CONNECTICUT DEPARTMENT OF
CONSUMER PROTECTION
DRUG CONTROL DIVISION

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Sterile Compounding Inspection Form

USP (797) Pharmaceutical Compounding - Sterile Preparations (2022)
and
Connecticut General Statutes and Regulations

Compounding Site Location		
Where are compounded sterile preparations (CSPs) being prepared?	Hospital or other healthcare institution	The minimum requirements described in (797) Pharmaceutical Compounding - Sterile Preparations apply to all places where CSPs are prepared.
	Infusion facility	
	Institutional pharmacy within a facility	
	Medical and surgical patient treatment site	
	Sterile compounding pharmacy	
	Physician practice site	
	Veterinarian practice site	

Compounding Site Personnel		
Who is preparing compounded sterile preparations (CSPs) at the compounding site?	Chiropractors	The minimum requirements described in (797) Pharmaceutical Compounding - Sterile Preparations apply to all persons who prepare CSPs.
	Dentists	
	Naturopaths	
	Nurses	
	Pharmacists	
	Physicians	
	Technicians	
	Veterinarians	
Are all compounding personnel TRAINED in the FOLLOWING AREAS associated with preparing compounded sterile preparations (CSPs)?	Recognizing potential DEVIATIONS and reporting any deviations to the designated person(s) or pharmacist, whichever is applicable	Must
	Recognizing potential ERRORS and reporting any errors to the designated person(s) or pharmacist, whichever is applicable	
	Recognizing potential FAILURES and reporting any failures to the designated person(s) or pharmacist, whichever is applicable	
	Recognizing potential PROBLEMS and reporting any problems to the designated person(s) or pharmacist, whichever is applicable	

Compounding Site Specifics		
Does the sterile compounding pharmacy PROVIDE PATIENT-SPECIFIC sterile pharmaceuticals? [Section 20-633b(e)(1)]		If yes ...
To whom does the sterile compounding pharmacy provide PATIENT-SPECIFIC sterile pharmaceuticals? [Section 20-633b(e)(1)]	a.) PATIENTS	Compliant
	b.) PRACTITIONERS of medicine, osteopathy, podiatry, dentistry, or veterinary medicine	
	c.) ACUTE CARE OR long-term care hospital or health care facility licensed by the Department of Public Health (DPH)	
	d.) OTHER	Non-compliant
Does the sterile compounding pharmacy PROVIDE sterile pharmaceuticals WITHOUT A PATIENT-SPECIFIC prescription or medical order? [Section 20-633b(e)(2)]		If yes ...
Did the sterile compounding pharmacy OBTAIN A CERTIFICATE OF REGISTRATION from the Department of Consumer Protection pursuant to Section 21a-70 of the Connecticut General Statutes (CGS) and any required federal license or registration? [Section 20-633b(e)(2)]		Shall
Does the sterile compounding pharmacy PREPARE AND MAINTAIN ON-SITE INVENTORY of sterile pharmaceuticals?		If yes ...
Does the sterile compounding pharmacy PREPARE AND MAINTAIN ON-SITE INVENTORY of sterile pharmaceuticals GREATER THAN A THIRTY (30)-DAY SUPPLY, calculated from the completion of compounding? [Section 20-633b(e)(2)]		No greater than a thirty (30) day supply
How does the compounding site prepare preparations?	Aseptic processing	
	Depyrogenation	
	Sterilization by Filtration	
	Sterilization by Dry Heat	
	Sterilization by Steam Heat	
Does the compounding site prepare any of the following preparations?	Allergenic extracts	See Allergenic Extracts
	Aqueous preparations for pulmonary inhalation	REQUIRED TO BE STERILE and have to meet the standards of (797) Pharmaceutical Compounding - Sterile Preparations.
	Baths for live organs and tissues	REQUIRED to meet the standards of (797) Pharmaceutical Compounding - Sterile Preparations.
	Blood-derived and other biological materials	See Blood-Derived and Other Biological Materials
	Category 1 compounded sterile preparations (CSPs)	REQUIRED to meet the standards of (797) Pharmaceutical Compounding - Sterile Preparations.
	Category 2 CSPs	
	Category 3 CSPs	
	Hazardous drugs (HDs) - NONSTERILE	MUST COMPLY with (795) Pharmaceutical Compounding - NonSterile Preparations and (800) Hazardous Drugs - Handling in Healthcare Settings.

Compounding Site Specifics		
Does the compounding site prepare any of the following preparations? (continued)	HDs - STERILE	MUST COMPLY with (797) Pharmaceutical Compounding - Sterile Preparations and (800) Hazardous Drugs - Handling in Healthcare Settings.
	Immediate-use CSPs	See Immediate-Use CSPs
	Implants	REQUIRED to meet the standards of (797) Pharmaceutical Compounding - Sterile Preparations.
	Infusions	
	Injections	
	Irrigations for internal body cavities that do not normally communicate with the environment outside of the body (i.e. bladder cavity or peritoneal cavity)	REQUIRED TO BE STERILE and have to meet the standards of (797) Pharmaceutical Compounding - Sterile Preparations.
	Ophthalmic dosage forms	REQUIRED to meet the standards of (797) Pharmaceutical Compounding - Sterile Preparations.
	Preparation per approved labeling	See Preparation Per Approved Labeling
	Proprietary bag and vial systems	See Proprietary Bag and Vial Systems
	Radiopharmaceuticals	NOT REQUIRED to meet the standards of (797) Pharmaceutical Compounding - Sterile Preparations as they are SUBJECT TO the requirements in (825) Radiopharmaceuticals - Preparation, Compounding, Dispensing, and Repackaging.
	Repackaging a sterile product or preparation from its original container into another container	MUST BE performed in accordance with the requirements of (797) Pharmaceutical Compounding - Sterile Preparations.
	Soaks for live organs and tissues	REQUIRED to meet the standards of (797) Pharmaceutical Compounding - Sterile Preparations.
	Solutions	
Which CLASSIFICATION(S) OF AIR QUALITY are maintained by the compounding site?	ISO 5	
	ISO 6	
	ISO 7	
	ISO 8	
Which TYPE OF secondary engineering controls (SECs) are used by the compounding site?	Anteroom	
	Buffer Room	
	Cleanroom Suite	
	Pass-through chambers	
	Segregated compounding area (SCA)	
Which TYPE OF primary engineering controls (PECs) are used by the compounding site?	Laminar airflow workbench (LAFW)	
	Integrated vertical laminar flow zone (IVLFZ)	

Compounding Site Specifics	
Which TYPE OF primary engineering controls (PECs) are used by the compounding site? (continued)	Class II biological safety cabinet (BSC)
	Compounding aseptic isolator (CAI)
	Compounding aseptic containment isolator (CACI)
	Pharmaceutical isolator
	Robotic enclosure

Starting Ingredients for Compounded Sterile Preparations (CSPs)		
Some sterile and some nonsterile starting ingredients and all nonsterile starting ingredients are used to compound Category 1, Category 2, and/or Category 3 CSPs		
Is the sterility of the Category 1, Category 2, and/or Category 3 CSPs achieved through a sterilization process (e.g., terminal sterilization in the final sealed container) or sterilizing filtration?		Must
Is the Category 1, Category 2, and/or Category 3 CSPs subsequently MANIPULATED after achieving sterility through a sterilization process (e.g., terminal sterilization in the final sealed container) or sterilizing filtration?		If yes ...
Is the sterility of the Category 1, Category 2, and/or Category 3 CSPs MAINTAINED when manipulated after achieving sterility through a sterilization process (e.g., terminal sterilization in the final sealed container) or sterilizing filtration?		Must
All nonsterile starting ingredients are used to compound Category 1, Category 2, and/or Category 3 CSPs		
Does the compounding site weigh, measure, or otherwise manipulate nonsterile starting ingredients (i.e., presterilization procedures) when preparing Category 2 and/or Category 3 CSPs?		If yes ...
Are the FOLLOWING REQUIREMENTS MET during presterilization procedures, such as weighing or mixing, when preparing Category 2 and/or Category 3 CSPs?	a.) FOLLOW hygiene and garbing requirements [See Section 3. Personal Hygiene and Garbing of (797) Pharmaceutical Compounding - Sterile Preparations]	Must
	b.) COMPLETED in an ISO 8 classification or better environment (e.g., anteroom or buffer room)	
	c.) PERFORMED in single-use containment glove bags, containment ventilated enclosures (CVEs), biological safety cabinets (BSCs), or compounding aseptic containment isolators (CACIs) to minimize the risk of airborne contamination	
	a.) Do presterilization procedures ADVERSELY AFFECT THE REQUIRED AIR QUALITY of the secondary engineering control (SEC) as demonstrated during certification under dynamic operating conditions?	Must Not
	b.) Are the BSCs, CVEs, or CACIs used for presterilization procedures CERTIFIED AT LEAST EVERY SIX (6) MONTHS?	Must
Only sterile starting ingredients are used to compound Category 1, Category 2, and/or Category 3 CSPs		
Is the sterility of the sterile starting ingredients MAINTAINED during compounding to produce Category 1, Category 2, and/or Category 3 CSPs?		Must

Allergenic Extracts		
Is there a DESIGNATED person(s) or pharmacist, whichever is applicable, RESPONSIBLE for ensuring that personnel who will be preparing allergenic extract prescription sets are trained, evaluated, and supervised?		Is responsible
Does the designated person(s) or pharmacist, whichever is applicable, have _____ in ALLERGEN IMMUNOTHERAPY?	a.) TRAINING	With
	b.) EXPERTISE	
Do personnel	a.) DEMONSTRATE KNOWLEDGE AND COMPETENCY in procedures by passing written or electronic testing BEFORE being ALLOWED TO compound allergenic extract prescription sets?	Must
	b.) who have NOT COMPOUNDED an allergenic extract prescription set IN MORE than SIX (6) months get EVALUATED in all core competencies BEFORE RESUMING compounding duties?	
	c.) PERFORM HAND HYGIENE AND GARBING procedures according to the facility's standard operating procedures (SOPs) BEFORE BEGINNING compounding of allergenic extract prescription sets?	
	d.) APPLY seventy (70) percent isopropyl alcohol (IPA) onto all surfaces of the gloves and allow them to dry thoroughly throughout the compounding process?	
Do the facility's MINIMUM GARB requirements include the FOLLOWING?	a.) LOW-LINT GARMENT with SLEEVES that fit snugly around the wrists and an enclosed neck (e.g., gowns)	Must
	b.) LOW-LINT, DISPOSABLE HEAD COVER that covers the hair and ears	
	c.) LOW-LINT, DISPOSABLE cover for FACIAL hair, if applicable	
	d.) FACE mask	
	e.) STERILE POWDER-FREE gloves	
Do all compounders SUCCESSFULLY complete gloved fingertip and thumb (GFT) sampling ON BOTH HANDS AFTER performing separate and complete hand hygiene and garbing procedures	a.) NO FEWER than three (3) SEPARATE TIMES before being allowed to INDEPENDENTLY COMPOUND?	Must
	b.) at least EVERY TWELVE (12) months after the initial competency evaluation?	
Do all compounders SUCCESSFULLY complete a MEDIA-FILL test at LEAST EVERY TWELVE (12) months to evaluate their sterile technique and related practices?		Must
The post-media-fill surface sample is not required if compounding outside of a primary engineering control (PEC).		
How does the facility HANDLE FAILED competency evaluations?	a.) Personnel successfully pass reevaluations in the deficient area(s) before resuming compounding of allergenic extract prescription sets.	Must
	b.) The designated person(s) or pharmacist, whichever is applicable, identifies the cause of failure and determines appropriate retraining requirements.	
Is ANNUAL personnel training and competency DOCUMENTED?		Must

Allergenic Extracts		
WHERE does the compounding process OCCUR?	a.) ISO Class 5 primary engineering control (PEC)	Compliant
	b.) Dedicated allergenic extract compounding area (AECA)	
	c.) Other	Non-compliant
Is the ISO Class 5 primary engineering control (PEC) or dedicated allergenic extract compounding area (AECA)	a.) located away from UNSEALED WINDOWS?	Must
	b.) located away from DOORS that connect to the OUTDOORS?	
	c.) located away from TRAFFIC FLOW?	
	d.) located where ENVIRONMENTAL CONTROL CHALLENGES (e.g., restrooms, warehouses, or food preparation areas) cannot negatively affect the air quality?	
	e.) located AT LEAST ONE (1) meter away from a sink?	
	f.) designed CAREFULLY CONSIDERING the IMPACT of ACTIVITIES conducted around or adjacent to the ISO Class 5 PEC or AECA?	
ISO Class 5 primary engineering control (PEC)		
Are the FOLLOWING REQUIREMENTS MET with respect to the ISO Class 5 PEC where the compounding process occurs?	a.) The PEC is CERTIFIED at least EVERY SIX (6) months.	Must
	b.) All INTERIOR SURFACES of the PEC are CLEANED AND DISINFECTED each day of use before compounding begins and when surface contamination is known or suspected.	
	c.) STERILE seventy (70) percent isopropyl alcohol (IPA) is APPLIED to the horizontal work surface between each prescription set.	
	d.) VIAL STOPPERS on packages of conventionally manufactured sterile ingredients are WIPED with STERILE seventy (70) percent isopropyl alcohol (IPA) to ensure that the critical sites are wet and allowed to dry before they are used to compound allergenic extract prescription sets.	
Dedicated Allergenic Extract Compounding Area (AECA)		
Are the FOLLOWING REQUIREMENTS MET with respect to the dedicated allergenic extract compounding area (AECA) where the compounding process occurs?	a.) There is a VISIBLE PERIMETER to define the AECA.	Must
	b.) There is RESTRICTED access to authorized personnel during compounding.	
	c.) NO OTHER activity occurs in the AECA during compounding activities.	
	d.) There are CLEANABLE surfaces (walls, floors, fixtures, shelving, counters, and cabinets).	
	e.) There is NO carpet.	
	f.) SURFACES are RESISTANT to damage by cleaning and disinfecting agents.	
	g.) SURFACES UPON WHICH allergenic extract prescription sets are prepared are smooth, impervious, free from cracks and crevices, and non-shedding to allow for easy cleaning and disinfecting.	

Allergenic Extracts		
Are the FOLLOWING REQUIREMENTS MET with respect to the dedicated allergenic extract compounding area (AECA) where the compounding process occurs? (continued)	h.) Dust-collecting OVERHANGS such as utility pipes, ledges, and windowsills are MINIMIZED.	Must
	i.) OVERHANGS or LEDGES are easily CLEANABLE, if present.	
	j.) There is a WELL-LIGHTED working environment, with TEMPERATURE AND HUMIDITY CONTROLS for the comfort of compounding personnel wearing the required garb.	
	k.) All work SURFACES in the AECA where direct compounding occurs are CLEANED AND DISINFECTED each day of use before compounding begins and when surface contamination is known or suspected.	
	l.) CEILINGS within the perimeter of the AECA are CLEANED AND DISINFECTED when visibly soiled and when surface contamination is known or suspected.	
	m.) VIAL STOPPERS on packages of conventionally manufactured sterile ingredients are WIPED with STERILE seventy (70) percent isopropyl alcohol (IPA) to ensure that the critical sites are wet and allowed to dry before they are used to compound allergenic extract prescription sets.	
Are BEYOND-USE DATES (BUDs) for prescription sets LATER than the earliest expiration date of any allergenic extract or diluent that is part of the prescription set?		Must not
Do BEYOND-USE DATES (BUDs) for prescription sets EXCEED ONE (1) year from the date the prescription set IS MIXED OR DILUTED?		Must not
Does the LABEL of EACH vial of an allergenic extract prescription set DISPLAY PROMINENTLY AND UNDERSTANDABLY	a.) Patient NAME?	Must
	b.) TYPE and FRACTIONAL DILUTION of each vial, with a corresponding vial number?	
	c.) BEYOND-USE date (BUD)?	
	d.) STORAGE conditions?	
Does the facility SHIP OR TRANSPORT allergenic extract prescription sets?		If yes ...
Do compounding personnel	a.) SELECT MODES OF TRANSPORT that are expected to deliver properly packed prescription sets in an undamaged, sterile, and stable condition?	Must
	b.) INCLUDE SPECIFIC HANDLING INSTRUCTIONS on the exterior of the container when shipping or transporting allergenic extract prescription sets that require special handling?	
Does the facility HAVE AND MAINTAIN written or electronic DOCUMENTATION that includes, but is not limited to, the FOLLOWING?	a.) STANDARD OPERATING PROCEDURES (SOPs) describing all aspects of the compounding process	Must
	b.) PERSONNEL training RECORDS, competency assessments, and qualification records including corrective actions for any failures	
	c.) CERTIFICATION REPORTS of the primary engineering control (PEC), if used, including CORRECTIVE ACTIONS for any failures	
	d.) TEMPERATURE LOGS for refrigerator(s)	

Allergenic Extracts		
Does the facility HAVE AND MAINTAIN written or electronic DOCUMENTATION that includes, but is not limited to, the FOLLOWING? (continued)	e.) COMPOUNDING RECORDS (CRs) for individual allergenic extract prescription sets	Must
	f.) Information related to COMPLAINTS AND ADVERSE EVENTS including CORRECTIVE ACTIONS taken	
	g.) INVESTIGATIONS and CORRECTIVE ACTIONS	

Blood-Derived and Other Biological Materials		
Do compounding activities REQUIRE THE MANIPULATION of a patient's blood-derived or other biological material (e.g., autologous serum)?		If yes ...
Are the manipulations of a patient's blood-derived or other biological material (e.g., autologous serum)	a.) CLEARLY SEPARATED from other compounding activities?	Must
	b.) CLEARLY SEPARATED from equipment used in compounded sterile preparation (CSP) preparation activities?	
	c.) CONTROLLED BY specific standard operating procedures (SOPs) to avoid any cross-contamination?	
Does the HANDLING of a patient's blood-derived or other biological material (e.g., autologous serum) COMPLY WITH LAWS AND REGULATIONS OF THE APPLICABLE REGULATORY JURISDICTION?		Must

Immediate-Use Compounded Sterile Preparations (CSPs)		
Is the compounding site preparing CSPs for DIRECT AND IMMEDIATE administration (i.e., immediate-use CSPs)?		If yes ...
Does the preparation of CSPs for direct and immediate administration (i.e., immediate-use CSPs) MEET EACH of the FOLLOWING CONDITIONS?	a.) ASEPTIC techniques, processes, and procedures are FOLLOWED, and WRITTEN STANDARD OPERATING PROCEDURES (SOPs) are in place to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other conventionally manufactured products of CSPs.	If each of the conditions IS NOT MET, the compounding of CSPs for direct and immediate administration IS SUBJECT to the requirements for Category 1, Category 2, or Category 3 CSPs. If each of the conditions IS MET, the compounding of CSPs for direct and immediate administration IS NOT SUBJECT to the requirements for Category 1, Category 2, or Category 3 CSPs.
	b.) PERSONNEL are TRAINED AND DEMONSTRATE COMPETENCY in aseptic processes as they relate to assigned tasks and the facility's SOPs.	
	c.) The preparation is PERFORMED IN ACCORDANCE WITH evidence-based information for physical and chemical compatibilitity of the drugs (e.g., approved labeling, stability, and compatibility studies).	
	d.) The preparation involves NOT MORE THAN THREE (3) different sterile products.	
	e.) ANY UNUSED starting component from a single-dose container is DISCARDED after preparation is complete. Single-dose containers are NOT USED FOR MORE THAN ONE (1) patient.	
	f.) Administration begins WITHIN FOUR (4) HOURS following the start of preparation. If administration has not begun within four (4) hours following the start of preparation, it is promptly, appropriately, and safely discarded.	
	g.) Unless directly administered by the person who prepared it or administration is witnessed by the preparer, the CSP is LABELED WITH the names and amounts of all active ingredients, the name or initials of the person who prepared the preparation, and the four (4)-hour time period within which administration must begin.	

Multiple-Dose Compounded Sterile Preparations (CSPs)		
Does the compounding site USE PRESERVATIVES when preparing multiple-dose CSPs?		If yes ...
Are the preservatives used by the compounding site	a.) appropriate for the CSP FORMULATION? - For example, 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).	Must
	b.) appropriate for the ROUTE OF ADMINISTRATION of the CSP? - For example, some preservatives are not appropriate for the route of administration (e.g., intrathecal or ophthalmic injection).	
	c.) considered as a substitute for ASEPTIC TECHNIQUE?	Best Practice
Is the compounding site preparing multiple-dose CSPs as Category 1, Category 2, and/or Category 3 CSPs?		Multiple-dose CSPs CANNOT be prepared as Category 1 CSPs
Does the compounding site PREPARE AQUEOUS multiple-dose CSPs?		If yes ...
Do the aqueous multiple-dose CSPs PASS ANTIMICROBIAL EFFECTIVENESS TESTING in accordance with (51) Antimicrobial Effectiveness Testing?		Must
The compounding site RELIES ON antimicrobial effectiveness testing	a.) CONDUCTED (or contracted for) ONCE FOR EACH FORMULATION IN THE PARTICULAR CONTAINER CLOSURE SYSTEM in which it will be packaged.	Compliant
	b.) RESULTS from a Food and Drug Administration (FDA)-REGISTERED FACILITY provided the antimicrobial effectiveness testing results from a FDA-registered facility for the EXACT SAME CSP formulation, including any preservative, and container closure system AS THOSE TESTED.	
	c.) RESULTS published in peer-reviewed LITERATURE SOURCES provided the antimicrobial effectiveness testing results published in peer-reviewed literature sources for the EXACT SAME CSP formulation, including any preservative, and container closure system AS THOSE TESTED.	
	d.) Other	Non-compliant
Was a BRACKETING STUDY PERFORMED when the CSP formulation, including any preservative, and container closure system were NOT EXACTLY THE SAME AS THOSE TESTED?		If yes ...
Was the SAME CONCENTRATION of all OTHER INGREDIENTS, including preservatives, USED THROUGHOUT the BRACKETING STUDY?		Compliant
Does the compounding site prepare multiple-dose, aqueous, NONPRESERVED CSPs intended for topical, including topical ophthalmic, administration?		If yes ...

Multiple-Dose Compounded Sterile Preparations (CSPs)		
Do the FOLLOWING CONDITIONS APPLY to multiple-dose, aqueous, nonpreserved CSPs intended for topical, including topical ophthalmic, administration that are prepared by the compounding site?	a.) For use by a SINGLE PATIENT	If each of the conditions IS MET, the requirement for passing antimicrobial effectiveness testing in accordance with (51) Antimicrobial Effectiveness Testing is REQUIRED. The requirement for passing antimicrobial effectiveness testing in accordance with (51) Antimicrobial Effectiveness Testing is NOT REQUIRED.
	b.) LABELED in the label or labeling to indicate that once opened, it must be discarded after twenty-four (24) hours when stored at controlled room temperature and/or that once opened, it must be discarded after seventy-two (72) hours when stored under refrigeration	
	c.) PREPARED as a Category 2 or Category 3 CSP	
Does the compounding site USE multiple-dose CSP containers AFTER INITIALLY ENTERING OR PUNCTURING the multiple-dose CSP containers for LONGER THAN THE ASSIGNED BUD OR TWENTY-EIGHT (28) DAYS if supported by antimicrobial effectiveness testing results on the CSP WHICHEVER IS SHORTER?		Must not
Does the compounding site USE multiple-dose, aqueous, NONPRESERVED CSPs intended for topical, including topical ophthalmic, administration AFTER INITIALLY ENTERING OR PUNCTURING the containers of multiple-dose, aqueous, nonpreserved CSPs intended for topical, including topical ophthalmic, administration for LONGER THAN THE ASSIGNED BUD OR TWENTY-EIGHT (28) DAYS if supported by antimicrobial effectiveness testing results on the CSP WHICHEVER IS SHORTER?		Must not
Container closure systems used to PACKAGE MULTIPLE-DOSE CSPs	a.) are EVALUATED for container closure integrity.	Must
	b.) CONFORM to container closure integrity.	
Does the compounding site CONDUCT a container closure integrity test ONCE ON	a.) EACH FORMULATION in the particular container closure system in which multiple-dose CSPs will be packaged?	Needs to
	b.) FILL VOLUME in the particular container closure system in which multiple-dose CSPs will be packaged?	

Preparation Per Approved Labeling		
Is the compounding site mixing, reconstituting, or other such acts that are performed in accordance with DIRECTIONS CONTAINED IN APPROVED LABELING or supplemental materials provided by the product's manufacturer?		If yes ...
Does the mixing, reconstituting, or other such acts performed in accordance with directions contained in approved labeling or supplemental materials provided by the product's manufacturer MEET the FOLLOWING CONDITIONS?	a.) Approved labeling includes information for the CONTAINER CLOSURE SYSTEM	If each of the conditions IS NOT MET, the preparation of the conventionally manufactured sterile product(s) IS WITHIN THE SCOPE of (797) Pharmaceutical Compounding - Sterile Preparations. If each of the conditions IS MET, the preparation of the conventionally manufactured sterile product(s) IS OUTSIDE THE SCOPE of (797) Pharmaceutical Compounding - Sterile Preparations.
	b.) Approved labeling includes information for the DILUENT	
	c.) Approved labeling includes information for the RESULTANT STRENGTH	
	d.) Approved labeling includes information for the STORAGE TIME	
	e.) Product is being prepared as a SINGLE DOSE for an INDIVIDUAL PATIENT	

Proprietary Bag and Vial Systems		
Does the compounding site DOCK AND ACTIVATE proprietary bag and vial systems?		If yes ...
Are proprietary bag and vial systems being docked and activated in accordance with the manufacturer's labeling FOR IMMEDIATE ADMINISTRATION to an individual patient?		The docking and activation of proprietary bag and vial systems in accordance with the manufacturer's labeling for IMMEDIATE administration to an individual patient IS NOT considered compounding and may be performed outside of an International Organization for Standardization (ISO) Class 5 environment.
Are proprietary bag and vial systems being docked for FUTURE ACTIVATION AND ADMINISTRATION?		If yes ...
Are the proprietary bag and vial systems being docked for FUTURE ACTIVATION AND ADMINISTATION being	a.) PREPARED IN an ISO Class 5 environment in accordance with (797) Pharmaceutical Compounding - Sterile Preparations with the exception of 14. Establishing Beyond-Use Dates?	Must
	b.) ASSIGNED beyond-use dates (BUDs) longer than those specified in the manufacturer's labeling?	Must not

Secondary Engineering Controls (SECs)		
Is ACCESS to SECs RESTRICTED to … …	a.) authorized PERSONNEL?	Must
	b.) required MATERIALS?	
Which of the FOLLOWING ARE USED to wipe items being introduced into SECs?	a.) Environmental Protection Agency (EPA)-registered disinfectant	Compliant
	b.) Sporicidal disinfectant	
	c.) Sterile seventy (70) percent isopropyl alcohol (IPA)	
	d.) Other	Non-compliant
Does WIPING with a sporicidal disinfectant, EPA-registered disinfectant, or sterile seventy (70) percent IPA before introducing items into SECs COMPROMISE PACKAGING INTEGRITY?		Will not
Are EPA-registered disinfectants and sporicidal disinfectants ALLOWED TO DWELL for the MINIMUM CONTACT TIME specified by the manufacturer when wiping items with an EPA-registered disinfectant or sporicidal disinfectant before introducing items into SECs?		Must
Is sterile seventy (70) percent IPA ALLOWED TO DRY when wiping items with sterile seventy (70) percent IPA before introducing items into SECs?		Must
Does the wiping PROCEDURE … …	a.) COMPROMISE the packaging INTEGRITY?	Best practice not to
	b.) RENDER the product label UNREADABLE?	
How are items wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile seventy (70) percent IPA before introducing items into SECs?	a.) using LOW-LINT wipers	Must
	b.) by personnel WEARING GLOVES	

Anteroom		
Is the anteroom APPROPRIATELY CONTROLLED to	a.) ACHIEVE the required air classifications?	Must
	b.) MAINTAIN the required air classifications?	
Does the anteroom PROVIDE ACCESS TO ONLY A POSITIVE-PRESSURE BUFFER ROOM?		If yes ...
Does the anteroom that provides access to only a positive-pressure buffer room MEET AT LEAST ISO 8 CLASSIFICATION of particulate matter in room air?		Must
Does the anteroom PROVIDE ACCESS TO A NEGATIVE-PRESSURE BUFFER ROOM?		If yes ...
Does the anteroom that provides access to a negative-pressure buffer room MEET AT LEAST ISO 7 CLASSIFICATION of particulate matter in room air?		Must
Is the compounding site DESIGNED WITH TWO (2) SEPARATE ANTEROOMS (a dirty anteroom and a clean anteroom)?		If yes ...
Is the anteroom ENTERED THROUGH THE DIRTY ANTEROOM?		Is
Is the CLEAN ANTEROOM the area CLOSEST TO THE BUFFER ROOM?		Is
Is the anteroom SEPARATED from areas not directly related to compounding?		Must
Is the compounding site DESIGNED WITH TWO (2) SEPARATE ANTEROOMS (a dirty anteroom and a clean anteroom)?		If no ...
Is the anteroom SEPARATED from areas not directly related to compounding?		Must
Is the CLEAN SIDE of the anteroom the area CLOSEST TO THE BUFFER ROOM?		Is
Is the anteroom ENTERED THROUGH THE DIRTY SIDE?		Is
Does the anteroom have a LINE OF DEMARCATION TO SEPARATE the clean side from the dirty side?		Must
Are ITEMS WIPED with a sporicidal disinfectant, Environmental Protection Agency (EPA)-registered disinfectant, or sterile seventy (70) percent isopropryl alcohol (IPA) BEFORE BEING INTRODUCED INTO THE CLEAN SIDE OF ANTEROOMS provided the packaging integrity will not be compromised?		Must

Buffer Room		
Is the buffer room APPROPRIATELY CONTROLLED to	a.) ACHIEVE the required air classifications?	Must
	b.) MAINTAIN the required air classifications?	
Does the buffer room MEET AT LEAST ISO 7 CLASSIFICATION of particulate matter in room air?		Must
Is the buffer room SEPARATED from areas not directly related to compounding?		Must

Cleanroom Suite		
Are the anteroom and buffer room SEPARATED FROM SURROUNDING UNCLASSIFIED AREAS of the compounding site by FIXED	a.) walls?	Must
	b.) doors?	
Are CONTROLS in place TO MINIMIZE the FLOW OF LOWER-QUALITY AIR into more controlled areas?		Must
Are classified rooms EQUIPPED with a PRESSURE-DIFFERENTIAL MONITORING SYSTEM?		Must
Is AIR supplied to the cleanroom suite INTRODUCED THROUGH HEPA FILTERS?		Must
Is air supplied to the cleanroom suite introduced through HEPA filters LOCATED IN THE CEILING of the	anteroom?	Must
	buffer room?	
Are AIR RETURNS in the cleanroom suite LOW ON THE WALL?		Must unless
Was a VISUAL SMOKE STUDY CONDUCTED to demonstrate an ABSENCE OF STAGNANT AIRFLOW?		Must
Did the VISUAL SMOKE STUDY DEMONSTRATE an ABSENCE OF STAGNANT AIRFLOW?		Must
Are AIRLOCKS USED to facilitate better control of air balance between areas of differing ISO classification or between a classified area and unclassified area (e.g., between the buffer room and anteroom or between the anteroom and a hallway)?		If no ...
Are INTERLOCKING DOORS USED to facilitate better control of air balance between areas of differing ISO classification or between a classified area and unclassified area (e.g., between the buffer room and anteroom or between the anteroom and a hallway)?		If no ...
Does the compounding site have a standard operating procedure (SOP) stating that the doors CANNOT BE OPEN AT THE SAME TIME between areas of differing ISO classification or between a classified area and unclassified area (e.g., between the buffer room and anteroom or between the anteroom and a hallway)?		Recommended
Are the FOLLOWING installed at doors between the buffer room and anteroom?	a.) Brushes	Best practice not to
	b.) Seals	
	c.) Sweeps	
Are ACCESS DOORS HANDS-FREE?		Best Practice
Are TACKY MATS placed WITHIN ISO-classified areas?		Must not
Is a visual smoke study REPEATED WHENEVER	a.) a CHANGE is made to the PLACEMENT OF EQUIPMENT within the room?	Must
	b.) ANY ALTERATION is performed within the cleanroom suite that AFFECTS THE QUALITY OF THE AIR [e.g., heating, ventilation, and air conditioning (HVAC) alterations, change of HEPA filter units]?	

Cleanroom Suite		
Is environmental monitoring REPEATED WHENEVER	a.) a CHANGE is made to the PLACEMENT OF EQUIPMENT within the room?	Must
	b.) ANY ALTERATION is performed within the cleanroom suite that AFFECTS THE QUALITY OF THE AIR [e.g., heating, ventilation, and air conditioning (HVAC) alterations, change of HEPA filter units]?	
Are MATERIALS (e.g., supplies and equipment) CONTROLLED as they are moved from classified areas of LOWER QUALITY TO those of HIGHER QUALITY [e.g., from an ISO Class 8 anteroom to an ISO Class 7 buffer room to an ISO Class 5 primary engineering control (PEC)] TO MINIMIZE the influx of contaminants?		Is
Are the DOORS of the PASS-THROUGH CHAMBER used to move materials (e.g. supplies and equipment) from classified areas of lower quality to those of higher quality to minimize the influx of contaminants INTERLOCKING?		If no ...
Are BOTH DOORS of the PASS-THROUGH CHAMBER used to move materials (e.g. supplies and equipment) from classified areas of lower quality to those of higher quality to minimize the influx of contaminants EVER OPENED AT THE SAME TIME?		Must never

Segregated Compounding Area (SCA)		
Are Category 1 CSPs prepared in the SCA?		May
Are Category 2 and/or Category 3 CSPs prepared in the SCA?		Must not
Is the SCA designed as FOLLOWS?	a.) SEPARATED from areas not directly related to compounding	Must
	b.) Located away from UNSEALED WINDOWS [May adversely affect the air quality in the primary engineering control (PEC)]	
	c.) Located away from DOORS THAT CONNECT TO THE OUTDOORS (May adversely affect the air quality in the PEC)	
	d.) Located away from TRAFFIC FLOW (May adversely affect the air quality in the PEC)	
	e.) Located where ENVIRONMENTAL CONTROL CHALLENGES cannot negatively affect the air quality of the PEC with the SCA (e.g., restrooms, warehouses, or food preparation areas)	
	f.) Carefully considering the IMPACT OF ACTIVITIES conducted around or adjacent to the SCA (e.g., patient care activities)	
	g.) PEC located in a manner that MINIMIZES conditions that could increase the risk of MICROBIAL CONTAMINATION [For example, strong air currents from opened doors, personnel traffic, or air streams from heating, ventilation, and air conditioning (HVAC) system(s) can disrupt the unidirectional airflow of an open-faced PEC such as a laminar airflow workbench (LAFW).]	
Is the AREA WITHIN ONE (1) METER of the PEC DEDICATED ONLY FOR STERILE PREPARATION (e.g., not storage, hand hygiene, donning and doffing garb, or other highly particle-generating activities such as patient care)?		Best practice
Are ITEMS WIPED with a sporicidal disinfectant, Environmental Protection Agency (EPA)-registered disinfectant, or sterile seventy (70) percent isopropyl alcohol (IPA) BEFORE BEING BROUGHT INTO SCAs provided packaging integrity will not be compromised?		Must

Primary Engineering Controls (PECs)		
Are the PECs DESIGNED TO MINIMIZE THE RISK OF CONTAMINATION during compounding of compounded sterile preparations (CSPs)?		Must
Is UNIDIRECTIONAL AIRFLOW MAINTAINED in the PECs?		Must
Is HEPA-FILTERED AIR SUPPLIED by the PECs?		If yes ...
Is HEPA-filtered air supplied by the PECs at a VELOCITY SUFFICIENT to	a.) SWEEP particles away from critical sites?	Must
	b.) MAINTAIN unidirectional airflow during operations?	
Are the PECs PLACED as FOLLOWS?	Out of TRAFFIC PATTERNS	Must
	Away from ROOM AIR CURRENTS that could disrupt the intended airflow patterns inside the PECs	
	In a manner that MINIMIZES conditions that could increase the risk of MICROBIAL CONTAMINATION [For example, strong air currents from opened doors, personnel traffic, or air streams from heating, ventilation, and air conditioning (HVAC) system(s) can disrupt the unidirectional airflow of an open-faced PEC such as a laminar airflow workbench (LAFW).]	
	In a manner that ALLOWS FOR CLEANING around the PECs [Proper placement of the PEC is critical to ensuring an ISO 5 classification environment for preparing compounded sterile preparations (CSPs)]	
Does the compounding site compound BOTH sterile and nonsterile preparations (e.g., presterilization procedures)?		If yes ...
Are the PECs used for sterile and nonsterile preparation placed IN SEPARATE ROOMS when BOTH sterile and nonsterile preparations (e.g., presterilization procedures) ARE BEING COMPOUNDED?		If no ...
Are the PECs used for sterile and nonsterile preparation SUFFICIENTLY EFFECTIVE that the ROOM can CONTINUOUSLY MAINTAIN ISO 7 classification when BOTH sterile and nonsterile preparations (e.g., presterilization procedures) ARE BEING COMPOUNDED?		Must
Are the PECs used for sterile and nonsterile preparation PLACED AT LEAST ONE (1) METER APART?		Must
Is PARTICLE-GENERATING ACTIVITY PERFORMED when sterile preparation is in process?		Must not
Are items wiped with sterile seventy (70) percent isopropryl alcohol (IPA) JUST BEFORE BEING INTRODUCED PECs?		Must
Are items wiped with sterile seventy (70) percent isopropyl alcohol (IPA) just before being introduced into PECs	a.) using LOW-LINT wipers?	Must
	b.) allowed to DRY BEFORE USE?	
	c.) without RENDERING the product label UNREADABLE?	
Does the compounding site receive STERILE ITEMS IN SEALED CONTAINERS designed to keep such items STERILE UNTIL OPENING?	Sterile items received in sealed containers designed to keep such items sterile until opening can be removed from the covering AS SUCH ITEMS ARE INTRODUCED INTO ISO classification 5 PECs WITHOUT BEING WIPED WITH STERILE seventy (70) percent isopropyl alcohol (IPA).	

Primary Engineering Controls (PECs)		
Are CRITICAL SITES (e.g., vial stoppers, ampule necks, and intravenous bag septums) WIPED WITH STERILE seventy (70) percent isopropyl alcohol (IPA) IN PECs	a.) to provide both chemical and mechanical actions to REMOVE CONTAMINANTS?	Must
	b.) allowed to DRY BEFORE personnel ENTER OR PUNCTURE stoppers and septums OR BREAK the necks of ampules?	
Does the compounding site COMPOUND Category 1, Category 2, and/or Category 3 CSPs in ISO 5 CLASSIFICATION OR BETTER PECs?		Must
Are the PECs certified to meet ISO 5 classification or better conditions DURING DYNAMIC OPERATING CONDITIONS?		Must

Laminar Airflow Systems (LAFS)		
Was an INITIAL DYNAMIC AIRFLOW SMOKE PATTERN TEST PERFORMED in the LAFS?		Must
Is a DYNAMIC AIRFLOW SMOKE PATTERN TEST PERFORMED in the LAFS AT LEAST EVERY SIX (6) MONTHS??		Must
Is the LAFS LOCATED	a.) OUT OF TRAFFIC patterns that could disrupt the intended airflow patterns inside the primary engineering control (PEC)?	Must
	b.) AWAY FROM ROOM air currents that could disrupt the intended airflow patterns inside the PEC?	
Is the LAFS LOCATED WITHIN A CLEANROOM SUITE?		If yes ...
Does the cleanroom suite have an ISO 7 CLASSIFICATION OR BETTER BUFFER ROOM?		Must
Does the cleanroom suite have an ISO 8 CLASSIFICATION OR BETTER ANTEROOM?		Must
Is the LAFS LOCATED WITHIN A CLEANROOM SUITE?		If no ...
Is the LAFS an integrated vertical laminar flow zone (IVLFZ)?		Must not
Is the LAFS LOCATED WITHIN A CLEANROOM SUITE?		If no ...
Is the LAFS PLACED IN a segregated compounding area (SCA)?		If yes ...
Which category of compounded sterile preparations (CSPs) are being prepared in the LAFS placed in a segregated compounding area (SCA)?	a.) Category 1 CSPs	Compliant
	b.) Category 2 and/or Category 3 CSPs	Non-compliant
Laminar Airflow Workbench (LAFW)		
Is the LAFW used for the preparation of	a.) ANTINEOPLASTICS?	Must not ... See (800) Hazardous Drugs - Handling in Healthcare Settings
	b.) active pharmaceutical ingredient (API) HAZARDOUS DRUGS (HDs)?	
Integrated Vertical Laminar Flow Zone (IVLFZ)		
Is the IVLFZ used for the preparation of	a.) ANTINEOPLASTICS?	Must not ... See (800) Hazardous Drugs - Handling in Healthcare Settings
	b.) active pharmaceutical ingredient (API) HAZARDOUS DRUGS (HDs)?	
Are air returns STRATEGICALLY LOCATED?		Required
Is there FULL COVERAGE of HEPA filters ABOVE THE WORK SURFACE?		Required
Is there a UNIDIRECTIONAL HEPA-FILTERED ZONE SEPARATED from the ISO 7 classification area WITH A PHYSICAL BARRIER?		Must
Were BOTH STATIC AND DYNAMIC SMOKE STUDIES	a.) PERFORMED to verify a continuous flow 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
	b.) DOCUMENTED?	

Laminar Airflow Systems (LAFS)		
Class II Biological Safety Cabinet (BSC)		
Is the Class II BSC used for preparation of … …	a.) ANTINEOPLASTICS?	See (800) Hazardous Drugs - Handling in Healthcare Settings
	b.) active pharmaceutical ingredient (API) HAZARDOUS DRUGS (HDs)?	

Restricted-Access Barrier Systems (RABS)		
Was an INITIAL DYNAMIC AIRFLOW SMOKE PATTERN TEST PERFORMED in the RABS?		Must
Is a DYNAMIC AIRFLOW SMOKE PATTERN TEST PERFORMED in the RABS AT LEAST EVERY SIX (6) MONTHS?		Must
Is the RECOVERY TIME AFTER OPENING the transfer chamber to achieve ISO 5 classification air quality DOCUMENTED (e.g., by the manufacturer)?		Must
Are INTERNAL PROCEDURES DEVELOPED to ensure that adequate recovery time is allowed after opening and closing the RABS, both before and during compounding operations?		Must
Are the DEFINED OPENINGS of the RABS OPENED DURING COMPOUNDING OPERATIONS?		Generally not
Is the RABS LOCATED WITHIN A CLEANROOM SUITE?		If yes ...
Does the cleanroom suite have an ISO 7 CLASSIFICATION OR BETTER BUFFER ROOM?		Must
Does the cleanroom suite have an ISO 8 CLASSIFICATION OR BETTER ANTEROOM?		Must
Is the RABS LOCATED WITHIN A CLEANROOM SUITE?		If no ...
Is the RABS PLACED IN a segregated compounding area (SCA)?		If yes ...
Which category of compounded sterile preparations (CSPs) are being prepared in the RABS placed in a segregated compounding area (SCA)?	Category 1 CSPs	Compliant
	Category 2 and/or Category 3 CSPs	Non-compliant
Compounding Aseptic Isolator (CAI)		
Does AIR EXCHANGE into the CAI from the surrounding environment OCCUR AFTER THE AIR PASSES THROUGH a HEPA FILTER?		Must not
Is the CAI used for the preparation of	ANTINEOPLASTICS?	Must not ... See (800) Hazardous Drugs - Handling in Healthcare Settings
	active pharmaceutical ingredient (API) HAZARDOUS DRUGS (HDs)?	
Compounding Aseptic Containment Isolator (CACI)		
See (800) Hazardous Drugs - Handling in Healthcare Settings		

Pharmaceutical Isolator		
Was an INITIAL DYNAMIC AIRFLOW SMOKE PATTERN TEST PERFORMED in the pharmaceutical isolator?		Must
Is a DYNAMIC AIRFLOW SMOKE PATTERN TEST PERFORMED in the pharmaceutical isolator AT LEAST EVERY SIX (6) MONTHS?		Must
Is the pharmaceutical isolator PLACED IN AN ISO 8 classification or better ROOM?		If no ...
Is the pharmaceutical isolator PLACED IN a segregated compounding area (SCA)?		If yes ...
Which category of compounded sterile preparations (CSPs) are being prepared in the pharmaceutical isolator placed in a segregated compounding area (SCA)?	Category 1 CSPs	Compliant
	Category 2 and/or Category 3 CSPs	Non-compliant

Robotic Enclosure	
Was an INITIAL DYNAMIC AIRFLOW SMOKE PATTERN TEST PERFORMED in the robotic enclosure?	Must
Is a DYNAMIC AIRFLOW SMOKE PATTERN TEST PERFORMED in the robotic enclosure AT LEAST EVERY SIX (6) MONTHS?	Must

Air Exchange Requirements for Non-Hazardous Drug (HD) Compounded Sterile Preparations (CSPs)		
Segregated Compounding Area (SCA)		
A SCA has no air changes per hour (ACPH) requirement.		
ISO 7 Classification Room(s)		
Do AT LEAST FIFTEEN (15) air changes per hour (ACPH) OF THE TOTAL AIR CHANGE RATE in a room COME FROM the heating, ventilation, and air conditioning (HVAC)?		Must
Do the air changes per hour (ACPH) from the heating, ventilation, and air conditioning (HVAC) come through HEPA filters LOCATED IN THE CEILING?		Must
Does the HEPA-filtered air from the primary engineering control (PEC) WHEN ADDED TO HVAC-SUPPLIED HEPA-filtered air INCREASE THE TOTAL HEPA-filtered air changes per hour (ACPH) TO AT LEAST THIRTY (30) ACPH?		Must
Is the primary engineering control (PEC) USED TO MEET THE MINIMUM TOTAL REQUIREMENT of thirty (30) air changes per hour (ACPH)?		If yes ...
Is the primary engineering control (PEC) TURNED OFF at the compounding site?		If yes ...
Is the primary engineering control (PEC) TURNED OFF at the compounding site ONLY FOR MAINTENANCE?		Only exception
Is the total HEPA-filtered air change rate ADEQUATE TO MAINTAIN ISO 7 classification DURING DYNAMIC operating conditions CONSIDERING THE FOLLOWING?	a.) NUMBER of personnel PERMITTED TO WORK in the area	Must
	b.) Number of PARTICLES that may be PARTICLES from activities and processes in the area	
	c.) EQUIPMENT located in the room	
	d.) Room PRESSURE	
ISO 8 Classification Room(s)		
Do AT LEAST FIFTEEN (15) air changes per hour (ACPH) OF THE TOTAL AIR CHANGE RATE in a room COME FROM the heating, ventilation, and air conditioning (HVAC)?		Must
Do AT LEAST FIFTEEN (15) air changes per hour (ACPH) OF THE TOTAL AIR CHANGE RATE in a room come from the heating, ventilation, and air conditioning (HVAC) through HEPA filters LOCATED IN THE CEILING?		Must
Is the total HEPA-filtered air change rate ADEQUATE TO MAINTAIN ISO 8 classification DURING DYNAMIC operating conditions CONSIDERING THE FOLLOWING?	a.) NUMBER of personnel PERMITTED TO WORK in the area	Must
	b.) Number of PARTICLES that may be PARTICLES from activities and processes in the area	
	c.) EQUIPMENT located in the room	
	d.) Room PRESSURE	

Certification and Recertification Timetable		
Was the compounding area independently certified using the requirements in (797) Pharmaceutical Compounding - Sterile Preparations and when applicable, manufacturer specifications BEFORE THE COMPOUNDING AREA WAS USED TO COMPOUND either Category 1, Category 2, or Category 3 compounded sterile preparations (CSPs)?		Must
Is RECERTIFICATION OF CLASSIFIED AREAS, including the primary engineering controls (PECs), in the compounding area PERFORMED AT LEAST EVERY SIX (6) MONTHS?		Must
Have ANY NON-EMERGENCY CHANGES, such as redesign, construction, replacement or relocation of any primary engineering control (PEC), or alteration in the configuration of the room that could affect airflow or air quality, been made to CLASSIFIED AREAS in the compounding area OR ANY SPACE, including adjacent space, utilized for the compounding of sterile pharmaceuticals?		If yes ...
Which of the FOLLOWING NON-EMERGENCY CHANGES were made to classified areas in the compounding area or any space, including adjacent space, utilized for the compounding of sterile pharmaceuticals?	Alteration in the configuration of the room that could affect airflow or air quality	
	Construction	
	Redesign	
	Relocation of any primary engineering control (PEC)	
	Relocation of any space utilized for the compounding of sterile pharmaceuticals	
	Remodel of any area utilized for the compounding of sterile pharmaceuticals or adjacent space	
	Replacement of any PEC	
	Upgrade or conduct a non-emergency repair to the heating, ventiliation, air conditioning, or primary or secondary engineering controls for any space utilized for the compounding of sterile pharmaceuticals	
Did the sterile compounding pharmacy NOTIFY the Connecticut Department of Consumer Protection (DCP) IN WRITING NOT LATER THAN FORTY-FIVE (45) DAYS PRIOR TO COMMENCING NON-EMERGENCY CHANGES, such as redesign, construction, replacement or relocation of any primary engineering control (PEC), or alteration in the configuration of the room that could affect airflow or air quality, to classified areas in the compounding area or any space, including adjacent space, utilized for the compounding of sterile pharmaceuticals? [Section 20-633b(f)(1)]		Shall
Were the classified areas in the compounding area or any space, including adjacent space, utilized for the compounding of sterile pharmaceuticals RECERTIFIED AFTER NON-EMERGENCY CHANGES, such as redesign, construction, replacement or relocation of any primary engineering control (PEC), or alteration in the configuration of the room that could affect airflow or air quality, were made to classified areas in the compounding area or any space, including adjacent space, utilized for the compounding of sterile pharmaceuticals?		Must
Did the sterile compounding pharmacy PROVIDE A COPY OF RECERTIFICATION to the Connecticut Department of Consumer Protection (DCP) AFTER NON-EMERGENCY CHANGES were made to classified areas in the compounding area or any space, including adjacent space, utilized for the compounding of sterile pharmaceuticals NOT LATER THAN FIVE (5) DAYS AFTER RECERTIFICATION APPROVAL? [Section 20-633b(f)(2)]		Shall
Was RECERTIFICATION PERFORMED BY an INDEPENDENT LICENSED environmental monitoring entity? [Section 20-633b(f)(2)]		Shall only
Have ANY EMERGENCY REPAIRS been made to CLASSIFIED AREAS in the compounding area OR ANY SPACE, including adjacent space, utilized for the compounding of sterile pharmaceuticals?		If yes ...
Did the sterile compounding pharmacy NOTIFY the Connecticut Department of Consumer Protection (DCP) IN WRITING NOT LATER THAN TWENTY-FOUR (24) HOURS AFTER EMERGENCY REPAIRS made to classified areas in the compounding area or any space, including adjacent space, utilized for the compounding of sterile pharmaceuticals COMMENCED? [Section 20-633b(f)(1)]		Shall

Certification and Recertification Records		
Does the compounding site MAINTAIN certification and recertification RECORDS IN WRITTEN OR ELECTRONIC FORM?		Must
Do the certification and recertification records meet the FOLLOWING REQUIREMENTS?		
Maintenance:	a.) IN COMPLIANCE with all laws and regulations of the applicable jurisdiction	Must
	b.) LEGIBLE	
	c.) STORED in a manner that prevents their deterioration and/or loss	
	d.) Readily RETRIEVABLE for AT LEAST THREE (3) YEARS AFTER PREPARATION of compounded sterile preparations (CSPs)	
Review:	a.) REVIEWED by the designated person(s) or pharmacist, whichever is applicable, to ensure classified environments meet the minimum requirements in (797)	Must
Airflow Testing:	a.) Documentation of the air changes per hour (ACPH) FROM heating, ventilation, and air conditioning (HVAC)	Must
	b.) Documentation of the ACPH CONTRIBUTED from the primary engineering controls (PECs)	
Dynamic Airflow Smoke-Pattern Testing:	a.) Documentation of the NUMBER OF PERSONNEL present in each primary engineering control (PEC) during testing	Must
	b.) Documentation of the NUMBER OF PERSONNEL present in each secondary engineering control (SEC) during testing	
	c.) Performed for EACH primary engineering control (PEC)	
	d.) Performed during DYNAMIC operating conditions	
HEPA Filter Integrity Testing:	a.) Leak tested at the FACTORY	Must
	b.) Leak tested after INSTALLATION	
	c.) Leak tested as part of RECERTIFICATION	
Total Airborne Particle Count Testing:	a.) Documentation of the NUMBER OF PERSONNEL present in each primary engineering control (PEC) during testing	Must
	b.) Documentation of the NUMBER OF PERSONNEL present in each secondary engineering control (SEC) during testing	
	c.) CONDUCTED under DYNAMIC operating conditions	
	d.) CONDUCTED using CALIBRATED ELECTRONIC equipment	
	e.) CONDUCTED in all CLASSIFIED areas	
	f.) CONDUCTED at least every SIX (6) MONTHS	
	g.) MEASUREMENTS taken IN EACH primary engineering control (PEC) at locations WHERE there is GREATEST RISK to the exposed compounded sterile preparations (CSPs), containers, and closures	
	h.) Sampling SITES SELECTED in all classified areas	
	i.) Sampling SITES DESCRIBED in the compounding site's standard operating procedures (SOPs)	

Certification and Recertification Records		
Total Airborne Particle Count Testing: (continued)	j.) ALL PROCEDURES DESCRIBED in the compounding site's standard operating procedures (SOPs)	Must
	k.) CONDUCTED with care to AVOID DISTURBING the UNIDIRECTIONAL AIRFLOW	Best practice
	l.) MEASUREMENTS taken at REPRESENTATIVE LOCATIONS in other classified areas	
Do the certification and recertification RECORDS DOCUMENT ANY OUT-OF-RANGE RESULTS?		If yes ...
Which of the following REQUIRED TESTS documented out-of-range results?		
AIRFLOW testing, Dynamic airflow SMOKE pattern test, and/or HEPA FILTER integrity testing		
Was a CORRECTIVE ACTION PLAN	a.) IMPLEMENTED in response to the out-of-range results documented in certification and recertification records?	Must
	b.) DOCUMENTED?	
Was the DATA COLLECTED in response to corrective actions REVIEWED TO CONFIRM that the actions taken have been EFFECTIVE?		Must
Total AIRBORNE particle count testing		
Did LEVELS measured during the total airborne sampling EXCEED THE CRITERIA for the ISO classification of the area sampled?		If yes ...
Was the CAUSE FOR LEVELS measured during the total airborne sampling EXCEEDING THE CRITERIA for the ISO classification of the area sampled INVESTIGATED?		Must
Was the EXTENT OF THE INVESTIGATION to determine the cause for levels measured during the total airborne sampling exceeding the criteria for the ISO classification of the area sampled CONSISTENT WITH THE DEVIATION?		Best practice
Did the INVESTIGATION to determine the cause for levels measured during the total airborne sampling exceeding the criteria for the ISO classification of the area sampled INCLUDE AN EVALUATION OF TRENDS?		Best practice
Was CORRECTIVE ACTION, such as process or compounding site improvements or HEPA filter replacement or repair, ...	a.) TAKEN when LEVELS measured during the total airborne sampling EXCEEDED THE CRITERIA for the ISO classification of the area sampled?	Must
	b.) DOCUMENTED when LEVELS measured during the total airborne sampling EXCEEDED THE CRITERIA for the ISO classification of the area sampled?	
Was the DATA COLLECTED IN RESPONSE TO CORRECTIVE ACTIONS taken when levels measured during the total airborne sampling exceeded the criteria for the ISO classification of the area sampled REVIEWED TO CONFIRM that the actions taken have been EFFECTIVE?		Must

Cleanable Conditions		
Cleanroom Suite		
Do the SURFACES in the CLEANROOM SUITE meet the following REQUIRED conditions so they can be cleaned and disinfected and to minimize spaces in which microorganisms and other contaminants can accumulate?	a.) FREE FROM cracks and crevices	Must
	b.) IMPERVIOUS	
	c.) NONSHEDDING	
	d.) SMOOTH	
Are SURFACES IN THE CLEANROOM SUITE RESISTANT TO DAMAGE (e.g., rust) by cleaning agents, sporicidal and other types of disinfectants, and tools used to clean?		Best practice
Does the CEILING consist of INLAID PANELS?		If yes ...
Are the INLAID PANELS CAULKED AROUND each inlaid panel TO SEAL them TO the SUPPORT FRAME?		Must
Are there PENETRATIONS through the ceiling?		If yes ...
Are ALL PENETRATIONS through the ceiling SEALED?		Must
Are JUNCTURES BETWEEN THE CEILING AND THE WALLS SEALED to eliminate cracks and crevices where dirt can accumulate?		Must
Are CEILING LIGHT FIXTURES PRESENT in the classified area?		If yes ...
Is the EXTERIOR LENS SURFACE of ceiling light fixtures	a.) SMOOTH?	Must
	b.) mounted FLUSH?	
	c.) SEALED?	
Are the WALLS CONSTRUCTED of, or may be covered with, DURABLE MATERIAL (e.g., epoxy painted walls or heavy-gauge polymer)?		Must
Is the INTEGRITY of WALL SURFACES MAINTAINED?		Must
Do the walls consist of WALL PANELS?		If yes ...
Are the WALL PANELS	a.) JOINED together?	Must
	b.) SEALED to each other and the support structure?	
Are there PENETRATIONS through the walls?		If yes ...
Are ALL PENETRATIONS through the walls SEALED?		Must
Are JUNCTURES between the	a.) walls and floors SEALED to eliminate cracks and crevices where dirt can accumulate?	Must
	b.) floor and the wall CAULKED?	
Does the FLOOR INCLUDE COVING TO THE SIDEWALL?		Must
Are dust-collecting overhangs and ledges (e.g., utility pipes and windowsills) PRESENT in the classified area?		If yes ...
Are the DUST-COLLECTING overhangs and ledges (e.g., utility pipes and windowsills)	a.) MINIMIZED?	Best practice
	b.) easily CLEANABLE?	Must

Cleanable Conditions		
Segregated Compounding Area (SCA)		
Is the SCA and all surfaces (e.g., walls, floors, counters, and equipment) … …	a.) CLEAN?	Must
	b.) UNCLUTTERED?	
	c.) DEDICATED to compounding?	
Do the SURFACES in the SCA MEET the FOLLOWING CONDITIONS so they can be cleaned and disinfected and to minimize spaces in which microorganisms and other contaminants can accumulate?	a.) FREE FROM cracks and crevices	Best practice
	b.) IMPERVIOUS	
	c.) NONSHEDDING	
	d.) SMOOTH	
Are SURFACES IN THE SCA RESISTANT TO DAMAGE (e.g., rust) by cleaning agents, sporicidal and other types of disinfectants, and tools used to clean?		Best practice
Are dust-collecting overhangs and ledges (e.g., utility pipes and windowsills) PRESENT?		If yes …
Are the DUST-COLLECTING overhangs and ledges (e.g., utility pipes and windowsills) … …	a.) MINIMIZED?	Best practice
	b.) easily CLEANABLE?	Must

Cleaning, Disinfecting, and Sporicidal Disinfectants		
Are STERILE cleaning, disinfecting, and sporicidal AGENTS USED	WITHIN primary engineering controls (PECs)?	Must
	in CLASSIFIED areas OUTSIDE PECs?	Best practice
Are CONCENTRATED cleaning and disinfecting AGENTS used by the compounding site?		If yes ...
Is STERILE WATER USED TO DILUTE concentrated cleaning and disinfecting agents for use	WITHIN primary engineering controls (PECs)?	Must
	in CLASSIFIED areas OUTSIDE PECs?	Best practice
Are sterile cleaning and disinfecting agents and supplies [e.g., closed containers of sterile wipers, sterile seventy (70) percent isopropyl alcohol (IPA)], once opened, REUSED FOR A TIME PERIOD	specified as by the MANUFACTURER?	May
	described in the compounding site's WRITTEN standard operating procedures (SOPs)?	
Are the manufacturer's directions or published data for the MINIMUM CONTACT TIME FOLLOWED FOR EACH cleaning agent, disinfecting agent, and sporicidal disinfectant used?		Must
Are ALL cleaning and disinfecting SUPPLIES (e.g., wipers, sponges, pads, and mop heads), with the exception of tool handles and holders, ...	LOW LINT?	Must
	used within primary engineering controls (PECs) STERILE?	
Are TOOL HANDLES AND HOLDERS CLEANED AND DISINFECTED PRIOR TO USE in primary engineering controls (PECs)?		Must
Are cleaning supplies used in classified areas and segregated compounding areas (SCAs) DISPOSED OF IN A MANNER THAT MINIMIZES the potential for DISPERSING CONTAMINANTS into the air (e.g., with minimal agitation, away from work surfaces)?		Must
Does the compounding site USE REUSABLE cleaning tools?		If yes ...
Are the REUSABLE cleaning tools MADE OF CLEANABLE MATERIALS?		Must
Are the HANDLES of REUSABLE cleaning tools MADE OF WOOD OR ANY OTHER POROUS MATERIAL?		Best practice not to
Are REUSABLE cleaning tools	cleaned and disinfected BEFORE each use?	Must
	cleaned and disinfected AFTER each use?	
	DISCARDED as determined based on the condition of the tools?	
	DEDICATED for use in classified areas or segregated compounding areas (SCAs)?	Must
Are REUSABLE cleaning tools DEDICATED FOR USE in classified areas or segregated compounding areas (SCAs) REMOVED from these areas for DISPOSAL ONLY?		Only exception
Does the compounding site USE DISPOSABLE cleaning supplies (e.g., wipers, sponges, pads, and mop heads)?		Best practice
Are DISPOSABLE cleaning supplies (e.g., wipers, sponges, pads, and mop heads) DISCARDED AFTER EACH CLEANING ACTIVITY?		Must
Is the SAME FLOOR MOP USED in BOTH the buffer room and anteroom where NON-HAZARDOUS drugs (HDs) are compounded?		If yes ...
Is the same floor mop used in both the buffer room and anteroom where non-HDs are compounded USED IN the BUFFER ROOM THEN the ANTEROOM?		Must
Is the same floor mop used in both the buffer room and anteroom where non-HDs are compounded USED in AREAS where HDs are compounded?		Must not
Are mops USED in AREAS where HDs are compounded DEDICATED for use ONLY in those AREAS?		Must
Are ALL CLEANING AND DISINFECTING activities PERFORMED	by TRAINED personnel?	Must
	by appropriately GARBED personnel?	
	using compounding site-APPROVED AGENTS?	
	using compounding site-APPROVED PROCEDURES?	

Cleaning, Disinfecting, and Sporicidal Disinfectants		
Are PERSONNEL TRAINED WHEN there are ANY CHANGES in the cleaning and disinfecting PROCEDURES?		Must
Do all cleaning personnel FOLLOW … …	FREQUENCY of cleaning, disinfecting, and applying sporicidal disinfectants?	Must
	LOCATION(s) of cleaning, disinfecting, and applying sporicidal disinfectants?	
	METHOD(s) of cleaning, disinfecting, and applying sporicidal disinfectants?	

Cleaning		
Are SURFACES in classified areas used to prepare Category 1, Category 2, and Category 3 CSPs CLEANED PRIOR TO being DISINFECTED WITH an Environmental Protection Agency (EPA)-REGISTERED DISINFECTANT?		If no ...
Is an Environmental Protection Agency (EPA)-REGISTERED ONE-STEP DISINFECTANT CLEANER USED on surfaces in classified areas used to prepare Category 1, Category 2, and Category 3 CSPs to accomplish both the cleaning and disinfecting in one step?		Compliant
Is cleaning PERFORMED in the direction of CLEAN TO DIRTY AREAS?		Must
Does the compounding site CLEAN the FOLLOWING SURFACES in classified areas used to prepare Category 1, Category 2, and/or Category 3 compounded sterile preparations (CSPs) AT LEAST DAILY?	a.) All interior surfaces of primary engineering controls (PECs) are cleaned ON DAYS WHEN compounding occurs AND WHEN surface contamination is known or suspected	Must
	b.) Equipment of PECs are cleaned ON DAYS WHEN compounding occurs AND WHEN surface contamination is known or suspected	
	c.) Floors are cleaned ON DAYS WHEN compounding occurs	
	d.) Work surfaces outside of PECs are cleaned ON DAYS WHEN compounding occurs	
Does the compounding site CLEAN the FOLLOWING SURFACES in classified areas used to prepare Category 1, Category 2, and/or Category 3 compounded sterile preparations (CSPs) AT LEAST MONTHLY?	a.) Bins	Must
	b.) Ceilings	
	c.) Doors	
	d.) Door frames	
	e.) Equipment outside primary engineering controls (PECs)	
	f.) Storage shelving	
	g.) Walls	
Does the compounding site CLEAN the FOLLOWING SURFACES in a segregated compounding area (SCA) used to prepare Category 1 compounded sterile preparations (CSPs) AT LEAST DAILY?	a.) All interior surfaces of primary engineering controls (PECs) are cleaned ON DAYS WHEN compounding occurs AND WHEN surface contamination is known or suspected	Must
	b.) Equipment of PECs are cleaned ON DAYS WHEN compounding occurs AND WHEN surface contamination is known or suspected	
	c.) Floors are cleaned ON DAYS WHEN compounding occurs	
	d.) Work surfaces outside of PECs are cleaned ON DAYS WHEN compounding occurs	
Does the compounding site CLEAN the FOLLOWING SURFACES in a segregated compounding area (SCA) used to prepare Category 1 compounded sterile preparations (CSPs) AT LEAST MONTHLY?	a.) Bins	Must
	b.) Doors	
	c.) Door frames	
	d.) Equipment outside primary engineering controls (PECs)	
	e.) Storage shelving	
	f.) Walls	

Cleaning		
Are CEILINGS in a SEGREGATED COMPOUNDING AREA (SCA) CLEANED AT LEAST WHEN visibly soiled and when surface contamination is known or suspected?		Must
Are PASS-THROUGH chamber(s) CLEANED DAILY ON DAYS WHEN COMPOUNDING OCCURS?		Must
Do any primary engineering controls (PECs) have a REMOVABLE WORK TRAY?		If yes ...
Does the compounding site CLEAN removable work trays of primary engineering controls (PECs) with the FOLLOWING FREQUENCIES?	a.) WORK SURFACE daily on days when compounding occurs	Must
	b.) ALL SURFACES monthly	
	c.) AREA UNDERNEATH monthly	
Is ALL cleaning DOCUMENTED ACCORDING TO the compounding site's standard operating procedures (SOPs)?		Must

Disinfecting		
Does the compounding site carefully MAKE the FOLLOWING CONSIDERATIONS when selecting and using disinfectants?	a.) ANTIMICROBIAL activity	Must
	b.) COMPATIBILITIES	
	c.) EFFECTIVENESS	
	d.) INACTIVATION by organic matter	
	e.) PREPARATION requirements of the agent	
	f.) RESIDUE	
	g.) Shelf LIFE	
	h.) SUITABILTY for surfaces being disinfected	
	i.) User SAFETY	
Does the compounding site DISINFECT the FOLLOWING SURFACES in classified areas used to prepare Category 1, Category 2, and/or Category 3 compounded sterile preparations (CSPs) AT LEAST DAILY?	a.) All interior surfaces of primary engineering controls (PECs) are disinfected ON DAYS WHEN compounding occurs AND WHEN surface contamination is known or suspected	Must
	b.) Equipment of PECs are disinfected ON DAYS WHEN compounding occurs AND WHEN surface contamination is known or suspected	
	c.) Floors are disinfected ON DAYS WHEN compounding occurs	
	d.) Work surfaces outside of PECs are disinfected ON DAYS WHEN compounding occurs	
Does the compounding site DISINFECT the FOLLOWING SURFACES in classified areas used to prepare Category 1, Category 2, and/or Category 3 compounded sterile preparations (CSPs) AT LEAST MONTHLY?	a.) Bins	Must
	b.) Ceilings	
	c.) Doors	
	d.) Door frames	
	e.) Equipment outside primary engineering controls (PECs)	
	f.) Storage shelving	
	g.) Walls	
Does the compounding site DISINFECT the FOLLOWING SURFACES in a segregated compounding area (SCA) used to prepare Category 1 compounded sterile preparations (CSPs) AT LEAST DAILY?	a.) All interior surfaces of primary engineering controls (PECs) are disinfected ON DAYS WHEN compounding occurs AND WHEN surface contamination is known or suspected	Must
	b.) Equipment of PECs are disinfected ON DAYS WHEN compounding occurs AND WHEN surface contamination is known or suspected	
	c.) Floors are disinfected ON DAYS WHEN compounding occurs	
	d.) Work surfaces outside of PECs are disinfected ON DAYS WHEN compounding occurs	

Disinfecting		
Does the compounding site DISINFECT the FOLLOWING SURFACES in a segregated compounding area (SCA) used to prepare Category 1 compounded sterile preparations (CSPs) AT LEAST MONTHLY?	a.) Bins	Must
	b.) Doors	
	c.) Door frames	
	d.) Equipment outside primary engineering controls (PECs)	
	e.) Storage shelving	
	f.) Walls	
Are CEILINGS in a SEGREGATED COMPOUNDING AREA (SCA) DISINFECTED AT LEAST WHEN visibly soiled and when surface contamination is known or suspected?		Must
Are PASS-THROUGH chamber(s) DISINFECTED DAILY ON DAYS WHEN COMPOUNDING OCCURS?		Must
Do any primary engineering controls (PECs) have a REMOVABLE WORK TRAY?		If yes ...
Does the compounding site DISINFECT removable work trays of primary engineering controls (PECs) with the FOLLOWING FREQUENCIES?	a.) WORK SURFACE daily on days when compounding occurs	Must
	b.) ALL SURFACES monthly	
	c.) AREA UNDERNEATH monthly	
Is STERILE seventy (70) percent IPA applied AS FOLLOWS?	a.) AFTER the application of a ONE-STEP DISINFECTANT CLEANER OR SPORICIDAL DISINFECTANT to remove any residue	Must
	b.) IMMEDIATELY BEFORE initiating compounding	
	c.) To the horizontal work surface, including any removable work trays, of a primary engineering control (PEC) AT LEAST EVERY THIRTY (30) MINUTES when a compounding process takes thirty (30) minutes or less	
	d.) To the horizontal work surface, including any removable work trays, of a PEC IMMEDIATELY AFTER COMPOUNDING WHEN a compounding process takes MORE THAN THIRTY (30) MINUTES	
	e.) Allowed to DRY	
Is compounding DISRUPTED WHEN a compounding process takes MORE THAN THIRTY (30) MINUTES?		Must not
Is ALL disinfecting DOCUMENTED ACCORDING TO the compounding site's standard operating procedures (SOPs)?		Must
Does the compounding site FOLLOW THE PROCEDURES, in the order listed below, for cleaning and disinfecting PECs?	a.) REMOVE visible particles, debris, or residue with an appropriate solution (e.g., sterile water for injection or sterile water for irrigation) using sterile, low-lint wipers, if necessary	Must
	b.) APPLY a sterile cleaning agent followed by a sterile Environmental Protection Ageny (EPA)-registered disinfectant or apply a sterile EPA-registered one-step disinfectant cleaner to equipment and all interior surfaces of the PEC using a sterile low-lint wiper	
	c.) ENSURE the CONTACT TIME specified by the manufacturer is achieved	
	d.) APPLY sterile seventy (70) percent isopropyl alcohol (IPA) to equipment and all interior surfaces in the PEC using a sterile low-lint wiper	
	e.) ALLOW the surface to dry completely before beginning compounding	

Sporicidal Disinfectants		
Does the compounding site apply SPORICIDAL DISINFECTANT to the FOLLOWING SURFACES in classified areas used to prepare Category 1, Category 2, and/or Category 3 CSPs AT LEAST MONTHLY?	a.) Bins	Must
	b.) Ceilings	
	c.) Doors	
	d.) Door frames	
	e.) Equipment outside primary engineering controls (PECs)	
	f.) Storage shelving	
	g.) Walls	
The compounding site CANNOT EXCEED the applicable beyond-use dates (BUDs) described in Table 13 of (797) Pharmaceutical Compounding - Sterile Preparations when the compounding site DOES NOT MEET all the conditions described in (797) Pharmaceutical Compounding - Sterile Preparations for the preparation of Category 3 CSPs		
Does the compounding site apply SPORICIDAL DISINFECTANT to the REQUIRED surfaces in CLASSIFIED AREAS used to prepare Category 1 and/or Category 2 CSPs AT LEAST MONTHLY?	a.) All interior surfaces of primary engineering controls (PECs)	Must
	b.) Equipment of PECs	
	c.) Floors	
	d.) Work surfaces outside of PECs	
Does the compounding site apply SPORICIDAL DISINFECTANT to the REQUIRED surfaces in CLASSIFIED AREAS used to prepare Category 3 CSPs AT LEAST WEEKLY?	a.) All interior surfaces of primary engineering controls (PECs)	Must
	b.) Equipment of PECs	
	c.) Floors	
	d.) Work surfaces outside of PECs	
The compounding site CANNOT EXCEED the applicable beyond-use dates (BUDs) described in Table 13 of (797) Pharmaceutical Compounding - Sterile Preparations when the compounding site DOES NOT MEET all the conditions described in (797) Pharmaceutical Compounding - Sterile Preparations for the preparation of Category 3 CSPs		
Does the compounding site apply SPORICIDAL DISINFECTANT to the FOLLOWING SURFACES in a segregated compounding area (SCA) used to prepare Category 1 CSPs AT LEAST MONTHLY?	a.) Bins	Must
	b.) Ceilings	
	c.) Doors	
	d.) Door frames	
	e.) Equipment outside primary engineering controls (PECs)	
	f.) Storage shelving	
	g.) Walls	
Do PASS-THROUGH chamber(s) have SPORICIDAL DISINFECTANT applied AT LEAST MONTHLY?		Must
Do any primary engineering controls (PECs) have a REMOVABLE WORK TRAY?		If yes ...
Does the compounding site APPLY SPORICIDAL DISINFECTANT to removable work trays of primary engineering controls (PECs) with the FOLLOWING FREQUENCIES?	a.) WORK SURFACE monthly	Must
	b.) ALL SURFACES monthly	
	c.) AREA UNDERNEATH monthly	
The compounding site CANNOT EXCEED the applicable beyond-use dates (BUDs) described in Table 13 of (797) Pharmaceutical Compounding - Sterile Preparations when the compounding site DOES NOT MEET all the conditions described in (797) Pharmaceutical Compounding - Sterile Preparations for the preparation of Category 3 CSPs		
Are ALL applications of sporicidal disinfectants DOCUMENTED ACCORDING TO the compounding site's standard operating procedures (SOPs)?		Must

Sporicidal Disinfectants		
Does the compounding site FOLLOW THE PROCEDURES, in the order listed below, for applying sporicidal disinfectant in PECs?	a.) REMOVE visible particles, debris, or residue with an appropriate solution (e.g., sterile water for injection or sterile water for irrigation) using sterile, low-lint wipers, if necessary	Must
	b.) APPLY sterile sporicidal disinfectant using a sterile low-lint wiper to all surfaces and the area underneath the work tray after cleaning and disinfecting	
	c.) SEPARATE cleaning and disinfecting steps are not required if the sporicidal disinfectant is a sterile Environmental Protection Agency (EPA)-registered one-step disinfectant sporicidal cleaner	
	d.) ENSURE the CONTACT TIME specified by the manufacturer is achieved	
	e.) APPLY sterile seventy (70) percent isopropyl alcohol (IPA) to all interior surfaces, including underneath the work tray, using a sterile low-lint wiper	
	f.) ALLOW the surface to dry completely before beginning compounding	

Humidity		
Is the cleanroom suite MAINTAINED at a relative humidity of sixty (60) percent or below?		Best practice
Is the humidity in the cleanroom suite CONTROLLED THROUGH a heating, ventilation, and air conditioning (HVAC) SYSTEM?		Must
Is the humidity monitored	a.) in EACH ROOM of the cleanroom suite?	Must
	b.) EACH DAY that compounding is performed?	
Are humidity monitoring devices	a.) VERIFIED for accuracy?	Must
	b.) verified for accuracy AT LEAST every twelve (12) months or as required by the manufacturer?	
Are the RESULTS of the humidity readings STORED in the continuous recording device?		If no ...
Are the results of the humidity readings documented AT LEAST ONCE DAILY?		Must
Are the RESULTS of the humidity readings	a.) RETRIEVABLE?	Must
	b.) REVIEWED as described IN the compounding site's standard operating procedures (SOPs)?	
Are humidifiers or dehumidifiers USED WITHIN a classified area or SCA?		Must not

Microbiological Monitoring Requirements		
Did the compounding site DEVELOP and IMPLEMENT written procedures for MICROBIOLOGICAL AIR AND SURFACE MONITORING?		Must
Is/Does the microbiological air and surface monitoring program	a.) CLEARLY DESCRIBED in the compounding site's standard operating procedures (SOPs)?	Must
	b.) DESIGNED IN A MANNER that minimized the chance of the sampling itself contributing to contamination of the compounded sterile preparation (CSP) or the environment?	
	c.) CONDUCTED IN A MANNER that minimizes the chance of the sampling itself contributing to contamination of the compounded sterile preparation (CSP) or the environment?	
	d.) INCLUDE SURFACE sampling?	
	e.) INCLUDE viable impact volumetric AIRBORNE PARTICULATE sampling?	
Does the microbiological air and surface monitoring program INCLUDE the FOLLOWING ELEMENTS?	a.) ACTION LEVELS that will trigger corrective action	Must
	b.) DIAGRAM of the sampling locations	
	c.) FREQUENCY of sampling	
	d.) PROCEDURES for collecting samples	
	e.) SIZE of samples (e.g., surface area, volume of air)	
	f.) TIME of day of sampling in relation to activities in the compounding area	
Did the compounding site PERFORM microbiological air and surface MONITORING INITIALLY TO ESTABLISH A BASELINE LEVEL of environmental quality?		Must
Does the compounding site PERFORM microbiological air and surface monitoring UNDER the FOLLOWING CIRCUMSTANCES?	a.) AFTER any SERVICING of facilities or equipment	Must
	b.) IN CONJUNCTION with the CERTIFICATION of new facilities and equipment	
	c.) IN RESPONSE to CHANGES that could impact the sterile compounding environment (e.g., change in cleaning agents)	
	d.) IN RESPONSE to identified PROBLEMS (e.g., positive growth in sterility tests of compounded sterile preparations (CSPs)	
	e.) 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)	
Is microbiological air and surface monitoring CONDUCTED	a.) in ALL CLASSIFIED AREAS (e.g., all primary engineering controls (PECs) and classified rooms) to confirm that the required environmental quality is maintained?	Must
	b.) during DYNAMIC operating conditions to obtain air samples that are representative of the typical compounding conditions at the compounding site?	
Does the compounding site CAREFULLY SELECT the FOLLOWING based on their relationship to the activities performed in the area?	a.) TIMES of sampling	Best practice
	b.) LOCATIONS of sampling	
Are PERSONNEL TRAINED AND COMPETENT in microbiological air and surface sampling PROCEDURES?		Important

Microbiological Monitoring Requirements		
Are REGULAR REVIEWS of the microbiological air and surface sampling results PERFORMED to detect trends?		Must
Are the RESULTS from REGULAR REVIEWS of the microbiological air and surface sampling results	a.) DOCUMENTED?	Must
	b.) REVIEWED IN CONJUNCTION WITH PERSONNEL DATA (e.g., training records, visual observations, competency assessments) to assess the state of control and to identify potential risks of contamination?	
Do the RESULTS from microbiological air and surface sampling DOCUMENT ANY ADVERSE FINDINGS?		If yes ...
Was CORRECTIVE ACTION TAKEN in response to ANY ADVERSE FINDINGS documented in the results from microbiological air and surface sampling?		Required
Were microbiological air and surface sampling RESULTS REVIEWED FOLLOWING the CORRECTIVE ACTIONS taken in response to any adverse findings documented in the results from microbiological air and surface sampling TO CONFIRM that the actions taken have been EFFECTIVE in achieving the required microbiological air and surface quality levels?		Must
Does the compounding site MAINTAIN microbiological air and surface monitoring RECORDS IN WRITTEN OR ELECTRONIC FORM?		Must
Do the microbiological air and surface monitoring records meet the FOLLOWING requirements?	a.) IN COMPLIANCE with all laws and regulations of the applicable jurisdiction	Must
	b.) LEGIBLE	
	c.) STORED in a manner that prevents their deterioration and/or loss	
	d.) Readily RETRIEVABLE for AT LEAST THREE (3) YEARS AFTER PREPARATION of compounded sterile preparations (CSPs)	

Microbiological Air Sampling		
Is volumetric active AIR SAMPLING CONDUCTED USING AN IMPACTION AIR SAMPLER?		Must
Are ALL IMPACTION AIR SAMPLERS … …	a.) SERVICED as recommended by the manufacturer?	Must
	b.) CALIBRATED as recommended by the manufacturer?	
Is volumetric active air sampling … …	a.) COMPLETED AT LEAST EVERY SIX (6) MONTHS when preparing Category 1 and/or Category 2 CSPs?	Must
	b.) COMPLETED WITHIN THIRTY (30) DAYS PRIOR to the commencement of any Category 3 compounding?	
	c.) COMPLETED AT LEAST MONTHLY AFTER initial air sampling regardless of the frequency of compounding Category 3 CSPs?	
The compounding site CANNOT EXCEED the applicable beyond-use dates (BUDs) described in Table 13 of (797) Pharmaceutical Compounding - Sterile Preparations when the compounding site DOES NOT MEET all the conditions described in (797) Pharmaceutical Compounding - Sterile Preparations for the preparation of Category 3 CSPs		
Is CARE TAKEN TO AVOID DISTURBING UNIDIRECTIONAL AIRFLOW when conducting microbiological air sampling of primary engineering controls (PECs)?		Best practice
Is a GENERAL MICROBIOLOGICAL GROWTH MEDIA USED for microbiological air SAMPLING?		Must
Do the general microbiological growth media … …	a.) SUPPORT the growth of bacteria and fungi [e.g., tryptic soy agar (TSA)]?	Must
	b.) have CERTIFICATES OF ANALYSIS (COAs) obtained from the manufacturer?	
	c.) undergo INCUBATION at the temperatures in Box 5 of (797) Pharmaceutical Compounding - Sterile Preparations?	
Do the certificates of analysis (COAs) VERIFY the FOLLOWING ELEMENTS concerning the microbiological growth media devices?	a.) Meets the expected GROWTH promotion	Must
	b.) Meets the pH	
	c.) Meets STERILIZATION requirements	
Are INCUBATOR TEMPERATURES MONITORED during incubation?		Must
Is the INCUBATOR PLACED IN A LOCATION OUTSIDE of the sterile compounding area?		Must
Are microbiological air SAMPLING RESULTS DOCUMENTED?		Must
Is the TOTAL NUMBER of discrete colonies of microorganisms on each air sampling media device recorded as colony-forming units (CFUs) … …	a.) EVALUATED AGAINST the action levels in TABLE 7 of (797) Pharmaceutical Compounding - Sterile Preparations?	Evaluate/Examine
	b.) EXAMINED IN RELATION to previous results to identify adverse results or trends?	
Are two (2) sampling media devices collected at a single location?		If yes …
Does the compounding site _____ when two (2) sampling media devices are collected at a single location?	a.) DOCUMENT all recovered growth on each sampling media device	Must
	b.) APPLY action levels to each sampling media device separately	

Microbiological Air Sampling		
Did LEVELS measured during microbiological air sampling EXCEED THE LEVELS IN TABLE 7 of (797) Pharmaceutical Compounding - Sterile Preparations for the ISO classification levels of the area sampled?		If yes ...
When levels measured during microbiological air sampling exceed the levels in Table 7 of (797) Pharmaceutical Compounding - Sterile Preparations for the ISO classification levels of the area sampled, ...	a.) is an ATTEMPT made with the ASSISTANCE of a MICROBIOLOGIST to IDENTIFY any microorganism recovered to the genus level? [See (1113) Microbial Characterization, Identification, and Strain Typing]	Best practice
	b.) is the cause INVESTIGATED?	
	c.) was the EXTENT of the investigation consistent with the DEVIATION?	
	d.) did the investigation INCLUDE an evaluation of TRENDS?	
	e.) is corrective action TAKEN? (Some examples of corrective action include process or facility improvements, personnel training, cleaning and disinfecting, or HEPA filter replacement and/or repair)	
	f.) did corrective action INCLUDE RESAMPLING of failed areas to confirm corrective action was successful?	
	g.) is the corrective action plan DEPENDENT ON the colony-forming unit (CFU) COUNT?	Must
	h.) is the corrective action plan DEPENDENT ON the microorganism RECOVERED?	
	i.) is the corrective action DOCUMENTED?	
	j.) is the DATA COLLECTED in response to corrective actions REVIEWED to confirm that the actions taken have been effective?	
Did the sterile compounding pharmacy REPORT IN WRITING to the Connecticut Department of Consumer Protection (DCP) of ANY KNOWN VIOLATION OR NONCOMPLIANCE with viable and nonviable ENVIRONMENTAL SAMPLING testing, as defined in the USP Chapters, NOT LATER THAN THE END OF THE NEXT BUSINESS DAY AFTER DISCOVERING such violation or noncompliance? [Section 20-633b(g)]		Shall

Microbiological Surface Sampling		
Is EACH classified area SAMPLED for microbial contamination using a risk-based approach?	Each room	Must
	Interior of each ISO 5 classiciation primary engineering control (PEC)	
Is the INTERIOR OF EACH PASS-THROUGH chamber connecting TO A CLASSIFIED AREA sampled for microbial contamination using a risk-based approach?		Must
Are samples TAKEN from the FOLLOWING classified AREAS?	EQUIPMENT contained within each primary engineering control (PEC)	Best practice
	Frequently TOUCHED surfaces	
	STAGING or work area(s) near each PEC	
Is microbiological surface SAMPLING	PERFORMED AT THE END OF a compounding ACTIVITY OR SHIFT?	Best practice
	PERFORMED BEFORE the area has been CLEANED AND DISINFECTED?	Must
	CONDUCTED in the direct compounding area (DCA) IN CONJUNCTION WITH MEDIA-FILL TESTING to assess aseptic manipulation competency?	
Is microbiological surface SAMPLING of all classified areas, and pass-through chambers connecting to classified areas, ...	CONDUCTED AT LEAST MONTHLY when preparing Category 1 and/or Category 2 CSPs?	Must
	COMPLETED PRIOR TO ASSIGNING A BEYOND-USE DATE (BUD) LONGER THAN THE LIMITS established in Table 13 of (797) Pharmaceutical Compounding - Sterile Preparations when preparing Category 3 CSPs?	
	COMPLETED AT LEAST WEEKLY ON A REGULARLY SCHEDULED BASIS AFTER initial surface sampling regardless of the frequency of compounding Category 3 CSPs?	
	CONDUCTED within primary engineering controls (PECs) used to prepare Category 3 CSPs AT THE END OF EACH BATCH?	
	CONDUCTED within primary engineering controls (PECs) used to prepare Category 3 CSPs BEFORE CLEANING AND DISINFECTION OCCURS?	
	CONDUCTED AT LEAST ONCE DAILY when a self-enclosed robotic device is used as the primary engineering control (PEC) to prepare Category 3 CSPs?	
	CONDUCTED AT THE END OF COMPOUNDING OPERATIONS when a self-enclosed robotic device is used as the primary engineering control (PEC) to prepare Category 3 CSPs?	
	CONDUCTED BEFORE CLEANING AND DISINFECTION OCCURS when a self-enclosed robotic device is used as the primary engineering control (PEC) to prepare Category 3 CSPs?	
The compounding site CANNOT EXCEED the applicable beyond-use dates (BUDs) described in Table 13 of (797) Pharmaceutical Compounding - Sterile Preparations when the compounding site DOES NOT MEET all the conditions described in (797) Pharmaceutical Compounding - Sterile Preparations for the preparation of Category 3 CSPs		
Are CERTIFICATES OF ANALYSIS (COAs) OBTAINED FROM THE MANUFACTURER for microbiological surface sampling media devices?		Must

Microbiological Surface Sampling		
Do the certificates of analysis (COAs) VERIFY the FOLLOWING ELEMENTS concerning the microbiological surface sampling media devices?	Meets the expected GROWTH promotion	Must
	Meets the pH	
	Meets STERILIZATION requirements	
Do the microbiological surface sampling media devices MEET the FOLLOWING REQUIREMENTS?	CONTAIN general microbial growth media [e.g., tryptic soy agar (TSA)]	Must
	SUPPLEMENTED WITH neutralizing additives (e.g., lecithin and polysorbate 80) to neutralize the effects of any residual disinfecting agents	
	RAISED CONVEX surface	
	INCUBATED at the temperatures in Box 6 of (797) Pharmaceutical Compounding - Sterile Preparations	
Are SAMPLED AREAS THOROUGHLY CLEANED AND DISINFECTED AFTER SAMPLING?		Must
Are INCUBATOR TEMPERATURES MONITORED during incubation?		Must
Is the INCUBATOR PLACED IN A LOCATION OUTSIDE of the sterile compounding area?		Must
Are microbiological surface SAMPLING RESULTS DOCUMENTED?		Must
Is the TOTAL NUMBER of discrete colonies of microorganisms on each surface sampling media device recorded as colony-forming units (CFUs)	EVALUATED AGAINST the action levels in TABLE 8 of (797) Pharmaceutical Compounding - Sterile Preparations?	Evaluate/Examine
	EXAMINED IN RELATION to previous results to identify adverse results or trends?	
Are two (2) sampling media devices collected at a single location?		If yes ...
Does the compounding site _____ when two (2) sampling media devices are collected at a single location?	DOCUMENT all recovered growth on each sampling media device	Must
	APPLY action levels to each sampling media device separately	
When levels measured during microbiological surface sampling exceed the levels in Table 8 of (797) Pharmaceutical Compounding - Sterile Preparations for the ISO classification levels of the area sampled, ...	is an ATTEMPT made with the ASSISTANCE of a MICROBIOLOGIST to IDENTIFY any microorganism recovered to the genus level ? [See (1113) Microbial Characterization, Identification, and Strain Typing]	Must
	is the cause INVESTIGATED?	
	is corrective action TAKEN? (Some examples of corrective action include process or facility improvements, personnel training, cleaning and disinfecting, or HEPA filter replacement and/or repair)	
	Was the EXTENT of the investigation consistent with the deviation?	Best practice
	Did the investigation INCLUDE an evaluation of trends?	
	Is the corrective action plan DEPENDENT ON the colony-forming unit (CFU) COUNT?	Must
	Is the corrective action plan DEPENDENT ON the microorganism RECOVERED?	
	Is the corrective action DOCUMENTED?	
	Is the DATA COLLECTED in response to corrective actions REVIEWED to confirm that the actions taken have been effective?	

Microbiological Surface Sampling	
Did the sterile compounding pharmacy REPORT IN WRITING to the Connecticut Department of Consumer Protection (DCP) of ANY KNOWN VIOLATION OR NONCOMPLIANCE with viable and nonviable ENVIRONMENTAL SAMPLING testing, as defined in the USP Chapters, NOT LATER THAN THE END OF THE NEXT BUSINESS DAY AFTER DISCOVERING such violation or noncompliance? [Section 20-633b(g)]	Shall

Placement and Movement of Materials in Classified Areas or Segregated Compounding Area (SCA)		
Are the FOLLOWING ITEMS IN a classified area or SCA?	a.) SHIPPING cartons	Not allowed
	b.) CORRUGATED cardboard	
	c.) UNCOATED cardboard	
Are the CARTS for the transport of components or equipment INTO A CLASSIFIED AREA	a.) CONSTRUCTED from nonporous materials?	Must
	b.) EQUIPPED with cleanable casters and wheels?	
Are the CARTS for the transport of components or equipment INTO A CLASSIFIED AREA MOVED from the DIRTY SIDE to the CLEAN SIDE OF THE ANTEROOM?		If yes ...
Is the ENTIRE CART, including the casters, CLEANED AND DISINFECTED WHEN MOVED from the dirty side to the clean side of the anteroom?		Must
Is the equipment, furniture, and/or other materials in the classified area or SCA	a.)NECESSARY for performing compounding activities?	Permitted
	b.) LOW-shedding?	Best practice
	c.) EASILY cleaned and disinfected?	
Does the NUMBER, DESIGN, LOCATION AND MANNER of installation of the equipment, furniture, and/or other materials in the classified area or SCA	a.) PROMOTE effective cleaning and disinfecting?	Must
	b.) have no IMPACT on environmental air quality?	
Is equipment, furniture, and/or other materials used in the classified area or SCA REMOVED from the classified area or SCA?		If yes ...
Is equipment, furniture, and/or other materials used in a classified area or SCA REMOVED ONLY FOR CALIBRATION, SERVICING, CLEANING, OR OTHER ACTIVITIES ASSOCIATED WITH MAINTENANCE?		Best practice
Is the equipment, furniture, and/or other materials removed from a classified area or SCA RETURNED TO A CLASSIFIED AREA OR SCA?		If yes ...
Is the equipment, furniture, and/or other materials removed from a classified area or SCA CLEANED AND WIPED WITH STERILE seventy (70) percent isopropyl alcohol (IPA) OR A SUITABLE DISINFECTANT BEFORE being RETURNED to the classified area or SCA?		Must
Have any MATERIALS necessary for performing compounding activities BEEN EXPOSED IN PATIENT CARE AND TREATMENT AREAS?		If yes ...
Did any of the materials necessary for performing compounding activities and exposed in patient care and treatment centers ENTER AN ANTEROOM?		If yes ...
Were the materials necessary for performing compounding activities and exposed in patient care and treatment centers THOROUGHLY CLEANED AND DISINFECTED BEFORE ENTERING THE ANTEROOM?		Must
Did any of the materials necessary for performing compounding activities and exposed in patient care and treatment centers ENTER A BUFFER ROOM?		If yes ...
Were the materials necessary for performing compounding activities and exposed in patient care and treatment centers THOROUGHLY CLEANED AND DISINFECTED BEFORE ENTERING THE BUFFER ROOM?		Must
Did any of the materials necessary for performing compounding activities and exposed in patient care and treatment centers ENTER a SCA?		If yes ...
Were the materials necessary for performing compounding activities and exposed in patient care and treatment centers THOROUGHLY CLEANED AND DISINFECTED BEFORE ENTERING the SCA?		Must
Is the DESIGNATED person(s) or pharmacist, whichever is applicable, RESPONSIBLE for ADDRESSING OTHER AREAS OF RISK related to the placement and movement of materials in a classified area or SCA IN THE compounding site's STANDARD OPERATING PROCEDURES (SOPs)?		Is

Placement and Movement of Materials in Classified Areas or Segregated Compounding Area (SCA)		
Have ACCOMMODATIONS BEEN PERMITTED to place and move materials in a classified area or SCA contrary to (797) Pharmaceutical Compounding - Sterile Preparations?		If yes ...
WHO PERMITTED the ACCOMMODATIONS to place and move materials in a classified area of SCA contrary to (797) Pharmaceutical Compounding - Sterile Preparations?	a.) Designated person(s) or pharmacist, whichever is applicable	Compliant
	b.) Not a designated person(s) or pharmacist, whichever is applicable	Non-compliant
Do the ACCOMMODATIONS to place and move materials in a classified area or SCA contrary to (797) Pharmaceutical Compounding - Sterile Preparations AFFECT THE QUALITY OF THE COMPOUNDED STERILE PREPARATION (CSP) AND ENVIRONMENT?		Will not
Are the ACCOMMODATIONS to place and move materials in a classified area or SCA contrary to (797) Pharmaceutical Compounding - Sterile Preparations DOCUMENTED?		Must

Pressure Differentials	
Is there CONTINUOUS DIFFERENTIAL POSITIVE PRESSURE to minimize airflow FROM an area with LOWER air-quality classification TO an area of HIGHER air-quality classification?	Required
See (800) Hazardous Drugs - Handling in Healthcare Settings for pressure requirements for compounding hazardous drug (HD) compounded sterile preparations (CSPs)	
Is there a MINIMUM differential positive pressure of 0.020-inch water column BETWEEN ADJACENT ISO-classified areas (e.g., between the buffer room and anteroom (e.g., between the buffer room and anteroom)?	Required
Is the pressure differential BETWEEN the ANTEROOM AND the UNCLASSIFIED AREA LESS THAN 0.020-inch water column?	Must not
Is a pressure differential monitoring device used to CONTINUOUSLY monitor pressure differentials?	Must
Are the quantitative results from the pressure differential monitoring device REVIEWED AND DOCUMENTED AT LEAST DAILY ON THE DAYS WHEN COMPOUNDING IS OCCURRING?	Must

Temperature		
Cleanroom Suite		
Is the cleanroom suite MAINTAINED at a temperature of twenty (20) DEGREES OR COOLER?		Best practice
Is the temperature in the cleanroom suite CONTROLLED THROUGH a heating, ventilation, and air conditioning (HVAC) SYSTEM?		Must
Is the temperature monitored	a.) in EACH ROOM of the cleanroom suite?	Must
	b.) EACH DAY that compounding is performed?	
Are temperature monitoring devices	a.) VERIFIED for accuracy?	Must
	b.) verified for accuracy AT LEAST every twelve (12) months or as required by the manufacturer?	
Are the RESULTS of the temperature readings STORED in the continuous recording device?		If no ...
Are the results of the temperature readings documented AT LEAST ONCE DAILY?		Must
Are the RESULTS of the temperature readings	a.) RETRIEVABLE?	Must
	b.) REVIEWED as described IN the compounding site's standard operating procedures (SOPs)?	
Segregated Compounding Area (SCA)		
Are free-standing air conditioners USED WITHIN a classified area or segregated compounding area (SCA)?		Must not

Water Sources		
Is the compounding site DESIGNED IN A MANNER that ACTIVITIES, such as hand hygiene and garbing, WILL NOT ADVERSEY AFFECT the ability of primary engineering controls (PECs) TO FUNCTION AS DESIGNED (e.g., between the buffer room and anteroom)?		Must
Do SINKS ENABLE HANDS-FREE USE?		Best practice
Are the surfaces of the sink(s) cleaned and disinfected EACH DAY OF USE?		Must
Cleanroom Suite		
Is the SINK USED FOR HAND HYGIENE placed INSIDE OR OUTSIDE of the ANTEROOM?		If outside ...
Is the sink used for hand hygiene LOCATED IN A CLEAN SPACE to minimize the risk of bringing contaminants into the anteroom?		Must
Is the SINK USED FOR HAND HYGIENE placed INSIDE OR OUTSIDE of the ANTEROOM?		If inside ...
Is the sink used for hand hygiene PLACED ON THE CLEAN SIDE OR DIRTY SIDE of the anteroom?	The order of hand washing and garbing depends on the placement of the sink. See Sections 3.2 Hand Hygiene and 3.3 Garbing Requirements of (797) Pharmaceutical Compounding - Sterile Preparations	
Does the ANTEROOM contain FLOOR DRAINS?		Must not
Does the BUFFER ROOM contain PLUMBED WATER SOURCES [e.g., sink(s), eyewash(es), shower(s), or floor drain(s)]?		Must not
Are SPRINKLER SYSTEMS INSTALLED?		If yes ...
Are the SPRINKLER SYSTEMS	a.) easily CLEANABLE?	Best practice
	b.) COVERED?	
	c.) RECESSED?	
Segregated Compounding Area (SCA)		
Is the SINK USED FOR HAND HYGIENE placed INSIDE the SCA OR IN CLOSE PROXIMITY TO THE SCA?		If inside ...
Is the SINK USED FOR HAND HYGIENE CLOSER THAN ONE (1) METER to any primary engineering control (PEC)?		Must not

Equipment Used in Compounding Compounded Sterile Preparations (CSPs)		
Is equipment that MUST BE BROUGHT into classified areas or segregated compounding area (SCA) WIPED WITH a sporicidal disinfectant, Environmental Protection Agency (EPA)-registered disinfectant, or sterile seventy (70) percent isopropyl alcohol (IPA) USING LOW-LINT WIPERS?		Must
Is equipment that MUST BE BROUGHT into classified areas CAPABLE of operating	a.) PROPERLY?	Must
	b.) WITHIN REQUIRED performance parameters?	
Is there any equipment NOT NECESSARY FOR PERFORMING COMPOUNDING ACTIVITIES in the primary engineering control (PEC)?		Not permitted
Is PROPER PLACEMENT of equipment in a PEC INITIALLY VERIFIED BY A DYNAMIC AIRFLOW SMOKE PATTERN TEST to demonstrate minimal disruption in airflow?		Must
Was the PLACEMENT of any equipment in a PEC CHANGED after proper placement of such equipment was initially verified by a dynamic airflow smoke pattern test?		If yes ...
Was a DYNAMIC AIRFLOW SMOKE PATTERN TEST REPEATED when equipment was placed in a different location?		Must
Does the compounding site use automated compounding devices (ACSs) or other similar equipment?		If yes ...
Is the equipment (e.g., ACDs and balances) USED IN COMPOUNDING CSPs of SUITABLE COMPOSITION such that SURFACES that contact components ARE NOT REACTIVE OR SORPTIVE?		Best practice
Do compounding personnel PERFORM the FOLLOWING when using ACDs or other similar equipment?	a.) conduct an accuracy ASSESSEMENT BEFORE first use?	Must
	b.) conduct an accuracy ASSESSEMENT EACH DAY USED to compound CSPs?	
	c.) maintain a DAILY RECORD of accuracy assessments EACH DAY USED to compound CSPs?	
	d.) implement CORRECTIVE ACTIONS when accuracy MEASUREMENTS are OUTSIDE the MANUFACTURER'S SPECIFICATION?	
Do compounding personnel FOLLOW the FOLLOWING?	a.) Established standard operating procedures (SOPs) for equipment CALIBRATION based on the manufacturer's recommendations	Must
	b.) Established SOPs for equipment CLEANING based on the manufacturer's recommendations	
	c.) Established SOPs for equipment MAINTENANCE based on the manufacturer's recommendations	
	d.) Established SOPs for equipment USE based on the manufacturer's recommendations	
Do personnel MAINTAIN the FOLLOWING RECORDS?	a.) Equipment CALIBRATION	Must
	b.) Equipment MAINTENANCE	
	c.) Equipment VERIFICATION	
Do personnel MAINTAIN RECORDS for equipment calibration, maintenance, and verification IN WRITTEN OR ELECTRONIC FORM?		Must
Do the equipment calibration, maintenance, and/or verification records MEET the FOLLOWING?	a.) IN COMPLIANCE with all laws and regulations of the applicable jurisdiction	Must
	b.) LEGIBLE	
	c.) STORED in a manner that prevents their deterioration and/or loss	
	d.) Readily RETRIEVABLE for AT LEAST THREE (3) YEARS AFTER PREPARATION of compounded sterile preparations (CSPs)	

Supplies		
Are supplies (e.g., beakers, utensils, needles, syringes, filters, and tubing sets) of SUITABLE COMPOSITION such that SURFACES that contact components ARE NOT REACTIVE OR SORPTIVE?		Best practice
Do any supplies have DIRECT CONTACT WITH compounded sterile preparations (CSPs)?		If yes ...
Are supplies that have direct contact with compounded sterile preparations (CSPs)	STERILE?	Must
	DEPYROGENATED?	

Component Selection		
Does the compounding site use APIs as components?		If yes ...
Do APIs COMPLY WITH THE CRITERIA in the USP-NF monograph, if one exists?		Must
Does each API have a certificate of analysis (COA) that INCLUDES the FOLLOWING?	a.) SPECIFICATIONS (e.g., compendial requirements for quality)	Must
	b.) TEST RESULTS showing that the API meets expected quality	
Is each API MANUFACTURED by a facility registered by the FOOD AND DRUG ADMINISTRATION (FDA)?		Must
Does the compounding site use components that ARE NOT APIs?		If yes ...
Does each component that is not an API COMPLY WITH THE CRITERIA in the USP-NF monograph, if one exists?		Must
Is each component that is not an API ACCOMPANIED BY DOCUMENTATION [e.g., certificate of analysis (COA), labeling] that INCLUDES the following?	a.) SPECIFICATIONS	Must
	b.) TEST RESULTS showing that the component that is not an API meets specifications	
Is each component that is not an API MANUFACTURED by a facility registered by the FOOD AND DRUG ADMINISTRATION (FDA)?		If no ...
Does the DESIGNATED person(s) or pharmacist, whichever is applicable, SELECT AN ACCEPTABLE AND RELIABLE SOURCE when components that are not APIs are manufactured by a facility not registered by the Food and Drug Administration (FDA)?		Must
Does the compounding site ESTABLISH the FOLLOWING by reasonable means [i.e., visual inspections, evaluation of a certificate of analysis (COA) supplied by the manufacturer, and/or verification by analytically testing a sample to determine conformance with the COA or other specifications] when ingredients are obtained from a supplier not registered by the Food and Drug Administration (FDA)?	a.) IDENTITY of the ingredient	Must
	b.) PURITY of the ingredient	
	c.) QUALITY of the ingredient	
	d.) STRENGTH of the ingredient	

Component Receipt		
Do facility personnel PERFORM the FOLLOWING upon receipt of each lot of a component?	a.) EXAMINE external packaging for evidence of deterioration and other aspects of unacceptable quality	Must
	b.) VERIFY the component's label	
	c.) VERIFY the component's condition [e.g., whether the outer packaging is damaged and whether temperature-sensing indicators show that the component has been exposed to excessive temperature(s)]	
How does the compounding site HANDLE components found to be of UNACCEPTABLE QUALITY?	a.) PROMPTLY rejected	Must
	b.) LABELED as rejected	
	c.) SEGREGATED from active stock to prevent use before appropriate disposal	
	d.) Other lots from the same vendor of the component found to be of unacceptable quality are EXAMINED to determine whether the other lots have the same defect	
Do any active pharmaceutical ingredients (APIs) or added substances LACK A VENDOR EXPIRATION DATE?		If yes ...
How does the compounding site HANDLE active pharmaceutical ingredients (APIs) or added substances that LACK A VENDOR EXPIRATION DATE?	a.) CLEARLY MARK the date the compounding site receives the APIs and added substances on each API and added substance	Must
	b.) ASSIGN a conservative expiration date that does not exceed one (1) year after the compounding site receives each API and added substance	

Component Handling and Storage		
Are all components handled and stored in a manner to PREVENT the FOLLOWING?	a.) CONTAMINATION	Must
	b.) DETERIORATION	
	c.) MIX-UPS	
Are components STORED IN CLOSED CONTAINERS?		Must
Are all components STORED in closed containers under the FOLLOWING CONDITIONS?	a.) LIGHTING consistent with that indicated in official monographs or specified by the suppliers and/or manufacturers	Must
	b.) HUMIDITY consistent with that indicated in official monographs or specified by the suppliers and/or manufacturers	
	c.) TEMPERATURE consistent with that indicated in official monographs or specified by the suppliers and/or manufacturers	
Do PERSONNEL MONITOR TEMPERATURE in the area(s) WHERE COMPONENTS ARE STORED to determine whether the temperature remains within the appropriate range?		Must
Is ALL MONITORING EQUIPMENT CALIBRATED OR VERIFIED for accuracy AS RECOMMENDED by the manufacturer OR EVERY TWELVE (12) MONTHS if not specified by the manufacturer?		Must
Are the RESULTS of the temperature readings in each area where components are stored STORED in the continuous recording device?		If no ...
Is the temperature in each area where components are stored MONITORED MANUALLY AT LEAST ONCE DAILY ON DAYS that the compounding site IS OPEN?		Must
Are the RESULTS of the temperature readings in each area where components are stored DOCUMENTED on a temperature log?		Must
Are the RESULTS of the temperature readings in each area where components are stored RETRIEVABLE?		Must

Component Evaluation Before Use		
Does the WEIGHING, MEASURING, OR OTHERWISE MANIPULATING of components [e.g., active pharmaceutical ingredients (APIs), added substances, conventionally manufactured products] GENERATE AIRBORNE CHEMICAL PARTICLES?		If yes ...
Is the weighing, measuring, or otherwise manipulating of components that generate airborne chemical particles EVALUATED TO DETERMINE IF THESE ACTIVITIES MUST BE PERFORMED IN a primary engineering control (PEC) OR OTHER CLOSED-SYSTEM PROCESSING DEVICE (e.g., single-use containment glove bag) to reduce the potential exposure to personnel or contamination of the facility or compounded sterile preparations (CSPs)?		Must
Is the PROCESS EVALUATION, the evaluation to determine if weighing, measuring, or otherwise manipulating components that generate airborne chemical particles must be performed in a primary engineering control (PEC) or other closed-system processing device, ...	a.) CARRIED OUT in accordance with the compounding site's standard operating procedures (SOPs)?	Must
	b.) DOCUMENTED?	
Are components REINSPECTED BEFORE USE?		Must
Are all packages REINSPECTED TO DETECT the FOLLOWING which might have occurred during storage?	a.) Container BREAKS	Must
	b.) LOOSENESS of the cap or closure	
	c.) DEVIATION from the expected appearance, aroma, and/or texture of the contents	
Are sterile container closures VISUALLY REINSPECTED to ensure the FOLLOWING?	a.) FREE FROM DEFECTS that could compromise sterility	Must
	b.) OTHERWISE SUITABLE for their intended use	
How does the compounding site HANDLE components found to be of UNACCEPTABLE QUALITY upon reinspection?	a.) PROMPTLY rejected	Must
	b.) LABELED as rejected	
	c.) SEGREGATED from active stock to prevent use before appropriate disposal	
	d.) Other lots from the same vendor of the component found to be of unacceptable quality are EXAMINED to determine whether the other lots have the same defect	
Do compounding personnel ASCERTAIN the FOLLOWING BEFORE USING components for compounded sterile preparations (CSPs)?	a.) Component is within EXPIRY DATE	Must
	b.) Correct IDENTITY of the component	
	c.) Appropriate QUALITY of the component	
	d.) Component STORED under appropriate conditions	
Do compounding personnel USE the FOLLOWING to ASCERTAIN the correct identity of a component, the appropriate quality of a component, if the component is within expiry date, and if the component is stored under appropriate conditions before using a component for CSPs?	a.) CERTIFICATES of analysis (COAs) of active pharmaceutical ingredients (APIs) and other components	Best practice
	b.) Compounding RECORDS (CRs)	
	c.) DOCUMENTATION of the compounding site's storage conditions and practices	
	d.) LABELING of CSPs	
	e.) Master formulation RECORDS (MFRs), if used	
	f.) PRESCRIPTIONS or medication orders	
	g.) Product labeling of any conventionally manufactured sterile products	
	h.) Vendor LABELS	

Use of Conventionally Manufactured Products as Components		
WHEN are conventionally manufactured STERILE products USED?	a.) When AVAILABLE	Best practice
	b.) When APPROPRIATE for the intended compounded sterile preparation (CSP)	
Are conventionally manufactured multiple-dose containers USED MORE THAN TWENTY-EIGHT (28) DAYS AFTER initially entering or puncturing such container?		If yes ...
Is it SPECIFIED BY THE MANUFACTURER ON THE LABEL that conventionally manufactured multiple-dose containers CAN BE USED MORE THAN TWENTY-EIGHT (28) DAYS AFTER initially entering or puncturing such container?		Unless
Are OPENED conventionally manufactured single-dose AMPULES STORED FOR ANY TIME PERIOD?		Must not
Are OPENED conventionally manufactured single-dose VIALS entered or punctured in ISO classification 5 or cleaner air USED UP TO TWELVE (12) HOURS AFTER initial entry or puncture?		If yes ...
Are the LABELED STORAGE REQUIREMENTS MAINTAINED when opened conventionally manufactured single-dose VIALS are used up to twelve (12) hours after initial entry or puncture in an ISO classification 5 or cleaner air?		Must
Are OPENED conventionally manufactured single-dose VIALS entered or punctured in ISO classification 5 or cleaner air USED UP TO TWELVE (12) HOURS AFTER initial entry or puncture?		If no ...
Are OPENED conventionally manufactured single-dose VIALS entered or punctured in ISO classification 5 or cleaner air USED MORE THAN TWELVE (12) HOURS AFTER initial entry or puncture?		May not
Are conventionally manufactured pharmacy bulk packages	a.) USED ACCORDING to the manufacturer's labeling?	Must
	b.) ENTERED OR PUNCTURED ONLY IN ISO classification 5 primary engineering controls (PECs)?	

Use of Compounded Sterile Preparations (CSPs) as Components to Prepare "Final" CSPs		
Are ALL active pharmaceutical ingredients (APIs) and other components USED FOR USE IN STERILE PREPARATION EVALUATED FOR SUITABILITY?		Must
Are any components used to compound CSPs for use as a component to compound additional CSPs LABELED with the FOLLOWING?	a.) "Not for human use" or equivalent statement	Must not
	b.) "Not for injectable use" or equivalent statement	
	c.) "Not for pharmaceutical use" or equivalent statement	
Is care taken to MINIMIZE the risk of contamination of the FOLLOWING?	a.) CSPs compounded for use as a STARTING COMPONENT to compound additional CSPs	Must
	b.) FINAL CSPs prepared from one or more starting component CSPs	
Are CSPs compounded for use as a starting component to compound additional CSPs STORED UNDER CONDITIONS for their assigned beyond-use dates (BUDs) WHEN NOT IN USE?		Must
Does the compounding site ASSIGN BEYOND-USE DATES (BUDs) to "FINAL" CSPs prepared from one or more starting component CSPs that EXCEED THE SHORTEST BUD of any starting component CSP?		Best practice not to
Does the compounding site assign beyond-use dates (BUDs) to "FINAL" CSPs that EXCEED THE SHORTEST BUD of any starting component CSP FOR AN ACCEPTABLE INSTANCE?		If yes ...
Are the FOLLOWING NEGATIVELY IMPACTED when assigned beyond-use dates (BUDs) of "FINAL" CSPs exceed the BUD of any starting component CSP?	a.) PHYSICAL quality of "Final" CSPs	Must not
	b.) CHEMICAL quality of "Final" CSPs	
	c.) MICROBIOLOGICAL quality of "Final" CSPs	
Are multiple-dose CSPs used as components to compound additional CSPs	a.) STORED UNDER THE CONDITIONS upon which their beyond-use dates (BUDs) ARE BASED (e.g., refrigerator or controlled room temperature)?	Must
	b.) USED BEYOND their assigned beyond-use dates (BUDs) OR twenty-eight (28) DAYS, whichever is shorter, AFTER INITIAL ENTRY OR PUNCTURE?	Must not
Are ORIGINAL compounded single-dose CSPs and CSP stock solutions used as components to compound additional CSPs	a.) ENTERED OR PUNCTURED IN ISO classification 5 or cleaner air?	Must
	b.) STORED UNDER the conditions (e.g., refrigerator or controlled room temperature) upon which their beyond-use dates (BUDs) are based?	
	c.) with a REMAINDER DISCARDED when it is BEYOND the shorter of their assigned BUDs or twelve (12) hours after initial entry or puncture?	
	d.) USED BEYOND the shorter of their assigned beyond-use date (BUD) OR twelve (12) hours after initial entry or puncture?	Must not
Do compounded single-dose CSPs and CSP stock solutions used as components to compound additional CSPs CONTAIN A PRESERVATIVE or equivalent?		If yes ...
Is the preservative or equivalent	a.) appropriate for the PATIENT?	
	b.) appropriate for the ROUTE of administration?	
	c.) INACTIVATED by any components in the CSP?	

Use of Sterile and Depyrogenated Containers and Container Closure Systems as Components	
Does the compounding site USE COMMERCIALLY AVAILABLE sterile, depyrogenated containers and container closure systems?	If yes ...
Is EACH LOT of commercially available sterile, depyrogenated containers and container closure systems ACCOMPANIED BY EITHER a CERTIFICATE OF ANALYSIS (COA) OR DOCUMENTATION other than a certificate of analysis (COA) showing conformance with establish specifications (i.e., sterility and depyrogenation requirements)?	Must
Does the compounding site perform STERILIZATION AND DEPYROGENATION of supplies and container closure systems ONSITE?	If yes ...
Is the EFFICACY of each process ESTABLISHED AND DOCUMENTED when supplies or container closure systems are sterilized and depyrogenated on site?	Must

Particulate Matter Testing		
Are the FOLLOWING MET when preparing Category 3 CSPs as injections and/or ophthalmic solutions?	a.) CONDUCT particulate-matter testing ONCE PER FORMULATION with acceptable results	Conduct/Evaluate
	b.) CONDUCT particulate-matter testing ONCE FOR EACH CONTAINER closure system used as packaging	
	c.) EVALUATE EACH CONTAINER closure system used as packaging for container closure INTEGRITY to the end of the beyond-use date (BUD)	
	d.) EACH CONTAINER closure system used as packaging CONFORMS to container closure INTEGRITY to the end of the BUD	

Depyrogenation of Compounded Sterile Preparations (CSPs)		
Are items that are not thermostable	a.) depyrogenated by MULTIPLE RINSES with STERILE, NONPYROGENIC WATER?	Must
	b.) THOROUGHLY DRAINED OR DRIED immediately before use in compounding?	
Are THERMOSTABLE ITEMS (e.g., glassware, metal, thermostable components, thermostable containers) subjected to DRY HEAT DEPYROGENATION by the compounding site to render such items pyrogen free?		Must
Are the FOLLOWING MET when thermostable items are subjected to dry heat depyrogenation?	a.) DURATION of the EXPOSURE PERIOD includes sufficient time for the thermostable items to reach the depyrogenation temperature	Must
	b.) REMAIN AT the depyrogenation temperature for the duration of the depyrogenation period	
Does the compounding site COMPLY WITH the FOLLOWING as it relates to the effectiveness of dry heat depyrogenation cycles?	a.) ESTABLISHED INITIALLY using endotoxin challenge vials (ECVs)	Must
	b.) VERIFIED ANNUALLY using ECVs	
	c.) DOCUMENTATION of the verification	
	d.) RE-ESTABLISHED when there are CHANGES (e.g., changes in load conditions, duration, or temperature) to the depyrogenation cycle DESCRIBED IN the compounding site's standard operating procedures (SOPs)	
	e.) ECVs demonstrate a capability to ACHIEVE a three (3) or more-log reduction in endotoxins [See (85) Bacterial Endotoxins Test]	

Sterilization of Compounded Sterile Preparations (CSPs)		
Are the FOLLOWING TAKEN INTO CONSIDERATION by personnel when SELECTING the STERILIZATION method for CSPs prepared from one or more nonsterile starting components or using nonsterile supplies or devices?	a.) CHEMICAL properties of the component(s)	Must
	b.) INTENDED container closure system	
	c.) NATURE of the component(s)	
	d.) PHYSICAL properties of component(s)	
Are the FOLLOWING TAKEN INTO CONSIDERATION by personnel when SELECTING the APPROPRIATE sterilization method for CSPs prepared from one or more nonsterile starting components or using nonsterile supplies or devices?	a.) CANNOT TOLERATE terminal sterilization	Must
	b.) EMULSIONS with a significant droplet size	
	c.) Moisture, pressure, or temperatures used DEGRADE the CSP	
	d.) Suspended drug PARTICLES	
Does the selected sterilization method STERILIZE the CSP WITHOUT DEGRADING	a.) its CHEMICAL stability (e.g., affecting its strength, purity, or quality)?	Must
	b.) its PHYSICAL stability (e.g., affecting its strength, purity, or quality)?	
	c.) its PACKAGING integrity [See (1229) Sterilization of Compendial Articles]?	
Are INJECTABLE compounded preparations STERILIZED WITHIN SIX (6) HOURS AFTER COMPLETING THE PREPARATION to minimize the generation of bacterial endotoxins in CSPs when the preparation	a.) CONTAINS NONSTERILE components?	Must
	b.) comes into CONTACT WITH NONSTERILE devices (e.g., containers, tubing) during any phase of the compounding procedure?	

Sterilization of Compounded Sterile Preparations (CSPs) by Dry Heat		
Does the compounding site COMPLY WITH the FOLLOWING as it relates to sterilization by dry heat?	a.) USES A PROCESS INTENDED TO ACHIEVE a probability of a nonsterile unit (PNSU) of 10 to the -6th [This is also called the sterility assurance level (SAL). A PNSU of 10 to the -6th is equivalent to a probability that 1 unit in a million is nonsterile.]	Must
	b.) DURATION OF EXPOSURE PERIOD includes sufficient time for the entire contents of CSPs and other items to reach the sterilizing temperature	
	c.) CSPs and other items REMAIN AT the sterilizing temperature for the duration of the sterilization period	
	d.) HEATED AIR is evenly distributed throughout the chamber (This is usually accomplished by an air blower.)	
	e.) Oven is CALIBRATED	
	f.) Oven is equipped with TEMPERATURE CONTROLS	
	g.) Oven is equipped with a TIMER	
	h.) SUFFICIENT SPACE is left between materials to allow for circulation of the hot air during sterilization	
	i.) CALIBRATED DATA RECORDER OR CHART is used to monitor each sterilization cycle	
	j.) DATA obtained from monitoring each sterilization cycle is REVIEWED to identify sterilization cycle irregularities (e.g., deviations in temperature or exposure time)	
Are TEMPERATURES LOWER THAN 160 degrees USED for dry heat sterilization?		If yes ...
Is dry heat sterilization performed with temperatures lower than 160 degrees SHOWN TO ACHIEVE EFFECTIVE STERILIZATION?		Must
Is the EFFECTIVENESS of the dry heat sterilization method	a.) VERIFIED with EACH sterilization run or load?	Must
	b.) DOCUMENTED with EACH sterilization run or load?	
Is the EFFECTIVENESS of the dry heat sterilization method VERIFIED with each sterilization run or load USING	a.) appropriate BIOLOGICAL INDICATORS [Such as spores of Bacillus atrophaeus (ATCC 9372). See (1229.5) Biological Indicators for Sterilization]?	Must
	b.) other CONFIRMATION METHODS (e.g., temperature-sensing devices)?	
Are CSP solutions PASSED THROUGH A FILTER IMMEDIATELY BEFORE FILLING AMPULES AND VIALS that will be sterilized by dry heat?		Must
Are the FILTERS through which CSP solutions are passed immediately before filling ampules and vials that will be sterilized by dry heat OF NOMINAL PORE SIZE OF LARGER THAN 1.2 MICROMETERS for removal of particulate matter?		Must not

Sterilization of Compounded Sterile Preparations (CSPs) by Filtration		
Do the FOLLOWING FEATURES APPLY to the sterilizing filters used by the compounding site?	a.) APPROPRIATE for pharmaceutical use	Must
	b.) CERTIFIED by the manufacturer to retain at least 10 to the 7th 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)	
	c.) DEPYROGENATED	
	d.) Do not bear LABELS STATING "for laboratory use only" or a similar statement	
	e.) Nominal PORE SIZE of 0.22 micrometer or smaller	
	f.) STERILE	
	g.) Subjected to the manufacturers' recommended INTEGRITY TESTING (Such as a post-use bubble point test)	
Do the FOLLOWING PERMIT the sterilization process to be completed without the need for replacement of the sterilizing filter during the process?	a.) CSPs to be sterilized by filtration	Best practice
	b.) DIMENSIONS of sterilizing filters	
Did any sterilizing filters FAIL INTEGRITY TESTING?		If yes ...
Did the compounding site DISCARD the CSPs prepared with the sterilizing filters that failed integrity testing?		If no ...
Did the compounding site REFILTER the CSPs prepared with sterilizing filters that failed integrity testing for sterilization NO MORE THAN one (1) additional time AFTER investigating the cause of the failure and selection of an appropriate filter?		Can
Are MULTIPLE sterilizing FILTERS REQUIRED for a compounding process?		If yes ...
Is EACH sterilizing FILTER required for the compounding process SUBJECTED TO the manufacturers' recommended INTEGRITY TESTING, such as a post-use bubble point test?		Must
Does the compounding site prepare any CSPs that CONTAIN EXCESSIVE particulate matter?		If yes ...
How does the compounding site PROCEED when CSPs contain excessive particulate matter?	a.) ASSESS formulation and process	Best practice
	b.) MODIFY formulation and process	
	c.) Perform a PREFILTRATION step using a FILTER OF LARGER NOMINAL SIZE (e.g., 1.2 micrometers) to remove gross particulate contaminants before the CSP is passed through a sterilizing-grade filter	Must
	d.) Place a SEPARATE FILTER OF LARGER NOMINAL SIZE (e.g., 1.2 micrometers) UPSTREAM (i.e., prior to) of the sterilizing filter to remove gross particulate contaminants before the CSP is passed through the sterilizing-grade filter	Best practice

Sterilization of Compounded Sterile Preparations (CSPs) by Steam Heat		
Does the compounding site COMPLY with the FOLLOWING as it relates to sterilization by steam heat?	a.) USES A PROCESS INTENDED TO ACHIEVE a probability of a nonsterile unit (PNSU) of 10 to the -6th [This is also called the sterility assurance level (SAL). A PNSU of 10 to the -6th is equivalent to a probability that 1 unit in a million is nonsterile.]	Must
	b.) ALL MATERIALS are DIRECTLY EXPOSED to steam under adequate pressure for the length of time necessary AS DETERMINED BY the use of appropriate biological indicators to render the items sterile [e.g., twenty (20) to sixty (60) minutes at 121 degrees saturated steam under a pressure of fifteen (15) pounds per square inch (PSI), depending on the volume or size of the compounded sterile preparation (CSP) being sterilized]	
	c.) DURATION OF EXPOSURE PERIOD includes sufficient time for the entire contents of CSPs and other items to reach the sterilizing temperature	
	d.) CSPs and other items REMAIN AT the sterilizing temperature for the duration of the sterilization period	
	e.) CSPs placed in the autoclave to allow steam to reach the CSPs WITHOUT ENTRAPMENT OF AIR (Flat, stainless-steel trays with low sides or ventilated bottoms will permit steam contact.)	
	f.) CALIBRATED DATA RECORDER OR CHART is used to monitor each sterilization cycle	
	g.) DATA obtained from monitoring each sterilization cycle is REVIEWED to identify sterilization cycle irregularities (e.g., deviations in temperature or exposure time)	
Do any items HAVE TO BE WRAPPED for steam sterilization?		If yes ...
Which of the following METHODS are used to wrap items for steam sterilization?	a.) Low-lint protective FABRIC	Compliant
	b.) Low-lint protective PAPER	
	c.) Seal in ENVELOPES	
	d.) Other	Non-compliant
Is the EFFECTIVENESS of the steam heat sterilization method	a.) VERIFIED with EACH sterilization run or load?	Must
	b.) DOCUMENTED with EACH sterilization run or load?	
Is the EFFECTIVENESS of the steam heat sterilization method VERIFIED with each sterilization run or load USING	a.) appropriate BIOLOGICAL INDICATORS [Such as spores of Geobacillus stearothermophilus (ATCC 12980, ATCC 7953, or equivalent). See (1229.5) Biological Indicators for Sterilization.]?	Must
	b.) other CONFIRMATION METHODS [Such as physicochemical indicators. See (1229.9) Physiochemical Integrators and Indicators for Sterilization.]?	

Sterilization of Compounded Sterile Preparations (CSPs) by Steam Heat	
Are CSP solutions PASSED THROUGH A FILTER IMMEDIATELY BEFORE FILLING CONTAINERS that will be steam sterilized?	Must
Are the FILTERS through which CSP solutions are passed immediately before filling containers that will be steam sterilized OF NOMINAL PORE SIZE OF LARGER THAN 1.2 MICROMETERS for removal of particulate matter?	Must not
Does the compounding site use SEALED CONTAINERS for the sterilization of CSPs by steam heat?	If yes ...
Can the sealed containers GENERATE STEAM INTERNALLY?	Must
Does the compounding site use STOPPERED AND CRIMPED EMPTY VIALS for the sterilization of CSPs by steam heat?	If yes ...
Do the stoppered and crimped empty vials CONTAIN A SMALL AMOUNT OF STERILE WATER to generate steam?	Must

Release Inspections and Testing of Compounded Sterile Preparations (CSPs)		
Are ALL release testing PROCEDURES (e.g., visual inspections and testing) for CSPs INCLUDED in the compounding site's documentation?		Must
Does the compounding site DISPENSE OR ADMINISTER CSPs BEFORE the RESULTS OF RELEASE TESTING ARE KNOWN?		If yes ...
Are the FOLLOWING PROCEDURES in place for the dispensing or administration of CSPs before the results of release testing are known?	a.) Procedure 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)	Must
	b.) Procedure to RECALL any unused dispensed CSPs and quarantine any stock remaining in the pharmacy	
	c.) Procedure to INVESTIGATE if other lots are affected and recall if necessary	
Are out-of-specification (OOS) results for CSPs INVESTIGATED?		Must
Has the compounding site had to IMPLEMENT RECALL procedures due to an out-of-specification (OOS)?		If yes ...
Did the compounding site	a.) DOCUMENT the implementation of the recall procedures?	Must
	b.) REPORT the recall to appropriate regulatory bodies as required by laws and regulations of the applicable regulatory jurisdiction?	
Is a CORRECTIVE ACTION PLAN	a.) IMPLEMENTED for out-of-specification results for CSPs?	Must
	b.) DOCUMENTED as part of the quality assurance (QA) and quality control (QC) program?	

Visual Inspections of Compounded Sterile Preparations (CSPs)		
Does the compounding site VISUALLY INSPECT CSPs at the COMPLETION OF COMPOUNDING BUT BEFORE RELEASE AND DISPENSING?		Must
Are CSPs visually inspected	a.) to DETERMINE whether the physical appearance of the CSPs are as expected (e.g., free of inappropriate visible particulates or other foreign matter, discoloration, or other defects)?	Must
	b.) to CONFIRM that the CSP and its labeling match the prescription or medication order?	
	c.) for container closure INTEGRITY (e.g., checking for leakage, cracks in the container, or improper seals)?	
Are CSPs found to be of UNACCEPTABLE QUALITY (e.g., observed defects)	a.) promptly REJECTED?	Must
	b.) clearly LABELED as rejected?	
	c.) SEGREGATED from active stock to prevent use before appropriate disposal?	
Are DEFECTS THAT INDICATE STERILITY OR STABILITY PROBLEMS INVESTIGATED to determine the cause according to the compounding site's standard operating procedures (SOPs)?		Must
Does the compounding site prepare CSPs on one day and RELEASE OR DISPENSE such CSPs ON ANOTHER DAY?		If yes ...
Are CSPs prepared on one day and released or dispensed on another day VISUALLY INSPECTED IMMEDIATELY BEFORE RELEASE AND DISPENSING TO MAKE SURE such CSPs DO NOT EXHIBIT ANY DEFECTS, such as precipitation, cloudiness, or leakage, which could develop during storage?		If yes ...
Are CSPs prepared on one day and released or dispensed on another day FOUND TO BE of UNACCEPTABLE QUALITY (e.g., observed defects)	a.) promptly REJECTED?	Must
	b.) clearly LABELED as rejected?	
	c.) SEGREGATED from active stock to prevent use before appropriate disposal?	
Are DEFECTS THAT INDICATE STERILITY OR STABILITY PROBLEMS INVESTIGATED to determine the cause according to the compounding site's standard operating procedures (SOPs)?		Must

Sterility Testing of Compounded Sterile Preparations (CSPs)	
Do Category 2 CSPs that have an assigned a beyond-use date (BUD) that requires sterility testing UNDERGO STERILITY TESTING?	Must
Do Category 3 CSPs UNDERGO STERILITY TESTING?	Must
Is sterility testing PERFORMED ACCORDING TO (71) Sterility Testing OR a validated alternative method [See (1223) Validation of Alternative Microbiological Methods] that is noninferior to (71) Sterility Testing?	Must
Is sterility testing PERFORMED EMPLOYING TWO OR MORE OF THE SPECIFIED MEDIUM as specified in (71) Sterility Testing?	Perform
Is the MINIMUM QUANTITY OF EACH CONTAINER tested for each medium as specified in Table 2 of (71) Sterility Testing?	As specified
Is the NUMBER OF CSPs to be COMPOUNDED in a SINGLE BATCH LESS THAN the NUMBER OF CSPs NEEDED for testing as specified in Table 3 of (71) Sterility Testing?	If yes ...
ARE ADDITIONAL UNITS COMPOUNDED to perform sterility testing when the number of CSPs to be compounded in a single batch is less than the number of CSPs needed for testing as specified in Table 3 of (71) Sterility Testing?	Must
Are the REQUIRED NUMBER OF CONTAINERS tested in relation to batch size as specified in Table 3 of (71) Sterility Testing?	As specified
ARE the CONTENTS OF EACH Category 2 and/or Category 3 CSP OF SUFFICIENT QUANTITY to be divided so that equal proportions are added to each of the specified medium?	If no ...
ARE TWICE THE REQUIRED NUMBER OF CONTAINERS USED when the contents of each Category 2 and/or Category 3 CSP DOES NOT CONTAIN SUFFICIENT QUANTITIES FOR EACH MEDIUM?	Use
Is the MAXIMUM BATCH SIZE for all CSPs requiring sterility testing LIMITED TO 250 FINAL YIELD UNITS?	Must
Is the METHOD SUITABILITY TEST (e.g., membrane filtration, direct inoculation) from (71) Sterility Testing PERFORMED to ensure that contamination can be recovered?	Must
Is the MEMBRANE FILTRATION method suitability test from (71) Sterility Testing the METHOD OF CHOICE when the CSP formulation permits?	Method of choice
Is the DIRECT INOCULATION method suitability test from (71) Sterility Testing the PREFERRED ALTERNATIVE to the membrane filtration method suitability test when the CSP formulation permits?	Preferred alternative
Is a METHOD OTHER THAN the membrane filtration method suitability test or direct inoculation method suitability test USED for sterility testing?	If yes ...
Is the METHOD OTHER THAN the membrane filtration method suitability test or direct inoculation method suitability test used for sterility testing VALIDATED AND DEMONSTRATED TO BE SUITABLE for the CSP formulation?	Must

Sterility Testing of Compounded Sterile Preparations (CSPs)		
Have any sterility tests performed by the compounding site in accordance to (71) Sterility Testing revealed FAILING RESULTS?		If yes ...
How did the compounding site PROCEED when sterility tests REVEALED FAILING RESULTS?	a.) Prompt INVESTIGATION into the possible causes that may have contributed to the sterility failure	Must
	b.) Possible CAUSES that may have contributed to the sterility failure	
	Evaluation of the COMPOUNDING SITE	
	Evaluation of the COMPOUNDING PROCESS	
	Evaluation of the PERSONNEL	
	Evaluation of the sterility testing PROCEDURE	
	IDENTIFICATION of the organism	
	c.) DETERMINE whether the conditions causing the sterility failure AFFECT OTHER CSPs	
	d.) DOCUMENTATION of the prompt INVESTIGATION	
	e.) DOCUMENTATION of resulting CORRECTIVE actions from the prompt investigation	
Was the source(s) of contamination CORRECTED?		Must

Bacterial Endotoxins Testing (BET) of Compounded Sterile Preparations (CSPs)		
Do Category 2 INJECTABLE CSPs compounded from one (1) or more nonsterile component(s) and assigned a beyond-use date (BUD) that requires sterility testing UNDERGO BET to ensure that such CSPs do not contain excessive bacterial endotoxins?		Must
Do Category 2 INJECTABLE CSPs compounded from one (1) or more nonsterile component(s) and assigned a beyond-use date (BUD) that does not require sterility testing UNDERGO BET to ensure that such CSPs do not contain excessive bacterial endotoxins?		Best practice
Do Category 3 INJECTABLE CSPs compounded from one (1) or more nonsterile component(s) UNDERGO BET to ensure that such CSPs do not contain excessive bacterial endotoxins?		Must
Does the compounding site USE ONLY product contact materials that have been DEPYROGENATED IN HOUSE OR RECEIVED AS STERILE and free of detectable bacterial endotoxins?		Best practice
Are DILUENTS COMMERCIALLY OBTAINED when diluents or intravenous (IV) solutions are used for preparing a product intended for IV, intramuscular (IM), intraocular, or intrathecal (IT) administration?		Best practice
Do DILUENTS MEET THE COMPENDIAL LIMITS when diluents or intravenous (IV) solutions are used for preparing a product intended for IV, intramuscular (IM), intraocular, or intrathecal (IT) administration?		Best practice
Does the compounding site use any REQUIRED DILUENTS that ARE NOT United States Pharmacopeia (USP) monograph articles?		If yes ...
Are REQUIRED DILUENTS that are not United States Pharmacopeia (USP) monograph articles PREPARED TO MEET THE COMPENDIAL LIMIT of 0.5 Endotoxin Units (EU)/milliliter (mL)?		Best practice
Are any of the required diluents that are not United States Pharmacopeia (USP) monograph articles USED FOR INTRATHECAL (IT) ADMINISTRATION?		If yes ...
Does the compounding site ENSURE that required diluents that are not United States Pharmacopeia (USP) monograph articles plus the drug product DO NOT EXCEED the more stringent intrathecal (IT) bacterial endotoxins limit?		Essential
Which of the following TECHNIQUE(S) does the compounding site use for the BET?	a.) Chromogenic technique (based on the development of color)	
	b.) Gel-clot technique (based on gel formation)	
	c.) Turbidmetric technique (based on development of turbidity)	
	d.) Other	If yes ...
Was the ALTERNATE TEST for the detection of bacterial endotoxins	a.) FULLY VALIDATED by the compounding site for the detection of bacterial endotoxins to ensure that decisions made using the alternate methodology are equivalent to or better than decisions made using the validated United States Pharmacopeia (USP) methods?	Must
	b.) ULTIMATELY APPROVED by the appropriate regulatory authority?	
Does the compounding site PROVIDE TRAINING for PERFORMING BET?		Best practice
Are the FOLLOWING included in the compounding site's training for BET?	a.) CLASSROOM training BY A SUBJECT MATTER EXPERT (SME)	Best practice
	b.) TRAINING EFFECTIVENESS confirmed by demonstration of competency in performing BET	

Bacterial Endotoxins Testing (BET) of Compounded Sterile Preparations (CSPs)		
Are the FOLLOWING AREAS STRESSED during the compounding site's training for BET?	a.) Appropriate laboratory ASEPTIC TECHNIQUE (It is important not to contaminate samples, diluents, or accessories used to perform BET.)	Best practice
	b.) USE OF a vortex mixer or another validated method (It is important to optimize the distribution of endotoxins in samples and the aggregation state of the purified standards in the standard series.)	
	c.) FOLLOW the manufacturers' INSTRUCTIONS for vortexing time, both for reconstitution of the vial of lipopolysaccharide (LPS) and in between dilutions. (The vortexing of lysate is not recommended as it may result in bubbles in the reagent.)	
	d.) ENSURE that the "open" date and "expiration" date are CLEARLY MARKED on the primary containers if reagents are saved	
	e.) Ensure that any HOLDING of unused reagents FOLLOWS manufacturers' INSTRUCTION if reagents are saved	
	f.) DO NOT STORE United States Pharmacopeia (USP) Endotoxin Reference Standard (RSE) or commercially-prepared control standard endotoxins (CSE) dilutions without a validation study that includes vessel type and materials of manufacture, concentrations of RSE or CSE that are to be held, hold temperature, and volume of the dilutions to be held	
	g.) PICK TUBES UP one at a time and invert 180 degrees when reading gel-clot results (Picking up more than one tube could jostle the contents; Once a gel is broken, it will not re-form, and the result may be a false-negative)	
	h.) Take care to AVOID the FORMATION OF BUBBLES when inoculating a microplate, tube, or cartridge (Bubbles will impact the accuracy of the test result.)	
	i.) Be certain EQUIPMENT is QUALIFIED when using heating equipment (e.g., bead baths, water baths, plate readers)	
	j.) CHANGE the WATER frequently if using a water bath for gel-clot incubation (The recommended frequency is at least once a week.)	
	k.) Ensure that all mechanical pipettors are CALIBRATED	
	l.) Ensure calibrated mechanical pipettors are used only WITHIN THE CALIBRATED RANGE	
	m.) USE LARGER volumes (milliliters) for dilution rather than small volumes (microliters), when possible (Smaller volumes increase variability.)	
	n.) PAY ATTENTION to the onset times of the standards to ensure that they are consistent from run to run, analyst to analyst, and day to day for any given combination of CSE lot and lysate lot	
	o.) INCLUDE AT LEAST one non-endotoxin control if using a monocyte activation test	

Bacterial Endotoxins Testing (BET) of Compounded Sterile Preparations (CSPs)		
Do the FOLLOWING AREAS PROMPT additional training in BET?	a.) FAILURE TO MEET the requirements of the initial performance training	Requires
	b.) FREQUENT INABILITY to meet system suitability parameters, yielding invalid test results	
	c.) ERRATIC RESULTS for slope and y-intercept for quantitative assays (e.g., confirmation of label claim for gel clot, demonstration of linearity for quantitative assays, inability to ensure that negative controls are nonreactive)	
	d.) ADVERSE TRENDS for out-of-specification (OOS) or out-of-trend (OOT) test result	
Is ALL INSTRUMENTATION AND EQUIPMENT including, but not limited to, mechanical pipettors, water bathes, heat blocks, and incubating plate readers, used in the performance of BET	a.) QUALIFIED using proper scientific standards and according to approved protocols and maintenance schedules?	Must/Best practice
	b.) properly CALIBRATED?	
	c.) MAINTAINED at frequencies that are in accordance with the equipment manufacturer's recommendations?	
	d.) EVALUATED for uniformity of heat distribution since BET incubation temperatures are critical?	
Does BET COMPUTER SOFTWARE	a.) COMPLY with all federal regulations and standards?	Must
	b.) allow for INDIVIDUAL user PASSWORDS?	
	c.) allow for AUDIT TRAILS?	
Does QUALITY CONTROL UNDERSTAND how the vendors of the BET computer software programmed their CALCULATIONS?		Best practice
Are laboratory or production DRY HEAT OVENS used to depyrogenate glassware or other heat-stable items used in the performance of any BET assays VALIDATED TO ENSURE APPROPRIATE	a.) TEMPERATURE exposure?	Must
	b.) TIME exposure?	
	c.) LOAD pattern?	
Does the compounding site depyrogenate all glassware and other heat-stable materials employed for BET in a dry heat oven USING A VALIDATED PROCESS?		Use
Do incubating plate or tube readers REFERENCE the FOLLOWING?	a.) User requirement specification (URS)	Best practice
	b.) Installation qualification (IQ)	
	c.) Operational qualification (OQ)	
	d.) Performance evaluation (PQ)	
Does the compounding site employ plastic apparatus for BET that	a.) is shown to be FREE OF DETECTABLE bacterial ENDOTOXIN?	Use
	b.) does NOT INTERFERE with BET?	
For which of the FOLLOWING does the compounding site USE aseptic technique?	a.) DILUTING standards	Best practice
	b.) HANDLING samples	
	c.) PREPARING standards	
Does the compounding site USE the FOLLOWING when performing BET?	a.) NORMAL laboratory personal protective equipment (PPE) when performing BET does not demand safety considerations due to toxicity or infectiousness	Best practice
	b.) TALC-FREE gloves (Talc may contain significant levels of bacterial endotoxins.)	

Bacterial Endotoxins Testing (BET) of Compounded Sterile Preparations (CSPs)		
Is equipment used for sample incubation (e.g., plate readers, water baths, and dry heat blocks) LOCATED AWAY FROM	a.) heating, ventilation, and air conditioning (HVAC) DUCTS?	Best practice
	b.) significant VIBRATION?	
	c.) TRAFFIC that can affect BET results?	
Are sample HOLD TIMES AND CONDITIONS	a.) DETERMINED to ensure that accurate BET results can be generated in the qualified time?	Best practice
	b.) DOCUMENTED?	
Are PRIMARY sample CONTAINER(S) ADEQUATELY MIXED before removing test aliquot(s) for either direct testing or subsequent dilution?		Best practice
Does the compounding site carry out BET IN A MANNER THAT AVOIDS bacterial endotoxin CONTAMINATION?		Is
Does the compounding site DETERMINE the MAXIMUM VALID DILUTION (MVD) BASED ON the FOLLOWING EQUATION?	MVD = (endotoxin limit x concentration of Sample Solution)/(h)	Determine
Does the compounding site OBTAIN the REAGENTS used in BET FROM REAGENT VENDORS?		If yes ...
Do the reagent vendors	a.) CONDUCT a lot-specific STANDARDIZATION of reagents used in BET?	Must
	b.) PROVIDE a lot-specific CERTIFICATE OF ANALYSIS (COA) in reagent kits for BET?	
Does the compounding site RETAIN a BET reagent kit's lot-specific certificate of analysis (COA) FOR REFERENCE?		Best practice
Does the compounding site PURCHASE commercially-prepared control standard endotoxin (CSE)	a.) FROM a third party for BET?	If yes ...
	b.) to CALIBRATE a liquid endotoxin preparation?	
Does the compounding site CONDUCT its own CALIBRATION STUDY against United States Pharmacopeia (USP) Endotoxin Reference Standard (RSE) when purchasing commercially-prepared CSE for BET and/or calibrating a liquid endotoxin preparation?		Must
Are ALL MATERIALS USED to sample materials for bacterial endotoxins content	a.) INERT with respect to the material(s) being sampled?	Must
	b.) STERILE AND FREE of detectable bacterial endotoxins?	
Are the FOLLOWING PRECAUTIONS taken by the compounding site when sampling for bacterial endotoxins content?	a.) The SAMPLE ITSELF is not contaminated in taking the sample.	Must
	b.) The REST OF THE MATERIAL in its original container is not contaminated upon taking the sample.	
Are the compounding site's SAMPLING SCHEMES for bacterial endotoxins content JUSTIFIED?		Best practice
Are the FOLLOWING A BASIS for the compounding site's SAMPLING SCHEMES for bacterial endotoxins?	a.) Historical KNOWLEDGE of the process	Best practice
	b.) Known VARIABILITY of the process	
	c.) MATERIALS used in compounding	
	d.) Unit OPERATIONS of the process	
Does the compounding site USE THE SAME EQUIPMENT FOR SAMPLING for bacterial endotoxins that is USED FOR COMPOUNDING to assure a representative sample?		Must

Bacterial Endotoxins Testing (BET) of Compounded Sterile Preparations (CSPs)		
Does the compounding site sample HIGHLY VISCOUS MATERIALS for bacterial endotoxins content?		If yes ...
Does the compounding site	a.) USE A SUITABLE INERT ROD free of detectable bacterial endotoxins to mix highly viscous materials PRIOR TO SAMPLING highly viscous materials for bacterial endotoxins content?	May/Best practice
	b.) DETERMINE THE NUMBER OF SAMPLES from highly viscous materials for bacterial endotoxins relative to the number of units compounded using appropriate statistical procedures because of the lack of assurance of homogeneity of the viscous materials?	
Does the compounding site sample POWDERED AND GRANULAR SOLIDS for bacterial endotoxins content?		If yes ...
Does the compounding site	a.) USE STERILE, PYROGEN-FREE spatulas and scoops to sample powdered and granular solids for bacterial endotoxins content?	May/Best practice
	b.) DETERMINE THE NUMBER OF SAMPLES from powdered and granular solids for powdered and granular solids relative to the number of units compounded using appropriate statistical procedures because of the lack of assurance of homogeneity of the powdered and granular solids?	
Does the compounding site HAVE TRAINING ON HOW TO SPOT SIGNS OF NON-UNIFORMITY in samples for bacterial endotoxins, particularly for samples of viscous and powdered materials?		Best practice
Are the FOLLOWING INDICATORS of non-uniformity in samples for bacterial endotoxins provided in the compounding site's training on how to spot signs of non-uniformity in samples for bacterial endotoxins?	a.) Differences in SHAPE	May
	b.) Differences in SIZE	
	c.) Differences in COLOR	
	d.) Evidence of MOISTURE in powdered materials	
	e.) STRATIFICATION of the material for viscous materials	
Does the compounding site POOL MATERIALS for BET?		If yes ...
Are the compounding site's sampling plans for BET, including INSTRUCTION TO POOL SAMPLES, SCIENTIFICALLY JUSTIFIED?		Best practice
Does the compounding site POOL MATERIALS for BET that could EXHIBIT VARIABILITY in bacterial ENDOTOXINS CONTENT?		Best practice not to
Does the compounding site ADJUST the maximum valid dilution (MVD) WHEN SAMPLES ARE POOLED for BET to account for the possibility of bacterial endotoxins in just one (1) of the samples?		Must

Bacterial Endotoxins Testing (BET) of Compounded Sterile Preparations (CSPs)		
Does the compounding site take the FOLLOWING points INTO CONSIDERATION when pooling samples for BET?	a.) Pooling MAY OBSCURE any non-uniformity in bacterial endotoxin content between the individual sample units. Information on variability may be valuable in troubleshooting or investigations.	There are
	b.) Taking aliquots of samples for pooling should always be performed using ASEPTIC TECHNIQUE and with individual units vigorously mixed prior to removing the aliquots. The original containers with remaining product should be retained for investigation in the event of an out-of-specification test result. Removing the aliquot through the disinfected rubber stopper using a pyrogen-free syringe is advisable to maintain the integrity of the unit container during subsequent storage for investigative testing.	
	c.) The concept of adjusted maximum valid dilution (MVD) DOES NOT APPLY to medical devices as they are, by convention, commonly pooled for testing.	
	d.) Any sampling scheme for drug products MUST REPRESENT the beginning, middle, and end of the batch. Additional samples may be taken if interventions in compounding raise concerns about possible bacterial endotoxin contamination.	
	e.) Samples should be TESTED INDIVIDUALLY if testing at the adjusted MVD causes an unacceptable increase in product-specific interference.	
	f.) Products with low calculated MVDs, or suspensions when there is no assurance of homogeneity in the removed aliquots, may NOT BE GOOD CANDIDATES for pooling.	
	g.) Pooling is NOT APPROPRIATE for in-process samples, particularly those representing different stages of compounding.	
Does the compounding site REPORT BET RESULTS AS Endotoxin Units (EU)/milliliter (mL)?		If no ...
Does the product being tested for bacterial endotoxins have a limit EXPRESSED IN Endotoxin Unit (EU) PER UNIT OF WEIGHT OR ACTIVITY [e.g., EU/milligram (mg)]?		If yes ...
Is a CALCULATION MADE TO CONVERT Endotoxin Units (EU)/milliliter (mL) to EU/milligram (mg) when the product being tested for bacterial endotoxins has a limit expressed in EU per unit of weight or activity?		Must

Bacterial Endotoxins Testing (BET) of Compounded Sterile Preparations (CSPs)		
How does the compounding site MAKE A FINAL DECISION in the event of CONFLICTING BET RESULTS WHEN a regulatory agency uses one BET method and the compounding site uses another BET method?	a.) Based upon REGULATORY agency	Compliant
	b.) Based upon the compounding SITE	Non-compliant
Does the compounding site INVESTIGATE NONCONFORMING BET results?		Necessitates
Does the compounding site perform an investigation IN A TIMELY MANNER to assure the accuracy of data in the event of nonconforming BET results?		Best practice
Which of the FOLLOWING does the compounding site INVESTIGATE in the event of nonconforming BET results?	a.) CALCULATIONS	
	b.) PERFORMANCE of the test	
	c.) PREPARATION of the sample	
	d.) SAMPLE itself	
How does the compounding site PROCEED when there are INVALID BET RESULTS versus a true out-of-specification (OOS) test failure?	a.) TRACK AND TREND INVALID BET results to look for patterns and trends	Best practice
	b.) Take CORRECTIVE ACTION when invalid BET results have patterns and trends	
Is there an ABSENCE OF A BACTERIAL ENDOTOXINS LIMIT IN an official United States Pharmacopeia - National Formulary (USP-NF) monograph or other compounded sterile preparation (CSP) formula source?		If yes ...
Do Category 2 and/or Category 3 INJECTABLE CSPs EXCEED THE bacterial ENDOTOXINS LIMIT CALCULATED as described in (85) Bacterial Endotoxins FOR THE APPROPRIATE ROUTE OF ADMINISTRATION FOR HUMANS?		Must not
Do Category 2 and/or Category 3 INJECTABLE CSPs EXCEED THE bacterial ENDOTOXINS LIMIT CALCULATED as described in (85) Bacterial Endotoxins FOR NONHUMANS based on the largest recommended dose and weight (or average weight for more than a single animal) of the target animal species unless a different limit is scientifically supported?		Must not

Beyond-Use Dates (BUDs)		
Are BUDs for CSPs ESTABLISHED CONSERVATIVELY to ensure that the drug maintains its required characteristics (i.e., stability and sterility) until its BUD?		Best practice
Are the FOLLOWING PARAMETERS that may affect quality of CSPs considered when establishing a BUD?	a.) Chemical STABILITY properties of the drug and/or its formulation	Must
	b.) COMPATIBILITY of the container closure system with the final preparation (e.g., leachables, interactions, adsorption, and storage conditions)	
	c.) Materials of COMPOSITION of the container closure system (e.g., leachables, interactions, adsorption, and storage conditions)	
	d.) Physical STABILITY properties of the drug and/or its formulation	
Are BUDs for CSPs based on the FOLLOWING FACTORS that affect the achievement and maintenance of sterility?	a.) Aseptic processing	Are based
	b.) Conditions of the environment in which the CSP is prepared	
	c.) Starting components (e.g., sterile or nonsterile ingredients)	
	d.) Sterilization method	
	e.) Storage conditions (e.g., packaging and temperature)	
	f.) Whether or not sterility testing is performed	
Does the compounding site ASSIGN A SHORTER BUD when the STABILITY of CSPs or their components IS LESS THAN THE HOURS OR DAYS for Category 1, Category 2, and/or Category 3 CSPs?		Must
Does the compounding site ASSIGN A BUD that EXCEEDS THE SHORTEST REMAINING expiration date of any of the commercially available starting components?		Must not
Are BUDs for Category 1 CSPs ESTABLISHED IN ACCORDANCE with Table 12 of (797) Pharmaceutical Compounding - Sterile Preparations which establishes the longest permitted BUDs for Category 1 CSPs?		Must
Are BUDs for Category 2 CSPs ESTABLISHED IN ACCORDANCE with Table 13 of (797) Pharmaceutical Compounding - Sterile Preparations which establishes the longest permitted BUDs for Category 2 CSPs?		Must
Does the compounding site MEET ALL THE CONDITIONS DESCRIBED IN (797) Pharmaceutical Compounding - Sterile Preparations for Category 3 CSPs?		If yes ...
Are BUDs for Category 3 CSPs ESTABLISHED IN ACCORDANCE with Table 14 of (797) Pharmaceutical Compounding - Sterile Preparations which establishes the longest permitted BUDs for Category 3 CSPs?		Must
Does the compounding site ASSIGN BUDS for Category 3 CSPs that are LONGER THAN THE LIMITS IN TABLE 14 of (797) Pharmaceutical Compounding - Sterile Preparations?		Must not
Does the compounding site EXCEED the applicable BUDs DESCRIBED IN Table 13 of (797) Pharmaceutical Compounding - Sterile Preparations?		Must not

Beyond-Use Dates (BUDs)		
Does the compounding site assign BUDs to Category 3 CSPs that are supported by STABILITY DATA OBTAINED USING A STABILITY-INDICATING ANALYTICAL METHOD?		Must
Does/Is the stability-indicating analytical method	a.) DISTINGUISH the active ingredient FROM its degradants and impurities (e.g., by forced degradation studies)?	Is able to
	b.) QUANTIFY the amount of active ingredient?	
	c.) VALIDATED based on characteristics such as those described in (1225) Validation of Compendial Procedures?	Must
Does the compounding site	a.) PREPARE Category 3 CSPs ACCORDING TO THE EXACT FORMULATION (e.g., active pharmaceutical ingredients (APIs) and other ingredients of identical grade and procedures) from which the stability data was derived?	Must
	b.) PACKAGE Category 3 CSPs in container closures of the SAME MATERIALS OF COMPOSITION as that used in the study from which the stability data was derived?	
	c.) STORE Category 3 CSPs in container closures of the SAME MATERIALS OF COMPOSITION as that used in the study from which the stability data was derived?	
	d.) have DOCUMENTATION of the stability study?	
Are the FOLLOWING INCLUDED in the compounding site's documentation of the stability study?	a.) All of the RESULTS of the study	Must
	b.) Description of the METHODOLOGY (e.g., number of samples taken, storage conditions)	
	c.) Stability-indicating analytical METHOD	
	d.) VALIDATION of the method	

Labeling of Compounded Sterile Preparations (CSPs)		
Does the compounding site label CSPs	a.) with APPROPRIATE, LEGIBLE identifying information to prevent errors during storage, dispensing, and use?	Must
	b.) IN COMPLIANCE with laws and regulations of the applicable regulatory jurisdiction?	
Is the FOLLOWING INFORMATION DISPLAYED on the label on each immediate container of CSPs?	a.) ACTIVE ingredient(s)	Must
	b.) ACTIVITY(ies) of active ingredients	
	c.) AMOUNT of active ingredient(s)	
	d.) Assigned internal IDENTIFICATION NUMBER (e.g., barcode, prescription, order, or lot number)	
	e.) BEYOND-USE date (BUD)	
	f.) CONCENTRATION(s) of active ingredient(s)	
	g.) Dosage FORM	
	h.) STORAGE conditions, if other than controlled room temperature	
	i.) Total AMOUNT or volume, if it is not obvious from the container	
Are any immediate containers of CSPs SINGLE-DOSE CONTAINERS?		If yes ...
Is there a STATEMENT DISPLAYED ON the LABEL on each immediate container of CSPs that it is a SINGLE-DOSE CONTAINER, when space permits?		Must
Are any immediate containers of CSPs MULTIPLE-DOSE CONTAINERS?		If yes ...
Is there a STATEMENT DISPLAYED ON the LABEL on each immediate container of CSPs that it is a MULTIPLE-DOSE CONTAINER?		Must
Is the FOLLOWING INFORMATION, as applicable, DISPLAYED on the labeling on CSPs?	a.) ROUTE(s) of administration	Must
	b.) Special HANDLING instructions	
	c.) WARNING statements	
Does the compounding site INDICATE ON the LABELING on CSPs that the PREPARATIONS ARE COMPOUNDED?		Best practice
Does the compounding site SEND CSPs OUTSIDE of the facility or healthcare system in which it was compounded?		If yes ...
Does the labeling on CSPs sent outside of the facility or healthcare system in which it was compounded DISPLAY the COMPOUNDING SITE'S	a.) CONTACT information?	Must
	b.) NAME?	
Does the compounding site VERIFY the LABEL of CSPs to ensure it CONFORMS with the	a.) Prescription or medication ORDER?	Must
	b.) MASTER formulation record (MFR), if required?	
	c.) COMPOUNDING record (CR), if required?	
Does the compounding site FOLLOW LABELING PROCEDURES as DESCRIBED IN the compounding site's STANDARD OPERATING PROCEDURES (SOPs) to prevent labeling errors and CSP mix-ups?		Must

Storing Compounded Sterile Preparations (CSPs)		
Do PERSONNEL MONITOR CONDITIONS in storage areas to help ensure that CSP quality is maintained during storage at the compounding site?		Must
Do the CSPs REMAIN _____ for the DURATION OF the beyond-use date (BUD)?	a.) CHEMICALLY stable	Must
	b.) PHYSICALLY stable	
Did the compounding site ESTABLISH a CONTROLLED TEMPERATURE AREA?		Must
Does the compounding site MONITOR the controlled temperature area DAILY to ensure that the temperature remains within the appropriate range for CSPs?		Must
Does the compounding site VERIFY temperature monitoring devices for accuracy AT LEAST EVERY TWELVE (12) MONTHS OR AS REQUIRED by the manufacturer?		Must
Does the compounding site _____ TEMPERATURE EXCURSIONS that are outside the temperature limits within the controlled temperature areas?	a.) DETECT	Must
	b.) MINIMIZE	
Does the compounding site STORE the TEMPERATURE READINGS of the controlled temperature area IN THE CONTINUOUS TEMPERATURE RECORDING DEVICE?		If no ...
Does the compounding site DOCUMENT the TEMPERATURE READINGS of the controlled temperature area IN A TEMPERATURE LOG per the COMPOUNDING SITE'S standard operating procedures (SOPs)?		Must
Are the TEMPERATURE READINGS of the controlled temperature area RETRIEVABLE?		Must
Does the compounding site STORE ANY CSPs IN A FROZEN STATE?		If yes ...
Can the container closure system of the CSPs WITHSTAND THE PHYSICAL STRESS during storage in a freezer (i.e., without breaking or cracking)?		Must
Are the CSPs stored in a frozen state THAWED IN APPROPRIATE CONDITIONS (e.g., do not heat in a microwave) to avoid compromising the physical land chemical stability of the preparation and its components?		Must
Are any THAWED CSPs REFROZEN?		Must not
Are any CSPs STORED UNDER DIFFERENT STORAGE CONDITIONS BEFORE USED (e.g., CSPs may first be frozen, then thawed in the refrigerator, and finally kept at controlled room temperature before administration)?		If yes ...
Are CSPs stored under a condition that REQUIRES a SHORTER BUD (e.g., controlled room temperature) USED WITHIN the TIME FRAME for that storage condition [e.g., 24 hours when stored for forty-five (45) days in a freezer, then four (4) days refrigerated, and then twenty-four (24) hours at controlled room temperature]?		Must
Does the STORAGE TIME of CSPs stored under different storage conditions before use EXCEED THE ORIGINAL BEYOND-USE DATE (BUD) placed on the CSPs for their labeled storage condition?		Must not
Does the compounding site use ADDITIVE BUDs when CSPs are stored under different storage conditions before use?		Must not

Handling, Packaging, Shipping, Transporting Compounded Sterile Preparations (CSPs)		
Are PERSONNEL who will be handling, storing, packaging, and transporting CSPs WITHIN the compounding site	a.) TRAINED in accordance with the RELEVANT SOPs concerning processes and techniques for handling, storing, packaging, and transporting CSPs?	Must
	b.) have their training in accordance with the relevant SOPs concerning processes and techniques for handling, storing, packaging, and transporting CSPs DOCUMENTED?	
Does the compounding site HANDLE CSPs IN A MANNER that maintains	a.) CSP QUALITY?	Must
	b.) packaging INTEGRITY?	
Does the compounding site prepare CSPs that REQUIRE SPECIAL HANDLING (e.g., CSPs with stability concerns)?		If yes ...
Do compounding personnel INCLUDE special handling INSTRUCTIONS on the EXTERIOR OF THE CONTAINER in which CSPs that require special handling (e.g., CSPs with stability concerns) are packaged?		Must
Do the FOLLOWING SUGGESTED features apply to the packaging materials used by the compounding site to package CSPs?	a.) Prevent INADVERTENT EXPOSURE to transport personnel	Best practice
	b.) Protect CSPs from ADSORPTION	
	c.) Protect CSPs from CONTAMINATION	
	d.) Protect CSPs from DAMAGE	
	e.) Protect CSPs from DEGRADATION	
	f.) Protect CSPs from LEAKAGE	
Are the FOLLOWING CRITERIA USED by the compounding site as a basis to select appropriate containers and packaging materials for CSPs?	a.) Information from VENDORS	Must
	b.) MODE of transport	
	c.) Product SPECIFICATIONS	
Does the compounding site prepare CSPs that are SENSITIVE TO LIGHT?		If yes ...
Does the compounding site use LIGHT-RESISTANT PACKAGING MATERIALS for CSPs that are sensitive to light?		Must
Does the compounding site prepare CSPs that are exposed to TEMPERATURE FLUCTUATIONS?		If yes ...
Does the compounding site package CSPs that are exposed to temperature fluctuations in SPECIAL CONTAINERS (e.g., cooler)?		Must
Does the PACKAGING of CSPs MAINTAIN ITS INTEGRITY for the DURATION OF the BUD?		Must
Are the following CRITERIA used by compounding personnel to select modes of transport for CSPs?	a.) Expected to deliver properly packed CSPs in a STABLE condition	Must
	b.) Expected to deliver properly packed CSPs in a STERILE condition	
	c.) Expected to deliver properly packed CSPs in an UNDAMAGED condition	

Master Formulation and/or Compounding Records		
Master Formulation Records (MFRs)		
Does the compounding site CREATE A MFR FOR CSPs prepared	a.) from NONSTERILE ingredient(s)?	Must
	b.) for MORE THAN ONE (1) patient?	
Are CHANGES OR ALTERATIONS to a MFR	a.) APPROVED according to the compounding site's standard operating procedures (SOPs)?	Must
	b.) DOCUMENTED the compounding site's SOPs?	
Is the FOLLOWING INFORMATION INCLUDED in the compounding site's MFRs?	a.) NAME of the CSP	Must
	b.) STRENGTH or activity of the CSP	
	c.) Dosage FORM of the CSP	
	d.) IDENTITY of all ingredients	
	e.) Type of CONTAINER closure system(s)	
	f.) Size of container closure system(s)	
	g.) Complete INSTRUCTIONS for preparing the CSP, including equipment, supplies, description of the compounding steps, and any special precautions	
	h.) BEYOND-USE date (BUD)	
	i.) STORAGE requirements	
	j.) REFERENCE source to support the stability of the CSP	
	k.) QUALITY control (QC) procedures (e.g., pH testing, filter integrity testing)	
	l.) Relevant CHARACTERISTICS of the components used by the compounding site to prepare CSPs (e.g., particle size, salt form, purity grade, solubility), if applicable	
	m.) OTHER information as needed to describe the compounding process and ensure repeatability (e.g., adjusting pH and tonicity; sterilization method, such as steam, dry heat, irradiation, or filter)	
Compounding Records (CRs)		
Does the compounding site CREATE a CR	a.) to DOCUMENT the compounding process?	Must
	b.) for ALL Category 1, Category 2, and/or Category 3 CSPs?	
	c.) for IMMEDIATE-USE CSPs prepared for MORE THAN ONE (1) PATIENT?	
Does the compounding site ELECTRONICALLY STORE the information required in the CR?		If yes ...
Can the compounding site READILY RETRIEVE the electronically stored information required in the CR?		Must

Master Formulation and/or Compounding Records		
Is the FOLLOWING INFORMATION INCLUDED in the compounding site's CRs?	a.) NAME of the CSP	Must
	b.) STRENGTH or activity of the CSP	
	c.) Dosage FORM of the CSP	
	d.) Assigned internal IDENTIFICATION NUMBER (e.g., prescription, order, or lot number)	
	e.) A METHOD to identify the individuals involved in the compounding process and individuals verifying the final CSP	
	f.) NAME of each component	
	g.) WEIGHT or volume of each component	
	h.) STRENGTH or activity of each component	
	i.) Total QUANTITY compounded	
	j.) Final YIELD (e.g., quantity, containers, number of units)	
	k.) Assigned BEYOND-USE date (BUD)	
	l.) STORAGE requirements	
	m.) Results of QUALITY CONTROL (QC) procedures (e.g., visual inspection, filter integrity testing, pH testing)	
	n.) CALCULATIONS made by the compounding site to determine and verify quantities and/or concentrations of components, if applicable	
	o.) Master formulation record (MFR) REFERENCE [e.g., CSPs prepared from nonsterile ingredient(s) or CSPs prepared for more than one patient], if applicable	
	IF compounded from non-sterile ingredients ...	
	a.) EXPIRATION date for each component	
	b.) LOT NUMBER for each component	
	c.) VENDOR for each component	
	IF sterilized by dry heat ...	
	a.) LOAD NUMBERS of the dry heat oven used to sterilize a CSP	
	b.) Sterilization by dry heat DATE	
	c.) Sterilization by dry heat RUN	
	IF sterilized by steam heat ...	
	a.) LOAD NUMBERS of the steam sterilizer used to sterilize a CSP	
	b.) Sterilization by steam heat DATE	
	c.) Sterilization by steam heat RUN	

Designated Person(s) or Pharmacist, whichever is applicable		
Designated Person(s)		
Did the compounding site DESIGNATE ONE OR MORE INDIVIDUALS TO BE RESPONSIBLE AND ACCOUNTABLE for the performance and operation of the site and personnel in the preparation of compounded sterile preparations (CSPs) and for performing other functions as described in (797) Pharmaceutical Compounding - Sterile Preparations?		Must
Designated Pharmacist (Sterile Compounding Pharmacy and Institutional Pharmacy that Compounds Sterile Pharmaceuticals within a Facility Licensed Pursuant to Section 19a-490 of the Connecticut General Statutes)		
Did the compounding site DESIGNATE A PHARMACIST to be RESPONSIBLE for overseeing the compounding of sterile pharmaceuticals and the application of the USP chapters, as said chapters pertain to sterile compounding? [Section 20-633b(m)(1)]		Shall
Did the pharmacy NOTIFY the Connecticut Department of Consumer Protection (DCP) of its designated pharmacist? [Section 20-633b(m)(2)]		Shall
Can the designated pharmacist PROVIDE PROOF OF COMPLETING A PROGRAM approved by the Connecticut Commissioner of Consumer Protection that DEMONSTRATES the COMPETENCE NECESSARY for the compounding of sterile pharmaceuticals, in compliance with all applicable federal and state statutes and regulations? [Section 20-633b(m)(3)]		Shall
Designated Person(s) or Pharmacist		
Does the designated person(s) or pharmacist, whichever is applicable, RECOGNIZE ONE'S RESPONSIBILITY to		
Air Quality Standard	a.) ENSURE EACH AREA related to compounded sterile preparation (CSP) preparation MEETS THE CLASSIFIED AIR QUALITY STANDARD for the activities being conducted in that area?	Are/Is/Must
	b.) ENSURE ISO 5-classified areas are LOCATED to have APPROPRIATE AIR QUALITY?	
	c.) ENSURE ISO 5-classified areas are OPERATED to have APPROPRIATE AIR QUALITY?	
	d.) ENSURE ISO 5-classified areas are MAINTAINED to have APPROPRIATE AIR QUALITY?	
	e.) ENSURE ISO 5-classified areas are MONITORED to have APPROPRIATE AIR QUALITY?	
	f.) ENSURE ISO 5-classified areas are CERTIFIED to have APPROPRIATE AIR QUALITY?	
Complaints	a.) REVIEW ALL COMPLAINTS to determine whether the complaint indicates a potential quality problem with a CSP?	
Corrective Actions	a.) FOLLOW UP to ensure that CORRECTIVE ACTIONS ARE TAKEN when problems, deviations, failures, or errors are identified?	
	b.) DOCUMENT the corrective actions taken when problems, deviations, failures, or errors are identified?	

Designated Person(s) or Pharmacist, whichever is applicable		
Handling, Storing, Packaging, Shipping, Transporting Compounded Sterile Preparations (CSPs)	a.) DETERMINE WHETHER CSPs are EXPECTED TO RETAIN THEIR INTEGRITY OR QUALITY when it is known that such CSPs have been exposed to temperatures either below or above the storage temperature limits for such CSPs (e.g., by consulting literature or analytical testing)?	Are/Is/Must
	b.) DISCARD CSPs when it CANNOT BE DETERMINED whether such CSPs are expected to retain their integrity or quality when it is known such CSPs have been exposed to temperatures either below or above the storage temperature limits for such CSPs?	
Personnel Competency	a.) ENSURE that compounders, personnel who have direct oversight of compounders, and personnel who perform restocking or cleaning and disinfection duties are INITIALLY TRAINED AND QUALIFIED by demonstrating knowledge and competency in maintaining the quality of the sterile compounding environment BEFORE BEING ALLOWED TO PERFORM JOB FUNCTIONS INDEPENDENTLY?	
	b.) PERFORM (or have an assigned trainer perform) the INITIAL TRAINING AND OBSERVATION of compounders, personnel who have direct oversight of compounders, and personnel who perform restocking or cleaning and disinfection duties demonstrating knowledge and competency in maintaining the quality of the sterile compounding environment?	
	c.) DOCUMENT the training and evaluation of personnel?	
Personnel Hygiene and Garbing	a.) EVALUATE whether individuals with a higher risk of contaminating a compounded sterile preparation (CSP) and the environment (e.g., personnel with rashes, recent tattoos, oozing sores, conjunctivitis, or active respiratory infections) SHOULD BE EXCLUDED FROM WORKING IN COMPOUNDING AREAS before their conditions resolve because of the risk of contaminating CSPs and the environment?	

Designated Person(s) or Pharmacist, whichever is applicable		
Quality Assurance (QA) and Quality Control (QC) Programs	a.) ENSURE the compounding site has FORMAL QA AND QC programs?	Are/Is/Must
	b.) ENSURE a system of APPROPRIATE INVESTIGATIONS AND CORRECTIVE ACTIONS is established in the compounding site's formal QA and QC programs?	
	c.) ENSURE a system of adherence to PROCEDURES is established in the compounding site's formal QA and QC programs?	
	d.) ENSURE a system of EVALUATION OF COMPLAINTS AND ADVERSE EVENTS is established in the compounding site's formal QA and QC programs?	
	e.) ENSURE a system of PREVENTION AND DETECTION of errors and other quality problems is established in the compounding site's formal QA and QC programs?	
	f.) REVIEW the compounding site's OVERALL QA and QC programs AT LEAST ONCE EVERY TWELVE (12) MONTHS?	
	g.) DOCUMENT reviewing the compounding site's overall QA and QC programs at least once every twelve (12) months?	
	h.) TAKE APPROPRIATE ACTION, if needed, after reviewing the compounding site's overall QA and QC programs?	
Standard Operating Procedures (SOPs)	a.) ENSURE that SOPs are IMPLEMENTED for the compounding site?	
	b.) ENSURE the compounding site's SOPs are APPROPRIATE, including that personnel demonstrate competency in performing every procedure that relates to their job function?	
	c.) INITIALLY REVIEW the compounding site's SOPs to ENSURE they REFLECT CURRENT PRACTICES?	
	d.) DOCUMENT initially reviewing the compounding site's SOPs?	
	e.) REVIEW the compounding site's SOPs AT LEAST EVERY TWELVE (12) MONTHS to ensure they reflect current practices?	
	f.) DOCUMENT reviewing the compounding site's SOPs at least every twelve (12) months?	
Sterilization by Filtration	a.) ENSURE that sterilizing filters are CHEMICALLY AND PHYSICALLY COMPATIBLE with all ingredients in the CSP (e.g., water-miscible alcohols may damage filter integrity)	
	b.) ENSURE that sterilizing filters are CHEMICALLY STABLE at the pressure and temperature conditions that will be used	
	c.) ENSURE that sterilizing filters have ENOUGH CAPACITY to filter the required volumes	
Training Program	a.) CREATE a training program for personnel?	
	b.) IMPLEMENT a training program for personnel?	

Designated Person(s) or Pharmacist, whichever is applicable		
Does the designated person(s) or pharmacist, whichever is applicable, HAVE the FOLLOWING TO PERFORM their duties concerning the compounding site's quality assurance (QA) program?	a.) AUTHORITY	Are/Is/Must
	b.) EXPERIENCE	
	c.) RESPONSIBILITY	
	d.)TRAINING	
HOW does the designated person(s) or pharmacist, whichever is applicable, ENSURE that sterilizing filters meet all requirements?	a.) Available published information	Compliant
	b.) Direct challenge [e.g., filtering the compounded sterile preparation (CSP)]	
	c.) Supplier documentation	
	d.) Other	Non-compliant

Written Training Program		
Did the compounding site develop a written training program?		Must
Are the FOLLOWING DESCRIBED in the compounding site's written training program?	a.) FREQUENCY of training	Must
	b.) PROCESS FOR EVALUATING the performance of individuals who compound, have direct oversight of compounding personnel, perform in-process checks, final verification, and dispensing of compounded sterile preparations (CSPs)	
	c.) REQUIRED training	
Does the compounding site's written training program	a.) EQUIP personnel with the APPROPRIATE KNOWLEDGE?	Must
	b.) TRAIN personnel in the REQUIRED SKILLS necessary to perform their assigned tasks?	
	c.) HAVE standard operating procedures (SOPs) SPECIFYING THE TRAINING required for personnel to perform their assigned tasks?	Best practice

Sterile Compounding Principles and Practices		
One person in the compounding operation		
Did/Does that one person	a.) DOCUMENT that they obtained TRAINING AND demonstrated COMPETENCY in the required sterile compounding principles and practices (i.e., core skills)?	Must
	b.) COMPLY with the other requirements in (797) Pharmaceutical Compounding - Sterile Preparations?	
More than one person in the compounding operation		
Is each person who compounds or has direct oversight of compounding personnel	a.) INITIALLY trained and qualified by demonstrating knowledge and competency in compounding compounded sterile preparations (CSPs) in sterile compounding principles and practices (i.e., core skills) BEFORE BEING ALLOWED TO PERFORM their job functions INDEPENDENTLY?	Must
	b.) trained and qualified AT LEAST EVERY TWELVE (12) MONTHS by demonstrating knowledge and competency in compounding CSPs in each of the required sterile compounding principles and practices (i.e., core skills)?	
Are the FOLLOWING sterile compounding principles and practices (i.e., core skills) INCLUDED in the training of personnel who compound or have direct oversight of compounding personnel?	a.) Achieving and/or maintaining APYROGENICITY if compounding with nonsterile components	Must
	b.) Achieving and/or maintaining STERILITY	
	c.) ASEPTIC technique	
	d.) CALCULATIONS, measuring, and mixing	
	e.) DOCUMENTATION of the compounding process	
	f.) GARBING	
	g.) Hand HYGIENE	
	h.) Principles of high-efficiency particulate air (HEPA)-filtered UNIDIRECTIONAL AIRFLOW within the ISO Class 5 area	
	i.) Principles of MOVEMENT of materials and personnel within the compounding area	
	j.) PROPER USE of primary engineering controls (PECs)	
	k.) Use of EQUIPMENT	
Does each person compounding only immediate-use CSPs COMPLETE TRAINING AS REQUIRED by the site's standard operating procedures (SOPs)?		Must
Does each person who ONLY performs restocking or cleaning and disinfecting duties outside of PECs COMPLETE ONGOING TRAINING as required by the compounding site's standard operating procedures (SOPs)?		Must

Garbing Competency		
Did each person who compounds or has direct oversight of compounding personnel SUCCESSFULLY COMPLETE NO FEWER THAN THREE (3) initial garbing competency evaluations IN SUCCESSION AFTER PERFORMING A SEPARATE AND COMPLETE hand hygiene and full garbing procedure?		Must
Will each person who compounds or has direct oversight of compounding personnel who FAILS to complete no fewer than three (3) initial garbing competency evaluations in succession REPEAT TESTING until successfully completing three (3) garbing competency evaluations in a row?		Must
Does each compounding person SUCCESSFULLY COMPLETE a garbing competency evaluation	a.) AT LEAST ONE (1) TIME EVERY SIX (6) MONTHS when preparing Category 1 and/or Category 2 CSPs?	Must
	b.) AT LEAST ONE (1) TIME EVERY THREE (3) MONTHS when preparing Category 3 CSPs?	
The compounding site CANNOT EXCEED the applicable beyond-use dates (BUDs) described in Table 13 of (797) Pharmaceutical Compounding - Sterile Preparations when the compounding site DOES NOT MEET all the conditions described in (797) Pharmaceutical Compounding - Sterile Preparations for the preparation of Category 3 CSPs		
Does each person who has direct oversight of compounding personnel and does not currently compound SUCCESSFULLY COMPLETE a garbing competency evaluation	a.) EVERY TWELVE (12) MONTHS?	Must
	b.) at the same intervals required for compounding personnel BEFORE COMPOUNDING?	
The compounding site CANNOT EXCEED the applicable beyond-use dates (BUDs) described in Table 13 of (797) Pharmaceutical Compounding - Sterile Preparations when the compounding site DOES NOT MEET all the conditions described in (797) Pharmaceutical Compounding - Sterile Preparations for the preparation of Category 3 CSPs		
Is each garbing competency evaluation	a.) COMPLETED WITH a gloved fingertip and thumb (GFT) sampling AFTER GARBING?	Must
	b.) COMPLETED WITH a DOCUMENTED VISUAL AUDIT while performing hand hygiene and garbing procedures?	
	c.) PERFORMED on donned STERILE GLOVES on BOTH HANDS BEFORE applying sterile seventy (70) percent isopropyl alcohol (IPA) to gloves IN A CLASSIFIED AREA OR SEGREGATED COMPOUNDING AREA (SCA)?	
Was any person who compounds or has direct oversight of compounding personnel	a.) visually observed to PERFORM IMPROPER hand hygiene and garbing procedures?	Must not
	b.) documented to have a gloved fingertip and thumb (GFT) sampling result that EXCEEDED MORE THAN ZERO (0) colony-forming units (CFUs) FROM BOTH HANDS?	
How does the compounding site proceed when personnel fail a garbing competency evaluation?	a.) TAKE corrective actions	Must
	b.) DOCUMENT corrective actions	
	c.) MAINTAIN documented corrective actions to provide a record and long-term assessment of personnel competency	
Are the RESULTS of each FAILED garbing competency evaluation	a.) DOCUMENTED?	Must
	b.) MAINTAINED to provide a record and long-term assessment of personnel competency?	

Garbing Competency		
Are the FOLLOWING ELEMENTS included in the documentation of FAILED garbing competency evaluations?	a.) DATE of EVALUATION	Must
	b.) DATES of INCUBATION	
	c.) Each component USED	
	d.) Each component's EXPIRATION DATE	
	e.) Each component's LOT NUMBER	
	f.) Each component's MANUFACTURER OR SUPPLIER	
	g.) EVALUATION TIME	
	h.) IDENTIFICATION of the OBSERVER	
	i.) IDENTIFICATION of person who READS AND DOCUMENTS the results	
	j.) Name of the PERSON EVALUATED	
	k.) RESULTS	
	l.) STARTING TEMPERATURE for each interval of incubation	

Aseptic Manipulation Competency		
Does each compounding person SUCCESSFULLY COMPLETE an aseptic manipulation competency evaluation	a.) BEFORE BEGINNING to compound Category 1, Category 2, or Category 3 CSPs?	Must
	b.) AT LEAST EVERY SIX (6) MONTHS after the initial aseptic manipulation competency evaluation when preparing Category 1 and/or Category 2 CSPs?	
	c.) AT LEAST EVERY THREE (3) MONTHS after the initial aseptic manipulation competency evaluation when preparing Category 3 CSPs?	
The compounding site CANNOT EXCEED the applicable beyond-use dates (BUDs) described in Table 13 of (797) Pharmaceutical Compounding - Sterile Preparations when the compounding site DOES NOT MEET all the conditions described in (797) Pharmaceutical Compounding - Sterile Preparations for the preparation of Category 3 CSPs		
Does each person who has direct oversight of compounding personnel and does not currently compound SUCCESSFULLY COMPLETE an aseptic manipulation competency evaluation	a.) BEFORE BEGINNING to have direct oversight of compounding personnel?	Must
	b.) ANNUALLY when having direct oversight of compounding personnel preparing Category 3 CSPs?	
	c.) that SIMULATES the most difficult and challenging aseptic compounding procedures encountered by the person at the same intervals required for compounding personnel BEFORE COMPOUNDING?	
The compounding site CANNOT EXCEED the applicable beyond-use dates (BUDs) described in Table 13 of (797) Pharmaceutical Compounding - Sterile Preparations when the compounding site DOES NOT MEET all the conditions described in (797) Pharmaceutical Compounding - Sterile Preparations for the preparation of Category 3 CSPs		
Does each aseptic manipulation competency evaluation consist of	a.) VISUAL observation?	Must
	b.) MEDIA-fill testing?	
	c.) GLOVED FINGERTIP AND THUMB (GFT) sampling?	
	d.) SURFACE sampling of the direct compounding area (DCA) to assess aseptic technique and related practices?	
Does the compounding site meet the FOLLOWING WHEN PERFORMING media-fill testing?	a.) INCUBATE final containers IN an INCUBATOR	Must
	b.) DESCRIBE the ORDER of INCUBATION TEMPERATURES in the site's standard operating procedures (SOPs)	
	c.) SIMULATE the MOST DIFFICULT AND CHALLENGING aseptic compounding procedures when replacing all the components used in CSPs with soybean-casein digest media	
Are the FOLLOWING ELEMENTS that could potentially affect the sterility of the CSP captured during the media-fill test?	a.) COMPLEXITY of manipulations	Must
	b.) FACTORS associated with the length of the process that can pose contamination risk (e.g., operator fatigue, quality of equipment)	
	c.) number of ASEPTIC additions or transfers	
	d.) number of MANIPULATIONS	
	e.) number of PERSONNEL in the buffer room or segregated compounding area (SCA)	
	f.) TYPE of manipulations	

Aseptic Manipulation Competency		
Is sterile microbial growth MEDIA PREPARED IN-HOUSE FOR STERILE-TO-STERILE media-fill testing?		If yes ...
Is the GROWTH POTENTIAL CAPABILITY of the sterile microbial growth media prepared in house for sterile-to-sterile media-fill testing	a.) DEMONSTRATED for each batch?	Must
	b.) DOCUMENTED AS DESCRIBED IN (71) Sterility Tests, Culture Media and Incubation Temperatures, Growth Promotion Test of Aerobes, Anaerobes, and Fungi?	
Is COMMERCIAL sterile microbial growth MEDIA USED for media-fill testing?		If yes ...
Does the compounding site meet the FOLLOWING REQUIREMENTS when using commercial sterile microbial growth media for media-fill testing?	a.) OBTAIN a certificate of analysis (COA) FROM THE SUPPLIER stating that the lot of such media will support the growth of microorganisms	Must
	b.) STORE such media in accordance with manufacturer instructions	
	c.) INITIATE media-fill tests by the expiration date of such media	
Does the compounding site meet the FOLLOWING WHEN PERFORMING GFT sampling?	a.) IMMEDIATELY FOLLOWS media-fill testing	Must
	b.) on BOTH hands	
Is the ISO Class 5 primary engineering control (PEC) a compounding aseptic isolator (CAI), compounding aseptic containment isolator (CACI), or a pharmaceutical isolator?		If yes ...
Are samples taken from the STERILE GLOVES PLACED OVER the gloves attached to the compounding aseptic isolator (CAI), compounding aseptic containment isolator (CACI), or pharmaceutical isolator SLEEVES?		Must
Did any person who compounds or has direct oversight of compounding personnel FAIL a media-fill test, gloved fingertip and thumb (GFT) sampling, or surface sample?		If yes ...
Did the FAILURE of the person who compounds or has direct oversight of compounding personnel TO SUCCESSFULLY COMPLETE a media-fill test, gloved fingertip and thumb (GFT) sampling, or surface sample CONSTITUTE AN OVERALL FAILURE of the aseptic manipulation competency evaluation?		Must
Does the compounding site	a.) DOCUMENT FAILED evaluation results?	Must
	b.) MAINTAIN documentation of FAILED evaluation results to provide a record and long-term assessment of personnel competency?	
	c.) TAKE corrective action when personnel fail an aseptic manipulation evaluation?	
	d.) DOCUMENT the corrective action taken when personnel fail an aseptic manipulation evaluation?	
	e.) MAINTAIN documentation of corrective action taken when personnel fail an aseptic manipulation evaluation to to provide a record and long-term assessment of personnel competency?	

Aseptic Manipulation Competency		
Are the FOLLOWING INCLUDED in the documentation of FAILED aseptic manipulation competency evaluations?	a.) DATE of EVALUATION	Must
	b.) DATES of INCUBATION	
	c.) Each component USED	
	d.) Each component's EXPIRATION DATE	
	e.) Each component's LOT NUMBER	
	f.) Each component's MANUFACTURER OR SUPPLIER	
	g.) Each media USED	
	h.) Each media's EXPIRATION DATE	
	i.) Each media's LOT NUMBER	
	j.) Each media's MANUFACTURER OR SUPPLIER	
	k.) EVALUATION TIME	
	l.) Name of the PERSON EVALUATED	
	m.) Names or other IDENTIFICATION of the OBSERVER	
	n.) Names or other IDENTIFICATION of person who READS AND DOCUMENTS the results	
	o.) RESULTS	
	p.) STARTING TEMPERATURE for each interval of incubation	

Personnel Hygiene and Garbing		
Do all individuals entering a compounding area MAINTAIN PROPER PERSONAL HYGIENE to minimize the risk of contamination to the environment and/or compounded sterile preparations (CSPs)?		Must
Do all personnel ENTERING A COMPOUNDING AREA where Category 1, Category 2, or Category 3 compounded sterile preparations (CSPs) are prepared TAKE APPROPRIATE STEPS TO MINIMIZE MICROBIAL CONTAMINATION for the environment and of the CSPs?		Must
Do individuals with a higher risk of contaminating a compounded sterile preparation (CSP) and the environment (e.g., personnel with rashes, recent tattoos, oozing sores, conjunctivitis, or active respiratory infections) REPORT THESE CONDITIONS TO THE DESIGNATED person(s) or pharmacist, whichever is applicable?		Must
Does the designated person(s) or pharmacist, whichever is applicable, EVALUATE whether individuals with a higher risk of contaminating a compounded sterile preparation (CSP) and the environment (e.g., personnel with rashes, recent tattoos, oozing sores, conjunctivitis, or active respiratory infections) SHOULD BE EXCLUDED FROM WORKING IN COMPOUNDING AREAS before their conditions resolve because of the risk of contaminating CSPs and the environment?		Is responsible
Do food, including mints and gum, and drinks ENTER the	a.) ANTEroom(s)?	Must not
	b.) Buffer room(s)?	
	c.) Segregated compounding areas (SCAs)?	
Are the FOLLOWING PREPARATIONS PERFORMED by individuals before entering a compounding area?	a.) REMOVE any item that is NOT EASILY CLEANABLE OR NOT NECESSARY for compounding	If no ...
	b.) Keep NAILS CLEAN AND NEATLY TRIMMED to minimize particle shedding and avoid glove punctures.	
	c.) NAIL PRODUCTS (e.g., polish, artificial nails, and extenders) are NOT WORN	
	d.) Do not bring ELECTRONIC DEVICES that are NOT NECESSARY for compounding or other required tasks into the compounding area	
	e.) Do not wear EARBUDS OR HEADPHONES	
	f.) REMOVE all COSMETICS because they shed flakes and particles	
	g.) REMOVE all hand, wrist, and other exposed JEWELRY, including piercing that could interfere with the effectiveness of garbing (e.g., the fit of gloves, cuffs of sleeves, and eye protection) or otherwise increase the risk of contamination of the compounded sterile preparation (CSP) [Cover any jewelry that cannot be removed]	
	h.) REMOVE personal OUTER GARMENTS (e.g., bandanas, coats, hats, jackets, sweaters, vests)	
	i.) WIPE EYEGLASSES, if applicable	
Did a designated person or pharmacist, whichever is applicable, PERMIT ACCOMMODATIONS TO PERSONNEL PREPARATION BEFORE ENTERING a compounding area?		If yes ...
Did the designated person or pharmacist, whichever is applicable, ...	a.) DETERMINE that the accommodations to personnel preparation before entering a compounding area WILL NOT AFFECT THE QUALITY of the compounded sterile preparation (CSP) and environment?	Must
	b.) DOCUMENT the accommodations to personnel preparation before entering a compounding area?	

Personnel Hygiene and Garbing		
Is hand hygiene completed OUTSIDE of a CLASSIFIED AREA?		If yes ...
Is ALCOHOL-BASED HAND RUB USED PRIOR TO DONNING GARB when hand hygiene is completed outside of a classified area?		Must
Do all personnel ENTERING a compounding area where Category 1, Category 2, or Category 3 compounded sterile preparations (CSPs) are prepared PERFORM THE FOLLOWING BEFORE initiating compounding activities?	a.) Wash HANDS with soap and water	Must
	b.) Wash FOREARMS UP TO THE ELBOWS with soap and water	
Do personnel ENTERING a compounding area where Category 1, Category 2, or Category 3 compounded sterile preparations (CSPs) are prepared	a.) BRUSHES for hand hygiene?	Must not
	b.) hand DRYERS?	
Does the compounding site use DISPOSABLE SOAP containers?		If yes ...
Are disposable soap containers	a.) REFILLED?	Must not
	b.) TOPPED OFF?	
Are the FOLLOWING PROCEDURES included in hand washing?	a.) CLEAN UNDERNEATH FINGERNAILS under warm running water using a disposable nail cleaner	Must
	b.) WASH HANDS AND FOREARMS up to the elbows with soap and water for at least thirty (30) seconds	
	c.) DRY HANDS AND FOREARMS up to the elbows completely with low-lint disposable towels or wipers	
	d.) ALL PERSONNEL FOLLOW all handwashing procedures	
Are hands SANITIZED with ALCOHOL-BASED HAND RUB BEFORE DONNING STERILE GLOVES?		Must
Are sterile gloves DONNED IN a CLASSIFIED ROOM OR segregated compounding area (SCA)?		Must
Are the FOLLOWING PROCEDURES INCLUDED in hand sanitizing?	a.) APPLY AN ALCOHOL-BASED hand rub to dry skin	Must
	b.) APPLY PRODUCT to one hand and RUB HANDS TOGETHER, covering all surfaces of hands and fingers, until hands are dry	
	c.) ALLOW HANDS TO DRY thoroughly before donning sterile gloves	
	d.) ALL PERSONNEL FOLLOW all hand sanitizing procedures	
Are all personnel ENTERING A COMPOUNDING AREA in which Category 1, Category 2, or Category 3 compounded sterile preparations (CSPs) are prepared PROPERLY GARBED?		Must
Is SKIN EXPOSED INSIDE an ISO CLASS 5 primary engineering control (PEC)?		Must not
Does DONNING AND DOFFING OCCUR in the SAME AREA at the SAME TIME?		Must not
Is garb DONNED AND DOFFED in an ORDER that REDUCES the RISK OF CONTAMINATION?		Must
Does the compounding site have	a.) REQUIRED GARB?	Required
	b.) a REQUIRED ORDER of garbing?	
	c.) a REQUIRED MANNER of STORAGE for garb?	
Is the required garb, order of garbing, and manner of storage for garb ...	a.) DETERMINED by the compounding site?	Must
	b.) DOCUMENTED IN the compounding site's standard operating procedures (SOPs)?	

Personnel Hygiene and Garbing		
Is the required MANNER OF STORAGE for garb in a manner (e.g., away from sinks to avoid splashing) that MINIMIZES CONTAMINATION?		Must
Are gloves	a.) STERILE?	Must
	b.) POWDER FREE?	
	c.) INSPECTED for holes, punctures, or tears?	
	d.) REPLACED IMMEDIATELY if holes, punctures, or tears are detected upon inspecting such gloves?	
Is STERILE seventy (70) percent isopropyl alcohol (IPA) APPLIED TO GLOVES	a.) IMMEDIATELY BEFORE compounding?	Must
	b.) REGULARLY THROUGHOUT the compounding process?	
Are restricted-access barrier system (RABS) SLEEVES AND GLOVES CHANGED	a.) per the MANUFACTURER'S recommendations?	Best practice
	b.) as defined in the compounding site's STANDARD OPERATING PROCEDURES (SOPs)?	
Are pharmaceutical isolator SLEEVES AND GLOVES CHANGED	a.) per the MANUFACTURER'S recommendations?	Best practice
	b.) as defined in the compounding site's STANDARD OPERATING PROCEDURES (SOPs)?	
Does the compounding site use REUSABLE EQUIPMENT (i.e., goggles, respirators)?		If yes ...
Do the compounding site's standard operating procedures (SOPs) describe DISINFECTION PROCEDURES for REUSING EQUIPMENT (i.e., goggles, respirators)?		Must
Is garb REPLACED IMMEDIATELY if it	a.) it becomes VISIBLY SOILED?	Must
	b.) its INTEGRITY is COMPROMISED?	
Is GARB DISCARDED when personnel exit the compounding area?		If no ...
Is GARB, except for gowns, REUSED when personnel exit the compounding area?		If yes ...
Is GARB LAUNDERED BEFORE REUSE when personnel exit the compounding area?		Must
Is APPROPRIATE personal protective equipment (PPE) WORN AND DISPOSED OF IN ACCORDANCE WITH (800) Hazardous Drugs - Handling in Healthcare Settings?		Must

Garbing for Non-Hazardous Drug (HD) Compounded Sterile Preparations (CSPs)		
Are GOWNS REUSED when preparing Category 1 and/or Category 2 non-HD CSPs?		If yes ...
Are the gowns REUSED	a.) WITHIN THE SAME SHIFT when preparing Category 1 and/or Category 2 non-HD CSPs?	If yes ...
	b.) BY THE SAME PERSON when preparing Category 1 and/or Category 2 non-HD CSPs?	
Are the gowns that are being reused within the same shift by the same person MAINTAINED IN A CLASSIFIED AREA when preparing Category 1 and/or Category 2 non-HD CSPs?		Must
Are GOWNS REUSED when preparing Category 1 non-HD CSPs?		If yes ...
Are the gowns REUSED	a.) WITHIN THE SAME SHIFT when preparing Category 1 non-HD CSPs?	If yes ...
	b.) BY THE SAME PERSON when preparing Category 1 non-HD CSPs?	
Are the gowns that are being reused within the same shift by the same person	a.) MAINTAINED ADJACENT TO OR WITHIN a SCA when preparing Category 1 non-HD CSPs?	Must
	b.) in a MANNER THAT PREVENTS CONTAMINATION when preparing Category 1 non-HD CSPs?	
Are the FOLLOWING INCLUDED in the compounding site's garbing requirements when preparing Category 1, Category 2 and/or Category 3 non-HD CSPs?	a.) Low-lint garment with SLEEVES (e.g., gown or coverall)	Must
	b.) Low-lint garment with SLEEVES fits SNUGLY AROUND THE WRISTS	
	c.) Low-lint garment with SLEEVES has an ENCLOSED NECK	
	d.) Low-lint covers for SHOES	
	e.) Low-lint cover for HEAD	
	f.) Low-lint cover for HEAD covers the HAIR AND EARS	
	g.) Low-lint FACE mask	
	h.) Low-lint covers for FACIAL HAIR, if applicable	
	i.) STERILE powder-free gloves	
The compounding site CANNOT EXCEED the applicable beyond-use dates (BUDs) described in Table 13 of (797) Pharmaceutical Compounding - Sterile Preparations when the compounding site DOES NOT MEET all the conditions described in (797) Pharmaceutical Compounding - Sterile Preparations for the preparation of Category 3 CSPs		
Are DISPOSABLE GLOVES worn INSIDE THE GLOVES ATTACHED to the RABS' sleeves [i.e., a compounding aseptic isolator (CAI) or compounding aseptic containment isolator (CACI)] when preparing Category 1, Category 2 and/or Category 3 non-HD CSPs?		Best practice
Are STERILE GLOVES worn OVER THE GLOVES ATTACHED to the RABS' sleeves [i.e., a compounding aseptic isolator (CAI) or compounding aseptic containment isolator (CACI)] when preparing Category 1, Category 2 and/or Category 3 non-HD CSPs?		Must
The compounding site CANNOT EXCEED the applicable beyond-use dates (BUDs) described in Table 13 of (797) Pharmaceutical Compounding - Sterile Preparations when the compounding site DOES NOT MEET all the conditions described in (797) Pharmaceutical Compounding - Sterile Preparations for the preparation of Category 3 CSPs		
Is all garb DONNED IN a CLASSIFIED AREA BEFORE ENTERING THE BUFFER ROOM when preparing Category 2 and/or Category 3 non-HD CSPs?		Best practice

Garbing for Non-Hazardous Drug (HD) Compounded Sterile Preparations (CSPs)		
Are the FOLLOWING garbing MET in the BUFFER ROOM in which Category 3 non-HD CSPs are prepared?	a.) No EXPOSED SKIN in the buffer room (i.e., face and neck must be covered)	Must
	b.) All low-lint outer garb is STERILE, including the use of sterile sleeves over gauntlet sleeves when a restricted-access barrier system (RABS) is used	
	c.) Standard operating procedures (SOPs) DESCRIBE DISINFECTION procedures for reusing goggles, respirators, and other reusable equipment	
	d.) Garbing requirements are CONTINUOUSLY MET	
	e.) ALL PERSONNEL FOLLOW the required garbing requirements REGARDLESS of whether Category 3 non-HD CSPs are compounded on a given day	
The compounding site CANNOT EXCEED the applicable beyond-use dates (BUDs) described in Table 13 of (797) Pharmaceutical Compounding - Sterile Preparations when the compounding site DOES NOT MEET all the conditions described in (797) Pharmaceutical Compounding - Sterile Preparations for the preparation of Category 3 CSPs		
Does the compounding site use DISPOSABLE GARBING items when preparing Category 3 non-HD CSPs?		If yes ...
Does the compounding site REUSE DISPOSABLE GARBING items when preparing Category 3 non-HD CSPs?		Must not
The compounding site CANNOT EXCEED the applicable beyond-use dates (BUDs) described in Table 13 of (797) Pharmaceutical Compounding - Sterile Preparations when the compounding site DOES NOT MEET all the conditions described in (797) Pharmaceutical Compounding - Sterile Preparations for the preparation of Category 3 CSPs		
Does the compounding site LAUNDER GARBING items when preparing Category 3 non-HD CSPs?		If yes ...
Does the compounding site REUSE LAUNDERED GARBING items WITHOUT such garbing items BEING LAUNDERED AND RESTERILIZED with a validated cycle when preparing Category 3 non-HD CSPs?		Must not
The compounding site CANNOT EXCEED the applicable beyond-use dates (BUDs) described in Table 13 of (797) Pharmaceutical Compounding - Sterile Preparations when the compounding site DOES NOT MEET all the conditions described in (797) Pharmaceutical Compounding - Sterile Preparations for the preparation of Category 3 CSPs		

Quality Assurance (QA) and Quality Control (QC)		
Did the compounding site FORMALLY ESTABLISH a _____ that ensures that all aspects of the preparation of compounded sterile preparations (CSPs) are conducted in accordance with the requirements in (797) Pharmaceutical Compounding - Sterile Preparations and the laws and regulations of the applicable regulatory jurisdiction?	a.) QA program b.) QC program	Must
Is the compounding site's formally established _____ DOCUMENTED IN the compounding facility's standard operating procedures (SOPs)?	a.) QA program b.) QC program	Must

Complaint Handling		
Has the compounding site received any COMPLAINTS potentially ASSOCIATED WITH the QUALITY of compounded sterile preparations (CSPs)?		If yes ...
Were any compounded sterile preparations (CSPs) RETURNED to the compounding site IN CONNECTION WITH ANY COMPLAINT?		If yes ...
Did the compounding site QUARANTINE the compounded sterile preparations (CSPs) RETURNED in connection with any complaint UNTIL destroyed after completion of an investigation and in accordance with laws and regulations of the applicable regulatory jurisdiction?		Must
Did the compounding site CONSIDER whether to CEASE STERILE COMPOUNDING processes until all underlying problems have been identified and corrected?		Best practice
Did the compounding site CONSIDER whether to INITIATE A RECALL of potentially affected compounded sterile preparations (CSPs)?		Best practice
Did the sterile compounding pharmacy INITIATE A RECALL of sterile pharmaceuticals dispensed pursuant to a PATIENT-SPECIFIC prescription or medical order?		If yes ...
Did the sterile compounding pharmacy NOTIFY each patient or patient care giver, the prescribing practitioner, and the Connecticut Department of Consumer Protection (DCP) of the recall NOT LATER THAN TWENTY-FOUR (24) HOURS AFTER INITIATING THE RECALL? [Section 20-633b(h)(1)]		Shall
Did the sterile compounding pharmacy INITIATE A RECALL of sterile pharmaceuticals that were NOT DISPENSED pursuant to a PATIENT-SPECIFIC prescription or medical order?		If yes ...
Did the sterile compounding pharmacy NOTIFY each purchaser of such sterile pharmaceuticals, to the extent such sterile compounding pharmacy posses contact information for each such purchase, the Connecticut Department of Consumer Protection (DCP), and the federal Food and Drug Administration (FDA) of the recall NOT LATER THEN THE END OF THE NEXT BUSINESS DAY AFTER INITIATING THE RECALL? [Section 20-633b(h)(2)]		Shall
What did the compounding site do when a complaint indicates a potential quality problem with a compounded sterile preparation (CSP)?	a.) INITIATE a thorough INVESTIGATION into the cause of the problem	Must
	b.) COMPLETE a thorough INVESTIGATION into the cause of the problem	
Did the compounding site's thorough investigation CONSIDER whether the quality problem with a compounded sterile preparation (CSP) EXTENDS TO OTHER CSPs?		Must
Did the compounding site IMPLEMENT CORRECTIVE ACTION, if necessary, for all potentially affected compounded sterile preparations (CSPs)?		Must
Does the compounding site KEEP a WRITTEN OR ELECTRONIC RECORD OF EACH COMPLAINT, regardless of the source of the complaint (e.g., email, telephone, or mail)?		Must
Is the FOLLOWING INFORMATION CONTAINED in the compounding site's written or electronic record of each complaint?	a.) NAME of the complainant or other unique identifier	Must
	b.) DATE the complaint was received	
	c.) NATURE of the complaint	
	d.) RESPONSE to the complaint	
	e.) FINDINGS of any investigation	
	f.) Any FOLLOW-UP to any investigation	
Is the FOLLOWING INFORMATION, to the extent that the information is known, recorded in the compounding site's written or electronic record of each complaint?	a.) Assigned internal IDENTIFICATION NUMBER (e.g., prescription, order, or lot number)	Best practice
	b.) NAME of the compounded sterile preparation (CSP)	
	c.) STRENGTH of the CSP	

Complaint Handling		
Do the compounding site's written or electronic record of each complaint record MEET THE FOLLOWING?	a.) Easily RETRIEVABLE for review and evaluation for possible trends	Must
	b.) Readily RETRIEVABLE for AT LEAST THREE (3) YEARS AFTER PREPARATION of compounded sterile preparations (CSPs) for review and evaluation of possible trends	
	c.) IN COMPLIANCE with all laws and regulations of the applicable jurisdiction	
	d.) LEGIBLE	
	e.) STORED in a manner that prevents their deterioration and/or loss	

Adverse Event Reporting	
Has the compounding site experienced any ADVERSE EVENTS potentially ASSOCIATED WITH the QUALITY of compounded sterile preparations (CSPs)?	If yes ...
Did the compounding site REPORT ADVERSE EVENTS potentially associated with the quality of compounded sterile preparations (CSPs) IN ACCORDANCE WITH the compounding site's standard operating procedures (SOPs) and all laws and regulations of the applicable regulatory jurisdiction?	Must
Did the compounding site INVESTIGATE the ADVERSE EVENTS potentially associated with the quality of compounded sterile preparations (CSPs)?	If yes ...
Did the INVESTIGATION of adverse events potentially associated with the quality of compounded sterile preparations (CSPs) REVEAL a quality problem with CSPs that is LIKELY TO AFFECT OTHER PATIENTS?	If yes ...
Did the compounding site INFORM PATIENTS AND PRESCRIBERS potentially affected when an investigation of adverse events potentially associated with the quality of compounded sterile preparations (CSPs) REVEALS such adverse event is likely to affect other patients?	Must

Standard Operating Procedures (SOPs)		
Compounding Site		
Does the compounding site have WRITTEN SOPS?		Must
Does the compounding site TRAIN all personnel who PERFORM OR OVERSEE compounding or support activities IN THE compounding site's SOPs?		Must
Sterile Compounding Pharmacy		
Did/Does the sterile compounding pharmacy	a.) PREPARE a policy and procedure manual? [Section 20-633b(i)]	Shall
	b.) MAINTAIN a policy and procedure manual? [Section 20-633b(i)]	
	c.) have WRITTEN SOPs?	Must
	d.) TRAIN all personnel who PERFORM OR OVERSEE compounding or support activities IN THE compounding site's SOPs?	
Does the sterile compounding pharmacy's policy and procedure manual COMPLY WITH USP CHAPTERS? [Section 20-633b(i)]		Shall
Institutional Pharmacy		
Did/Does the institutional pharmacy within a facility licensed pursuant to Section 19a-490 of the Connecticut General Statutes (CGS)	a.) PREPARE a policy and procedure manual? [Section 20-633b(i)]	Shall
	b.) MAINTAIN a policy and procedure manual? [Section 20-633b(i)]	
	c.) have WRITTEN SOPs?	Must
	d.) TRAIN all personnel who PERFORM OR OVERSEE compounding or support activities IN THE compounding site's SOPs?	
Does the institutional pharmacy's policy and procedure manual COMPLY WITH USP CHAPTERS? [Section 20-633b(i)]		Shall
Who makes changes or alterations to the compounding site's SOPs?	a.) Designated person(s) or designated pharmacist, whichever is applicable	Compliant
	b.) Other	Non-compliant
Are CHANGES/ALTERATIONS/REVISIONS to the compounding site's SOPs	a.) DOCUMENTED?	Must
	b.) COMMUNICATED TO ALL PERSONNEL involved in the processes and procedures?	
Do personnel DOCUMENT ACKNOWLEDGMENT OF THE COMMUNICATION of REVISIONS to the compounding site's SOPs?		Best practice

Standard Operating Procedures (SOPs)		
Did the compounding site DEVELOP SOPs that address	a.) the compounding PROCESS and the ACTIVITIES supporting the compounding process?	Must
	b.) CLEANING, DISINFECTING, and applying SPORICIDAL disinfectants?	
	c.) microbiological sampling SITES AND PROCEDURES?	
	d.) compounded sterile preparation (CSP) COMPONENTS?	
	e.) STERILIZATION?	
	f.) TERMINAL sterilization?	
	g.) DEPYROGENATION?	
	h.) PERSONNEL RESPONSIBLE for the QUALITY ASSURANCE (QA) program?	
	i.) RECALLS of out-of-specification (OOS) dispensed compounded sterile preparations (CSPs)?	
	j.) for handling COMPLAINTS?	
	k.) the processes and techniques for HANDLING, STORING, PACKAGING, and TRANSPORTING CSPs?	
Compounding Process and Activities		
Do the compounding site's SOPs include the TYPES of compounded sterile preparations (CSPs) PREPARED by the compounding site (i.e., Category 1, Category 2, Category 3)?		Must
Cleaning, Disinfecting, and Applying Sporicidal Disinfectants		
1. Do the compounding site's SOPs	a.) DESCRIBE compounding site-approved cleaning and disinfecting AGENTS?	Must
	b.) DESCRIBE compounding site-approved cleaning and disinfecting PROCEDURES?	
	c.) ESTABLISH FREQUENCY of cleaning, disinfecting, and applying sporicidal disinfectants in accordance with the manufacturer's instructions?	
	d.) ESTABLISH LOCATION(S) of cleaning, disinfecting, and applying sporicidal disinfectants in accordance with the manufacturer's instructions?	
	e.) ESTABLISH METHOD(S) of cleaning, disinfecting, and applying sporicidal disinfectants in accordance with the manufacturer's instructions?	

Standard Operating Procedures (SOPs)		
Compounded Sterile Preparation (CSP) Components		
Do the compounding site's SOPs include	a.) DOCUMENTATION of all CSP components, including all ingredients and container closures?	Must
	b.) EVALUATION of all CSP components, including all ingredients and container closures?	
	c.) HANDLING of all CSP components, including all ingredients and container closures?	
	d.) RECEIPT of all CSP components, including all ingredients and container closures?	
	e.) SELECTION of all CSP components, including all ingredients and container closures?	
	f.) STORAGE of all CSP components, including all ingredients and container closures?	
Sterilization		
Do the compounding site's SOPs include	a.) COMPETENCY of personnel on all sterilization EQUIPMENT used by the compounding site?	Must
	b.) COMPETENCY of personnel on all sterilization METHODS used by the compounding site?	
	c.) METHODS for CLEANING sterilizing equipment?	
	d.) METHODS for MAINTAINING sterilizing equipment?	
	e.) TRAINING of personnel on all sterilization EQUIPMENT used by the compounding site?	
	f.) TRAINING of personnel on all sterilization METHODS used by the compounding site?	

Standard Operating Procedures (SOPs)		
Terminal Sterilization		
Do the compounding site's SOPs include	a.) DESCRIPTION of the terminal sterilization PROCESS?	Must
	b.) DURATION for each cycle?	
	c.) METHOD for ESTABLISHING the EFFECTIVENESS of the terminal sterilization methods selected?	
	d.) METHOD for VERIFYING the EFFECTIVENESS of the terminal sterilization methods selected?	
	e.) permissible LOAD conditions for each cycle?	
	f.) PRESSURE for each cycle, if applicable?	
	g.) SCHEDULE for ESTABLISHING the EFFECTIVENESS of the terminal sterilization methods selected?	
	h.) SCHEDULE for VERIFYING the EFFECTIVENESS of the terminal sterilization methods selected?	
	i.) TEMPERATURE for each cycle?	
	j.) use of biological INDICATORS for each cycle?	
	k.) use of endotoxin CHALLENGE VIALS (ECVs) for each cycle?	
Depyrogenation		
Do the compounding site's SOPs include	a.) DESCRIPTION of the depyrogenation PROCESS?	Must
	b.) DURATION for each cycle?	
	c.) METHOD for ESTABLISHING the EFFECTIVENESS of the depyrogenation methods selected?	
	d.) METHOD for VERIFYING the EFFECTIVENESS of the depyrogenation methods selected?	
	e.) METHODS for CLEANING depyrogenation EQUIPMENT?	
	f.) METHODS for MAINTAINING depyrogenation EQUIPMENT?	
	g.) permissible LOAD conditions for each cycle?	
	h.) PRESSURE for each cycle, if applicable?	
	i.) SCHEDULE for ESTABLISHING the EFFECTIVENESS of the depyrogenation methods selected?	
	j.) SCHEDULE for VERIFYING the EFFECTIVENESS of the depyrogenation methods selected?	
	k.) TEMPERATURE for each cycle?	
	l.) use of biological INDICATORS for each cycle?	
	m.) use of endotoxin CHALLENGE VIALS (ECVs) for each cycle?	

Standard Operating Procedures (SOPs)		
Quality Assurance (QA) Program		
Do the compounding site's SOPs include	a.) DUTIES of the personnel responsible for each aspect of the QA program?	Must
	b.) ROLES of the personnel responsible for each aspect of the QA program?	
	c.) TRAINING of the personnel for each aspect of the QA program?	
Recalls		
Do the compounding site's SOPs for the recall of out-of-specification (OOS) dispensed compounded sterile preparations (CSPs) include	a.) procedure to DETERMINE SEVERITY of the problem?	Must
	b.) procedure to DETERMINE URGENCY for implementation and completion of a recall?	
	c.) procedure to DETERMINE DISTRIBUTION of any affected CSPs, including the date and quantity of distribution?	
	d.) procedure to IDENTIFY PATIENTS who have received the CSPs?	
	e.) procedure for DISPOSAL of recalled CSPs?	
	f.) procedure for DOCUMENTATION of recalled CSPs?	
	g.) procedure to INVESTIGATE the reason for failure?	
	h.) procedure to DOCUMENT the reason for failure?	
Complaint Handling		
Did the compounding site IMPLEMENT SOPs for HANDLING COMPLAINTS?		Must

Documentation		
How does the compounding site DEMONSTRATE COMPLIANCE with the requirements of (797) Pharmaceutical Compounding - Sterile Preparations?	a.) HAS written or electronic documentation	Must
	b.) MAINTAINS written or electronic documentation	
Are the FOLLOWING INCLUDED in either written or electronic documentation to demonstrate compliance with the requirements of (797) Pharmaceutical Compounding - Sterile Preparations?	a.) Personnel TRAINING RECORDS, including corrective actions for any failures	Must
	b.) Personnel COMPETENCY ASSESSMENT records, including corrective actions for any failures	
	c.) Personnel QUALIFICATION RECORDS, including corrective actions for any failures	
	d.) CERTIFICATION REPORTS, including corrective actions for any failures	
	e.) Environmental AIR monitoring PROCEDURES	
	f.) Environmental AIR monitoring RESULTS	
	g.) Environmental SURFACE monitoring PROCEDURES	
	h.) Environmental SURFACE monitoring RESULTS	
	i.) RECEIPT of components	
	j.) Standard operating procedures (SOPs)	
	k.) Release INSPECTION records	
	l.) Release TESTING records	
	m.) Information related to COMPLAINTS, including corrective actions taken	
	n.) Information related to ADVERSE EVENTS, including corrective actions taken	
	o.) Results of INVESTIGATIONS, including corrective actions taken	
	p.) COMPOUNDING records (CRs), if applicable	
	q.) MASTER formulation records (MFRs), if applicable	

Overall Compliance with (797) Pharmaceutical Compounding - Sterile Preparations		
Does the compounding site FOLLOW the REQUIREMENTS in (797) Pharmaceutical Compounding - Sterile Preparations TO MINIMIZE HARM, including death, to human and animal patients that could result FROM	a.) microbial contamination [NON-STERILITY]?	Must
	b.) excessive bacterial ENDOTOXINS?	
	c.) VARIABILITY from the intended strength of correct ingredients?	
	d.) chemical and physical CONTAMINANTS?	
	e.) use of ingredients of INAPPROPRIATE QUALITY?	
Does the compounding site HAVE processes and procedures IN PLACE to MINIMIZE the POTENTIAL for	a.) contact with NONSTERILE surfaces?	Must
	b.) introduction of PARTICULATE matter or biological fluids?	
	c.) MIX-UPS with other products or compounded sterile preparations (CSPs)?	
Does the compounding site FOLLOW ASEPTIC techniques, processes, and procedures for preparing any sterile medication?		Must
Is the compounding site DESIGNED, OUTFITTED, and MAINTAINED PROPERLY to minimize the risk of contamination of compounded sterile preparations (CSPs)?		Must
Does the DESIGN of the compounding site TAKE INTO ACCOUNT the number of personnel and their movements, and the impact the placement of equipment, supplies, and components could have on the maintenance of air quality?		Must
Sterile Compounding Pharmacy		
Does the sterile compounding pharmacy COMPLY WITH	a.) the APPLICABLE United States Pharmacopeia (USP) CHAPTERS? [Section 20-633b(c)]	Shall
	b.) all APPLICABLE FEDERAL AND STATE statutes and regulations? [Section 20-633b(c)]	
Has the sterile compounding pharmacy had any ADMINISTRATIVE OR LEGAL ACTION COMMENCED against it by any state or federal regulatory agency or accreditation entity?		If yes ...
Did the sterile compounding pharmacy REPORT the administrative or legal action NOT LATER THAN FIVE (5) BUSINESS DAYS AFTER RECEIVING notice of the commencement of such action? [Section 20-633b(j)]		Shall
Institutional Pharmacy		
Does the institutional pharmacy that compounds sterile pharmaceuticals within a facility licensed pursuant to Section 19a-490 of the Connecticut General Statutes (CGS) COMPLY WITH	a.) the APPLICABLE United States Pharmacopeia (USP) CHAPTERS? [Section 20-633b(d)]	Shall
	b.) all APPLICABLE FEDERAL AND STATE statutes and regulations? [Section 20-633b(d)]	
Did the institutional pharmacy that compounds sterile pharmaceuticals within a facility licensed pursuant to Section 19a-490 of the Connecticut General Statutes (CGS) REQUEST from the Connecticut Commissioner of Consumer Protection AN EXTENSION OF TIME TO COMPLY, for state enforcement purposes, with ANY AMENDMENTS to United States Pharmacopeia (USP) Chapters?		May and if yes ...
Did the Connecticut Commissioner of Consumer Protection GRANT AN EXTENSION OF TIME for the institutional pharmacy that compounds sterile pharmaceuticals within a facility licensed pursuant to Section 19a-490 of the Connecticut General Statutes (CGS) TO COMPLY, for state enforcement purposes, with ANY AMENDMENTS to United States Pharmacopeia (USP) Chapters?		May and if yes ...

Overall Compliance with (797) Pharmaceutical Compounding - Sterile Preparations	
Did the EXTENSION OF TIME granted by the Connecticut Commissioner of Consumer Protection for the institutional pharmacy that compounds sterile pharmaceuticals within a facility licensed pursuant to Section 19a-490 of the Connecticut General Statutes (CGS) TO COMPLY, for state enforcement purposes, with ANY AMENDMENTS to United States Pharmacopeia (USP) Chapters EXCEED SIX (6) MONTHS? [Section 20-633b(d)]	Not to exceed
Has the institutional pharmacy that compounds sterile pharmaceuticals within a facility licensed pursuant to Section 19a-490 of the Connecticut General Statutes (CGS) had any ADMINISTRATIVE OR LEGAL ACTION COMMENCED against it by any state or federal regulatory agency or accreditation entity?	If yes ...
Did the institutional pharmacy that compounds sterile pharmaceuticals within a facility licensed pursuant to Section 19a-490 of the Connecticut General Statutes (CGS) REPORT the administrative or legal action NOT LATER THAN FIVE (5) BUSINESS DAYS AFTER RECEIVING notice of the commencement of such action? [Section 20-633b(j)]	Shall