 13.14.05	Damaged item is enclosed in an impervious container and labeled "hazardous";		
HD 13.14.06	Damaged item is returned to the supplier or disposed of as hazardous waste;		
HD 13.14.07	Deactivate, decontaminate, and clean the C-PEC in accordance with SOPs; and		
HD 13.14.08	If a sterile compounding C-PEC must be used, it is also disinfected after cleaning prior to resuming any sterile compounding activities.		
HD 13.16	Dispensing SOPs		
HD 13.17	Packaging and labeling SOPs		
HD 13.18	Transport SOPs		
HD 13.20	Environmental monitoring (e.g., wipe sampling) SOPs		
HD 13.21	HD waste segregation and disposal (including reference to following local, state, and federal regulations)		
HD 13.22	Spill prevention and direction of spill cleanup and control SOPs must address the following:		
HD 13.22.01	Size and scope of spill;		
HD 13.22.02	Responsible person for handling spills;		
HD 13.22.03	Location of spill kits and clean-up materials;		
HD 13.22.04	Capacity of the spill kits;		
HD 13.22.05	PPE to be worn during spills;		
HD 12.22.06	Handling of worn PPE and any exposed clothing under PPE;		
HD 13.22.07	Use of appropriate full-face, chemical cartridge-type respirator or powered air-purifying respirators (PAPR) if capacity of spill kit is exceeded or known or suspected airborne exposure to vapors/gases; and		
CC	**Hazard Communication Program**		
HD 15.00	The pharmacy's hazard communication program includes, at a minimum, all the following:		
HD 15.01	A written plan that describes how the standard will be implemented;		
HD 15.02	How containers of HDs/hazardous chemicals will be labeled, tagged, or marked with the identity of the material and appropriate hazard warnings;		
HD 15.03	SDSs are maintained for each hazardous chemical they use (29 CFR 1910.1200);		
HD 15.04	How SDSs are readily accessible to personnel during each work shift and when they are in their work areas;		

Item #	Requirement	Yes/No/N/A	Comment
CC	**Hazard Communication Program**		
HD 15.05	Information and training provided to personnel prior to initial assignment to work with a hazardous chemical and whenever the hazard changes; and		
HD 15.06	Personnel of reproductive capability confirm in writing that they understand the risks of handling HDs.		
DD	**Hazardous Drug Training**		
HD 16.00	All personnel handling HDs are trained based on their job function prior to independently handling HDs.		
HD 19.00	For sterile HD compounding, personnel competency is observed and assessed at least annually for proper sterile compounding aseptic technique, with no concerns identified.		
HD 20.00	After initial HD training, personnel are trained prior to introduction of any new HD or new equipment, or prior to any significant change in process or SOP.		
HD 21.00	All HD training and assessments are documented for each employee who transports, compounds, or administers HDs, and meets Occupational Safety and Health Administration Standard 1910.120 and any other requirements of law or regulation.		
HD 22.00	All personnel who perform custodial HD waste removal and cleaning in HD handling areas are trained in appropriate procedures to protect themselves and the environment.		
HD 23.00	HD training, based on employee file review, all the following are present:		
HD 23.01	Overview of pharmacy's HD list and their risks;		
HD 23.02	Review of the SOPs related to HDs;		
HD 23.03	Proper use of PPE;		
HD 23.04	Proper use of equipment and devices (e.g., engineering controls);		
HD 23.05	Appropriate procedures for deactivation, decontamination, cleaning, and disinfection (if applicable);		
HD 23.07	Spill management;		
HD 23.08	Proper disposal of HDs and trace-contaminated materials; and		
HD 23.09	New HD drug/new equipment or prior to any significant change in process or SOP.		
HD 24.00	If respiratory protection is needed for any HDs handled, personnel are fit tested and trained in the proper use of the respirator.		
HD 25.00	For sterile and compounding with HDs, personnel wear gowns; head, hair, and shoe covers; and two pairs of chemotherapy gloves.		
HD 26.00	Appropriate PPE is readily accessible where HD is handled, include all the following:		
HD 26.01	Receipt (PPE appropriate to HD as set forth in SOPs, and at a minimum, chemotherapy gloves worn);		
HD 26.02	Storage;		
HD 26.03	Transport;		
HD 26.05	Sterile Compounding (if performed by the pharmacy);		
HD 26.06	Administration, if applicable;		

Item #	Requirement	Yes/No/N/A	Comment
DD	**Hazardous Drug Training**		
HD 26.07	Deactivation/decontamination, cleaning, and disinfecting (appropriate PPE resistant to the agents used, two pairs of chemotherapy gloves, impermeable disposable gowns, and eye, face, and respiratory protection if warranted/addressed in SOPs);		
HD 26.08	Spill control;		
HD 26.09	Waste disposal; and		
HD 27.00	Disposable PPE is not reused.		
HD 28.00	Reusable PPE is decontaminated and cleaned after each use.		
EE	**Gloves**		
HD 29.00	The pharmacy is using appropriate gloves for the activities conducted (chemotherapy gloves meet ASTM standard D6978 -- or its successor -- and are resistant to cleaning agents used) and are resistant to cleaning agents used.		
HD 29.01	Recommendation: Are chemotherapy gloves worn for handling all HDs including non-antineoplastics and for reproductive risk only HDs?		
HD 29.02	Chemotherapy gloves are powder-free.		
HD 29.03	Chemotherapy gloves are inspected for physical defects before use and defective gloves (e.g., pin holes, tears, weak spots) are discarded		
HD 29.04	For sterile compounding, the outer chemotherapy gloves are sterile.		
HD 29.05	Chemotherapy gloves are changed when torn, punctured, or contaminated.		
HD 29.06	Recommendation: Are chemotherapy gloves changed every 30 minutes (unless otherwise recommended by the manufacturer)?		
HD 29.07	Hands are washed with soap and water after removing chemotherapy gloves.		
FF	**Gowns & Garb: Personal Protection Equipment (PPE)**		
HD 30.00	The pharmacy is using appropriate gowns for the activities conducted (if required for type of compounding based on standards or assessment of risk).		
HD 30.01	Gowns are disposable.		
HD 30.02	Gowns resist permeability of HDs and are not laboratory coats, surgical scrubs, or isolation gowns (selected based on HDs handled).		
HD 30.03	Gowns close in the back, are long sleeved, and have closed cuffs that are elastic or knit.		
HD 30.04	Gowns do not have seams or closures that will allow HDs to pass through.		
HD 30.05	Gowns are changed in accordance with the manufacturer's instructions, or if no permeation information is available, they are changed every two to three hours or immediately after a spill or splash.		
HD 30.06	Gowns worn in HD areas are not worn in other areas.		
HD 31.00	Head, hair (beard and moustache, if appropriate), and shoe and sleeve covers. The pharmacy is using appropriate head, hair, and shoe and sleeve covers for the type of compounding based on standards or assessment of risk to provide protection from contact with HD residue, if required.		

Item #	Requirement	Yes/No/N/A	Comment
FF	**Gowns & Garb: Personal Protection Equipment (PPE)**		
HD 31.01	When HD compounding, a second pair of shoe covers are donned before entering the C-SEC and doffed when exiting the C-SEC.		
HD 31.02	Shoe covers worn in HD areas are not worn in other areas of the facility.		
GG	**Eye and Face Protection**		
HD 32.00	The pharmacy is using appropriate eye and face PPE protection for the activities conducted (based on assessment of risk that HDs are irritating to the eyes and mucous membranes, where there is risk of spills or splashes when working outside of a C-PEC), if required.		
HD 32.01	If a risk to eyes, goggles (or a full-face respirator) are worn. Eyeglasses or safety glasses with side shields are not substituted for goggles.		
HD 32.02	If a risk to face and eyes, goggles plus a face shield (or a full-face respirator) are worn.		
HH	**Respiratory Protection**		
HD 33.00	The pharmacy is using appropriate respiratory PPE protection for the activities conducted (receiving, transport, compounding, administration, and waste disposal) based on assessment of risk based on type of HD and type of activity, if required. Indicate what type of PPE which is available to employees (and is fit tested, when required		
HD 34.00	Surgical masks are not used as PPE when respiratory protection is needed.		
HD 35.00	The pharmacy uses an appropriate respiratory PPE for large HD spills; deactivating, decontaminating, and cleaning underneath the work surface of the C-PEC; and when there is known or suspected airborne exposure to powders or vapors. Indicate what type of PPE which is available to employees (and is fit tested, when required).		
HD 36.00	Surgical masks are not used as PPE when respiratory protection is needed.		
II	**Disposal of Personal Protective Equipment (PPE)**		
HD 37.00	Is all PPE worn during handling of HDs considered contaminated with at least trace quantities?		
HD 37.01	Worn PPE is placed in an appropriate HD waste container.		
HD 37.02	The HD waste container is in reasonable proximity to HD PPE doffing activities.		
HD 37.03	Chemotherapy gloves, and sleeve covers if worn, are carefully removed, and discarded immediately into an approved HD trace waste container inside the C-PEC or contained in a sealable bag for discarding outside the C-PEC.		
HD 38.00	There are signs prominently displayed before the entrance to all HD handling areas designating the hazard.		
HD 38.01	Access to these areas is restricted to authorized personnel who have been appropriately trained.		

Item #	Requirement	Yes/No/N/A	Comment
II	**Disposal of Personal Protective Equipment (PPE)**		
HD 38.02	HD areas are located away from breakrooms/refreshment areas for personnel, patients, and/or visitors.		
HD 39.00	There are designated HD areas for any of the following:		
HD 39.01	Receiving and unpacking of HDs		
HD 39.02	Storage of HDs		
HD 39.04	Sterile HD compounding		
HD 40.00	Recommendation: If there is a requirement for certain designated areas to have negative pressure from surrounding areas, is there an uninterrupted power source (UPS) to the ventilation systems to maintain negative pressure in the case of power loss?		
JJ	**Receipt of Hazardous Drugs**		
HD 41.00	Are HDs received and unpacked (removed from external shipping containers) in an appropriate environment? Describe.		
HD 41.01	Antineoplastics and HD APIs are unpacked in an area with air pressure relative to surrounding areas that is either neutral or negative pressure. Indicate the type of environment. If the environment is positive pressure, it is non-compliant.		
HD 41.01.01	Neutral		
HD 41.01.02	Negative		
HD 42.00	HDs are not unpacked in a sterile compounding area (e.g., no external containers are brought into C-SEC).		
KK	**Storage of Hazardous Drugs**		
HD 43.00	Are HDs stored in a manner to minimize accidental exposure? Describe.		
HD 43.01	HDs are not stored on the floor.		
HD 43.02	HDs are stored in a manner to minimize breakage and spillage.		
HD 43.03	If the facility is in an area prone to specific types of natural disasters, appropriate precautions are taken (e.g., raised front lips on shelving in earthquake prone areas).		
HD 44.00	Antineoplastic HDs that require manipulation (other than counting and repackaging final dosage forms) and HD API are stored separately from non-HDs.		
HD 44.01	These HDs are stored in an externally ventilated, negative pressure room.		
HD 44.02	The HD storage room has at least 12 air changes per hour (ACPH).		
HD 44.03	Refrigerated antineoplastic HDs are stored in a dedicated refrigerator in a negative pressure area with at least 12 ACPH (e.g., storage room, buffer room, or containment segregated compounding area [CSCA]).		
HD 45.00	If non-antineoplastic, reproductive risk only, and final dosage forms of antineoplastics are stored with another non-HD inventory, there is a written policy/SOP addressing it.		

Item #	Requirement	Yes/No/N/A	Comment
LL	**Compounding Environment**		
HD 46.00	There are appropriate engineering controls to protect the HD preparation from cross-contamination, and if sterile compounding, from microbial contamination, during all phases of the compounding process.		
HD 47.00	All HD compounding is performed within a C-PEC located in a CSEC room.		
HD 47.01	The C-SEC for both sterile HD compounding has all the following:		
HD 47.01.01	Has fixed walls;		
HD 47.01.02	Is externally vented;		
HD 47.01.03	Can meet (12) or exceed ACPH requirements;		
HD 47.01.04	Is physically separated (i.e., a different room) from other preparation areas; and		
HD 47.01.05	Has a negative pressure differential of between 0.01 inches and 0.03 inches of water column relative to all adjacent areas.		
HD 48.00	The C-PEC operates continuously if it supplies some or all the negative pressure in the C-SEC or if it is used for sterile compounding.		
HD 49.00	There is a sink readily available for handwashing on the hazardous side.		
HD 49.01	There is an eyewash station readily available.		
HD 49.02	Water sources and drains are a minimum of 1 meter away from the C-PEC.		
HD 50.00	Does the pharmacy engage in nonsterile HD compounding?		
HD 50.01.01	C-PECs used for sterile HD compounding are in a different room than C-PECs used for nonsterile HD compounding		
HD 50.01.02	C-PECs used for sterile HD compounding are in the same room as C-PECs used for nonsterile HD compounding.		***Not Allowable: MA DRAFT 247 CMR 17.03 (8)***
HD 52.00	Does the pharmacy use the same C-PEC (Class II BSC or CACI) used for sterile HD compounding and nonsterile HD compounding?		***Not Allowable: MA DRAFT 247 CMR 17.03 (8)***
HD 53.00	The C-SEC has at least 12 ACPH. Verify documentation and monitoring.		
HD 54.00	The ceilings, walls, floors, fixtures, shelving, counters, and cabinets are smooth, impervious, free from cracks and crevices, and non-shedding. If non-compliant describe.		
HD 55.00	Does the pharmacy engage in sterile HD compounding?		
HD 55.01	Select the type(s) of containment primary engineering control(s) used for sterile HD compounding:		
HD 55.01.01	CACI		
HD 55.01.02	Class II BSC, Type A1 (formerly Type A and not suitable for volatile toxic chemicals and volatile radionuclides)		
HD 55.01.03	Class II BSC, Type A2 (formerly Type B3)		
HD 55.01.04	Class II BSC, Type B1		

Item #	Requirement	Yes/No/N/A	Comment
LL	**Compounding Environment**		
HD 55.01.05	Class II BSC, Type B2 (total exhaust for volatile components)		
HD 55.01.06	Class III BSC		
HD 55.01.07	LAFW (not for antineoplastics)		
HD 55.01.08	CAI (not for antineoplastics)		
HD 56.00	The C-PEC maintains ISO Class 5 or better air quality and is under continuous operation, unless power loss or repair occurs.		
HD 57.00	Is the C-PEC used for sterile HD compounding externally vented?		
HD 58.00	If a BSC or CACI that is used for sterile HD compounding is also used for non-HD preparations, is the non-HD preparation placed into a protective outer wrapper during removal from the C-PEC?		
HD 58.01	If used for both, is the non-HD preparation labeled to require PPE handling precautions?		
HD 59.00	If the C-SEC is an unclassified containment segregated HD compounding area (C-SCA: enclosed separate room with fixed walls, but not ISO classified), beyond-use dates (BUDs) are limited in accordance with Category 1 compounded sterile preparations.		
HD 59.01	The C-SEC (C-SCA) has at least 12 ACPH. Verify documentation and monitoring.		
HD 59.02	A handwashing sink is at least one meter or more away from the CPEC		
HD 59.02.01	Describe whether the sink is inside the C-SCA or directly outside the CSCA		
HD 60.00	If BUDs are longer than the Category 1 BUDs specified in, the PEC is in a C-SEC, which is an ISO Class 7 buffer room adjacent to an ISO Class 7 anteroom.		
HD 60.01	The buffer room has fixed walls.		
HD 60.02	The buffer room is externally vented.		
HD 60.03	The buffer room has HEPA-filtered supply air.		
HD 60.04	The buffer room has at least 30 ACPH.		
HD 60.05	The buffer room has a negative pressure differential of between 0.01 inches and 0.03 inches of water column relative to the anteroom.		
HD 60.06	The anteroom has fixed walls.		
HD 60.07	The ante room has a minimum of 30 ACPH of HEPA-filtered supply air.		
HD 60.08	The ante room maintains positive pressure of at least 0.02 inches of water column relative to any adjacent unclassified areas.		
HD 60.09	The handwashing sink is in the anteroom at least 1 meter or more away from the door to the buffer room to prevent contamination into the negative pressure buffer room.		
HD 61.00	If the negative-pressure HD buffer room is entered through a positive pressure non-HD buffer room, there is a line of demarcation within the buffer room for donning and doffing PPE.		

Item #	Requirement	Yes/No/N/A	Comment
LL	**Compounding Environment**		
HD 61.01	There is a design and method to contain and minimize HD contamination when transporting HDs, HD CSPs, and HD waste into and out of the negative pressure buffer room:		
HD 61.02	Indicate how HD contamination is minimized:		
HD 61.02.01	Pass-through chamber between negative pressure buffer room and adjacent space included in the facility's certification not compromising air quality in the buffer room (verified in the facility's semi-annual certification report that pass through has not compromised air quality in the buffer room).		
HD 61.02.02	Use of sealed containers		
HD 61.02.03	Other, describe		
HD 62.00	Recommendation: Surface wipe sampling is performed routinely (initially and at least every six months) to monitor HD containment processes and trends, which includes all the following:		
HD 62.01	Interior of C-PEC and equipment within the C-PEC		
HD 62.02	Pass-through chambers		
HD 62.03	Surfaces in staging or work areas near the C-PEC		
HD 62.04	Areas adjacent to the C-PEC (e.g., floors directly under, staging, and dispensing areas)		
HD 62.05	Areas immediately outside the HD buffer room or the C-SCA		
HD 63.00	Recommendation: HDs are packaged by the supplier in impervious plastic to segregate them from other drugs and decrease possibility of exposure during unpacking and internal transfer.		
MM	**Delivery and Packing/Unpacking of Hazardous Drugs**		
HD 64.00	HDs are delivered to the HD storage area immediately after unpacking.		
HD 65.00	A spill kit is readily accessible in the receiving area.		
HD 66.00	Containers are visually examined for signs of damage or breakage prior to opening.		
HD 67.00	If a shipping container appears damaged and does not need to be opened, it is sealed, enclosed in an impervious container, labeled "hazardous" on the outside, and returned to the supplier after contact or disposed of as hazardous waste.		

Item #	Requirement	Yes/No/N/A	Comment
MM	**Delivery and Packing/Unpacking of Hazardous Drugs**		
HD 67.01	If a damaged shipping container must be opened, it is done so according to SOPs, to include sealing the container in plastic or an impervious container, transporting it to the C- PEC for unpacking, removing, and wiping the outside of the undamaged items with disposable wipes, resealing the damaged items in an impervious container and marking it "hazardous," returning it to the supplier after contact or disposing as hazardous waste, and deactivating, decontaminating, and cleaning the C-PEC.		
HD 68.00	Damaged packages are considered spills and reported to the designated person. List last date of damaged package receipt.		
HD 69.00	HDs requiring special HD handling are always clearly labeled as hazardous during transport and in accordance with any laws related to labeling of HDs.		
HD 70.00	Labeling processes do not introduce contamination into non-HD handling areas.		
HD 71.00	Packaging materials are chosen that protect the HD and healthcare worker against damage, leakage, contamination, and degradation during transport, but also maintains the physical integrity, stability, and sterility of the HD.		
HD 72.00	Pneumatic tubes are not used for transporting any liquid HDs or antineoplastic HDs.		
HD 73.00	Labeling on HDs shipped outside the pharmacy meets all the following requirements:		
HD 73.01	Labeling specified in SDS for transport;		
HD 73.02	Storage and disposal instructions; and		
HD 73.03	Labeled with HD category.		
HD 74.00	Counting of antineoplastics is done by hand (e.g., not placed into automated counting devices).		
HD 75.00	Clean, dedicated (not used for non-HD purposes), or disposable equipment is used for counting, packaging, and compounding of HDs.		
HD 75.01	Recommendation: Equipment is decontaminated after every use.		
HD 75.02	Recommendation: When compounding, a plastic-backed preparation mat is placed on the C-PEC work surface and changed and discarded appropriately as HD waste. All the following should apply to make this a Yes.		
HD 75.02.01	Immediately if a spill occurs		
HD 75.02.02	Regularly during use		
HD 75.02.03	At the end of a shift		
HD 76.00	APIs or other powdered HDs are handled in a C-PEC during particle generating activities, such as crushing, opening capsules, and weighing powders		

Item #	Requirement	Yes/No/N/A	Comment
NN	**Deactivation, Decontamination, Cleaning and Disinfection (DDCD)**		
HD 77.00	The pharmacy has chosen appropriate oxidizing agent(s) for deactivation and decontamination and proven effective by testing.		
HD 78.00	Wipes or other appropriate delivery mechanisms (e.g., not a spray bottle) are used for deactivation and decontamination.		
HD 79.00	The C-PEC must be decontaminated. All the following must be done to be compliant:		
HD 79.01	Between compounding of different HDs		
HD 79.02	At least daily when used		
HD 79.03	Any time a spill occurs		
HD 79.04	Before and after certification		
HD 79.05	Any time voluntary interruption occurs		
HD 79.06	If the ventilation tool is moved		
HD 80.00	HD containers are wiped down prior to placing them in the C-PEC and the solution used does not alter the product label.		
HD 81.00	Areas other than the work surface of the C-PEC, where contamination can build up (such as areas under the work tray), are deactivated, decontaminated, and cleaned at least monthly.		
HD 82.00	Additional PPE (e.g., respirator) is used in accordance with SOPs, to protect the worker if containment airflows are compromised by opening the cabinets to get to these areas		
HD 83.00	Spills are contained and cleaned immediately.		
HD 84.00	Trained/qualified personnel are always available during operation with HDs to handle spills.		
HD 85.00	Only trained/qualified personnel engage in spill containment and cleanup.		
HD 86.00	There are signs available to restrict access to spill areas.		
HD 87.00	Spill kits, containing all ingredients necessary to clean HD spills, are readily available in all areas where HDs are routinely handled.		
HD 88.00	Spill materials are disposed of as hazardous waste.		
HD 89.00	The circumstances and management of all spills are documented. Review documentation		

800 Comments:

Additional Comments:

Plan of Correction Issued: ☐ Yes ☐ No

If yes, I will provide a plan of correction for all findings within 15 business days. **Due Date**: _____

Inspector: _____ **Date:** _____

Inspector: _____ **Date:** _____

Inspector: _____ **Date:** _____

Inspector: _____ **Date:** _____