STERILE COMPOUNDING INSPECTION REPORT

	FULL	**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
239 Causeway Street, Suite 500, Boston, MA 02114
Tel: (617) 973-0800
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DATE(S) OF INSPECTION:	
ISP NUMBER:	
PHARMACY DBA NAME:	
STORE NUMBER:	
STREET ADDRESS:	
CITY / STATE / ZIP:	
TELEPHONE:	
FAX:	
EMAIL:	
PHARMACY LIC. NUMBERS:	
PHARMACY LIC. EXPIRATION:	
DEA REG. NUMBER:	
DEA REG. EXPIRATION:	
MANAGER OF RECORD (MOR):	
MOR LICENSE NUMBER:	
FACILITY TYPE	☐ Community ☐ Community/Infusion/Closed Door ☐ Long Term Care ☐ Institutional/Inpatient ☐ Institutional/Satellite ☐ Institutional/Outpatient
DAILY PHARMACY VOLUME (STERILE COMPOUNDING):	
HOURS OF OPERATION:	**M-F:** **SAT:** **SUN:**

INSPECTION FORM:	**FORM**	**MODULES**
	☐ Standard Form ☐ Full Form (Standard + All Modules)	☐ #1 Training/Competency/Proficiency ☐ #2 Facility and Engineering Controls ☐ #3 Cleaning/Disinfection/Aseptic Technique ☐ #4 Environmental Monitoring ☐ #5 Quality Assurance/Records Management ☐ #6 High Risk Compounding/Sterilization ☐ #7 Hazardous Handling ☐ #8 Robotics

PHARMACY STAFF PRESENT AT TIME OF INSPECTION		
Supervisory ratios compliant with 247 CMR 8.06 (3):	☐ Yes ☐ No	
PHARMACISTS	**LICENSE#**	**CURRENT?**
1		☐ Yes ☐ No
2		☐ Yes ☐ No
3		☐ Yes ☐ No
4		☐ Yes ☐ No
5		☐ Yes ☐ No
6		☐ Yes ☐ No
PHARMACY INTERNS	**LICENSE#**	**CURRENT?**
1		☐ Yes ☐ No
2		☐ Yes ☐ No
3		☐ Yes ☐ No

PHARMACY TECHNICIANS	CERTIFIED?	LICENSE#	CURRENT?
1	☐ Yes ☐ No		☐ Yes ☐ No
2	☐ Yes ☐ No		☐ Yes ☐ No
3	☐ Yes ☐ No		☐ Yes ☐ No
4	☐ Yes ☐ No		☐ Yes ☐ No
5	☐ Yes ☐ No		☐ Yes ☐ No
6	☐ Yes ☐ No		☐ Yes ☐ No
7	☐ Yes ☐ No		☐ Yes ☐ No
8	☐ Yes ☐ No		☐ Yes ☐ No
9	☐ Yes ☐ No		☐ Yes ☐ No
10	☐ Yes ☐ No		☐ Yes ☐ No

OTHER PHARMACY STAFF including trainees	POSITION	TRAINEE HOURS
1		
2		
3		
4		
5		
6		

Item#	Requirements	Yes	No	N/A	Additional Information
	Regulatory Requirements				
1	The pharmacy does not hold an outsourcing facility registration issued by the federal Food and Drug Administration ("FDA") pursuant to 21 U.S.C. § 353b? Draft 247 CMR 17.02 (2)				
2	Are the following documents conspicuously displayed within the pharmacy or pharmacy department? a) the pharmacy Retail Drug Store License; ☐ Yes ☐ No b) the pharmacy's Massachusetts Controlled Substance Registration; ☐ Yes ☐ No c) the pharmacy's U.S. Drug Enforcement Administration Controlled Substance Registration; and ☐ Yes ☐ No d) the pharmacy's Sterile Compounding License, as applicable ☐ Yes ☐ No ☐ N/A e) the pharmacy's Institutional Sterile Compounding License, as applicable ☐ Yes ☐ No ☐ N/A 247 CMR 6.02(3) (a-c), M.G.L. c. 112, § 39H				
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 maintain a written policy and procedure to effectuate a recall of sterile compounded preparations in accordance with M.G.L. c. 112, § 39D(e)? 247 CMR 18.02(4)				
9	Does the pharmacy keep a defective drug preparation log documenting all recalled drug preparations? M.G.L. c. 112, § 39D(e)				
Item#	**Requirements**	**Yes**	**No**	**N/A**	**Additional Information**
	Regulatory Requirements (continued)				

10	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[1] as determined by the prescribing practitioner[2]? Draft 247 CMR 17.02 (1); M.G.L. c. 112, § 39D(a)1					
11	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?					
12	If the pharmacy compounds FDA approved products using non-sterile powders or other components, can the pharmacy provide documentation confirming backorder?					
13	Does the Pharmacy only prepare quantities of compounded 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)					
14	Does the pharmacy maintain a written continuity of care plan that describes the way patient needs will be met in the event the pharmacy is unexpectedly unable to provide pharmacy services? 247 CMR 9.17 (15); Draft 247 CMR 17.32 (5) **Documentation Required; Best Practice**					
15	Does the pharmacy conduct ***High Risk Level Compounding***? If yes, a) Has the pharmacy submitted an attestation of intent to engage in high risk level sterile compounding? b) Has the pharmacy received notification from the Board regarding successful inspection and approval to engage in high risk level compounding? Draft 247 CMR 17.06 (1) (a-b)	☐ Yes ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A				
16	Does the pharmacy compounding sterile preparations for investigational use have the appropriate documentation showing acknowledgment and approval from the Board of Registration in Pharmacy? Policy 2017-04 Retail Pharmacy Participation in Research Studies; In conjunction with Massachusetts Drug Control Program (DCP).					

[1] 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.

[2] M.G.L. c.112 § 39D(a)(1); for use on or 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 as determined by the prescribing practitioner 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#	Requirements	Yes	No	N/A	Additional Information
	Sterile Compounding Facility; General				
17	Does the pharmacy allow for visual observation of the classified space from outside the classified space through windows or technology?[3] Draft 247 CMR 17.12 (2) **Best Practice**				
	HVAC Systems				
18	Does the pharmacy have a dedicated air handling unit for ISO classified areas or can they ensure that HVAC systems supplying HEPA-filtered air to ISO classified areas are designed to minimize contamination of recirculated air and maintain proper temperature and humidity? Draft 247 CMR 17.18 (1) **Best Practice**				
19	Does the pharmacy maintain a detailed HVAC design plan that includes air flow diagrams and pressure differential schematics? Draft 247 CMR 17.18 (2) **Documentation Required; Best Practice**				
20	Does the pharmacy utilize a closed loop ducted system, a sealed plenum system, or other similar contamination control system approved by the Executive Director or his/her designee for HVAC systems supplying HEPA-filtered air to ISO-classified spaces? Draft 247 CMR 17.18 (3) **Best Practice**				
21	Is the conditioned supply air provided to classified area(s) exclusively through ceiling HEPA filters? Draft 247 CMR 17.18 (4)				
22	Does the pharmacy ensure all pre-filters and HVAC components are maintained in accordance with manufacturer specifications? Draft 247 CMR 17.18 (5)				
23	Does the pharmacy conduct engineering control performance verification[4] in accordance with USP <797> in the event of a planned or unplanned interruption of HVAC operations? Draft 247 CMR 17.18 (6) **Best Practice**				
24	Does the pharmacy operate and monitor the HVAC systems that supply conditioned air to the non-classified areas of the pharmacy 24 hours per day, seven days per week? Draft 247 CMR 17.18 (7) **Best Practice**				
25	Does the pharmacy operate and monitor the HVAC systems that supply HEPA filtered air to ISO classified areas 24 hours per day, seven days per week? Draft 247 CMR 17.18 (8) **Best Practice**				
26	Does the pharmacy immediately assess the impact on the classified environment for any HVAC failure and implement a Corrective Action Preventative Action (CAPA) plan? Draft 247 CMR 17.18 (9)				
27	Does each secondary engineering control (positive and negative pressure) have ducted air returns mounted low on the wall to create a general top-down dilution of room air with HEPA-filtered make-up air? Draft 247 CMR 17.18 (10) **Best Practice**				
Item#	**Requirements**	**Yes**	**No**	**N/A**	**Additional Information**

[3] Applies to ISO Classified areas built after January 1, 20XX,

[4] Engineering Control Performance Verification—PECs (LAFWs, BSCs, CAIs, and CACIs) and secondary engineering controls (buffer and ante-areas) are essential components of the overall contamination control strategy for aseptic compounding. As such, it is imperative that they perform as designed and that the resulting levels of contamination be within acceptable limits. Certification procedures such as those outlined in *Certification Guide for Sterile Compounding Facilities* (CAG-003-2006) shall be performed by a qualified individual no less than every 6 months and whenever the device or room is relocated or altered or major service to the facility is performed. (Add list of elements for certification testing)

	HVAC Systems (continued)				
28	Does each secondary engineering control (positive and negative pressure) have relief air vents mounted low on the wall and designed to prevent the ingress of less clean air or contaminants from adjacent ISO classified space or ambient air? Draft 247 CMR 17.18 (11) **Best Practice**				
	HEPA Filters				
29	Does the pharmacy use IEST rated type C or K HEPA filters that have been tested to achieve a minimum of 99.97% efficiency rating using 0.3 µm micron particle size which have been leak tested using the most penetrating particle size according to the most current CETA guidelines at the factory, then leak tested again in situ after installation as part of initial certification and recertification (every 6 months) and any time a HEPA filter is repaired or replaced? Draft 247 CMR 17.19 (1-2) **Documentation Required**				
30	Does the pharmacy immediately remediate a failed HEPA filter by properly repairing or replacing the HEPA filter, recertifying the affected ISO classified area, and performing environmental monitoring (air and surface, bacterial and fungal) in all classified areas according to the full environmental monitoring sampling map? Draft 247 CMR 17.19 (3)				
31	Does the pharmacy ensure that nothing comes in contact with the HEPA filters, including cleaning and sanitizing agents, aspirate from syringes or compounding equipment, or glass from ampules? Draft 247 CMR 17.19 (4)				
32	Does the pharmacy visually inspect the external portion of PEC filters at least daily? Draft 247 CMR 17.19 (5) **Documentation Required; Best Practice**				
	Airflows and Pressure Differential Monitoring				
33	When compounding non-hazardous CSPs, does the pharmacy maintain a minimum differential positive pressure of 0.02 inches' water column between: a) the buffer room and ante room; ☐ Yes ☐ No ☐ N/A b) the ante room and unclassified space; and ☐ Yes ☐ No ☐ N/A c) ISO Class 8 area and unclassified space. ☐ Yes ☐ No ☐ N/A Draft 247 CMR 17.20 (1) **Documentation Required**				
34	Do the ISO Class 5 Primary Engineering Controls (PEC) include a pressure differential gauge and/or a low flow device displaying the positive pressure differential between the upstream and downstream air flow.[5] [6] Draft 247 CMR 17.20 (2) **Documentation Required; Best Practice**				
35	Does the pharmacy measure the differential pressure between each ISO-classified area with a gauge and document the differential pressure at each location 24 hours per day, seven days per week, by a continuous recording device? Draft 247 CMR 17.20 (3) **Documentation Required; Best Practice**				
36	Does the pharmacy have visual and auditory alarms for pressure differential gauges for secondary engineering controls in the non-classified area adjacent to the classified areas?[7] Draft 247 CMR 17.20 (4) **Best Practice; Best Practice**				
37	Does the pharmacy review differential pressure logs and/or continuous monitoring device reports daily? Draft 247 CMR 17.20 (5) **Documentation Required**				
Item#	**Requirements**	**Yes**	**No**	**N/A**	**Additional Information**
	Airflows and Pressure Differential Monitoring (continued)				

[5] The pressure shall be logged daily prior to compounding. Should the PEC display a loss of pressure exceeding 10% of the last reading, compounding in the PEC shall be suspended until remediated.
[6] All airflow and pressure differentials must be maintained within manufacturers specifications.
[7] Applies to ISO Classified areas built after January 1, 20XX,

38	Does the pharmacy respond to any out of range pressure? Draft 247 CMR 17.20 (5) **Documentation Required**				
	ISO Classified Areas				
39	Does the ISO Class 7 buffer room and ISO Class 7 ante room maintain a minimum of 30 air changes per hour? Draft 247 CMR 17.13 (1)				
40	Does the ISO Class 8 room maintain a minimum of 20 air changes per hour? Draft 247 CMR 17.13 (2) **Best Practice**				
41	Do all air changes come from HEPA filtered room air supplied at the ceiling?[8] Draft 247 CMR 17.13 (3) **Best Practice**				
42	Does the pharmacy ensure that ISO classified areas are not used for both sterile and non-sterile compounding? Draft 247 CMR 17.13 (4) **Best Practice**				
43	Does the pharmacy limit access to all ISO Classified areas to authorized individuals only? Draft 247 CMR 17.13 (5)				
44	Are the doors to all classified areas: a) constructed of a nonporous, smooth, non-shedding, impermeable material such as acrylic, polycarbonate or similar fiberglass-reinforced plastic, glass, or stainless steel; ☐ Yes ☐ No ☐ N/A b) free from cracks and crevices; ☐ Yes ☐ No ☐ N/A c) cleanable and resistant to degradation by cleaning agents; ☐ Yes ☐ No ☐ N/A Draft 247 CMR 17.13 (6)				
45	Are the doors to all classified areas constructed with an interlocking design to prevent the ante room door and buffer room door from opening at the same time?[9] Draft 247 CMR 17.13 (7) **Best Practice**				
46	Is the buffer room, ante room, and other ISO Classified areas well lit? Draft 247 CMR 17.13 (8)				
47	The pass-through[10]: a) is constructed of a nonporous, smooth, non-shedding, impermeable material such as acrylic, polycarbonate or similar fiberglass-reinforced plastic, glass, or stainless steel; ☐ Yes ☐ No ☐ N/A b) has a double interlocking door design; ☐ Yes ☐ No ☐ N/A c) does not have an opening larger than 4 square feet; ☐ Yes ☐ No ☐ N/A d) is located between: 1) ISO Class 7 buffer room and ISO Class 8 area or better; ☐ Yes ☐ No ☐ N/A 2) ISO Class 8 area to unclassified space or better; or ☐ Yes ☐ No ☐ N/A 3) ISO Class 7 ante room to unclassified space or better; ☐ Yes ☐ No ☐ N/A e) Is not a refrigerator unit. ☐ Yes ☐ No ☐ N/A Draft 247 CMR 17.13 (9) **Best Practice**				
Item#	**Requirements**	**Yes**	**No**	**N/A**	**Additional Information**
	ISO Classified Areas (continued)				
48	Does the pharmacy ensure each ISO Class 5 PEC is operated 24 hours per day, 7 days per week?				

[8] Any air exchanges supplied to buffer room from the PEC must be in addition to the 30 ACPH.
[9] Applies to ISO Classified areas built after January 1, 20XX,
[10] Applies to ISO Classified areas built after January 1, 20XX.

	Draft 247 CMR 17.13 (10)				
49	If there is an interruption in the operation of the ISO Class 5 PEC, does the pharmacy not resume compounding until the PEC operates for at least 30 minutes, in accordance with manufacturer specifications, or in accordance with the PEC's validated recovery time? Draft 247 CMR 17.13 (11) **Documentation Required**				
50	Has the pharmacy determined the recovery time of each primary and secondary engineering control for particle count, temperature, and humidity, following activities including personnel entering and exiting, gowning, staging, material transfer, compounding, labeling, cleaning, testing and planned or unplanned instances of loss of power or HVAC operations? Draft 247 CMR 17.13 (12) **Documentation Required, Best Practice**				
51	Does the pharmacy limit furniture, equipment, supplies, and activities in an anteroom, buffer room, and other ISO classified areas to those essential for sterile compounding related activities? Draft 247 CMR 17.13 (13)				
52	Refrigerators, dishwashers, incubators, or other appliances are not located in an ISO Classified area? Draft 247 CMR 17.13 (14)				
53	Is all equipment in the ante room, buffer room, and other ISO classified areas nonporous, non-shedding, impermeable, cleanable, and resistant to degradation by cleaning agents? Draft 247 CMR 17.13 (15)				
54	Are all counter tops, work surfaces, and racks, constructed of stainless steel or other non-porous material? Draft 247 CMR 17.13 (16)				
55	Does the pharmacy only utilize stainless steel or non-porous molded plastic carts that are cleanable and resistant to degradation by cleaning agents in ISO classified areas? Draft 247 CMR 17.13 (17)				
56	Do ISO classified areas not contain dust-collecting overhangs or ledges?[11] Draft 247 CMR 17.13 (18)				
57	Does the pharmacy utilize sealed cleanroom grade lights in all classified areas? Draft 247 CMR 17.13 (19)				
58	Are the exterior surfaces of ceiling lighting fixtures smooth, mounted flush with the ceiling surface, and sealed? Draft 247 CMR 17.13 (20)				
59	Are ceiling surfaces in ISO classified areas impervious and hydrophobic? Draft 247 CMR 17.13 (21)				
60	Are ceiling panels, fixtures, and other penetrations through the ceiling (e.g. sprinkler heads[12]) smooth, mounted flush with ceiling tiles, and sealed around the perimeter? Draft 247 CMR 17.13 (22)				
Item#	**Requirements**	**Yes**	**No**	**N/A**	**Additional Information**
	ISO Classified Areas (continued)				

[11] Applies to ISO Classified areas built after January 1, 20XX,

[12] Draft 247 CMR 17.16 (23) Applies to ISO Classified areas built after January 1, 20XX, Sprinkler heads in all ISO classified areas shall be specifically designed for clean rooms and installed in such a manner to withstand weight-bearing loads on the ceiling.

61	Are the walls made of solid surface, locking sealed panels, or epoxy-coated gypsum board and impervious, cleanable, and non-shedding? Draft 247 CMR 17.13 (24)				
62	Are the floors cleanable and composed of wide sheet vinyl that is heat welded at seams or other solid, smooth surface? Draft 247 CMR 17.13 (25)				
63	Are the floors coved at the wall or appropriately sealed? Draft 247 CMR 17.13 (25)				
	ISO Class 5 Primary Engineering Controls				
64	Are all ISO Class 5 PECs used for non-hazardous drug compounding located within a positive pressure ISO Class 7 buffer room? Draft 247 CMR 17.14 (1) & (4)				
65	Has the pharmacy conducted smoke studies to determine if equipment in the PEC does not impact the direct compounding area? Draft 247 CMR 17.14 (2) **Documentation Required**				
66	Does the ISO Class 5 PEC provide HEPA filtered unidirectional air over the direct compounding area as verified through dynamic smoke studies? Draft 247 CMR 17.14 (7) **Documentation Required**				
67	Is the supporting base of a PEC constructed of stainless steel or other non-shedding, coated metal? Draft 247 CMR 17.14 (3) **Best Practice**				
68	Does the pharmacy prepare CSPs in a commercially manufactured ISO Class 5 PEC[13] Draft 247 CMR 17.14 (5)				
69	Does the pharmacy ensure that computer screens, keyboards, a computer mouse, or printer is not located within an ISO Class 5 area unless it is essential to compounding? Draft 247 CMR 17.14 (6)				
	Buffer Room				
70	Is the buffer room at least 144 square feet? Draft 247 CMR 17.15 (1) (a) **Best Practice**				
71	Does the pharmacy ensure that the buffer room does not contain a sink, drain, or any other source of water? Draft 247 CMR 17.15 (1) (b)				
72	Are the buffer room doors hands-free? Draft 247 CMR 17.15 (1) (c)				
73	Is the buffer room supplied with HEPA filtered air? Draft 247 CMR 17.15 (1) (d)				
74	Is the buffer room certified to ISO Class 7? Draft 247 CMR 17.15 (1) (e) **Documentation Required**				
75	Is the buffer room physically separated from the ante room by walls, doors, or pass-throughs? Draft 247 CMR 17.15 (1) (f)				
Item#	**Requirements**	**Yes**	**No**	**N/A**	**Additional Information**
	Buffer Room (continued)				
76	Does the buffer room only have one door? (Unless prohibited by local building or fire code) Draft 247 CMR 17.15 (1) (g) **Best Practice**				

[13] Draft 247 CMR 17.17 (5): A pharmacy may not prepare CSPs in a vertically integrated ISO Class 5 workbench or ISO Class 5 open buffer room design.

	Ante Room				
77	Is the ante room supplied with HEPA filtered air? Draft 247 CMR 17.15 (2) (a)				
78	Is the ante room certified to at least ISO Class 8? (An ante room adjacent to a negative pressure buffer room is to be at least ISO Class 7) Draft 247 CMR 17.15 (2) (b) **Documentation Required**				
79	Does the ante room only have one door between unclassified space? (Unless prohibited by local building or fire code) Draft 247 CMR 17.15 (2) (c) **Best Practice**				
80	Is the ante room at least 100 square feet? Draft 247 CMR 17.15 (2) (d) **Best Practice**				
81	Does the ante room have a line of demarcation that separates the less clean area from the cleaner area? Draft 247 CMR 17.15 (2) (e)				
82	Does the ante room have a stainless-steel sink that? a) is equipped with hands-free controls for water and soap dispensing; ☐ Yes ☐ No ☐ N/A b) has proper depth and capacity for hand washing up to the elbows; ☐ Yes ☐ No ☐ N/A c) is designed or installed to prevent standing water; ☐ Yes ☐ No ☐ N/A d) is located on the clean side of the line of demarcation away from the buffer room door; and ☐ Yes ☐ No ☐ N/A e) minimizes splashing and dripping of water on adjacent walls and floor. ☐ Yes ☐ No ☐ N/A Draft 247 CMR 17.15 (2) (f)				
83	Does the pharmacy ensure that the ante room sink does not have an aerator mechanism on the nozzle? Draft 247 CMR 17.15 (2) (g) **Best Practice**				
84	Does the ante room have lint-free, disposable towels located in proximity to the sink to minimize water dripping and splashing?[14] Draft 247 CMR 17.15 (2) (h)				
85	Are the ante room's plumbing systems maintained in a good state of repair and free of defects that could create conditions favorable for microbial growth? Draft 247 CMR 17.15 (2) (j) **Best Practice**				
86	Are exposed plumbing system pipes within the ante room limited to the immediate drain pipe and constructed of cleanable, non-corrosive material such as copper, PVC, or stainless steel? Draft 247 CMR 17.15 (2) (k) **Best Practice**				
87	Does the pharmacy ensure that "tacky" mats are not placed inside an ISO classified area?[15] . Draft 247 CMR 17.15 (2) (l) **Best Practice**				
88	Are all carts used in the ante room dedicated to one side of the line of demarcation?[16] Draft 247 CMR 17.15 (2) (m)				
Item#	**Requirements**	**Yes**	**No**	**N/A**	**Additional Information**
	Segregated Compounding Areas (SCA)				
89	Does the pharmacy ensure that the SCA is restricted to sterile compounding activities to minimize the risk of CSP contamination?				

[14] Draft 247 CMR 17.18 (2) (i): An ante room may not contain automatic hand dryers.
[15] If using a tacky mat outside of the ante room door, the pharmacy shall replace the "tacky" mat at least once per day and when visibly soiled
[16] Only carts dedicated to the cleaner side of the line of demarcation may enter the buffer room after proper cleaning and disinfecting.

90	Does the pharmacy ensure that Beyond-Use-Dates (BUDs) applied to CSPs prepared within a PEC located in a SCA do not exceed 12 hours? Draft 247 CMR 17.20 (2)				
91	The SCA does not contain, and/or not adjacent to unsealed windows or doors that connect to the outdoors or high traffic flow, or adjacent to construction sites, warehouses, or food preparation, etc.?				
92	Does the pharmacy ensure that compounding devices and /or equipment are not used in PECs located in a SCA? **Best Practice**				
93	Does the SCA have a line of demarcation identifying the clean and less clean area of the room or compounding area minimizing risk of contamination from extraneous processes?				
94	Does the SCA contain a sink that is positioned away from the ISO 5 PEC and in a way to minimize the risk of CSP contamination?				
	Compounding Aseptic Isolators ("CAI")[17]				
95	Does the pharmacy locate a CAI inside an ISO Class 7 buffer room? ☐ Yes ☐ No ☐ N/A If no, the following criteria must be met[18]: a) documentation from the manufacturer validating that the CAI maintains positive pressure ISO Class 5 conditions during dynamic operating conditions, including transferring ingredients and components into and out of the CAI and during preparation of CSPs? ☐ Yes ☐ No ☐ N/A b) documentation of recovery time to achieve ISO Class 5 air quality and internal procedures to ensure that adequate recovery time is allowed during material transfer? ☐ Yes ☐ No ☐ N/A				
	Temperature and Humidity Monitoring				
96	Do all ISO Classified areas maintain a temperature of 68 degrees or less? Draft 247 CMR 17.21 (1) **Documentation Required**				
97	Do all ISO Classified areas maintain a relative humidity of 65% or less? Draft 247 CMR 17.21 (2) **Documentation Required, Best Practice**				
98	Do all secondary engineering controls have a probe or sensor to measure temperature and humidity? Draft 247 CMR 17.21 (3)				
99	Does the pharmacy document the temperature and humidity of each secondary engineering control 24 hours per day, seven days per week, by a continuous recording device? Draft 247 CMR 17.21 (4) **Documentation Required; Best Practice**				
100	Does the pharmacy document the controlled room temperature of drug storage areas at least once daily or by a continuous recording device?[19] Draft 247 CMR 17.21 (5) **Documentation Required; Best Practice**				
Item#	**Requirements**	**Yes**	**No**	**N/A**	**Additional Information**
	Temperature and Humidity Monitoring (continued)				
101	Does the pharmacy respond to each out of limit temperature or humidity condition? Draft 247 CMR 17.21 (6) **Documentation Required; Best Practice**				
	Certification of Classified Areas				

[17] All CSPs compounded within a CAI located in unclassified space must be labeled with a 12 hour or less BUD. All CAIs must meet unidirectional airflow requirements.

[18] Extension of BUD past 12 hours when using a CAI located in unclassified space, the facility must meet all personnel training and competency, environmental monitoring, and cleaning and disinfection requirements.

[19] Drugs shall be stored according to USP and package insert directions. If no temperature storage recommendations are provided, utilize standard USP temperature and humidity ranges as guides. Freezer: -25°C to -10°C (-13°F to 14°F); Cold: 2°C - 8°C (36°F to 46°F); Controlled Room: 20°C to 265°C (68°F to 77°F).

102	Does the pharmacy ensure that primary and secondary engineering controls are certified at least? a) once every 6 months; b) whenever a PEC is relocated, added, or removed; c) whenever the room is altered[20]; and d) immediately following any major repair or major servicing of the compounding facility or engineering controls. Draft 247 CMR 17.22 (1)	☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A				
103	Does the pharmacy ensure that the certification testing includes the following tests? a) airflow and velocity test; b) airflow smoke pattern test; c) room pressurization test; d) air flow displacement test, as applicable; e) HEPA filter leak test; f) induction leak and back streaming test; **Best Practice** g) airborne total particle counting, conducted under dynamic operating conditions; h) temperature and humidity test. **Best Practice** Draft 247 CMR 17.22 (2) **Documentation Required;**	☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A				
104	Have the primary or secondary engineering controls required major repair or major servicing? If yes, did the pharmacy stop compounding and not resume compounding until: a) the repair or service is complete; b) the affected engineering control has been certified; and c) environmental monitoring results in the affected engineering control within USP <797> action levels are obtained. Draft 247 CMR 17.22 (3) **Documentation Required**	☐ Yes ☐ No ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A				

[20] Altered is defined as any modification or reconfiguration made to the design or set up of the SEC that could cause changes to airflow dynamics or environmental control. Licensees are required to submit a Renovation/Expansion request form prior to conducting the alteration or major/minor servicing/repair.

Item#	Requirements		Yes	No	N/A	Additional Information
	Certification of Classified Areas (continued)					
105	Does the pharmacy ensure that the certification meets the following requirements? a) All sterile compounding facilities are certified to most current CETA application guide and NSF/ANSI 49 standards? b) Certification reports for all primary and secondary engineering controls indicate that the most current CETA application guide have been followed? c) Certification reports for all primary and secondary engineering controls list all elements of the most current CETA application guide. d) CETA National Board of Testing (CNBT)-accredited certifiers are used. **Best Practice** Draft 247 CMR 17.22 (4) **Documentation Required**	☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A				
106	Does the manager of record or his/her pharmacist designee review and sign the certification report? Draft 247 CMR 17.22 (5) **Best Practice**					
107	Does the pharmacy verify the maximum number of compounding personnel simultaneously capable of working in a buffer room or buffer space without disrupting ISO classification at least once per year? The verification procedures shall include non-viable air, viable air, and surface sampling. Draft 247 CMR 17.22 (6) **Documentation Required; Best Practice**					
	Smoke Studies					
108	Does the pharmacy conduct a smoke study of primary and secondary engineering controls? a) upon initial certification; b) annually at recertification for secondary engineering controls; c) at least each certification for PECs; and d) immediately following any major repair or service, movement of engineering control, addition, or permanent removal of equipment located within the primary engineering control. Draft 247 CMR 17.23 (1) **Documentation Required**	☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A				
109	Does the smoke study[21] conducted on the pharmacy primary and secondary engineering controls verify the following? <u>Primary Engineering Controls</u> a) unidirectional airflow, sweeping action over and away from the critical compounding area, and interface with compounding personnel for each primary engineering control; b) airflow around compounding equipment <u>Secondary Engineering Controls</u> c) a general top-down dilution of room air with HEPA-filtered make-up air and sweeping action to the low wall mounted returns for each secondary engineering control; d) positive or negative pressure around all openings, doorways, and pass-throughs; e) air flow around equipment and or devices Draft 247 CMR 17.23 (2) **Documentation Required**	☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A				

[21] Smoke studies are to be conducted in accordance with CETA CAG Standards

Item#	Requirements	Yes	No	N/A	Additional Information
	Smoke Studies (continued)				
110	Does the pharmacy conduct smoke studies during dynamic operating conditions that represent the most challenging compounding conditions encountered by compounding personnel?[22] Draft 247 CMR 17.23 (4)				
111	Does the pharmacy have a video record of the smoke study for each primary and secondary engineering control conducted at least once per year? Draft 247 CMR 17.23 (5) **Documentation Required**				
112	Does the pharmacy document the results of each smoke study? Draft 247 CMR 17.23 (6) **Documentation Required**				
113	Does the pharmacy initiate an investigation and develop and implement a Corrective Action Preventative Action ("CAPA") plan in response to a failed smoke study? Draft 247 CMR 17.23 (7) **Documentation Required**				

[22] A smoke study is required to demonstrate that compounding personnel performing manipulations and/or equipment used in the direct compounding area inside of the ISO Class 5 environment are not disrupting the flow of first air (HEPA filtered air stream) over critical sites.

Item#	Requirements	Yes	No	N/A	Additional Information
	Environmental Monitoring[23]				
114	Has the pharmacy developed an environmental monitoring sampling plan in conjunction with a qualified professional such as a microbiologist, industrial hygienist, or infection control professional? Draft 247 CMR 17.24 (1)				
115	Does the pharmacy conduct viable air and surface sampling for bacterial and fungal organisms utilizing a general growth media and a fungal specific media? Draft 247 CMR 17.24 (2)				
116	Does the pharmacy collect environmental monitoring samples from each primary and secondary engineering control at locations that are prone to contamination? Draft 247 CMR 17.24 (3)				
117	Does the pharmacy maintain an environmental monitoring plan that clearly denotes the frequency and location of viable bacterial and fungal air and surface sampling and non-viable particulate sampling? Draft 247 CMR 17.24 (5)				
118	Does the pharmacy maintain an environmental sampling log that states the location of each sample, sampling time, sampling methodology, and activities taking place in the respective classified areas? Draft 247 CMR 17.24 (6)				
	Frequency of Monitoring				
119	Does the pharmacy compound low and medium risk CSPs with standard BUDs? ☐ Yes ☐ No ☐ N/A If yes, is environmental monitoring conducted that includes; a) Non-viable Air Monitoring? ☐ Yes ☐ No ☐ N/A b) Viable Air Monitoring? ☐ Yes ☐ No ☐ N/A c) Viable Surface monitoring? ☐ Yes ☐ No ☐ N/A d) In all primary and secondary engineering controls (i.e. hoods, buffer room, ante room and other classified spaces)? ☐ Yes ☐ No ☐ N/A e) Monitoring is conducted at least monthly? **Best Practice** ☐ Yes ☐ No ☐ N/A Draft 247 CMR 17.24 (8)(a)				
120	Does the pharmacy compound low and medium risk CSPs… a) With extended BUDs? ☐ Yes ☐ No ☐ N/A b) Prepared in batches that will be stored in the freezer? ☐ Yes ☐ No ☐ N/A If yes to either (a) or (b), is ***viable air*** monitored… c) In all primary and secondary engineering controls? ☐ Yes ☐ No ☐ N/A d) Monitoring is conducted at least monthly? ☐ Yes ☐ No ☐ N/A If yes to either (a) or (b), is ***non-viable air*** and ***viable surface*** monitored… e) In the primary engineering control utilized for such compounding and buffer room in which that PEC is located? ☐ Yes ☐ No ☐ N/A f) On the day that such compounding occurred? ☐ Yes ☐ No ☐ N/A If yes to either (a) or (b), is ***non-viable air*** and ***viable surface*** monitored… g) In the Ante Room and other classified areas? ☐ Yes ☐ No ☐ N/A h) Monitoring is conducted at least monthly? ☐ Yes ☐ No ☐ N/A Draft 247 CMR 17.24 (8)(b) **Best Practice**				
Item#	**Requirements**	**Yes**	**No**	**N/A**	**Additional Information**

[23] Environmental monitoring of each primary and secondary engineering control is to be conducted in accordance with USP<797> and Draft 247 CMR 17.24.

	Frequency of Monitoring (continued)				
121	Does the pharmacy ensure that environmental monitoring samples are collected from ISO Class 5, then ISO Class 7, and then ISO Class 8? Draft 247 CMR 17.24 (9)				
	General				
122	Does the pharmacy ensure that personnel performing environmental monitoring are qualified and have demonstrated competency and proficiency in all the following sampling techniques? a) media selection, ☐ Yes ☐ No b) media preparation, ☐ Yes ☐ No c) sample collection, ☐ Yes ☐ No d) incubation protocols, ☐ Yes ☐ No e) identification of positive results, ☐ Yes ☐ No f) proper handling of samples for contracted lab distribution, and ☐ Yes ☐ No g) proper disposal of sampling plates ☐ Yes ☐ No h) Proper selection and use of equipment ☐ Yes ☐ No Draft 247 CMR 17.24 (10-11)				
123	If the pharmacy has qualified internal personnel collect environmental monitoring samples, do they validate sampling procedures at least once every six months through a qualified third-party vendor? Draft 247 CMR 17.24 (21) **Best Practice**				
124	Is the equipment used for environmental monitoring maintained and calibrated for use at least annually or more frequently in accordance with manufacturer's specifications? Draft 247 CMR 17.24 (12) **Documentation Required**				
125	Does the pharmacy ensure environmental monitoring samples are incubated at the appropriate temperature and length of time?[24] Draft 247 CMR 17.24 (17)				
126	Does the environmental monitoring for viable organisms include negative controls? Draft 247 CMR 17.24 (18)				
127	Does the pharmacy ensure that all Staphylococcus organisms are identified as coagulase positive or negative? Draft 247 CMR 17.24 (19)				
128	Does the pharmacy utilize a two-plate method for collection of viable air and surface samples?[25] Draft 247 CMR 17.24 (20) **Best Practice**				
129	Does the pharmacy obtain a "Growth Promotion Certificate" for environmental monitoring plates to validate that the media can support microbial growth? Draft 247 CMR 17.24 (22) **Documentation Required**				
130	Does the pharmacy utilize plates intended for environmental monitoring?[26] Draft 247 CMR 17.24 (23)				

[24] Utilize manufacturer specific information when available. If information is not available, the following standards should be followed: Tryptic Soy Agar (TSA) - 86ºF – 95ºF (30ºC – 35°C) for 48-72 hours (2-3 days); Malt Extract Agar (MEA) or Other Differentiating Fungal Media Plates - 78ºF – 86ºF (26ºC – 30°C) for 5-7 days.

[25] One plate shall be a general growth medium and the other plate shall be a medium that specifically supports the growth of fungus.

[26] Sampling plates intended for research only cannot be utilized for environmental monitoring purposes.

Item#	Requirements	Yes	No	N/A	Additional Information
	General (continued)				
131	Does the pharmacy trend routine environmental monitoring results to facilitate decision-making for requalification of a controlled environment, remediation efforts, and for maintenance and sanitization schedules? Draft 247 CMR 17.24 (25) **Documentation Required**				
132	Does the pharmacy ensure its environmental monitoring reports include at a minimum? a) date report prepared; ☐ Yes ☐ No ☐ N/A b) sample collection date and time; ☐ Yes ☐ No ☐ N/A c) type of sample; ☐ Yes ☐ No ☐ N/A d) date sample received by lab; ☐ Yes ☐ No ☐ N/A e) date sample read by the lab; ☐ Yes ☐ No ☐ N/A f) sampling methodology: ☐ Yes ☐ No ☐ N/A g) dates of incubation; ☐ Yes ☐ No ☐ N/A h) identification of sampling locations; ☐ Yes ☐ No ☐ N/A i) sampling conditions (i.e. dynamic); ☐ Yes ☐ No ☐ N/A j) activities taking place in the respective classified areas when samples are taken; ☐ Yes ☐ No ☐ N/A k) media type(s); ☐ Yes ☐ No ☐ N/A l) media lot number, expiration date, and growth promotion confirmation; ☐ Yes ☐ No ☐ N/A m) incubation time and temperatures; ☐ Yes ☐ No ☐ N/A n) results of each sample (raw and calculated CFU count); ☐ Yes ☐ No ☐ N/A o) the identity of each CFU to at least the genus level; and ☐ Yes ☐ No ☐ N/A p) indication that the Manager of Record or his/her pharmacist designee reviewed the environmental monitoring sample collection. ☐ Yes ☐ No ☐ N/A q) Signature of microbiologist on report ☐ Yes ☐ No ☐ N/A Draft 247 CMR 17.24 (26-27) **Documentation Required; Best Practice**				
133	Does the pharmacy test source water, and water at point of use for microorganisms at least quarterly? Draft 247 CMR 17.24 (13) **Documentation Required; Best Practice**				
134	Does the pharmacy utilizing a water purification system ensure the system is properly functioning in accordance with the manufacturer specifications? Draft 247 CMR 17.24 (14) **Documentation Required**				
135	Does the pharmacy utilizing a water filtration system change pre-filters and filters in accordance with manufacturer specifications? Draft 247 CMR 17.24 (15) **Documentation Required**				
	Non-Viable and Viable Air Sampling[27]				
136	Does the pharmacy collect air samples under dynamic operating conditions? Draft 247 CMR 17.25 (1)				
137	Does the pharmacy collect viable air samples with a volumetric air sampling device?[28] Draft 247 CMR 17.25 (2)				
138	Does the pharmacy collect non-viable air samples with an electronic particle counting air sampling device? Draft 247 CMR 17.25 (3)				
Item#	**Requirements**	**Yes**	**No**	**N/A**	**Additional Information**

[27] Non-viable air sampling for each ISO classified area must be conducted in accordance with CAG standards.
[28] A pharmacy cannot utilize passive viable air sampling methodology (i.e. – settling plates) as a means of compliance to Draft 247 CMR 17.25.

	Non-Viable and Viable Air Sampling (continued)				
139	Does the pharmacy sample a minimum volume of 1000 liters of air at each sampling location? Draft 247 CMR 17.25 (5) **Best Practice**				
140	Are the results of viable air samples described as the number of CFU per cubic meter of air sampled? Draft 247 CMR 17.25 (6)				
141	If pharmacy personnel conduct viable air sampling, are positive results evaluated by a microbiologist? Draft 247 CMR 17.25 (6) **Best Practice**				
	Surface Sampling				
142	Does the pharmacy collect surface samples following compounding and prior to cleaning?[29] Draft 247 CMR 17.26 (1) Best Practice				
143	Does the pharmacy utilize the contact plate method to collect surface samples? Draft 247 CMR 17.26 (2)				
144	Does the pharmacy ensure that media used for surface sampling is supplemented with additives to neutralize the effects of disinfecting agents (e.g., TSA with lecithin and polysorbate 80)? Draft 247 CMR 17.26 (3)				
145	Does the pharmacy utilize a 24-30 cm² sized plate to collect and incubate each surface sample? Draft 247 CMR 17.26 (4)				
146	Does the pharmacy clean and disinfect surfaces following collection of a surface sample?[30] Draft 247 CMR 17.26 (5)				
	Action Levels				
147	Does the pharmacy adhere to action levels set forth in USP <797> regarding viable air and surface sampling and non-viable particulate monitoring? Draft 247 CMR 17.27 (3-5)				
148	Does the pharmacy take immediate remedial actions if environmental monitoring results exceed action levels? Draft 247 CMR 17.27 (1) **Documentation Required**				
149	Does the pharmacy conduct a root cause analysis in response to any above action level environmental monitoring result or adverse trend in environmental monitoring? Draft 247 CMR 17.27 (2) **Documentation Required**				
	Remediation of Above Action Level Environmental Monitoring Results				
150	Does the pharmacy… a) maintain a policy and procedure for remediation of above action level environmental monitoring results in accordance with the Board advisory, *Recommended Pharmacy Response to Above Action Level Environmental Monitoring Results?* ☐ Yes ☐ No ☐ N/A b) Report excursion to The Board in a timely fashion? ☐ Yes ☐ No ☐ N/A Draft 247 CMR 17.28 (1) **Best Practice**				

[29] Adequate time should be provided between cleaning of the entire compounding suite (floors, wall, ceilings, storage bins, etc.) and environmental monitoring to ensure worst case scenarios are achieved. Testing in worst case scenarios provides valuable information regarding aseptic work practices, cleaning procedures, and environmental state of control that can foster change and reduce risk.

[30] Outlined in policy and procedures.

Item#	Requirements	Yes	No	N/A	Additional Information
	Cleaning and Disinfecting				
151	Does the pharmacy document each cleaning in a cleaning log that includes the date, time, cleaning agents utilized, and personnel who performed the cleaning? Draft 247 CMR 17.29 (1) **Documentation Required**				
152	Does the pharmacy use mops, wipes, and/or other cleaning equipment that is non-shedding? Draft 247 CMR 17.29 (2)				
153	Does the pharmacy utilize mops or other cleaning equipment that are re-usable and dedicated to the specific classified area(s)? Draft 247 CMR 17.29 (2)				
154	Does the pharmacy ensure that cleaning equipment used in hazardous drug compounding environments are not used in non-hazardous drug compounding environments? Draft 247 CMR 17.29 (3)				
155	Does the pharmacy ensure that personnel who perform cleaning are trained and have successfully passed initial and annual competency assessments conducted by trained and qualified compounding personnel in both of the following areas? a) hand hygiene and garbing; and ☐ Yes ☐ No ☐ N/A b) cleaning and disinfecting. ☐ Yes ☐ No ☐ N/A Draft 247 CMR 17.29 (4)				
156	Does the pharmacy ensure that only trained compounding personnel clean inside an ISO Class 5 work area and that competency assessments on proper cleaning and disinfecting procedures are performed and documented at least one time per year? Draft 247 CMR 17.29 (5)				
157	Does the pharmacy maintain a policy and procedure that describes the cleaning and disinfection of the critical areas where compounding occurs inside an ISO Class 5 environment at the following intervals and specific instances? a) at the beginning of each work shift; ☐ Yes ☐ No ☐ N/A b) between each batch; ☐ Yes ☐ No ☐ N/A c) immediately following any spill; and ☐ Yes ☐ No ☐ N/A d) in the event of, or suspicion of, a breach in compounding procedures or aseptic technique. ☐ Yes ☐ No ☐ N/A Draft 247 CMR 17.29 (6)				
158	Does the pharmacy maintain a policy and procedure that requires compounding personnel to allow sterile 70% isopropyl alcohol ("IPA") to remain in contact with surfaces to be disinfected for 30 seconds before compounding activities are started? Draft 247 CMR 17.29 (7)				
159	Does the pharmacy maintain a policy and procedure that requires compounding personnel to disinfect all rubber stoppers of vials and bottles, the necks of ampules and other items by wiping with sterile 70% IPA and waiting for at least 10 seconds before they are used to prepare CSPs? Draft 247 CMR 17.29 (8)				
160	Do compounding personnel clean horizontal work surfaces daily? Draft 247 CMR 17.29 (9) **Documentation Required**				
Item#	**Requirements**	**Yes**	**No**	**N/A**	**Additional Information**
	Cleaning and Disinfecting (continued)				

160	Does the pharmacy ensure floors are cleaned daily? Draft 247 CMR 17.29 (10) **Documentation Required**				
161	Does the pharmacy ensure the sink drain is sanitized with a disinfectant at least once per week? Draft 247 CMR 17.29 (11) **Documentation Required, Best Practice**				
162	Does the pharmacy ensure that walls, ceilings, storage areas, and supply bins are cleaned at least once per month? Draft 247 CMR 17.29 (12) **Documentation Required**				
163	Does the pharmacy refrain from compounding during daily or monthly cleaning activities? Draft 247 CMR 17.29 (13)				
164	Has the pharmacy verified that its cleaning agents are appropriate and effective against bacteria, viruses, fungi, and/or spores?[31] Draft 247 CMR 17.29 (14) **Documentation Required**				
165	If fatigue mats are utilized within the ISO classified areas, does the pharmacy ensure that both sides are cleaned and disinfected daily and allowed to dry thoroughly before placing them back on the floor?				
	Hand Hygiene and Garbing				
166	Does the pharmacy ensure that compounding personnel remove personal outer garments, jewelry, piercings, cosmetics, artificial nails, and nail polish before entering the ante room? **Note:** Natural nails shall be trimmed to ¼ inch or less. Draft 247 CMR 17.30 (1)				
167	Does the pharmacy maintain a policy and procedure that requires compounding personnel wear clean, laundered scrubs only worn within the facility? Draft 247 CMR 17.30 (2) **Best Practice**				
168	Does the pharmacy maintain a policy and procedure that requires compounding personnel to launder scrubs following each use? Draft 247 CMR 17.30 (2) **Best Practice**				
169	Does the pharmacy have a changing area for sterile compounding personnel to change that minimizes travel through non-classified areas? Draft 247 CMR 17.30 (2) **Best Practice**				
170	Do compounding personnel use dedicated shoes or shoe covers while in classified areas? Draft 247 CMR 17.30 (3) **Best Practice**				
171	Prior to entering an ante room, do compounding personnel don scrubs and dedicated shoes or shoe covers? Draft 247 CMR 17.30 (4); Draft 247 CMR 17.30 (3) **Best Practice**				
172	Once inside the ante room, but prior to crossing the line of demarcation, do compounding personnel perform the tasks in the following order: don a head cover, facial hair cover if applicable, and face mask. While crossing line of demarcation, don shoe covers? Draft 247 CMR 17.30 (5)				

[31] A pharmacy shall maintain a certificate of analysis for each cleaning product, if available.

Item#	Requirements		Yes	No	N/A	Additional Information
	Hand Hygiene and Garbing (continued)					
173	Once on the clean side of the line of demarcation, but prior to entering the buffer room, do compounding personnel perform the tasks in the following order? a) wash hands and forearms to the elbows for at least 30 seconds with antimicrobial soap and water[32]. b) dry with lint-free disposable towels. c) don: 1) a non-shedding disposable coverall for low and medium risk level compounding; **(Best Practice**) or 2) a non-shedding sterile disposable coverall for high risk level compounding. **(Best Practice)** Draft 247 CMR 17.30 (6)	☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A				
174	Once garbing and hand hygiene procedures are completed, do compounding personnel access the buffer room without touching hands on any surface? Draft 247 CMR 17.30 (7)					
175	Once inside the buffer room, do compounding personnel perform antiseptic hand cleansing using a waterless alcohol-based surgical hand scrub with persistent activity following manufacturers' recommendations and allow hands to dry thoroughly before donning sterile powder-free gloves? Draft 247 CMR 17.30 (8)					
176	Do compounding personnel routinely disinfect gloves with sterile 70% IPA after contacting non-sterile objects and after exposure to less than ISO Class 5 air? Draft 247 CMR 17.30 (9)					
177	Do compounding personnel repeat all hand hygiene and garbing activities if they cross the line of demarcation from the clean to the less clean side of ante-room or if exposed to less than ISO Class 8 air? Draft 247 CMR 17.30 (11)					
178	Does the pharmacy ensure that if the non-shedding disposable coverall is removed and retained in the compounding area that it is not visibly soiled and to only be re-donned by the same personnel during that shift? **Note:** All other garb must be discarded and replaced with new garb before entering the compounding area. Draft 247 CMR 17.30 (12)					
179	Do sterile compounding personnel doff garb appropriately to minimize contamination to the ISO classified area?[33] a) Remove gloves; b) Remove mask, goggles, or face shield; c) Remove disposable coveralls; d) Remove dedicated shoes or shoe covers. Draft 247 CMR 17.30 (13) **Best Practice**	☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A				

[32] The hand cleansing procedure shall be performed by removing debris from underneath fingernails using a nail cleaner under warm running water followed by vigorous hand washing.

[33] Gowns to be re-used should be removed on clean side of line of demarcation and maintained in appropriate location to minimize risk for contamination. Gowns not to be reused should be removed on "less" clean side of line of demarcation and discarded upon exit from classified space.

Item#	Requirements	Yes	No	N/A	Additional Information
	Aseptic Technique				
180	Does the pharmacy ensure that food and drinks are not allowed in any ISO Classified area? Draft 247 CMR 17.31 (1)				
181	Does the pharmacy ensure that corrugated cardboard boxes or other particulate producing materials are not stored in any ISO Classified area?[34] Draft 247 CMR 17.31 (2)				
182	Does the pharmacy ensure that paper is not used in an ISO 5 Classified area?[35] Draft 247 CMR 17.31 (3)				
183	Do compounding personnel remove supplies, equipment, and other materials from shipping cartons and cardboard boxes in an unclassified area and wipe said supplies, equipment, and other materials with residue free disinfectant before transporting said items into the ante area and again on the less clean side of the line of demarcation prior to entering the buffer area? Draft 247 CMR 17.31 (4)				
184	Do compounding personnel disinfect all supplies and drug components with an appropriate agent prior to moving said supplies and drug components into the ISO Class 5 compounding area? Draft 247 CMR 17.31 (5)				
185	Are syringes, needles, and tubing removed from their outer wrapper packaging within the ISO Class 5 area only? Draft 247 CMR 17.31 (6)				
186	Do compounding personnel don sterile gloves for all sterile compounding, regardless of the type of PEC? Draft 247 CMR 17.31 (7)				
187	Do compounding personnel inspect sterile-gloved hands and gauntlet sleeves prior to compounding for wear and tear and replace gloves as needed? Draft 247 CMR 17.31 (8)				
188	Do compounding personnel routinely disinfect sterile-gloved hands with sterile 70% IPA prior to entering/re-entering an ISO Class 5 area and after contacting non-sterile objects? Draft 247 CMR 17.31 (9)				
189	Do compounding personnel perform manipulations in the direct compounding area inside of the ISO Class 5 environment in such a way as to not disrupt the flow of first air (HEPA filtered air stream) over critical sites? Draft 247 CMR 17.31 (10)				
190	Do compounding personnel inspect each component for visible particulate matter, tampering, breaks in packaging, water damage or moisture and other changes which would render the item unacceptable for use in sterile compounding? Draft 247 CMR 17.31 (11)				

[34] Corrugated cardboard should not be located directly outside ISO classified spaces to minimize ingress of bioburden and contamination.

[35] The pharmacy should conduct a risk assessment related to the use of paper products (i.e. labels, etc.) within ISO classified areas to ensure procedures to minimize contamination are implemented. Low particulate generating paper products (USP paper) are recommended.

Item#	Requirements	Yes	No	N/A	Additional Information
	Miscellaneous				
191	Does the pharmacy use filtered needles or straws for any compounding involving the use of glass ampules? Draft 247 CMR 17.32 (1)				
192	Does the pharmacy ensure that non-hazardous drug environments are not exposed to hazardous drugs or components in ISO classified areas? Draft 247 CMR 17.32 (3)				
193	Does the pharmacy immediately respond to and remediate any broken, damaged, or spilled CSP? Draft 247 CMR 17.32 (3)				
194	Does the pharmacy ensure all classified areas allow for the orderly placement of equipment and materials to prevent confusion among ingredients, containers, labels, in-process materials, and finished preparations and are designed, arranged, and used to prevent cross-contamination? Draft 247 CMR 17.32 (4)				
	Commercially Available Single and Multiple Dose Vials and Containers				
195	Does the pharmacy discard single dose vials punctured in ISO Class 5 air within 6 hours after puncture? Draft 247 CMR 17.03 (1)				
196	Does the pharmacy ensure that single dose vials punctured in ISO Class 5 environments are not pooled or used to prepare stock solutions to extend BUD beyond 6 hours? [36]. Draft 247 CMR 17.03 (2)				
197	Does the pharmacy ensure that multiple dose vials are discarded within 28 days after initial puncture or as directed by the manufacturer? Draft 247 CMR 17.03 (3)				
	Allergen Extracts as CSPs				
198	Does the pharmacy prepare allergen extracts? ☐ Yes ☐ No If yes… a) Does the pharmacy prepare allergen extracts in an ISO 5 Classified Area located within an ISO Class 7 buffer room or CAI located within a SCA? ☐ Yes ☐ No ☐ N/A b) Does the pharmacy maintain policy and procedures for proper preparation and assignment of BUD and storage of CSPs with allergen extracts? ☐ Yes ☐ No ☐ N/A Draft 247 CMR 17.10 (1 – 3)				
	Sterile Compounding for Veterinary Patients[37]				
199	Does the pharmacy separate drugs, ingredients, and components intended for animal use only from drugs, ingredients, and components intended for human use? Draft 247 CMR 17.11				
200	Does the pharmacy handle and clean compounding supplies and equipment in a manner that prevents cross contamination of animal use only and human use drugs, ingredients, and components? Draft 247 CMR 17.11				

[36] Pooling or preparation of stock solutions is permitted during anticipatory compounding procedures. The single dose vials must be dedicated for the individual procedure and not used for prior patient specific compounding. The procedure must follow a master formulation record, an individual compounding record must be complete, and the procedure must follow all other regulations specific for the type of CSP.

[37] Unless otherwise permitted, does the pharmacy ensure the preparation of CSPs for veterinary patients meet the same standards that apply to CSPs for human patients and they comply with all laws and regulations governing the practice of pharmacy?

Item#	Requirements	Yes	No	N/A	Additional Information
	Implantable Infusion Pumps				
201	Does the pharmacy ensure that BUDs are calculated from the time of compounding and include the time a drug will reside inside an implantable infusion pump reservoir? Draft 247 CMR 17.07 (1) **Documentation Required; Best Practice**				
202	In addition to standard prescription labeling requirements, does the pharmacy include the date of compounding on the label for CSPs prepared for administration by an implantable pump? Draft 247 CMR 17.07 (2)				
	CSPs as Stock Solutions				
203	Does the pharmacy ensure that BUDs applied to intermediate or stock solutions from commercially available sterile components, excluding the pooling of commercially available single dose vials, do not exceed USP standards for medium risk compounding and Draft 247 CMR 17.41? Draft 247 CMR 17.08 (1)				
204	Does the pharmacy ensure that sterilization procedures are conducted immediately when compounding high risk level intermediate or stock solutions?[38] Draft 247 CMR 17.08 (2)				
	CSPs made from Blood-Derived or Biological Material				
205	Does the pharmacy maintain a policy and procedure pertaining to compounding that involves blood-derived or other biological material? Draft 247 CMR 17.09 (1) **Documentation Required; Best Practice**				
206	Does the pharmacy maintain procedures for compounding CSPs using blood-derived or other biological material that require compounding to be separate from routine material-handling procedures and define cleaning of PEC and other equipment used in CSP preparation to avoid cross-contamination? Draft 247 CMR 17.09 (2) **Documentation Required; Best Practice**				
207	After compounding CSPs with blood-derived or other biological material, do compounding personnel: a) thoroughly clean the PEC, equipment, and materials according to the pharmacy's daily cleaning protocol; ☐ Yes ☐ No ☐ N/A b) repeat all hand hygiene and garbing activities; and ☐ Yes ☐ No ☐ N/A c) change garbing. ☐ Yes ☐ No ☐ N/A Draft 247 CMR 17.09 (3) **Documentation Required; Best Practice**				
	CSPs made Blood-Derived or Biological Material				
208	Does the pharmacy immediately respond to and remediate any broken, damaged, or spilled container involving blood-derived or other biological material? Draft 247 CMR 17.09 (4) **Best Practice**				
209	Does the pharmacy maintain a policy and procedure for an immediate and systematic response (i.e. spill kit) to broken, damaged, or spilled container involving blood-derived or other biological material? Draft 247 CMR 17.09 (5) **Documentation Required; Best Practice**				

[38] High risk level intermediate solutions or stock solutions must be sterilized prior to storage. Non-sterilized solutions cannot be stored for future sterilization.

Item#	Requirements	Yes	No	N/A	Additional Information
	Sterile Compounding Personnel Training; General				
210	Do compounding personnel remain outside of ISO classified areas when experiencing active infection and when skin areas are burned, sunburned, or has lesions, abrasions, or cuts? Draft 247 CMR 17.33 (1)				
211	Does the pharmacy ensure all compounding personnel are properly trained in sterile compounding, have successfully completed gloved/thumb fingertip sampling, and have been media-fill qualified for the risk level and type of compounding conducted? Draft 247 CMR 17.33 (2) **Documentation Required**				
212	Does the pharmacy maintain documentation of all training activities, competency assessments, and compounding qualifications? Draft 247 CMR 17.33 (3) **Documentation Required**				
213	Does the pharmacy maintain a written or electronic file for all sterile compounding personnel that contains that individual's job description, roles and responsibilities, documentation of initial and ongoing competency assessments, and documentation of initial and ongoing compounding qualification activities? Draft 247 CMR 17.33 (4) **Documentation Required**				
214	Do compounding personnel, including supervising pharmacists, pass didactic coursework, practical skill assessment through competency evaluation, media fill testing, and gloved fingertip/thumb sampling before being allowed to compound sterile preparations? Draft 247 CMR 17.33 (5) **Documentation Required**				
215	Are compounding personnel requalified in all core competencies if a pause in compounding exceeds three months? Draft 247 CMR 17.33 (6) **Documentation Required; Best Practice**				
216	Does the pharmacy ensure that all compounding personnel, including supervising pharmacists, are evaluated on hand hygiene and garbing, cleaning and disinfecting, and aseptic technique initially and at least once per year for compounding personnel engaged in or overseeing low and medium risk level compounding? Draft 247 CMR 17.33 (7) **Documentation Required**				
217	Does the pharmacy document competency evaluations for all sterile compounding personnel? Draft 247 CMR 17.33 (8) **Documentation Required**				
218	In the event a compounding individual fails a written sterile compounding assessment exam, gloved fingertip/thumb sampling, or media-fill test, does the pharmacy ensure he/she does not compound until he/she is requalified and successfully retested? Draft 247 CMR 17.33 (9) **Documentation Required**				
219	Does the pharmacy send each failed gloved fingertip/thumb sample and media fill sample for microbial identification to the genus level?[39] Draft 247 CMR 17.33 (11) **Documentation Required; Best Practice**				
220	In the event a compounding individual fails a gloved fingertip/thumb sample or media fill sample; does the pharmacy evaluate the CSPs prepared by that individual to detect potential contamination of the CSP? Draft 247 CMR 17.33 (12) **Documentation Required; Best Practice**				

[39] All Staphylococcus organisms must be identified as coagulase positive or negative.

Item#	Requirements	Yes	No	N/A	Additional Information
	General (continued)				
221	Does the pharmacy obtain a "Growth Promotion Certificate" for each lot of media for personnel monitoring to validate that the media can support microbial growth? Draft 247 CMR 17.33 (13) **Documentation Required; Best Practice**				
222	Does personnel monitoring gloved fingertip/thumb sampling include the use of positive and negative controls? Draft 247 CMR 17.33 (14) **Documentation Required; Best Practice**				
223	Do personnel monitoring media fills include the use of negative controls? Draft 247 CMR 17.33 (15) **Documentation Required; Best Practice**				
224	Does personnel monitoring media fills also include the use of positive controls if; a) the pharmacy prepares growth promotion media from non-sterile powder; or ☐ Yes ☐ No ☐ N/A b) growth promotion certificates for media are not available. ☐ Yes ☐ No ☐ N/A Draft 247 CMR 17.33 (15) **Documentation Required; Best Practice**				
225	Does inoculation of positive controls occur outside of the classified areas? Draft 247 CMR 17.33 (16) **Documentation Required; Best Practice**				
	Gloved Fingertip/Thumb Sampling				
226	Does the pharmacy utilize an action level for a gloved fingertip/thumb sample for hand hygiene and gloving of ≥1 CFU for both gloves?[40] Draft 247 CMR 17.34 (1)				
227	Does the pharmacy utilize an action level for a gloved fingertip/thumb sample for aseptic technique performed after compounding of >3 CFU for both gloves? Draft 247 CMR 17.34 (2)				
228	Do all compounding personnel successfully complete at least 3 gloved fingertip/thumb sampling procedures before initially being allowed to prepare CSPs and once annually thereafter. The action level for this gloved fingertip/thumb sample is ≥1 CFU for both gloves. Draft 247 CMR 17.34 (3)				
229	During the initial gloved fingertip/thumb sampling, does the pharmacy ensure fingertip/thumb samples are taken of both gloved hands onto media plates immediately after compounders perform hand hygiene and garbing but before their gloves are cleaned with sterile 70% IPA? Draft 247 CMR 17.34 (4)				
230	Does the pharmacy ensure all gloved fingertip/thumb sampling performed after the initial qualification is performed after compounding? Draft 247 CMR 17.34 (5)				

[40] Any contamination identified on gloved fingertip/thumb samples during initial qualification or during hand hygiene and garbing activities is considered a failure. Re-education, re-training, and re-testing is required and must be documented.

Item#	Requirements	Yes	No	N/A	Additional Information
	Gloved Fingertip/Thumb Sampling (continued)				
231	Does the pharmacy ensure gloved fingertip/thumb sampling is conducted at the following frequencies? a) Compounding personnel shall perform gloved fingertip/thumb sampling at least quarterly. ☐ Yes ☐ No ☐ N/A b) In addition to quarterly gloved fingertip/thumb sampling, an individual who prepares low or medium risk level CSPs with extended BUDs; shall perform gloved fingertip/thumb sampling each day he/she prepares such CSPs. ☐ Yes ☐ No ☐ N/A Draft 247 CMR 17.34 (6) **Documentation Required; Best Practice**				
232	When the pharmacy prepares low and medium risk level CSPs with extended BUDs, do they utilize both a general growth media and a fungal specific growth media for all gloved fingertip/thumb sampling? Draft 247 CMR 17.34 (7) **Best Practice**				
233	Are gloved fingertip/thumb sampling media supplemented with additives to neutralize the effects of disinfecting agents (e.g., TSA with lecithin and polysorbate 80)? Draft 247 CMR 17.34 (8) **Documentation Required**				
234	Does the pharmacy utilize a 24-30 cm^2 sized plate to collect and incubate each gloved fingertip/thumb sample? Draft 247 CMR 17.34 (9)				
235	Does the pharmacy ensure gloved fingertip/thumb samples are incubated at the appropriate temperature and interval based on media type and in accordance with USP <797> and Draft 247 CMR 17? Draft 247 CMR 17.34 (10)				
	Media Fill Challenge Testing				
236	Does the pharmacy ensure compounding personnel who prepare low, medium, and high-risk level CSPs complete the following? a) three (3) media fills before initially being allowed to prepare CSPs; ☐ Yes ☐ No ☐ N/A b) following initial qualification, one (1) media fill at least quarterly; ☐ Yes ☐ No ☐ N/A c) one (1) gloved fingertip/thumb sampling immediately following the last media fill test procedure. ☐ Yes ☐ No ☐ N/A Draft 247 CMR 17.35 (1) **Documentation Required; Best Practice**				
237	Does the pharmacy maintain a master formulation record for the media fill procedure that includes all equipment and steps of the media fill process for each risk level? Draft 247 CMR 17.35 (3) **Documentation Required; Best Practice**				
238	Is the media fill challenge testing performed under conditions that closely simulate the most challenging or stressful conditions encountered during compounding? Draft 247 CMR 17.35 (4) **Best Practice**				
239	Does the pharmacy utilize microbial growth promotion media, such as Soybean-Casein Digest? Draft 247 CMR 17.35 (5)				
240	Does the pharmacy ensure media fill units utilizing general microbial growth promotion media are incubated at 30-35˚C (86-95˚F) for a minimum of 7 days, followed by an incubation at 20-25˚C (68-77°F) for 7 days? Draft 247 CMR 17.35 (6)				

Item#	Requirements	Yes	No	N/A	Additional Information
	Sterile Compounding Equipment				
241	Does the pharmacy clean, maintain, calibrate, and service equipment associated with compounding or used to monitor controlled environments in accordance with manufacturer's specifications? Draft 247 CMR 17.36 (1) **Documentation Required**				
242	Does the pharmacy ensure personnel who use equipment received training, demonstrated the ability to use the equipment properly, and can appropriately respond to an equipment malfunction? Competency assessments shall be performed and documented at least one time per year. Draft 247 CMR 17.36 (2) **Documentation Required**				
243	Does the pharmacy test Automated Compounding Devices ("ACD") for volumetric and gravimetric accuracy at least daily or more frequently in accordance with manufacturer specifications? Draft 247 CMR 17.36 (3) **Documentation Required**				
244	Does the pharmacy have a balance capable of accurately weighing quantities as small as 13 milligrams, and is tested and sealed by the state or local sealer of weights and measures annually? 247 CMR 6.01 (5) (a) (4); (247 CMR 9.01 (1)); Draft 247 CMR 17.36 (4) **Documentation Required** **NOTE:** All new equipment must meet the requirements in Massachusetts General Law: Ch. 98 Section 29.				
245	Does the pharmacy ensure incubators are calibrated and certified to NSIT standards at least annually or more frequently in accordance with manufacturer specifications? Draft 247 CMR 17.36 (5) **Documentation Required**				
246	Does the pharmacy maintain incubators in accordance with manufacturer specifications? Draft 247 CMR 17.36 (6) **Documentation Required**				
247	Does the pharmacy record temperatures of incubator daily? Draft 247 CMR 17.36 (7) **Documentation Required**				
	Sterile Compounding Robotics				
248	Is the pharmacy robotic compounding equipment constructed with a hard-solid cleanable surface that is resistant to degradation by cleaning agents and disinfectants? Draft 247 CMR 17.37 (1)				
249	Is the pharmacy sterile compounding robot utilized to prepare CSPs considered a primary engineering control and maintain unidirectional airflow at the critical site and ISO Class 5 conditions during dynamic operating conditions? Draft 247 CMR 17.37 (2) **Documentation Required**				
250	Does the pharmacy locate the sterile compounding robot in an ISO Class 7 buffer area? Draft 247 CMR 17.37 (3)				
251	Does the pharmacy perform routine maintenance and calibration of the aseptic filling robot at least twice per year or more often if required by the device manufacturer? Draft 247 CMR 17.37 (4) **Documentation Required**				
252	Does the pharmacy maintain a daily record of the accuracy of the sterile compounding robot? Draft 247 CMR 17.37 (5) **Documentation Required**				
253	Does the pharmacist MOR ensure the precision of the sterile compounding robot is maintained and all records are reviewed and any out of specifications are responded to immediately? Draft 247 CMR 17.37 (5) **Documentation Required**				

Item#	Requirements	Yes	No	N/A	Additional Information
	Sterile Compounding Robotics (continued)				
254	Does the pharmacy sterile compounding robot utilize two separate verifications, such as bar code verification, electronic verification, weight verification, radio frequency identification (RFID), or another similar process, to identify ingredients and components during set up and replacement of components? Draft 247 CMR 17.37 (6)				
255	Is the pharmacy sterile compounding robot equipped with the capability to identify all ingredients, components, and volumes to ensure CSPs are accurately prepared and labeled? Draft 247 CMR 17.37 (7)				
256	Does the pharmacy validate the sterile compounding robot maintains sterility of final CSPs through media fill challenges, in accordance with Draft 247 CMR 17.35, Personnel Media-Fill Challenge Testing? Draft 247 CMR 17.37 (8) **Documentation Required**				
257	Does the pharmacy assure that tubing set(s) used for the sterile compounding robot are traced from the source container to the port where it is attached during the initial daily set up and with each change in the source container? Draft 247 CMR 17.37 (9)				
258	Does the pharmacy ensure compounding personnel are trained and demonstrate competency in the use of the aseptic filling robot? Draft 247 CMR 17.37 (10) **Documentation Required**				
259	Does the pharmacy document initial training, as well as annual competency assessments? Draft 247 CMR 17.37 (10) **Documentation Required**				
260	Does the pharmacist in charge or his/her designee validate changes to the sterile compounding robot product database? Draft 247 CMR 17.37 (11)				
261	Does the pharmacist review and document any overrides to alerts from the sterile compounding robot upon final verification? Draft 247 CMR 17.37 (12) **Documentation Required**				
262	Does the pharmacy adhere to manufacturer recommendations pertaining to the maximum time ingredients or components may be stored in the sterile compounding robot? Draft 247 CMR 17.37 (13)				
263	Does the pharmacy document each instance an ingredient or component is added or replaced? Draft 247 CMR 17.37 (13) **Documentation Required**				
264	Does the pharmacy clean and disinfect the critical areas where compounding occurs inside the ISO Class 5 environment of the aseptic filling robot: a) at the beginning of each work shift? ☐ Yes ☐ No ☐ N/A b) immediately following any spill; ☐ Yes ☐ No ☐ N/A c) in the event of, or suspicion of, a breach in compounding procedures or aseptic process? ☐ Yes ☐ No ☐ N/A d) in accordance with manufacturer's specifications? ☐ Yes ☐ No ☐ N/A Draft 247 CMR 17.37 (14) **Documentation Required**				
265	Does the pharmacy properly disinfect all ingredients and components prior to placement in the sterile compounding robot? Draft 247 CMR 17.37 (15)				

Item#	Requirements	Yes	No	N/A	Additional Information
	Sterile Compounding Ingredient and Component Selection				
266	Does the pharmacy store compounding ingredients and components according to manufacturer specifications or USP storage conditions? Draft 247 CMR 17.38 (1)				
267	Does the pharmacy ensure that components are not obtained from a facility that is not registered by the FDA unless said components are not available from any FDA registered facility? In the event a pharmacy obtains components from a facility that is not registered by the FDA, does the pharmacist evaluate the Certificate of Analysis, manufacturer reputation, and the reliability of the source? Draft 247 CMR 17.38 (2)				
268	Does the pharmacy performing high risk level sterile compounding confirm that Active Pharmaceutical Ingredients (APIs) meet the requirements of the federal Food, Drug & Cosmetics Act, § 503a(b)(1)(B)? Draft 247 CMR 17.38 (3)				
269	Does the pharmacy utilize API intended for human-use when compounding CSPs for human patients? Draft 247 CMR 17.38 (4)				
270	Does the pharmacy obtain components utilized in high risk level sterile compounding, including buffers, diluents, excipients, preservatives, and vehicles from commercially available sources if available in the marketplace?[41] Draft 247 CMR 17.38 (5)				
271	Does the pharmacy use commercially available sterile containers and sterile container closure systems if available in the marketplace? Draft 247 CMR 17.38 (6)				
272	Does the pharmacy have a method for tracking on hand quantities of APIs used for sterile compounding?				
	High Risk Level CSPs				
273	The pharmacy does not prepare high risk level CSPs in suspension, emulsion, pellet, metered dose inhaler, or depot form? Draft 247 CMR 17.06 (2)				
274	Does the pharmacy prepare high risk level CSPs with components that the pharmacy sterilized by different sterilization methods? ☐ Yes ☐ No ☐ N/A If yes, is the final patient CSP sterilized prior to dispensing? ☐ Yes ☐ No ☐ N/A Draft 247 CMR 17.06 (3)				
275	The pharmacy does not use lyophilization equipment to prepare drug substances or ingredients used in CSPs? Draft 247 CMR 17.06 (4)				
276	The pharmacy does not compound a component of a CSP from API when a version of that component is commercially available?[42] Draft 247 CMR 17.06 (5)				

[41] A pharmacy may not compound or produce high risk level sterile compounding components, including buffers, diluents, excipients, preservatives, and vehicles, if said products are commercially available.

[42] The use of API in place of commercially available ingredient can only be used when compounding for an individual patient to produce for that patient a significant clinical difference. This difference is to be determined by the prescribing practitioner.

Item#	Requirements	Yes	No	N/A	Additional Information
	High Risk Level CSPs (continued)				
277	Are pre-sterilization procedures for high risk level CSPs, such as weighing and mixing, completed in an ISO Class 8 or cleaner environment? Draft 247 CMR 17.06 (6)				
278	Does the pharmacy sterilize all high-risk level CSPs, including intermediate and stock solutions and ensure that it is tested for sterility in accordance with USP <71>? Draft 247 CMR 17.06 (7); Draft 247 CMR 17.08 (2)				
279	The pharmacy does not dispense high-risk level CSPs without preservatives unless the CSP is dispensed in a single use container and labeled as "single use only?" Draft 247 CMR 17.06 (8)				
280	Does the pharmacy ensure the high-risk level media fill procedure utilizes non-sterile growth media to start and simulates the most complicated high-risk level CSP process? Draft 247 CMR 17.35 (2)				
280	Does the pharmacy preparing high risk level CSPs with extended BUDs, high risk level CSPs prepared in anticipation of a patient specific prescription or order, or high-risk level intermediate or stock solutions also utilize a fungal specific growth promotion media in addition to the general microbial growth promotion media? Draft 247 CMR 17.35 (5)				
282	Does the pharmacy engaged in high risk level compounding have a water purification system for water supplied to the sink used for handwashing? Draft 247 CMR 17.24 (16) **Best Practice**				
283	Does the pharmacy ensure that all compounding personnel, including supervising pharmacists, are evaluated on hand hygiene and garbing, cleaning and disinfecting, and aseptic technique initially and at least semiannually for compounding personnel engaged in or overseeing high risk level compounding? Draft 247 CMR 17.33 (7) **Documentation Required;**				
284	Does the pharmacy ensure gloved fingertip/thumb sampling is conducted at the following frequencies for high risk level compounding? a) At least once per month and each day he/she prepares high risk CSPs with standard BUDs? ☐ Yes ☐ No ☐ N/A b) At least weekly and each day he/she prepares the following CSPs: 1) CSPs with extended BUDs; ☐ Yes ☐ No ☐ N/A 2) CSPs in anticipation of a patient specific prescription or order; or ☐ Yes ☐ No ☐ N/A 3) CSPs as intermediate or stock solutions. ☐ Yes ☐ No ☐ N/A Draft 247 CMR 17.34 (6) **Documentation Required; Best Practice**				
285	When the pharmacy prepares high risk level CSPs do they utilize both a general growth media and a fungal specific growth media for all gloved fingertip/thumb sampling? Draft 247 CMR 17.34 (7) **Best Practice**				

Item#	Requirements		Yes	No	N/A	Additional Information
	High Risk Level CSPs (continued)					
286	Does the pharmacy compound high risk CSPs… a) With standard BUDs? b) With extended BUDs and/or intermediate or stock solutions? If yes to (a), ***viable air*** monitoring is conducted… c) In all primary and secondary engineering controls? d) Monitoring is conducted at least monthly? If yes to (b), ***viable air*** monitoring is conducted… e) In all primary and secondary engineering controls? f) Monitoring is conducted at least weekly? If yes to (a), ***non-viable air*** monitoring is conducted… g) In the primary engineering control utilized for such compounding and buffer room in which that PEC is located? h) At least monthly and prior to compounding on each day that such compounding occurs? If yes to (b), ***non-viable air*** monitoring is conducted… i) In the primary engineering control utilized for such compounding and buffer room in which that PEC is located? j) At least weekly and prior to compounding on each day that such compounding occurs? If yes to (a), ***viable surface*** monitoring is conducted… k) In the primary engineering control utilized for such compounding and buffer room in which that PEC is located? l) At least monthly and at the conclusion of compounding on each day that such compounding occurs? If yes to (b), ***viable surface*** monitoring is conducted… m) In the primary engineering control utilized for such compounding and buffer room in which that PEC is located? n) Monitoring is at least weekly and at the conclusion of compounding on each day that such compounding occurs? If yes to (a), all environmental monitoring (***viable air, non-viable air, viable surface***) conducted… o) In the ante room and other classified areas? p) Monitoring is conducted at least monthly? If yes to (b), all environmental monitoring (***viable air, non-viable air, viable surface***) is conducted… q) In the ante room and other classified areas? r) Monitoring is at least weekly? Draft 247 CMR 17.24 (8)(c-d) **Best Practice**	a) ☐ Yes ☐ No ☐ N/A b) ☐ Yes ☐ No ☐ N/A c) ☐ Yes ☐ No ☐ N/A d) ☐ Yes ☐ No ☐ N/A e) ☐ Yes ☐ No ☐ N/A f) ☐ Yes ☐ No ☐ N/A g) ☐ Yes ☐ No ☐ N/A h) ☐ Yes ☐ No ☐ N/A i) ☐ Yes ☐ No ☐ N/A j) ☐ Yes ☐ No ☐ N/A k) ☐ Yes ☐ No ☐ N/A l) ☐ Yes ☐ No ☐ N/A m) ☐ Yes ☐ No ☐ N/A n) ☐ Yes ☐ No ☐ N/A o) ☐ Yes ☐ No ☐ N/A p) ☐ Yes ☐ No ☐ N/A q) ☐ Yes ☐ No ☐ N/A r) ☐ Yes ☐ No ☐ N/A				

Item#	Requirements	Yes	No	N/A	Additional Information
	Sterilization and Depyrogenation				
287	The pharmacy does not utilize ethylene oxide gas or irradiation to sterilize components, equipment, ingredients, or CSPs? Draft 247 CMR 17.39 (1)				
288	Does the pharmacy ensure that steam sterilization or dry heat sterilization is not used if the CSP can be sterilized using filtration? Draft 247 CMR 17.39 (2)				
289	Does the pharmacy sterilize the final preparation of a high-risk level CSP, even if intermediate or stock solutions were previously sterilized? Draft 247 CMR 17.39 (3)				
290	Does the pharmacy depyrogenate all glassware and containers, able to withstand dry heat, utilized for sterile compounding with dry heat? Draft 247 CMR 17.39 (4)				
	Sterilization by Filtration				
291	Does the pharmacy perform sterilization by filtration in an ISO Class 5 environment using sterilizing (pharmaceutical) grade, pyrogen-free, 0.2-micron sterile filters? Draft 247 CMR 17.39 (5)				
292	Does the pharmacy perform and document a filter integrity test (such as bubble point) after the compounding procedure? Draft 247 CMR 17.39 (5)				
293	Does the pharmacy utilize sterile filters that are intended for human-use applications in sterilizing CSPs and suitable for the intended use? Draft 247 CMR 17.39 (5)				
	Sterilization by Dry Heat and Steam				
294	Does the pharmacy ensure that dry heat sterilization is not utilized if the materials can be sterilized using steam? Draft 247 CMR 17.39 (6)				
295	Does the pharmacy pass CSPs through a filter with a nominal pore size not larger than 1.2 µm immediately prior to filling containers that will undergo terminal dry heat sterilization or steam sterilization? Draft 247 CMR 17.39 (6)				
296	Prior to steam sterilization, does the pharmacy tightly wrap plastic and glass in low particle shedding paper or sealed in envelopes that prevent post sterilization microbial penetration? Draft 247 CMR 17.39 (6)				
	Dry Heat Ovens and Steam Sterilizers				
297	Does the pharmacy ensure that dry heat ovens or steam sterilizers are not located in a buffer room? Draft 247 CMR 17.39 (7)				
298	Does the pharmacy ensure each dry heat oven and steam sterilizer operates properly and in accordance with manufacturer specifications pertaining to required temperatures, sterilizing cycle time, depyrogenation cycle time, loading patterns, loading capacity, temperature monitoring, placement of thermocouplers or other temperature sensing device, use of biological indicators and endotoxin challenge vials, and filter integrity testing, as applicable? Draft 247 CMR 17.39 (7)				
Item#	**Requirements**	**Yes**	**No**	**N/A**	**Additional Information**

	Dry Heat Ovens and Steam Sterilizers (continued)				
299	Does the pharmacy verify the effectiveness of each dry heat sterilization, dry heat depyrogenation, and steam sterilization process using appropriate Biologic Indicators or Endotoxin Challenge Vials in accordance with USP Chapter <1035>? Draft 247 CMR 17.39 (7)				
300	Does the pharmacy ensure dry heat ovens and steam sterilizers are equipped with a system for controlling and recording temperature and exposure time? Draft 247 CMR 17.39 (7)				
301	Does the pharmacy maintain a log of temperature and exposure time for each use of the dry heat oven or steam sterilizer?[43] Draft 247 CMR 17.39 (7)				
	Sterility and Endotoxin Testing				
302	Does the pharmacy conduct sterility testing on the following types of CSPs? a) CSPs with extended BUDs, regardless of risk level; ☐ Yes ☐ No ☐ N/A b) high risk CSPs prepared in anticipation of a patient specific prescription or order; ☐ Yes ☐ No ☐ N/A c) high risk intermediate or stock solutions; ☐ Yes ☐ No ☐ N/A d) high risk level CSPs exposed longer than 12 hours at refrigerated temperature 2-8 ºC (36-46 ºF) before being sterilized; and ☐ Yes ☐ No ☐ N/A e) high risk level CSPs exposed longer than 6 hours at room temperature 8 ºC (46 ºF) before being sterilized. ☐ Yes ☐ No ☐ N/A Draft 247 CMR 17.40 (1)				
303	Does the pharmacy ensure that CSPs requiring sterility testing are not dispensed until and unless it receives negative sterility testing results? Draft 247 CMR 17.40 (2)				
304	Does the pharmacy utilize both a general growth media for bacteria and a fungal specific media for all high-risk level CSP sterility tests? Draft 247 CMR 17.40 (3)				
305	Does the pharmacy conduct sterility testing and test the proper number of articles in accordance with USP Chapter <71>? Draft 247 CMR 17.40 (4)				
306	Does the pharmacy send each failed sterility test specimen for microbial identification to at least the genus level?[44] Draft 247 CMR 17.40 (5); **Best Practice**				
307	Does the pharmacy conduct bacterial endotoxin assay testing according to USP Chapter <85> on all high-risk level CSPs? Draft 247 CMR 17.40 (6)				
308	Does the pharmacy ensure that CSPs requiring endotoxin testing are not dispensed until it receives endotoxin testing results within limits in accordance with USP <85>? Draft 247 CMR 17.40 (7)				
Item#	**Requirements**	**Yes**	**No**	**N/A**	**Additional Information**
	Sterility and Endotoxin Testing (continued)				

[43] The log shall be readily retrievable and maintained for at least 2 years.
[44] All Staphylococcus organisms must be identified as coagulase positive or negative.

309	Does the pharmacy conduct bacterial endotoxin testing in accordance with USP Chapter <85>? Draft 247 CMR 17.40 (8) **Documentation Required**					
310	Does the pharmacy conducting sterility and endotoxin testing internally, ensure; a) personnel are trained through an accredited certificate program; b) and that the pharmacy utilizes an accredited laboratory to conduct sterility and endotoxin testing at least once per quarter? Draft 247 CMR 17.40 (9) **Documentation Required; Best Practice**	☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A				
311	Does the pharmacy initiate an investigation and document a Corrective Action Preventative Action (CAPA) for any out of specification product testing results? Draft 247 CMR 17.40 (10) **Documentation Required**					
	Storage and Beyond-Use-Dating ("BUD")					
312	Does the pharmacy ensure that BUDs applied to CSPs are appropriate for the risk level of compounding conducted and the location for which compounding occurs? Draft 247 CMR 17.41 (1-2); Draft 247 CMR 17.05; Draft 247 CMR 17.12					
313	Does the BUD assignment begin on the date the pharmacy prepared the CSP? Draft 247 CMR 17.41 (3)					
314	Does the pharmacy maintain onsite scientific evidence that the CSP remains potent, stable, and sterile under specified storage conditions when applying BUDs that exceed USP <797> standards and Draft 247 CMR 17 regulations? Such evidence may be from relevant and reliable sources or direct testing. Draft 247 CMR 17.41 (4) **Documentation Required**					
315	Does the pharmacy ensure BUDs assigned to low or medium risk level CSPs do not exceed 90 days from the date of compounding? Draft 247 CMR 17.41 (5) **Best Practice**					
316	Does the pharmacy ensure that BUDs assigned to high-risk level CSPs do not exceed 45 days from the date of compounding? Draft 247 CMR 17.41 (6) **Best Practice**					
317	Does the pharmacy assign a new BUD if the storage conditions change that does not exceed the original BUD or the maximum BUD for the new storage temperature, whichever period is shorter? Draft 247 CMR 17.41 (7)					
318	Does the pharmacy ensure that BUDs assigned to a CSP do not exceed the expiration date of any component or BUD of any intermediate or stock solution CSP used to produce the final patient CSP? Draft 247 CMR 17.41 (8)					
319	Does the pharmacy ensure that CSPs prepared outside of a classified area are solely intended for immediate use in an emergent or urgent situation in accordance with USP <797>? Draft 247 CMR 17.04					
320	Does the pharmacy utilize freezer units that freeze CSPs to a frozen state? Draft 247 CMR 17.41 (9)					

Item#	Requirements	Yes	No	N/A	Additional Information
	Packaging and Preparation Containers				
321	Does the pharmacy verify and document the impact of freezing and thawing CSPs on product sterility, stability, potency, container/vial membrane, and container closure systems initially before compounding and whenever there is a change to the container closure system, components, or process? Draft 247 CMR 17.42				
	Inventory Storage and Handling; Delivery of CSPs				
322	Does the pharmacy conduct testing, such as a shipping validation study, to ensure the methods used to package and transport CSPs from the pharmacy to the patient do not damage the CSP and maintain appropriate temperatures during transit? Draft 247 CMR 17.47 (1) **Documentation Required**				
323	Does the pharmacy store finished CSPs and drug components separate from food or specimens? Draft 247 CMR 17.47 (2)				
324	Does the pharmacy verify that packaging, containers, and materials maintain physical integrity, sterility, stability, and purity of CSPs? Draft 247 CMR 17.47 (3)				
	Master Formulation Records				
325	Does the pharmacy maintain and follow a master formulation record for the following types of CSPs? a) high risk level CSPs; ☐ Yes ☐ No ☐ N/A b) low or medium risk level CSPs with extended BUDs; ☐ Yes ☐ No ☐ N/A c) low or medium risk level CSPs compounded in anticipation of a patient specific prescription or order; ☐ Yes ☐ No ☐ N/A d) allergen extracts as CSPs; ☐ Yes ☐ No ☐ N/A e) media fill challenge testing; and ☐ Yes ☐ No ☐ N/A f) CSPs prepared by a sterile compounding robot. ☐ Yes ☐ No ☐ N/A Draft 247 CMR 17.43 (1) **Documentation Required**				
326	Does the pharmacy verify each master formulation record to ensure CSPs compounded pursuant to that master formulation record are stable and sterile and have the correct potency: a) upon the creation of the master formulation record; ☐ Yes ☐ No ☐ N/A b) at least annually for high risk CSPs; ☐ Yes ☐ No ☐ N/A c) upon any change in product, process, equipment, or supplies; ☐ Yes ☐ No ☐ N/A d) at least quarterly for high risk CSPs with extended BUDs or intermediate or stock solutions. ☐ Yes ☐ No ☐ N/A Draft 247 CMR 17.43 (1) **Documentation Required; Best Practice**				
327	Does the pharmacy utilize a qualified professional to conduct the stability, sterility, and potency tests? Draft 247 CMR 17.43 (1)				

Item#	Requirements		Yes	No	N/A	Additional Information
	Master Formulation Records					
328	Do all master formulation records include? a) the risk level of compounding; b) all ingredients; c) detailed compounding processes; d) BUD assignment; e) all equipment; f) the primary and secondary engineering controls utilized; g) product testing including sterility, stability, and potency, as applicable; h) quality control procedures including final release checks; i) depyrogenation and sterility procedures and validations, as applicable; j) compounding personnel; k) garbing protocol; l) endotoxin limit, as applicable; m) storage conditions; and n) container closure system. Draft 247 CMR 17.43 (1) **Documentation Required**	☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A				
	Compounding Record					
329	Does the compounding record include the following? a) official or assigned name, strength, and dosage of the preparation; b) reference to the master formulation record, if applicable; c) any deviation to the master formulation record, if applicable; d) names and quantities of all ingredients; e) all calculations; f) sources, lot numbers, and expiration dates of all ingredients and components; g) total quantity compounded; h) name of the person who prepared the preparation and name of the pharmacist who verified the preparation; i) identity of any automated compounding device, if applicable; j) date and time of preparation; k) lot number, if applicable; l) prescription or order number; m) assigned BUD; n) duplicate container label if prepared in a batch; o) identification of the specific PEC where the CSP was compounded. Draft 247 CMR 17.44 (1) **Documentation Required**	☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A				

Item#	Requirements		Yes	No	N/A	Additional Information
	Verification of Compounding Accuracy; Release Checks					
330	Does the pharmacist perform a release check that includes verification of the following? a) correct fill volume and quantity; b) drug identity and strength; c) the CSP matches the compounding record, master formulation record, and prescription or order, as applicable; d) the ingredients measured during compounding; e) packaging; f) labeling; and g) expected physical appearance. Draft 247 CMR 17.45 (1) **Documentation Required**	☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A				
331	Does the pharmacy complete a compounding record each time he/she prepares a CSP? Draft 247 CMR 17.44 (3)					
332	Does the pharmacy review the compounding record for accuracy and completeness? Draft 247 CMR 17.44 (3)					
333	Does the pharmacist verify the compounding record prior to releasing to inventory or dispensing the CSP?[45] Draft 247 CMR 17.44 (3)					
334	Does the pharmacist verify that the compounding record followed the master formulation record, if applicable, to ensure that errors did not occur in the compounding process and that the preparation is suitable for use? Draft 247 CMR 17.44 (4)					
335	After compounding is completed, does the pharmacist visually examine each CSP for the presence of particulate matter with a lighted white and black background or high intensity LED light, unless the CSP is light sensitive? Draft 247 CMR 17.45 (2)					
336	Does the pharmacist visually inspect CSPs for container closure integrity and any other potential defect? Draft 247 CMR 17.45 (3)					
337	If CSPs are not distributed immediately after compounding and are stored in the pharmacy, does the pharmacist perform a pre-release check prior to dispensing to ascertain container defects, damage, particulates, or other unexpected and undesirable circumstance?[46] Draft 247 CMR 17.45 (4) **Documentation Required**					
338	In the event a CSP does not pass a release check, does the pharmacy: a) quarantine the CSP? b) perform a root cause analysis? and c) document the results of the root cause analysis and remediation plan? d) Document issue on defective drug log[47]? Draft 247 CMR 17.45 (5); M.G.L c.112 §39D(e) (1-7) **Documentation Required**	☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A				
Item#	**Requirements**		**Yes**	**No**	**N/A**	**Additional Information**
	Verification of Compounding Accuracy; Release Checks (continued)					

[45] Verification is done with a physical signature and date conducted written on the compounding record.

[46] Pre-release checks are required for intermediate or stock solutions upon completion of compounding and prior to storage.

[47] A defective drug preparation log documenting the recalled drug preparation shall be kept by the pharmacy including information on (1) the drug preparation name, potency and dosage form; (2) the reason for the recall; (3) the amount of the drug preparation made; (4) the date that the drug preparation was made; (5) the amount of the drug preparation dispensed or distributed; (6) the actual drug preparation potency and dosage form; and (7) any and all serious adverse drug events related to the drug preparation in question. The defective drug preparation log shall be made available to the board within 7 days of the recall and shall be kept on record for at least 10 years. Upon submission of the defective drug preparation log to the board, the pharmacy shall work with the board to develop a corrective action plan that rectifies the error that resulted in the defective drug preparation.

339	Does the pharmacy immediately recall any CSP that is contaminated or defective or suspected to be contaminated or defective? Draft 247 CMR 17.51 **Documentation Required**					
	Labeling					
340	In addition to standard prescription labeling requirements, does the pharmacy include the following information on the label or container of each CSP: a) Beyond Use Date ("BUD"); b) batch or lot number of anticipatorily prepared CSPs; c) storage and handling information; and d) the statement, "this is a sterile compounded drug preparation." Draft 247 CMR 17.46	☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A				
	Drug Utilization Review and Patient Counseling[48]					
341	Does the pharmacist or pharmacy intern perform a Drug Utilization Review in accordance with 247 CMR 9.07? Draft 247 CMR 17.48 (1)					
342	In addition to the counseling described in M.G.L. c. 94C, § 21A, does counseling on a CSP include the proper use, possible side effects, storage, handling, and disposal of the medication, as applicable? Draft 247 CMR 17.48 (2)					
343	Does the pharmacist or pharmacy intern instruct the patient or the patient's agent to report any adverse event related to the CSP to the compounding pharmacy? Draft 247 CMR 17.48 (3)					
344	Does the pharmacist or pharmacy intern instruct the patient or patient's agent to observe and report any changes in the physical characteristics of the CSP to the pharmacy? Draft 247 CMR 17.48 (4)					
	Quality Assurance ("QA") Program					
345	Does the pharmacy maintain a formal, written Quality Assurance Program in accordance with USP <1163> and 247 CMR 15.00? Draft 247 CMR 17.49					

[48] Draft 247 CMR 17.48 (5) - Draft 247 CMR 17.48(2) - (4) do not apply to institutional sterile compounding pharmacies.

Item#	Requirements		Yes	No	N/A	Additional Information
	Sterile Compounding Policies and Procedures					
346	Does the pharmacy maintain a written policy and procedure pertaining to the following? a) aseptic technique; b) hand hygiene and garbing processes; c) compounding procedures specific to each risk level; d) environmental monitoring, including non-viable air and viable air and surface testing; e) proper storage, handling, shipping, packaging, transportation, and delivery of CSPs; f) assignment of BUD; g) final release checks and verification of all CSPs; h) response (i.e. spill kit) to broken, damaged, or spilled CSPs; i) proper waste handling and disposal. j) Quality Assurance Program, including RCA and CAPA; k) personnel monitoring, including gloved fingertip/thumb sampling and media fill challenge testing; l) ISO classified area monitoring, including airflows and pressure differential monitoring and temperature and humidity monitoring; m) maintenance, calibration, and cleaning intervals for all pieces of equipment; n) change control, including planning, implementation, and validation of new or changed facilities, equipment, or processes; o) patient monitoring in response to suspected or identified problems with CSPs or reported adverse events; p) patient monitoring and adverse event reporting; q) sterilization and depyrogenation processes, as applicable; r) sterility and endotoxin testing, as applicable Draft 247 CMR 17.50 **Documentation Required; Best Practice**	☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A				

I have participated in a sterile compounding audit and have reviewed the audit 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. **Date Due:**_____

Print Name: _____ **Signature:** _____

Title: _____ **License Number:** _____

Inspector: _____ **Date:** _____

Inspector: _____ **Date:** _____

Inspector: _____ **Date:** _____

Comments: