STERILE COMPOUNDING REPORT

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

Board of Registration in Pharmacy
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Tel: (617) 973-0800
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DATE(S) OF ASSESSMENT:			
ISP NUMBER:			
INSTITUTION NAME:			
PHARMACY NAME:			
STREET ADDRESS:			
CITY / STATE / ZIP:			
TELEPHONE:			
FAX:			
EMAIL:			
PHARMACY LICENSE #:		EXP DATE:	
DEA REGISTRATION #:		EXP DATE:	
MANAGER OF RECORD (MOR):			
MOR LICENSE NUMBER:			
FACILITY TYPE:	☐ Hospital Inpatient/Main ☐ Hospital Inpatient/Satellite ☐ Hospital Outpatient	☐ Community ☐ Community/Infusion	☐ Long Term Care
TYPES OF COMPOUNDING:	☐ Patient Specific ☐ Anticipatory	☐ Hazardous ☐ Robotics ☐ Allergen Extracts	☐ High Risk Level ☐ Investigational Use ☐ Radiopharmaceuticals
DAILY PHARMACY VOLUME (STERILE COMPOUNDING):			
HOURS OF OPERATION:	M-F:	SAT:	SUN:

Sterile Compounding Documents for Inspection

Licenses (as applicable):

- ☐ Massachusetts Drug Store Pharmacy License
- ☐ Massachusetts Controlled Substance Registration
- ☐ DEA Controlled Substance Registration Certificate
- ☐ Non-Resident Drug Store Pharmacy Licenses for all States Doing Business In
- ☐ Institutional Sterile Compounding Pharmacy License
- ☐ Pharmacist, Pharmacy Intern, and Pharmacy Technician Licenses & Registration Cards
  - ☐ Technician Trainee Hours
- ☐ Other (DCP, FDA, etc.)

Policy and Procedure Manual:

- ☐ Personnel Monitoring (e.g. Aseptic Media Fills, Gloved Finger Tip Sampling, etc.)
- ☐ Environmental Monitoring (e.g. Air, Surface, Non-Viable)
- ☐ ISO Classified Area Monitoring (e.g. Certification based tests for PECs and SECs)
- ☐ Proper Storage, handling, shipping, packaging, transportation, and delivery
- ☐ Final release checks and verification of CSPs
- ☐ Quality assurance program including RCA and CAPA
- ☐ Change control, validation of new or changed facilities, equipment, or processes
- ☐ Hand hygiene and garbing processes
- ☐ Aseptic technique
- ☐ Patient monitoring and adverse event reporting, including recalls of CSPs
- ☐ Maintenance, calibration, and cleaning intervals
- ☐ Response to broken, damaged, or spilled CSPs
- ☐ Compounding procedures specific to each risk level
- ☐ Sterilization and depyrogenation processes, as applicable
- ☐ Sterility and endotoxin testing, as applicable
- ☐ Assignment of BUD
- ☐ Proper waste handling and disposal

Personnel Training, Competency and Proficiency Tests:

- ☐ Training program for new and veteran compounding personnel
- ☐ Aseptic manipulation proficiencies for compounding personnel
- ☐ Gloved fingertip/thumb proficiencies for compounding personnel and external staff members (Initial and Ongoing)
- ☐ Hand Hygiene and Garbing competencies for compounding personnel and external staff members
- ☐ Cleaning and Disinfection competencies for compounding personnel and external staff members

Quality Related Documentation:

- ☐ Environmental monitoring results including trending analysis and sampling map
- ☐ Certification report for compounding environment
- ☐ Example of Out of Specification reports for Environment, Personnel and Product including Root Cause Analysis (RCA) and Corrective Action Preventative Action (CAPA).
- ☐ Compounding Master Formulation Record and Individual Compounding Record
- ☐ Logs: Cleaning and Disinfection, Pressure Differentials, Temperature and Humidity, Incubator
- ☐ Cleaning and Disinfection chemicals, activity, contact time, ready-to-use (RTU) or dilution (Instructions required)
- ☐ Sterility and Endotoxin Testing Report
- ☐ Extended Stability Analytical Testing Reports
- ☐ List of CSPs Produced and/or Outsourced
- ☐ List of CSPs Recalled, for any Reason

Item#	Massachusetts Regulatory Requirements	Yes	No	N/A	Notes
1	Is every prescription written in the Commonwealth in a prescription format that conforms to the requirements as set forth in 105 CMR 721.020[1]? 247 CMR 9.01 (1); 105 CMR 721.020				
2	Does the pharmacist conduct a prospective drug utilization review (DUR)? a) before each new prescription is dispensed or delivered to a patient or a person acting on behalf of the patient? ☐ Yes ☐ No ☐ N/A b) which includes a review of the patient record and each new prescription presented for dispensing, for the purposes of promoting therapeutic appropriateness? ☐ Yes ☐ No ☐ N/A 247 CMR 9.07 (1) (a) and (2) (a)				
3	Does the pharmacy keep a perpetual inventory of each controlled substance in Schedule II which the pharmacy has received, dispensed or disposed of in accordance with the law? Is this inventory reconciled at least once every ten days? 247 CMR 9.01(14)				
4	Does the pharmacy maintain records associated with disposal or destruction of controlled substances pursuant to Sec.1304.03? 247 CMR 9.01 (1); 21 CFR 1304.21 (a)?				
5	Does the pharmacy have a current copy or electronic version of the Board regulations? (247 CMR 6.01 (5) (a) (3))				
6	Does the pharmacy have a current copy or electronic version (with quarterly updates) of a compendium appropriate to the practice setting approved by the pharmacist manager of record? 247 CMR 6.01 (5) (a) (2)				
7	Does the pharmacy maintain a written copy of its Continuous Quality Improvement (CQI) Program description on the pharmacy premises readily available to all pharmacy personnel? 247 CMR 15.04(1)				
8	Does the Pharmacy conducting sterile compounding have documentation certifying that their employees have been trained in lean concepts (at least annually), which are tools that assist in the identification and steady elimination of waste and promote continuous improvement in quality and efficiency? MGL c. 112 § 39I (a)(7).				
9	Does the pharmacy maintain a written policy and procedure to effectuate a recall of sterile compounded preparations in accordance with M.G.L. c. 112, § 39D(e)?				
10	Does the pharmacy keep a defective drug preparation log documenting all recalled drug preparations? M.G.L. c. 112, § 39D(e)				

[1] 105 CMR 721.020 - http://www.mass.gov/courts/docs/lawlib/104-105cmr/105cmr721.pdf

Item#	Requirements	Yes	No	N/A	Notes
11	Does the Pharmacy only prepare compounded sterile preparations for a patient as a result of a practitioner's prescription order, based on the relationship between the practitioner, patient and pharmacist in the course of routine professional practice to meet the unique medical need of an individual patient by producing a significant difference between the compounded drug preparation and a comparable commercially available drug that is justified by a documented medical need[2] as determined by the prescribing practitioner? M.G.L. c. 112, § 39D(a)1				
12	Does the pharmacy ensure that compounding of FDA approved commercially available products (not on backorder) using non-sterile powders or other components does not occur?				
13	If the pharmacy compounds FDA approved products using non-sterile powders or other components, can the pharmacy provide documentation confirming backorder?				
14	Does the Pharmacy only prepare quantities of compounded non-sterile preparations in anticipation of prescription orders based on routine, regularly-observed prescribing patterns which can be verified by accountability documentation? M.G.L. c. 112, § 39D(a)(2)				

[2] Including, but not limited to, the removal of a dye for medical reasons, a change in strength, a change in dosage, form or delivery mechanism; provided, that a price difference shall not be a significant difference to justify compounding.

Item#	USP <797> Appendix Statements	Yes	No	N/A	Notes
	Standard Operating Procedures (SOPs)				
1	† Facility has standard operating procedures specific to sterile compounding.				
	Facility Design and Environmental Controls				
2	† Compounding facilities are physically designed and environmentally controlled to minimize airborne contamination from contacting critical sites.				
3	† Compounding facilities shall provide a comfortable and well-lighted working environment, which typically includes a temperature of 20° or cooler to maintain comfortable conditions for compounding personnel when attired in the required aseptic compounding garb.				
4	† Primary engineering controls provide unidirectional (i.e., laminar) HEPA air at a velocity sufficient to prevent airborne particles from contacting critical sites.				
5	† In situ air pattern analysis via smoke studies shall be conducted at the critical area to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions.				
6	† Policies and procedures for maintaining and working within the primary engineering control area shall be written and followed. The policies and procedures will be determined by the scope and risk levels of the aseptic compounding activities used during the preparation of the CSPs.				
7	† The principles of HEPA-filtered unidirectional airflow in the work environment shall be understood and practiced in the compounding process in order to achieve the desired environmental conditions.				
8	† Clean rooms for nonhazardous and nonradioactive CSPs are supplied with HEPA that enters from ceilings with return vents low on walls, and that provides not less than 30 air changes per hour.				
9	† Buffer areas maintain 0.02 to 0.05 inch water column positive pressure, and do not contain sinks or drains.				
10	† Air velocity from buffer rooms or zones to ante-areas is at least 40 feet/minute.				
11	† The primary engineering controls shall be placed within a buffer area in such a manner as to avoid conditions that could adversely affect their operation.				
12	† The primary engineering controls shall be placed out of the traffic flow and in a manner to avoid disruption from the HVAC system and room cross drafts.				
13	† HEPA-filtered supply air shall be introduced at the ceiling.				
14	† All HEPA filters shall be efficiency tested using the most penetrating particle size and shall be leak tested at the factory and then leak tested again in situ after installation.				
15	† Activities and tasks carried out within the buffer area shall be limited to only those necessary when working within a controlled environment.				
16	† Only the furniture, equipment, supplies, and other material required for the compounding activities to be performed shall be brought into the room.				
17	† Surfaces and essential furniture in buffer rooms or zones and clean rooms shall be nonporous, smooth, nonshedding, impermeable, cleanable, and resistant to disinfectants.				
18	† The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area shall be smooth, impervious, free from cracks and crevices, and nonshedding, thereby promoting cleanability, and minimizing spaces in which microorganisms and other contaminants may accumulate.				
Item#	Requirement	Yes	No	N/A	Notes

	Facility Design and Environmental Controls (continued)				
19	† The surfaces shall be resistant to damage by disinfectant agents.				
20	† Junctures of ceilings to walls shall be coved or caulked to avoid cracks and crevices where dirt can accumulate.				
21	† Ceiling tiles shall be caulked around each perimeter to seal them to the support frame.				
22	† The exterior lens surface of ceiling lighting fixtures shall be smooth, mounted flush, and sealed.				
23	† Any other penetrations through the ceiling or walls shall be sealed.				
24	† The buffer area shall not contain sources of water (sinks) or floor drains. Work surfaces shall be constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that they are easily cleaned and disinfected.				
25	† Carts shall be of stainless-steel wire, nonporous plastic, or sheet metal construction with good quality, cleanable casters to promote mobility.				
26	† Storage shelving, counters, and cabinets shall be smooth, impervious, free from cracks and crevices, nonshedding, cleanable, and disinfectable.				
27	† Their number, design, and manner of installation of the items above shall promote effective cleaning and disinfection.				
28	‡ If ceilings consist of inlaid panels, the panels should be impregnated with a polymer to render them impervious and hydrophobic.				
29	‡ Dust-collecting overhangs, such as ceiling utility pipes, or ledges, such as windowsills, should be avoided.				
30	‡ Air returns should be mounted low on the wall creating a general top-down dilution of room air with HEPA-filtered make-up air.				
	Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas				
31	† Primary engineering controls for nonhazardous and nonradioactive CSPs are located in buffer areas, except for CAIs that are proven to maintain ISO Class 5 air when particle counts are sampled 6 to 12 inches upstream of critical site exposure areas during performance of normal inward and outward transfer of materials, and compounding manipulations when such CAIs are located in air quality worse than ISO Class 7.				
32	† Pre-sterilization procedures for high-risk level CSPs, such as weighing and mixing, shall be completed in no worse than an ISO Class 8 environment.				
33	† Primary engineering controls shall be located out of traffic patterns and away from room air currents that could disrupt the intended airflow patterns.				
34	† When isolators are used for sterile compounding, the recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations.				
35	† When compounding activities require the manipulation of a patient's blood-derived or other biological material (e.g., radiolabeling a patient's or a donor's white blood cells), the manipulations shall be clearly separated from routine material-handling procedures and equipment used in CSP preparation activities, and they shall be controlled by specific standard operating procedures in order to avoid any cross-contamination.				

Item#	Requirement	Yes	No	N/A	Notes
	Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas (continued)				
36	† Food, drinks, and items exposed in patient care areas, and unpacking of bulk supplies and personnel cleansing and garbing are prohibited from buffer areas or rooms.				
37	† Demarcation designation between buffer areas or rooms and ante-areas.				
38	† Antiseptic hand cleansing and sterile gloves in buffer areas or rooms.				
39	‡ Packaged compounding supplies and components, such as needles, syringes, tubing sets, and small- and large-volume parenterals, should be uncartoned and wiped down with a disinfectant that does not leave a residue (e.g., sterile 70% IPA) when possible in an ante-area, of ISO Class 8 air quality, before being passed into the buffer areas.				
	Exposure of Critical Sites				
40	† ISO Class 5 or better air.				
41	† Preclude direct contact (e.g., touch and secretions) contamination.				
	ISO Class 5 Air Sources, Buffer Areas, and Ante-Areas				
42	† A buffer area is an area that provides at least ISO Class 7 air quality.				
43	† New representations of facility layouts.				
44	† Each compounding facility shall ensure that each source of ISO Class 5 environment for exposure of critical sites and sterilization by filtration is properly located, operated, maintained, monitored, and verified.				
45	† Devices (e.g., computers and printers) and objects (e.g., carts and cabinets) can be placed in buffer areas and shall be verified by testing or monitoring.				
	Single Dose and Multiple-Dose Containers				
46	† Beyond-use-date 28 days, unless specified otherwise by the manufacturer, for closure sealed multiple-dose containers after initial opening or entry.				
47	† Beyond-use time of 6 hours, unless specified otherwise by the manufacturer, for closure sealed single-dose containers in ISO Class 5 or cleaner air after initial opening or entry.				
48	† Beyond-use time of 1 hour for closure sealed single-dose containers after being opened or entered in worse than ISO Class 5 air.				
49	† Storage of opened single-dose ampules is not permitted.				
	Allergen Extracts as CSPs				
50	† Allergen extracts as CSPs are not subject to the personnel, environmental, and storage requirements for all CSP Microbial Contamination Risk Levels when certain criteria are met as detailed in USP <797> *Allergen Extracts as CSPs*.				
	Viable and Nonviable Environmental Sampling (ES) Testing				
51	† Environmental sampling shall occur as part a comprehensive quality management program and shall occur minimally when several conditions exist.				
52	‡ The ES program should provide information to staff and leadership to demonstrate that the engineering controls are maintaining an environment within the compounding area that consistently maintains acceptably low viable and nonviable particle levels.				
Item#	Requirement	Yes	No	N/A	Notes

	Environmental Nonviable Particle Testing Program				
53	† Certification and testing of primary (LAFWs, BSCs, CAIs and CACIs) and secondary engineering controls (buffer and ante areas) shall be performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed. Certification procedures such as those outlined in the CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006) shall be used.				
	Total Particle Counts				
54	† Certification that each ISO classified area (e.g., ISO Class 5, 7 and 8) is within established guidelines shall be performed no less than every 6 months and whenever the LAFW, BSC, CAI, or CACI is relocated or the physical structure of the buffer room or ante-area has been altered.				
55	† Testing shall be performed by qualified operators using current, state-of-the-art electronic equipment with results meeting ISO Class 5, 7, or 8 depending on the requirements of the area.				
56	† All certification records shall be maintained and reviewed by supervising personnel or other designated employee to ensure that the controlled environments comply with the proper air cleanliness, room pressures, and air changes per hour.				
	Pressure Differential Monitoring				
57	† A pressure gauge or velocity meter shall be installed to monitor the pressure differential or airflow between the buffer area and ante-area, and the ante-area and the general environment outside the compounding area.				
58	† The results shall be reviewed and documented on a log at least every work shift (minimum frequency shall be at least daily) or by a continuous recording device.				
59	† The pressure between the ISO Class 7 and general pharmacy area shall not be less than 5 Pa (0.02-inch water column (w.c.)).				
60	† In facilities where low- and medium-risk level CSPs are prepared, differential airflow shall maintain a minimum velocity of 0.2 meter/second (40 fpm) between buffer area and ante-area.				
	Environmental Viable Airborne Particle Testing Program—Sampling Plan				
61	† An appropriate environmental sampling plan shall be developed for airborne viable particles based on a risk assessment of compounding activities performed.				
62	† Selected sampling sites shall include locations within each ISO Class 5 environment and in the ISO Class 7 and 8 areas, and the segregated compounding areas at greatest risk of contamination (e.g., work areas near the ISO Class 5 environment, counters near doors, pass-through boxes).				
63	† The plan shall include sample location, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels.				
64	‡ It is recommended that compounding personnel refer to USP Chapter Microbiological Control and Monitoring of Aseptic Processing Environments <1116> and the CDC Guidelines for Environmental Infection Control in Healthcare Facilities-2003 for more information.				

Item#	Requirement	Yes	No	N/A	Notes
	Growth Media				
65	† A general microbiological growth medium such as Soybean–Casein Digest Medium (also known as trypticase soy broth (TSB) or agar (TSA)) shall be used to support the growth of bacteria.				
66	† Malt extract agar (MEA) or some other media that supports the growth of fungi shall be used in high-risk level compounding environments.				
67	† Media used for surface sampling shall be supplemented with additives to neutralize the effects of disinfecting agents (e.g., TSA with lecithin and polysorbate 80).				
	Viable Air Sampling				
68	† Evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments shall be performed by properly trained individuals for all compounding risk levels.				
69	† Impaction shall be the preferred method of volumetric air sampling.				
70	† For low, medium, and high-risk level compounding, air sampling shall be performed at locations that are prone to contamination during compounding activities and during other activities like staging, labeling, gowning, and cleaning.				
71	† Locations shall include zones of air backwash turbulence within laminar airflow workbench and other areas where air backwash turbulence may enter the compounding area.				
72	† For low-risk level CSPs with 12-hour or less BUD, air sampling shall be performed at locations inside the ISO Class 5 environment and other areas that are in close proximity to the ISO class 5 environment, during the certification of the primary engineering control.				
73	‡ Consideration should be given to the overall effect the chosen sampling method will have on the unidirectional airflow within a compounding environment.				
	Air Sampling Devices				
74	† The instructions in the manufacturer's user manual for verification and use of electric air samplers that actively collect volumes of air for evaluation shall be followed.				
75	† A sufficient volume of air (400–1000 liters) shall be tested at each location in order to maximize sensitivity.				
76	‡ It is recommended that compounding personnel also refer to USP Chapter <1116>, which can provide more information on the use of volumetric air samplers and volume of air that should be sampled to detect environmental bioburden excursions.				
	Air Sampling Frequency and Process				
77	† Air sampling shall be performed at least semiannually (i.e. every 6 months), as part of the re-certification of facilities and equipment for area where primary engineering controls are located.				
78	† A sufficient volume of air shall be sampled and the manufacturer's guidelines for use of the electronic air sampling equipment followed.				
79	‡ Any facility construction or equipment servicing may require the need to perform air sampling during these events.				

Item#	Requirement	Yes	No	N/A	Notes
	Incubation Period				
80	† The microbial growth media plates used to collect environmental sampling are recovered, covers secured (e.g., taped), inverted, and incubated at a temperature and for a time period conducive to multiplication of microorganisms.				
81	† The number of discrete colonies of microorganisms shall be counted and reported as colony-forming units (cfu) and documented on an environmental monitoring form. Counts from air monitoring need to be transformed into cfu/cubic meter of air and evaluated for adverse trends.				
82	‡ TSA should be incubated at 35° ± 2 ° for 2–3 days.				
83	‡ MEA or other suitable fungal media should be incubated at 28° ± 2 ° for 5–7 days.				
	Action Levels, Documentation and Data Evaluation				
84	† Sampling data shall be collected and reviewed on a periodic basis as a means of evaluating the overall control of the compounding environment.				
85	† Competent microbiology personnel shall be consulted if an environmental sampling consistently shows elevated levels of microbial growth.				
86	† An investigation into the source of the environmental contamination shall be conducted.				
87	‡ Any cfu count that exceeds its respective action level should prompt a re-evaluation of the adequacy of personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency within the aseptic compounding location.				
88	‡ Table titled, Recommended Action Levels for Microbial Contamination should only be used as a guideline				
	Cleaning and Disinfecting the Sterile Compounding Areas				
89	† Trained personnel write detailed procedures including cleansers, disinfectants, and non-shedding wipe and mop materials.				
90	† Cleaning and disinfecting surfaces in the LAFWs, BSCs, CAIs, and CACIs shall be cleaned and disinfected frequently, including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods of individual CSPs, when there are spills, and when surface contamination is known or suspected from procedural breaches.				
91	† Trained compounding personnel are responsible for developing, implementing, and practicing the procedures for cleaning and disinfecting the DCAs written in the SOPs.				
92	† Cleaning and disinfecting shall occur before compounding is performed. Items shall be removed from all areas to be cleaned, and surfaces shall be cleaned by removing loose material and residue from spills, e.g., water-soluble solid residues are removed with Sterile Water (for Injection or Irrigation) and low-shedding wipes. This shall be followed by wiping with a residue-free disinfecting agent, such as sterile 70% IPA, which is allowed to dry before compounding begins.				
93	† Work surfaces in ISO Class 7 and 8 areas and segregated compounding areas are cleaned at least daily.				
94	† Dust and debris shall be removed when necessary from storage sites for compounding ingredients and supplies, using a method that does not degrade the ISO Class 7 or 8 air quality.				
95	† Floors in ISO Class 7 and 8 areas are cleaned daily when no compounding occurs.				
Item#	Requirement	Yes	No	N/A	Notes

	Cleaning and Disinfecting the Sterile Compounding Areas (continued)				
96	† IPA (70% isopropyl alcohol) remains on surfaces to be disinfected for at least 30 seconds before such surfaces are used to prepare CSPs.				
97	† Emptied shelving, walls, and ceilings in ante-areas are cleaned and disinfected at least monthly.				
98	† Mopping shall be performed by trained personnel using approved agents and procedures described in the written SOPs.				
99	† Cleaning and disinfecting agents, their schedules of use and methods of application shall be in accordance with written SOPs and followed by custodial and/or compounding personnel.				
100	† All cleaning materials, such as wipers, sponges, and mops, shall be nonshedding, preferably composed of synthetic micro fibers, and dedicated to use in the buffer area, or ante-area, and segregated compounding areas and shall not be removed from these areas except for disposal.				
101	† If cleaning materials are reused (e.g., mops), procedures shall be developed (based on manufacturer recommendations) that ensure that the effectiveness of the cleaning device is maintained, and repeated use does not add to the bioburden of the area being cleaned.				
102	† Supplies and equipment removed from shipping cartons shall be wiped with a suitable disinfecting agent (e.g., sterile 70% IPA) delivered from a spray bottle or other suitable delivery method.				
103	† After the disinfectant is sprayed or wiped on a surface to be disinfected, the disinfectant shall be allowed to dry, and during this time the item shall not be used for compounding purposes.				
104	† Sterile 70% IPA wetted gauze pads or other particle-generating material shall not be used to disinfect the sterile entry points of packages and devices.				
	Personnel Cleansing and Garbing				
105	† Personnel shall also be thoroughly competent and highly motivated to perform flawless aseptic manipulations with ingredients, devices, and components of CSPs.				
106	† Personnel with rashes, sunburn, weeping sores, conjunctivitis, active respiratory infection, and cosmetics are prohibited from preparing CSPs.				
107	† Compounding personnel shall remove personal outer garments; cosmetics; artificial nails; hand, wrist, and body jewelry that can interfere with the fit of gowns and gloves; and visible body piercing above the neck.				
108	† Order of compounding garb and cleansing in ante-area: shoes or shoe covers, head and facial hair covers, face mask, fingernail cleansing, hand and forearm washing and drying; non-shedding gown.				
109	† Order of cleansing and gloving in buffer room or area: hand cleansing with a persistently active alcohol-based product with persistent activity; allow hands to dry; don sterile gloves.				
110	† Routinely disinfect gloves with sterile 70% IPA after contacting nonsterile objects.				
111	† Inspect gloves for holes and replace when breaches are detected.				
112	† Personnel repeat proper procedures after they are exposed to direct contact contamination or worse than ISO Class 8 air.				

Item#	Requirement	Yes	No	N/A	Notes
	Personnel Cleansing and Garbing (continued)				
113	† These requirements are exempted only for immediate-use CSPs and CAIs for which manufacturers provide written documentation based on validated testing that such personnel practices are not required to maintain sterility in CSPs.				
	Personnel Training and Evaluation In Aseptic Manipulation Skills				
114	† Proper training and evaluation of personnel, proper cleansing and garbing of personnel, proper cleaning and disinfecting of compounding work environments, and proper maintenance and monitoring of controlled environmental locations (all of which are detailed in their respective sections).				
115	† Pass didactic, practical skill assessment and media-fill testing initially, followed by an annual assessment for a low and medium-risk level compounding and semi-annual assessment for high-risk level compounding.				
116	† Compounding personnel who fail written tests, or whose media-fill test vials result in gross microbial colonization, shall be immediately reinstructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic practice deficiencies.				
	Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures				
117	† Personnel who prepare CSPs shall be trained conscientiously and skillfully by expert personnel, multi-media instructional sources, and professional publications in the theoretical principles and practical skills of garbing procedures, aseptic work practices, achieving and maintaining ISO Class 5 environmental conditions, and cleaning and disinfection procedures.				
118	† This training shall be completed and documented before any compounding personnel begin to prepare CSPs.				
119	† Compounding personnel shall complete didactic training, pass written competence assessments, undergo skill assessment using observational audit tools, and media-fill testing.				
120	† Media-fill testing of aseptic work skills shall be performed initially before beginning to prepare CSPs and at least annually thereafter for low- and medium-risk level compounding; and semiannually for high-risk level compounding.				
121	† Compounding personnel who fail written tests, observational audits, or whose media-fill test vials have one or more units showing visible microbial contamination, shall be reinstructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic work practice deficiencies.				
122	† Compounding personnel shall pass all evaluations prior to resuming compounding of sterile preparations.				
123	† Compounding personnel must demonstrate proficiency of proper hand hygiene, garbing, and consistent cleaning procedures in addition to didactic evaluation and aseptic media fill.				
124	† Cleaning and disinfecting procedures performed by other support personnel shall be thoroughly trained in proper hand hygiene, and garbing, cleaning, and disinfection procedures by a qualified aseptic compounding expert.				
125	† Support personnel shall routinely undergo performance evaluation of proper hand hygiene, garbing, and all applicable cleaning and disinfecting procedures conducted by a qualified aseptic compounding expert.				

Item#	Requirement	Yes	No	N/A	Notes
	Competency Evaluation of Garbing and Aseptic Work Practices				
126	† Compounding personnel shall be evaluated initially prior to beginning compounding CSPs and whenever an aseptic media fill is performed.				
127	† Monitoring of compounding personnel glove fingertips shall be performed for all CSP risk level compounding.				
128	† Glove fingertip sampling shall be used to evaluate the competency of personnel in performing hand hygiene and garbing procedures in addition to educating compounding personnel on proper work practices.				
129	† All personnel shall demonstrate competency in proper hand hygiene and garbing procedures in addition to aseptic work practices.				
130	† Sterile contact agar plates shall be used to sample the gloved fingertips of compounding personnel after garbing to assess garbing competency and after completing the media-fill preparation.				
131	† Gloves shall not be disinfected with sterile 70% IPA immediately prior to sampling.				
	Garbing and Gloving Competency Evaluation				
132	† Compounding personnel shall be visually observed during the process of performing hand hygiene and garbing procedures.				
133	† The visual observation shall be documented on a Sample Form for Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel and maintained to provide a permanent record of and long-term assessment of personnel competency.				
	Gloved Fingertip Sampling				
134	† Immediately after the compounder completes the hand hygiene and garbing procedure, the evaluator shall collect a gloved fingertip and thumb sample from both hands of the compounder onto appropriate agar plates by lightly pressing each fingertip into the agar.				
135	† The plates shall be incubated for the appropriate incubation period and at the appropriate temperature.				
136	† All employees shall successfully complete an initial competency evaluation and gloved fingertip/thumb sampling procedure (0 cfu) no less than three times before initially being allowed to compound CSPs for human use.				
137	† After completing the initial gowning and gloving competency evaluation, re-evaluation of all compounding personnel shall occur at least annually for low- and medium-risk level CSPs and semiannually for high-risk level CSPs before being allowed to continue compounding CSPs.				
138	† Gloves shall not be disinfected with sterile 70% IPA prior to testing.				
139	† The sampled gloves shall be immediately discarded, and proper hand hygiene performed after sampling. The nutrient agar plates shall be incubated as stated below.				
140	† The cfu action level for gloved hands shall be based on the total number of cfu on both gloves and not per hand.				
141	‡ Results should be reported separately as number of cfu per employee per hand (left hand, right hand).				
	Incubation Period				
142	† At the end of the designated sampling period, the agar plates are recovered, covers secured, inverted and incubated at a temperature and for a time period conducive to multiplication of microorganisms. Trypticase soy agar (TSA) with lecithin and polysorbate 80 shall be incubated at 35°± 2° for 2–3 days.				
Item#	Requirement	Yes	No	N/A	Notes

	Aseptic Manipulation Competency Evaluation				
143	† All compounding personnel shall have their aseptic technique and related practice competency evaluated initially during the media-fill test procedure and subsequent annual or semiannual media-fill test procedures on the Sample Form for Assessing Aseptic Technique and Related Practices of Compounding Personnel.				
	Media-Fill Test Procedure				
144	† The skill of personnel to aseptically prepare CSPs shall be evaluated using sterile fluid bacterial culture media-fill verification.				
145	† Media-filled vials shall be incubated within a range of 35° ± 2° for 14 days.				
	Surface Cleaning and Disinfection Sampling and Assessment				
146	† Surface sampling shall be performed in all ISO classified areas on a periodic basis and can be accomplished using contact plates and/or swabs and shall be done at the conclusion of compounding.				
147	† Locations to be sampled shall be defined in a sample plan or on a form.				
	Cleaning and Disinfecting Competency Evaluation				
148	† Compounding personnel and other personnel responsible for cleaning shall be visually observed during the process of performing cleaning and disinfecting procedures during initial personnel training on cleaning procedures, changes in cleaning staff and at the completion of any Media-Fill Test Procedure.				
149	† Visual observation shall be documented on a Sample Form for Assessing Cleaning and Disinfection Procedures and maintained to provide a permanent record of, and long-term assessment of, personnel competency.				
	Surface Collection Methods				
150	† Immediately after sampling a surface with the contact plate, the sampled area shall be thoroughly wiped with a non-shedding wipe soaked in sterile 70% IPA.				
151	‡ Results should be reported as cfu per unit of surface area.				
	Action Levels, Documentation, and Data Evaluation				
152	† Environmental sampling data shall be collected and reviewed on a routine basis as a means of evaluating the overall control of the compounding environment.				
153	† If an activity consistently shows elevated levels of microbial growth, competent microbiology personnel shall be consulted.				
154	† An investigation into the source of the contamination shall be conducted.				
155	† When gloved fingertip sample results exceeds action levels after proper incubation, a review of hand hygiene and garbing procedures as well as glove and surface disinfection procedures and work practices shall be performed and documented.				
156	‡ Any cfu count that exceeds its respective action level should prompt a re-evaluation of the adequacy of personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency within the aseptic compounding location.				

Item#	Requirement	Yes	No	N/A	Notes
	Determining Beyond-Use Dates				
157	† Use the general criteria in USP <797> in the absence of direct stability-indicating assays or authoritative literature that supports longer durations.				
	Low-Risk Level CSPs				
158	† Aseptic manipulations within an ISO Class 5 environment using three or fewer sterile products and entries into any container.				
159	† In absence of passing sterility test, store not more than 48 hours at controlled room temperature, 14 days at cold temperature, and 45 days in solid frozen state at −25° to −10° or colder.				
160	† Media-fill test at least annually by compounding personnel.				
	Low-Risk Level CSPs with 12-Hour or Less BUD				
161	† Fully comply with all four specific criteria as detailed in USP <797> *CSP Microbial Contamination Risk Levels.*				
162	‡ Sinks should not be located adjacent to the ISO Class 5 primary engineering control.				
163	‡ Sinks should be separated from the immediate area of the ISO Class 5 primary engineering control device.				
	Medium-Risk Level CSPs				
164	† Aseptic manipulations within an ISO Class 5 environment using prolonged and complex mixing and transfer, more than three sterile products and entries into any container, and pooling ingredients from multiple sterile products to prepare multiple CSPs.				
165	† In absence of passing sterility test, store not more than 30 hours at controlled room temperature, 9 days at cold temperature, and 45 days in solid frozen state at −25° to −10° or colder.				
166	†Media-fill test at least annually by compounding personnel.				
	High-Risk Level CSPs				
167	† Confirmed presence of nonsterile ingredients and devices or confirmed or suspected exposure of sterile ingredients for more than one hour to air quality inferior to ISO Class 5 before final sterilization.				
168	† Sterilization method verified to achieve sterility for the quantity and type of containers.				
169	† Meet allowable limits for bacterial endotoxins.				
170	† Maintain acceptable strength and purity of ingredients and integrity of containers after sterilization.				
171	† In absence of passing sterility test, store not more than 24 hours at controlled room temperature, 3 days at cold temperature, and 45 days in solid frozen state at −25° to −10° or colder.				
172	† Media-fill test at least semiannually by compounding personnel.				
	Verification of Compounding Accuracy and Sterility				
173	† Review labels and document correct measurements, aseptic manipulations, and sterilization procedures to confirm correct identity, purity, and strength of ingredients in, and sterility of, CSPs.				
174	‡ Assay finished CSPs to confirm correct identity and, or, strength of ingredients.				
175	‡ Sterility test finished CSPs.				
	Sterilization Methods				
176	† Verify methods achieve sterility while maintaining appropriate strength, purity, quality, and packaging integrity.				
177	‡ Prove effectiveness by USP chapter <71>, equivalent, or superior sterility testing.				
Item#	Requirement	Yes	No	N/A	Notes

	Sterilization of High-Risk Level CSPs by Filtration				
178	† Nominal 0.2 mm pore size sterile membranes that are chemically and physically compatible with the CSP.				
179	† Complete rapidly without filter replacement.				
180	† Subject filter to manufacturer's recommended integrity test (e.g., bubble point test) after filtering CSPs.				
	Sterilization of High-Risk Level CSPs by Steam				
181	† Test to verify the mass of containers to be sterilized will be sterile after the selected exposure duration in the particular autoclave.				
182	† Ensure live steam contacts all ingredients and surfaces to be sterilized.				
183	† Pass solutions through a 1.2 mm or smaller nominal pore size filter into final containers to remove particulates before sterilization.				
184	† Heated filtered air shall be evenly distributed throughout the chamber by a blower device.				
185	† Dry heat shall only be used for those materials that cannot be sterilized by steam, when the moisture would either damage or be impermeable to the materials.				
186	† Sufficient space shall be left between materials to allow for good circulation of the hot air.				
187	† The description of dry heat sterilization conditions and duration for specific CSPs shall be included in written documentation in the compounding facility. The effectiveness of dry heat sterilization shall be verified using appropriate biological indicators and other confirmation.				
188	‡ The oven should be equipped with a system for controlling temperature and exposure period.				
	Depyrogenation by Dry Heat				
189	† Dry heat depyrogenation shall be used to render glassware or containers, such as vials free from pyrogens as well as viable microbes.				
190	† The description of the dry heat depyrogenation cycle and duration for specific load items shall be included in written documentation in the compounding facility.				
191	† The effectiveness of the dry heat depyrogenation cycle shall be verified using endotoxin challenge vials (ECVs).				
192	‡ The bacterial endotoxin test should be performed on the ECVs to verify the cycle is capable of achieving a 3 log reduction in endotoxin.				
	Sterility Testing				
193	† High-risk level CSPs prepared in batches of more than 25 identical containers or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8° before being sterilized.				
	Bacterial Endotoxin (Pyrogen) Testing				
194	† High-risk level CSPs, excluding those for inhalation and ophthalmic administration, prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8°, before being sterilized.				
	Immediate-Use CSPs				
195	† Fully comply with all six specified criteria as detailed in USP <797> *Immediate-Use CSPs.*				

Item#	Requirement	Yes	No	N/A	Notes
	Finished Preparation Release Checks				
196	† Review procedures and documents to ensure sterility, purity, correct identities and amounts of ingredients, and stability.				
197	† Visually inspect for abnormal particulate matter and color, and intact containers and seals.				
198	† Written procedures to verify correct identity, quality, amounts, and purities of ingredients used in CSPs.				
199	† Written procedures to ensure labels of CSPs contain correct names and amounts or concentrations of ingredients, total volumes, beyond-use dates, storage conditions, and route(s) of administration.				
	Maintaining Sterility, Purity, and Stability of Dispensed and DIistributed CSPs				
201	† Written procedures for proper packaging, storage, and transportation conditions to maintain sterility, quality, purity, and strength of CSPs.				
	Redispensed CSPs				
202	† When sterility, and acceptable purity, strength, and quality can be ensured.				
203	† Assignment of sterility storage times and stability beyond-use dates that occur later than those of originally dispensed CSPs must be based on results of sterility testing and quantitative assay of ingredients.				
	Packaging and Transporting CSPs				
204	† Packaging maintains physical integrity, sterility, stability, and purity of CSPs.				
205	† Modes of transport that maintain appropriate temperatures and prevent damage to CSPs.				
	Patient or Caregiver Training				
206	† Multiple component formal training program to ensure patients and caregivers understand the proper storage, handling, use, and disposal of CSPs.				
	Patient Monitoring and Adverse Events Reporting				
207	† Written standard procedures describe means for patients to ask questions and report concerns and adverse events with CSPs, and for compounding supervisors to correct and prevent future problems.				
208	‡ Adverse events and defects with CSPs reported to FDA's MedWatch and USP's MEDMARX programs.				

Comments:

Comments:

I have participated in a sterile compounding inspection and have reviewed the report with the inspectors.

Plan of Correction Issued: ☐ Yes ☐ No

If yes, I will provide a plan of correction for all findings within 15 business days.

Print Name: _____ Signature: _____

Title: _____ License Number: _____

Inspector: _____ Date: _____

Inspector: _____ Date: _____

Inspector: _____ Date: _____