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1	**Tennessee Board of Pharmacy GAP Analysis**										
3	**Sterile Compounding Pharmacy Inspection**										
4		Business or Corporation:			Telephone Number:				Date:		
5		DBA:			Fax Number:				Start Time:		
6		Address:			Pharmacy Hours:				End Time:		
7		City:					Inspector(s):				
8		State and Zip Code:									
9		Pharmacy Web site:									
10		Pharmacy E-mail:									
11		Name of the PIC:									
12	**Licensure Information for State of Residence and Federal (DEA, FDA, etc.)**										
13		License/Registration Agency:		License/Registration Type:		Business Name on License/Registration:			License/Registration Number:		Expiration Date:
14											
15											
16											
17											
18											
19											
20											
21		Inspector Notes:									

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22	**Type of practice (select all that apply)**					**Facility**			**Personnel**		
23		Traditional Retail		Mail Order		Size of Facility **(in Square Feet)**:			Total Pharmacists:		
24		HMO/PBM only		Central Fill/Processing		Size of Nonsterile Compounding Area:			Total Technicians:		
25		Institutional		Internet Pharmacy		Size of Sterile Clean Room/Buffer Room:			Interns/Students:		
26		Closed Door		Telepharmacy		Size of Ante-Room:			Other Personnel:		
27		Open to the Public		Wholesale Distributor		Total Prescriptions per Day Dispensed:			Compounding Pharmacists:		
28		Provide products for "Office Use"		Manufacturer		Total Orders per Day Distributed:			Compounding technicians:		
29											
30		Inspector Notes:									

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50	General Administrative						Y/N/?/NA	Note			
51	1.0	Is the most recent Board of Pharmacy inspection report(s) available to review?									
52	2.0	Are there any prior deficiencies corrected?									
53	3.0	Does the pharmacy hold ANY wholesale distributor or manufacturer licenses? *List the licenses.*									
54	4.0	Is the pharmacy licensed in any other state as a non-resident pharmacy? *List states.*									
55	5.0	Has this pharmacy been inspected by any other state for which it holds a license? *If so, note the state and date of inspection.*									
56	6.0	Is the pharmacy operating under an exemption or restriction granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If so, note the exemption or restriction.*									

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57	7.0	Is the pharmacy operating under a waiver or variance granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If so, note the waiver or variance.*									
58	8.0	Has the pharmacy been inspected **under current ownership** by the Drug Enforcement Agency (DEA)? *If so, indicate inspection date.*									
59	9.0	Has the pharmacy been inspected **under current ownership** by the Federal Drug Administration (FDA)? *If so, indicate inspection date.*									
60	10.0	Are your compounded sterile products (CSPs) for DISTRIBUTION listed with the FDA?									
61	11.0	Do you have NDC numbers for your CSPs for DISTRIBUTION if required?									
62	12.0	Have FDA warning letters or guidance documents been addressed to now be in compliance?									
63	13.0	Is there appropriate licensure to have employees or contract personnel who act as representatives (for example sales forces) for the CSPs? *If so, indicate if they provide samples of products. Provide a list of these samples.*									
64	14.0	Does the pharmacy hold any accreditations (DMEPOS, VIPPS, VAWD, Vet-VIPPS, PCAB, etc.)? *If so, indicate which in notes.*									

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65	15.0	Are all pharmacy accreditations or certifications, obtained by the current owner, in good standing? If not, list any suspensions or revocations and why.									
66	16.0	Are policies and procedures (P&Ps) available regarding the compounding, dispensing, delivery, storage, and use of prescription products and include the handling of hazardous or infectious waste or spills? *Indicate if hard copy or on- line.*									
67	17.0	Are the P&Ps reviewed and updated regularly by the PIC? *Describe procedure including frequency of review and by whom.*									
68	18.0	Does the pharmacy have appropriate compounding references including USP Chapter 797, injectable drug compatibility, hazardous materials references? List references and indicate if hard copy or electronic.									
69		Inspector Notes:									
70											

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71	General Operations *If any part of a question is no, answer the whole question "no" and explain the observation.*						Y/N/?/NA	Note			
72	19.0	Does the pharmacy dispense compounded prescriptions pursuant to a prescription? *View record for legitimate prescription including a complete patient profile (allergies, disease states, other prescriptions and over the counter meds taken, etc.) and DUR performed. Watch for "list " of patients where the compounded product is delivered to the practitioner and no patient profile kept and no DUR performed.*									
73	20.0	Does the pharmacy distribute compounded products to practitioners, hospitals, clinics, or surgery centers for office use in a compliant manner?									
74	21.0	Does the pharmacy distribute ***controlled substance*** compounded products to practitioners, hospitals, clinics, or surgery centers for office use in a compliant manner?									
75	22.0	Are quarterly sterile compounding reports current and been submitted to the Board office? (view copy of report)									
76	23.0	If the pharmacy compounds for animals, does the compounding meet the same standards as compounding for human patients?									
77	24.0	Does the pharmacy compound allergen extracts?									
78	25.0	Does the pharmacy compound radiopharmaceuticals?									
79	26.0	Does the pharmacy compound any vitamin supplements (i.e., Fe, MVI)?									
80	27.0	Does the pharmacy compound using Active Pharmaceutical Ingredients (APIs) *Non-sterile bulk powders for CSPs?*									
81	28.0	Does the pharmacy purchase APIs directly from the FDA approved supplier? *If not, indicate the source of APIs.*									
82	29.0	Are Certificates of Analysis (COAs) obtained for all APIs? *Are COAs domestic or foreign in origin?* **If COA is not obtained from an approved supplier, continue to next question. If COA is obtained, skip to question 35.0** *Select several products from the shelf and ask to see the COAs for those products.*									
83	30.0	Does the pharmacy perform appropriate testing/analysis of API if required? *If so, indicate what tests are performed if in house or sent to an outside lab - indicate lab in notes.*									
84	31.0	If the source is a foreign FDA facility, does the pharmacy obtain information on the last FDA inspection of that facility and a copy of the report?									

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85	32.0	Is labeling appropriate on APIs?									
86	33.0 P20	Are all APIs labeled with the ***date they were received and an expiration date?***									
87	34.0	If an expiration date is not listed on the product or ingredient to be used in sterile compounding, is it used within one year of being received unless testing or other proof is documented that quality and purity are retained?									
88	35.0	Does the pharmacy repackage APIs into smaller containers for ease of use? *If so, how is the expiration date determined for the repackaged product?*									
89	36.0	Does the pharmacy make a copy of an approved product? *The reason why does not affect the yes/no answer but can be indicated in the comments. For example, if a product is in short supply.*									
90	37.0 P. 4-5	Are products to be compounded appropriately identified as **low-risk**? 1. Not more than three sterile drug packages used 2. Sterile equipment 3. Compounded in an ISO Class 5 hood in an ISO Class 7 clean room (if ISO Class 5 hood NOT in ISO Class 7 clean room, max BUD 12 hours) 4. Limited basic closed system aseptic transfers and manipulations									
91	38.0 P. 5,6	Are products to be compounded appropriately identified as **medium-risk**? 1. Uses four or more sterile ingredients 2. Complex aseptic manipulations other than single volume transfer 3. CSP is to be administered to multiple patients or to one patient on multiple occasions 4. Compounding process of unusually long duration (dissolution, homogeneous mixing)									
92	39.0 P6	Are products to be compounded appropriately identified as **high-risk**? 1. Made with nonsterile ingredients, nonsterile devices, or nonsterile containers 2. Prepared with sterile ingredients but exposed to <ISO Class 5 air 3. Greater than a six-hour delay before sterilization 4. Purity of components assumed but not verified									

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93	40.0 P7	Are **immediate use** compounds appropriately identified? 1. Aseptically compounded 2. Simple transfer ≤ 3 commercially manufactured non-hazardous products 3. Not > 2 entries into any container 4. Admin begins ≤ 1 hour from start of compounding									
94	41.0 P7, 8	Are products to be compounded appropriately identified as **hazardous and labeled as such**? *National Institute for Occupational Safety and Health list of drugs. Hazardous drugs exhibit: carcinogenicity, teratogenicity, or other developmental toxicity, reproductive toxicity, organ toxicity at low dose, or genotoxicity.*									
95	42.0 P22,23	Does the pharmacy compound its own stock solutions or components that are then used to compound a finished product? *If so, how are BUDs determined?*									
96	43.0	Are all compounded stock solutions that will be used as a component of a finished product tested for sterility and stability if used beyond acceptable USP 797 BUD? *Explain process.*									
97	44.0	When using its own compounded stock solution, is it used without dilution in a final preparation (repackaged as-is into smaller or unit-of-use packages)? *If so, are these preparations given extended BUDs? How is the BUD determined?*									
98	45.0	When using its own compounded stock solution, is it used as a component of a preparation (made less concentrated by the addition of a diluent or other component)? *If so, are these preparations given extended BUDs? How is the BUD determined?*									
99		Inspector Notes:									

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100	**Primary Engineering Controls** **part of a question is no, answer the whole question "no" and explain the observation.**					**If any**	**Y/N/NA**	**Note**			
101	46.0	1.) Is the Primary Engineering Control (PEC) located within a restricted ISO Class 7 buffer area?									
102	47.0	**Is the PEC a CAI or CACI designed to maintain an aseptic compounding environment "within itself"? If yes, then answer the following questions and complete the applicable parts of the document . If no, proceed to question 52.0 below and complete the applicable parts of the document.**									
103	48.0 P13	1. Does the CAI/CACI provide isolation from the room and maintain ISO Class 5 under dynamic conditions including transferring of ingredients, components, and devices into and out of the isolator and during preparation of CSPs? NOTE: for certification, particle counts must be sampled approximately 6 to 12 inches upstream of the critical exposure site.									
104	49.0 P13	2. Does the pharmacy have documentation from the manufacturer that the CAI or CACI will meet this standard when located in worse than ISO Class 7 environments?									
105	50.0 P13	3. Is the CAI or CACI located in an area that is maintained under sanitary conditions and only be traveled by persons engaging in the compounding of sterile preparations?									
106	51.0 P28	4. For hazardous compounding in a CACI that is NOT located in a buffer area, is the CACI located in a physically separated area that maintains a negative pressure of 0.01" water column pressure to adjacent areas and a minimum of 12 ACPH?									
107	52.0	If the PEC is an LAFW, or BSC is located outside of an ISO Class 7 environment, are all of the following yes?									
108	53.0 P5	1. Is compounding restricted to low-risk preparations with a maximum BUD of 12 hours?									
109	54.0 P16	2. Are all garbing requirements adhered to?									

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110	55.0 P12	3. Is the LAFW located in an area that is maintained under sanitary conditions and only traveled by persons engaging in the compounding of sterile preparations?									
111	56.0 P5	4. Is the location free from any unsealed windows or doors that connect to the outdoors or areas of high traffic flow, or are adjacent to construction sites, warehouses, or food preparation areas?									
112	Environment ***If any part of a question is no, answer the whole question "no" and explain the observation.***						Y/N/NA	Note			
113	57.0 P10,11	If the facility performs both sterile and nonsterile compounding, are the areas separated and distinct?									
114	58.0 P7	Is entry into the sterile compounding areas limited to task critical employees (limited to only the pharmacist(s) and other trained and authorized personnel under the pharmacist's supervision and discussed in the pharmacy SOP)?									
115	59.0 P15	Does the ante-room have a line of demarcation or other separation of the dirty to the clean side?									
116	60.0 P19	Are carts used to bring supplies from the storeroom kept on the outside of the line of demarcation?									
117	61.0 P19	Are carts used in the clean room/buffer room kept on the clean side of the line of demarcation?									
118	62.0 P16,17	If performing sterile compounding, is appropriate attire available and being used?									
119	63.0 P31	Are all surfaces of the sterile product compounding area carts, shelves, stools, chairs, and other items resistant to disinfectants, non-permeable, non-carpeted or upholstered, and low particulate generating?									
120	64.0 P12	Are walls painted with epoxy based paint or other impermeable surface, and are they seamless or have sealed seams where panels meet and corners with no cracks?									

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121	65.0 P12	Are the ceiling tiles composed of a vinyl surface, with the tiles caulked and sealed and are the seams where the walls meet the ceiling caulked and sealed? *If no, describe what is present.*									
122	66.0 P12	Is the floor overlaid with wide sheet flooring and seamless or with heat welded seams, with coving to the sidewall, and a sealed seam where the coving meets the wall? *If no, describe what is present.*									
123	67.0 P12	Is the clean room or ante-room free from dust collecting overhangs, such as ceiling utility pipes, or ledges? *Are all sprinkler heads flush with the ceiling?*									
124	68.0 P12	Are the exposed surfaces of the light fixtures smooth, mounted flush, and sealed?									
125	69.0 P15	Is there a sink with hot and cold running water located in the ante room or near the sterile compounding area that enables pharmacy personnel to wash hands and enter the sterile compounding area without contaminating his/her hands, and is there an eyewash station?									
126	70.0 P30	Is the pharmacy compliant in having no sink or floor drain in the clean room or buffer room area? A yes answer means pharmacy is in complaince)									
127	71.0 P10,11	Are all air ducts controlling air flow into the sterile compounding area equipped with High Efficiency Particulate Air filtered air that maintains the cleanroom with an ISO Class 7 environment?									
128	72.0 P12	Are incoming air ducts through HEPA filters on or near the ceiling and are air return ducts low on the walls to facilitate turbulent air flow in the ante-room and clean room?									
129	73.0 P19	Is there limited or absense of use of any particle generating equipment (computers, refrigerators, etc.) in the clean room/buffer room or anteroom? *If so, indicate equipment and room and if cleanroom certification was passed while items were in use.*									
130	74.0 P12	If there is particle generating equipment in the clean room or ante-room, is the equipment located by an air return so air flows over and out of the room taking particles with it, and has this air flow been confirmed by smoke testing? *View certification report for the room and specifically look at particle counts taken in the area of the equipment.*									

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131	75.0 P15	Are coffee, water, chewing gum, candy, or food items prohibited from the clean room/buffer area or ante-room?									
132	76.0 P27	Are sterile compounded products prepared with aseptic manipulations entirely within ISO Class 5 or better air quality hood or shielded laminar flow work area using only sterile ingredients, products, components, and devices?									
133	77.0 P9,10	Does the pharmacy have appropriate equipment to sterilize the finished product if appropriate?									
134	78.0 P31	Is the ISO Class 5 compounding area located within an ISO Class 7 clean room or buffer area?									
135	79.0	Does the ISO Class 7 clean room or buffer area door lead into an ISO Class 7 or 8 ante room? *Indicate if the ante room is ISO Class 7 or 8.*									
136	80.0 P8	Is the ISO 7 clean room positive pressure to the ISO 7 or 8 ante room? *Record pressure differential.*									
137	81.0 P8	Is the hazardous compounding room and hazardous drug storage area negative pressure to the ISO 7 ante room? *Record pressure differential.*									
138	82.0	Is the ISO Class 7 or 8 ante room positive pressure to the general pharmacy areas? *Record the pressure differential.*									
139	83.0 P13,14	Are pressure differential monitoring procedures in place? *Verify by viewing daily logs and ensure a plan is in place if discrepancy is found.*									
140	84.0	If the clean room and anteroom are not fully enclosed, is the air flow measured across the openings? *Record the air flow.*									
141	85.0	Are air flow monitoring procedures in place? *Verify by viewing daily logs and ensure a plan is in place if discrepancy is found.*									

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142	86.0 P12	Is the temperature of the compounding area controlled by a thermostat and an adequate air conditioning system (anteroom and cleanroom) maintained at a comfortable temperature (20°C or cooler)? *View records and record temperature of the clean room at the time of inspection.*									
143	87.0	Is the humidity monitored daily and in the range of 35-60% in the sterile compounding area? *View records and record humidity at the time of inspection.* Relative Humidity levels between 35% and 60% are recommended (below 35% allows static levels above recommended values. Above 60% promotes microbial growth).									
144	88.0	Are the blowers on ISO 5 laminar airflow workbenches or barrier isolators operated continuously during compounding activity, including during interruptions of less than eight hours?									
145	89.0 P19	When the LAFW blower is turned off and before other personnel enter to perform compounding activities, is only the least amount of garbed persons needed to clean, allowed to enter the buffer area for the purposes of turning on the blower (for at least 30 minutes) and of sanitizing the work surfaces?									
146	Inspector Notes:										
147	Cleaning and Disinfection ***If any part of a question is no, answer the whole question "no" and explain the observation.***						Y/N/NA	Note			
148	90.0	Are all personnel that perform cleaning activities in the compounding areas appropriately trained (including housekeeping or other outside personnel if used for cleaning)?									
149	91.0 P38	Are all personnel performing cleaning appropriately garbed?									
150	92.0 P16	Is the sterile compounding area equipped with appropriate nonshedding cleaning equipment and supplies? *All cleaning tools, such as wipers, sponges, and mops, must be nonshedding, dedicated to and labeled for use in either the buffer or clean area (no wooden handles are allowed).*									

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151	93.0 P16	If cleaning tools are reused, is there a procedure to rinse and sanitize the tools and an appropriate clean storage area and are buckets inverted to prevent moisture accumulation?									
152	94.0 P16	Are tools appropriately labeled to prevent them from being used inappropriately? For example, a mop used for the floors cannot also be used for the ceilings and walls.									
153	95.0	Are there formulas and instructions for mixing or diluting the cleaning and sanitizing agents prior to use and is the preparation of cleaning supplies documented?									
154	96.0	Are cleaning and sanitizing agents appropriately labeled including expiration dates? *Note if any cleaning agents are expired.*									
155	97.0 P35	Are appropriate cleaning agents used that are effective for bacteria, viruses, fungi, and spores? *Indicate how often a sporicidal agent is used.*									
156	98.0 P38	Is the ISO 5 PEC cleaned at the beginning of each shift, between compounding activities, at least every 30 minutes while compounding and after spills or suspected surface contamination?									
157	99.0 P38	Does the cleaning of the ISO 5 PEC include cleaning with sterile water **and** sanitizing with sterile 70% IPA using a nonlinting wipe?									
158	100.0 P38	Does daily cleaning and sanitizing include counters and easily cleanable work surfaces?									
159	101.0 P38	Does daily cleaning include the floors starting from the clean room and working outwards? *Floor cleaning is not to occur during compounding.*									
160	102.0	Are fatigue mats used? If so, are they cleaned daily and let dry on both sides?									
161	103.0	Is a tacky mat used and if so, is there a procedure in place regarding replacement? *Note frequency of change.*									

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162	104.0 P38	Are the ceilings, walls, all shelving, bins, carts, chairs, and the tops and sides of the PECs thoroughly cleaned monthly? *Meaning everything removed from shelves and bins before cleaning, cleaning undersides of cart surfaces and stools, wheels, etc. Check inside bins and shelving for dust if you are garbed.*									
163	105.0	Is enough time allocated for cleaning activities?									
164	Inspector Notes:										
165	Training and Garbing ***If any part of a question is no, answer the whole question "no" and explain the observation.***						Y/N/NA	Note			
166	106.0 P24	Are pharmacists and technicians performing compounding appropriately trained and certified? *View documentation of training (to include cleaning and disinfection, garb, working in an ISO Class 5, manipulation of ingredients including aseptic technique, sterilization, and labeling).*									
167	107.0 P8	Are pharmacists and technicians performing compounding using hazardous drugs appropriately trained in the safe handling, garbing, cleaning, and disinfection procedures and waste disposal of hazardous drugs and materials?									
168	108.0 P8	Have all compounding personnel of reproductive capability confirmed in writing that they understand the risks of handling hazardous drugs?									
169	108.0	Does the pharmacy use relief personnel from outside agencies to perform sterile compounding? How are training and certifications verified? *View documentation.*									
170	109.0 p17, P20	Does training include operation of any equipment that may be used when preparing compounded sterile products? *Documentation needs to include training on operation, troubleshooting, and annual competency evaluation.*									

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171	110.0 P8	Is there documentation of training for other employees that may have contact with hazardous drugs (including drivers, warehouse, receiving, admin, etc.) of chemotherapy spill kit procedures and hazardous drug handling?									
172	111.00 P8	Is there documentation that all compounding personnel have passed an initial and subsequent annual written exams for quality assurance procedures for the appropriate risk level and including hazardous drugs?									
173	112.0 P8	Is there documentation that all compounding personnel have passed an initial and subsequent annual competency assessments of aseptic compounding skills using observational audit tools including handling hazardous drugs?									
174	113.0 P16	Are personnel prohibited from entering the clean room or ante room if they have a rash, sunburn, weeping sores, conjunctivitis, or an active respiratory infection?									
175	114.0 P19	Are personnel required to remove all personal outer garments such as hats, scarves, sweaters, vests, coats, or jackets and any makeup or cosmetics before entering compounding areas? *Include observations in the comments.*									
176	115.0 P19	Are personnel required to remove all hand and wrist jewelry, and all visible jewelry or piercings such as earrings, lip or eyebrow piercings, etc.? *Include observations in the comments.*									
177	116.0 P32	Are personnel prohibited from wearing artificial nails or extenders, and required to keep natural nails neat and trimmed? *Include observations in the comments.*									
178	117.0 P16	Is garbing performed from the dirtiest to the cleanest starting with dedicated shoes or shoe covers that are donned as the line of demarcation is crossed (with the dedicated or covered shoe never touching the same side of the line of demarcation as the dirty shoe)?									
179	118.0 P16	Does garbing then progress to head and facial hair covers and masks? *Eye shields are optional unless using cleaning agents or preparing hazardous drugs.*									

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180	119.0 P16	Is hand cleaning performed in the ante-room and does it include removing debris from under the nails with a nail cleaner followed by a vigorous washing of the hands and forearms with soap for at least 30 seconds? Are hands and arms then dried with a non-linting disposable towel or a hand dryer? *Scrub brushes are NOT recommended as they cause skin irritation and damage.*									
181	120.0 P16	Is the gown nonshedding (and preferably disposable) with sleeves that fit snugly around the wrists (some prefer to cut a small hole for the thumb to keep the sleeves from riding up) and enclosed at the neck?									
182	121.0 P16	Prior to donning sterile gloves, is a waterless alcohol based surgical hand scrub with persistent activity used and are hands allowed to dry?									
183	122.0 P16	Upon leaving the sterile product compounding area, are gowns taken off and disposed of?									
184	123.0 P16	If gowns are not disposed of, are they left in the ante-room and not reused for longer than one shift?									
185	124.0 P36	Is appropriate garbing performed anytime the line of demarcation is crossed?									
186	125.0	Is appropriate washing and garbing performed before entering the clean room?									
187	126.0 P32,33	Is there documentation that new compounding personnel have passed an initial observed gowning procedure and three gloved fingertip sampling tests? *Personnel must pass the tests upon initial validation before being allowed to compound. Action required if the tests yield any garbing deficiencies, or if the sampling results are >0 CFU/plate on the three initial validations.*									
188	127.0 P17	Is there documentation that compounding personnel have passed an annual (every six months for those performing high risk compounding) observed gowning procedure and gloved fingertip sampling test? *Action required if the tests yield any garbing deficiencies, or if the sampling results are >3 CFU/plate upon revalidation.*									

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189	128.0 P32	Is there documentation that a media fill test procedure is performed for each compounding employee at least annually for individuals that compound low or medium risk-level products. *The test conditions must closely simulate the most challenging or stressful conditions encountered during compounding of the highest risk level product. Media-filled vials are incubated and failure is indicated by visible turbidity in the medium on or before 14 days.*									
190	129.0 P27	Is there documentation that a media fill test procedure is performed for each compounding employee at least semi-annually for individuals that compound high risk-level products. *The test conditions must closely simulate the most challenging or stressful conditions encountered during compounding of the highest risk level product. Media-filled vials are incubated and failure is indicated by visible turbidity in the medium on or before 14 days.*									
191	130.0 P3	Media fill testing Sterile Compounding: Do the media-fill testing procedures include media selection, fill volume, incubation time and temperature, inspection of filled units, documentation, interpretation of results, and action levels with the corrective actions required?									
192		Inspector Notes:									
193	Radiopharmaceauticals ***If any part of a question is no, answer the whole question "no" and explain the observation.***						Y/N/NA	Note			
194	131.0	Does the pharmacy compound Radiopharmaceuticals?									
195	132.0	If yes, are SOPs in place that speak to receipt, storage, compounding, dispensing, disposal?									
196	133.0 P8	If yes, and the pharmacy compounds for positron emission tomography (PET), does the pharmacy comply with USP 823? (Radiopharmaceuticals for PET)									
197	134.0	Does the pharmacy compound Low-Risk Level Radiopharmaceutical CSPs?									

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198	135.0	Is compounding practiced in an ISO Class 5 PEC located in an ISO Class 8 or better environment?									
199	136.0 P8	Is the compounding performed with appropriate shielded vials and syringes?									
200	137.0 P28	If technetium-99m is compounded with use of multi-dose vials in an ISO Class 5 environment and punctured by needles with no direct contamination, is it used up to the time indicated by the manufacturer's recommendations?									
201	138.0 P8	Are technetium-99m/molybdenum-99 generator systems stored and eluted under conditions approved by the manufacturer and applicable state and federal regulations?									
202	139.0 P8	Does personnel inspect with the recommendations of ALARA (As Low As Reasonably Achievable)?									
203	140.0 P5	If applicable, are low-risk level CSPs with a 12 hours or less BUD prepared in a segregated compounding area as prescribed?									
204		Inspector Notes:									
205	Environmental Monitoring ***If any part of a question is no, answer the whole question "no" and explain the observation.***						Y/N/NA	Note			
206	141.0 P5	Sterile Compounding: Have all cleanrooms, laminar airflow workbenches, BSCs, CAIs, CACIs, and barrier isolators been certified?									
207	142.0	Does the pharmacy have an ISO Class 5 shielded laminar workflow area built in to the room (not a hood) and is it certified?									
208	143.0 P29	Is certification performed at least every six months and whenever a device or room is moved or major work is done to the space?									
209	144.0 P31	Are all hoods or isolators located in an area that are at least certified to ISO Class 7? If not, p*rovide explanation.*									

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210	145.0 P29	Are certification reports available? *Note the date of the last certification. Obtain copies the certification reports and use them to answer the following questions. Note any findings that are "fail " and any findings outside of guidelines that require action yet are indicated as "pass ". Indicate whether the PIC was aware of these findings and what action was taken as a result.*									
211	146.0	Is the PIC familiar with what testing is required and interpretation of results, have action levels have been identified, and are these further customized based on trended data of performance?									
212	147.0 P29	Is certification performed by a qualified certifier? Note the name of certifier, company, and contact information, and if the certifier is Controlled Environment Testing Association (CETA) National Board of Testing (CNBT) accredited.									
213	148.0 P29	Is certification to the CETA standard (USP: CETA CAG-003-2006-11 Certification Guide for Sterile Compounding Facilities) and is it noted on the report? *If not, indicate the standards used as indicated on the report. (Environmental monitoring to CETA CAG-009-00 Viable Environmental Sampling and Gowning Evaluation may also be listed)*									
214	149.0 P14	List any equipment used by the certifier identified in the report by model, Serial number, last calibration date noted and date when next calibration is due? *The certification report may typically include the calibration certificates for the equipment used.*									
215	150.0	Does each test on the certification report have a clear indication of pass or fail?									
216	151.0 P30	Are the HEPA filtered air changes per hour (ACPH) measured for the compounding rooms?									
217											
218	152.0 P12	Is the ISO Class 7 non-hazardous sterile compounding room certified as having a minimum of 30 ACPH with at least 15 ACPH from outside air sources? *No more than half the total ACPH are allowed from air recirculated through PECs.*									

	A	B	C	D	E	F	G	H	I	J	K
219	153.0 P12	Is the ISO class 7 ante-room certified as having a minimum of 30 ACPH?									
220	154.0	Is the ISO class 8 ante-room certified as having a minimum of 20 ACPH? *A minimum of 20 ACPH is commonly referred to by the FDA and others.*									
221	155.0 P12	Is the ISO class 7 hazardous sterile compounding room certified as having a minimum of 30 ACPH? *Typically all of the air will be from outside.*									
222	156.0 P8	If a CACI is used, is the room in which it is located certified to maintain a minimum of 12 ACPH?									
223	157.0 P12	Was air pattern analysis using smoke testing performed?									
224		*And is the smoke flow described in the report for the various tests such as turbulent, sluggish, smooth, etc.?*									
225	158.0 P12	Was air pattern analysis conducted at the critical area (direct compounding area inside the ISO Class 5 PEC) to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions?									
226	159.0 P12	Was air pattern analysis conducted to confirm positive pressure (and negative pressure into hazardous compounding rooms) at all points around all openings, doorways, and pass-throughs?									
227	160.0 P12	Was differential pressure or displacement airflow measured? *Will be one or the other for each room.*									
228	161.0 P12	Was the differential pressure measured to be at least 0.02 water column positive from the cleanroom to the ante-room and between the ante-room and all adjacent spaces with the doors closed?									
229	162.0 P13	Was the displacement airflow (for low and medium-risk non-hazardous rooms only) measured at a minimum differential velocity of 40 feet per minute from the cleanroom to the ante-room. *Note that it is very important to maintain this velocity across the entire opening and the report should indicate multiple points of measure across all openings.*									
230	163.0 P13	Were particle counts measured? *Include particles of 0.5mm and larger.*									

	A	B	C	D	E	F	G	H	I	J	K
231	164.0 P12	Were all particle counts taken during dynamic conditions? *How is this noted in the report – does it list personnel working in the hoods or just number of personnel present?*									
232	165.0 P13	Are ISO Class 5 areas and hoods certified as having less than 3,520 particles per cubic meter of air?									
233	166.0 P13	Are ISO Class 7 areas certified as having less than 352,000 particles per cubic meter of air?									
234	167.0 P13	Are ISO Class 8 areas certified as having less than 3,520,000 particles per cubic meter of air?									
235	168.0 P12	Was HEPA filter testing performed?									
236	169.0 P12	Were all room HEPA filters leak tested?									
237	170.0 P12	Were any leaks identified and fixed?									
238	171.0 P13	Were all hood HEPA filters leak tested and air flow velocity measured?									
239	172.0 P12	Were any leaks identified and fixed?									
240	173 P.014	Were viable air and surface sampling test conducted?									
241	174.0 P14	Is appropriate growth media used that supports both bacterial and fungal growth?									
242	175.0 P14	Was viable air sampling by active impaction using a volumetric air sampling device? *NOTE: Passive air sampling is not compliant with USP Chapter <797>.*									
243	176.0 P14	Was each air sample taken in the ISO Class 5 areas or hoods at least 1000 liters in volume *(not 500 liters for a bacterial plate and 500 liters for fungal/mold plate)?*									
244	177.0 P14	Was each air sample taken in the ISO Class 7 or 8 areas at least 400 liters in volume?									

	A	B	C	D	E	F	G	H	I	J	K
245	178.0 P14	Was viable surface sampling performed on all direct compounding areas (inside of ISO 5 rooms or hoods), in each room, inside any pass-throughs, and on surfaces likely to be contaminated due to position relative to doorways, etc., performed?									
246	179.0 P15	Are all viable samples within the USP recommended microbial action levels (or internal									
247		Classification	Air Sample	Surface Sample							
248		ISO Class 5	>1 CFU/m3	>3 CFU/plate							
249		ISO Class 7	>10 CFU/m3	>5 CFU/plate							
250		ISO Class 8	>100 CFU/m3	>100 CFU/plate							
251	180.0 P15	Were all CFUs detected analyzed to determine the organism down to the genus? *All CFUs detected must be identified even if the number of CFUs does not exceed an action level. (Specific to Air Sampling).*									
252	181.0 P15	Were all sample free from any mold, yeast, coagulase positive staphylococcus, or gram negative rods detected? I*mmediate remediation and investigation into the cause must be conducted.*									
253	182.0 P15	Did the testing report indicate that it included growth promotion testing and sterility quality control testing of the media plates? *Positive and negative control tests important to validate results of viable testing.*									
254	183.0 P15	Did the testing results report include media lot numbers and expiration dates and a signature of the laboratory analyst and/or reviewer?									
255		Inspector Notes:									
256	Compounding equipment						Y/N/NA	Note			
257	***If any part of a question is no, answer the whole question "no" and explain the observation.***										
258	184.0 P20	Sterile Compounding: Appropriate equipment available and in good working order including appropriate equipment for handling hazardous materials. *View maintenance and calibration logs.*									

	A	B	C	D	E	F	G	H	I	J	K
259	185.0 P20	Are scales, balances, and other equipment used for measuring or weighing calibrated at least annually? *Indicate by whom.*									
260	186.0 P20	Are any Automated Compounding Devices (ACDs) used? *Such as those used to compound parenteral nutrition.*									
261	187.0 P20,21	Are there written policies for the use, daily calibration, maintenance and annual competency testing of the ACD?									
262	188.0 P20	Is there documentation of the ACD tubing being changed every 24 hours?									
263	189.0 P20	Is the ACD used when performing media fill testing?									
264	190.0 P14	Does the pharmacy have a lyophilizer? *If so, note the volume or percent of products per week produced using the lyophilizer and if the lyophilizer is part of the viable air and surface sampling and media fill testing procedures.*									
265	191.0 P3	Does the pharmacy have any other automated compounding preparation equipment (such as repeater pumps)? *If so, note the equipment and the volume or percent of products per week produced using the equipment and if it is used as part of the media fill procedures.*									
266											
267	Inspector Notes:										
268	Compounding Procedures						Y/N/NA	Note			
269	***If any part of a question is no, answer the whole question "no" and explain the observation.***										
270	192.0 P19	Are all procedures performed in a manner designed to minimize the risk of touch contamination and are gloves and critical sites sanitized with adequate frequency and with an approved disinfectant, such as sterile 70% IPA spray and a nonlinting wipe?									
271	193.0 P19	Are objects that shed particles prohibited in the buffer or clean area, including pencils, cardboard cartons, paper towels, reading material, and cotton items (e.g., gauze pads)?									

	A	B	C	D	E	F	G	H	I	J	K
272	194.0 P19	Are essential paper related products (syringe overwraps, work records contained in a protective plastic sleeve) wiped down with sterile 70% IPA before bring brought into the buffer or clean area?									
273	195.0 P19	Are supplies required for the scheduled operations of the shift prepared and decontaminated by wiping or spraying the outer surface with sterile 70% IPA (or removing the outer wrap as the item is introduced into the aseptic work area) and brought into the buffer or clean area (preferably) on one or more movable carts?									
274	196.0 P20	Are compounding employees using appropriate aseptic technique? Observe from outside. *May require inspector to garb and enter clean room. Inspector to record observations after exit from the clean room (may not bring in objects, pens, paper, etc.). Pay Attention to first air, entry and exit of materials in ISO Class 5 PEC, appropriate frequent sanitization of gloves, appropriate cleaning and cleanliness of the DCA, etc.*									
275 276	197.0 P19	Are supplies required for back-up or general support of operations stored on the designated shelving in the buffer or clean area? *Look for excessive accumulation as all products will have to be re-cleaned upon monthly cleaning.*									
277	198.0 p19	Are all rubber stoppers of vials and bottles and the neck of ampules sanitized every time with sterile 70% IPA (and a wait of at least 10 seconds to dry) prior to the introduction of a needle or spike for the removal of product?									
278	199.0 P19	After the preparation of every admixture, are the contents of the container ***thoroughly mixed and then inspected for the presence of particulate matter*** , evidence of incompatibility, or other issues?									
279	200.0 P7	Are opened or needle punctured single-dose containers (bags, bottles, syringes, or vials) that are opened or punctured in worse than ISO Class 5 air used within 1 hour and the remaining contents discarded? *How are they marked?*									
280	201.0 P7	Are single-dose vials exposed to ISO Class 5 or cleaner air used within 6 hours of the initial puncture and any remaining contents discarded? *How are they marked?*									
281	202.0 P7	Are the remaining contents of opened single-dose ampules discarded immediately? *May not be stored for any time period.*									

	A	B	C	D	E	F	G	H	I	J	K
282	203.0 P7	Are multiple-dose vials that are formulated for removal of portions on multiple occasions (usually containing preservatives) assigned a BUD of 28 days or the manufacturer's specific BUD (whichever is less) after the initial entry or puncture?									
283	204.0 P21	Before being dispensed (and/or administered), are the clarity of solutions visually confirmed; the identity and amounts of ingredients, procedures to prepare and sterilize CSPs, and specific release criteria are reviewed to assure their accuracy and completeness?									
284	205.0 P3	Are procedure for in-process checks followed? *These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists that includes visual inspection of product and documentation of the compounding accuracy is by someone other than the compounder to ensure proper measurement, reconstitution, and component usage.*									
285	206 P22	Are BATCH labels (not to be confused with dispensing labels) placed on preparations to easily track the information needed for compliance and recall including the name and quantity of all contents, date, and time of preparation (or internal code indicating this information), preparer and verification pharmacist identifiers, stability (beyond-use date), and any auxiliary labels indicated including appropriate packaging and labeling of hazardous materials?									
286	207.0 P7,22	Do labels on PATIENT-SPECIFIC containers, in addition to standard label requirements, also include identifiers for the persons preparing and performing the final verification, stability or beyond-use date, flow rate (if applicable), and appropriate packaging and labeling of hazardous materials?									
287	208.0	Is CSP free of particulate? Inspect several different finished products and look for any particulates. List the products including lot and expiration date and obtain photos (if possible). **REQUEST THE PRODUCT BE QUARANTINED AND NOTIFY THE EXECUTIVE DIRECTOR OF THE BOARD IMMEDIATELY.**									
288	209.0 P22	Sterile Compounding: Are beyond-use-dates (BUDs) greater than 24 hours **(or allowed by USP 797 standards as listed in question #210.0)** documented with justification based on testing or literature. *Documentation should be available for review.*									

	A	B	C	D	E	F	G	H	I	J	K
289	210.0 P6,7	Are BUDs assigned within the USP Chapter 797 guidelines?									
290		**Low Risk**									
291		48 hours room temp, 14 days refrigerated, 45 days frozen									
292		**Medium Risk**									
293		30 hours room temp, 9 days refrigerated, 45 days frozen									
294		**High Risk**									
295		24 hours room temp, 3 days refrigerated, 45 days frozen									
296	211.0 P21	For all sterile compounded products for which sterility testing is required (including assigning a BUD that exceeds USP Chapter <797> dating and certain high risk preparations) are the products dispensed or distributed in advance of the completion of the sterility study?									
297	212.0 P21	Are all high-risk level CSPs for administration by injection prepared in groups of more than 25 single-dose packages (such as ampules, bags, syringes, vials), or in multiple dose vials for administration to multiple patients, or exposed longer than 12 hours at 2-8°C (25-46°F) or longer than 6 hours at warmer than 8°C (46°F) before they are sterilized tested to ensure that they do not contain excessive bacterial endotoxins? *View results of testing and indicate number or percentage of units tested.*									
298	213.0	Is there a process for handling and determining BUD that addresses single-dose containers, multiple-dose containers, and proprietary bag ad vial systems?									
299	214.0 P22	*Are there multiple dose containers marked with a BUD of 28 days after initial opening or entry, six hours for single dose containers kept in ISO Class 5 air, and one hour for worse than ISO Class 5 air, 0 for opened ampules (not allowed) or other if by documentation from manufacturer.*									
300	215.0 P23	Are appropriate sterilization methods used and documented? Ensure P&Ps in place that addresses determining type of sterilization, equipment used, documentation kept and testing									
301	216.0	Does the pharmacy use non-sterile empty vials and vial stoppers or closures and terminally sterilize them with on on-site autoclave?									

	A	B	C	D	E	F	G	H	I	J	K
302		Filter sterilization: Is there documentation that:									
303		1. The 0.2 micron sterile microporous membrane filter used to sterilize CSP solutions is chemically and physically compatible with the CSP									
304	217.0 P29	2. That filtering is completed rapidly without filter replacement									
305		3. That confirmation of filter integrity (bubble testing) is performed for each filter used with each batch sterilized by filtration? *View documentation on batch records of items sterilized by filtration to confirm.*									
306		Steam sterilization: Is there documentation that:									
307		1. The autoclave has been validated for the exposure time and mass of the items to be sterilized									
308		2. Ensures live steam contacts all ingredients and surfaces to be sterilized									
309		3. Solutions are passed through a 1.2 micron or smaller filter into the final containers to remove particulates before sterilization									
310	218.0 P29	4. Heated filtered air is evenly distributed throughout the chamber with a blower									
311		5. That the CSP will not be adversely affected by the steam and heat									
312		6. The description of steam sterilization includes conditions and duration for specific CSPs									
313		7. All materials are exposed at 121° under 15 psi for properly proven time									

	A	B	C	D	E	F	G	H	I	J	K
314		Dry heat sterilization: Is there documentation that:									
315		1. Dry heat is only used for those items that cannot be sterilized by steam or would be damaged by moisture									
316		2. Sufficient space is left between materials to allow for air circulation									
317	219.0 P29	3. The description of dry heat sterilization includes conditions and duration for specific CSPs									
318		4. That the effectiveness of steam sterilization is verified each time using appropriate biological indicators									
319		5. The oven is equipped with a system for controlling temperature and exposure period?									
320		Depyrogenation by dry heat: Is there documentation that:									
321		1. Dry heat depyrogenation is used to render glassware and containers (such as vials) free from pyrogens as well as viable microbes									
322	220.0 P29	2. The description of the cycle and duration for specific load items									
323		3. The effectiveness of the cycle is verified using endotoxin challenge vials (ECVs)									
324		4. Bacterial endotoxin testing is performed on the ECVs to verify the cycle is capable of achieving a three log reduction in endotoxins									
325		Inspector Notes:									
326	Finished Preparation Release Checks and Tests						Y/N/NA	Note			
327	***If any part of a question is no, answer the whole question "no" and explain the observation.***										
328	221.0	Sterile Compounding: Is there a process in place to sample prepared products for potency and/or contamination and recall actions to take if discrepancies are found?									
329	222.0 P21	Are products checked for particulates or other foreign matter against both a light and a dark colored background?									
330	223.0 P21	Are there checks for container and closure integrity?									
331	224.0 P21	Is compounding accuracy documented by verification of steps?									

	A	B	C	D	E	F	G	H	I	J	K
332	225.0 P21	Is verification of ingredient identity and quantity verified? *Is there a reconciliation of components?*									
333	226.0 P21	Are labels verified as being correct and is a copy of the label included in the record? *Complies to regulation, contains the correct names and amounts or concentrations of ingredients, total volumes, BUDs, storage conditions, and route of administration.*									
334	227.0 P21,22	Sterility testing: Is sterility testing performed for CSPs that have extended BUDS, or are prepared in batches of more than 25 identical containers, or are exposed longer than 12 hours at 2-8°C or longer than six hours at warmer than 8°C before being sterilized?									
335	228.0	Are the appropriate quantities of units for each batch tested?									
336		For parenterals, if the number of units in the batch is:									
337		1. Less than 100, test 10% or four units, whichever is greater									
338		2. 100 up to 500, test 10 units									
339		3. More than 500, test 2% or 20 units, whichever is less									
340		*View records to confirm appropriate number tested. View records of products failing*									
341	229.0 P21	If items are dispensed or distributed prior to sterility testing completion, is there a written procedure requiring daily observation of the incubated media and requirement of an immediate recall if there is any evidence of microbial growth? *In addition, is the patient and the physician of the patient to whom a potentially contaminated CSP was administered notified of the potential risk?*									
342	230.0 P21	Is appropriate endotoxin (pyrogen) testing performed for high risk level CSPs (excluding ophthalmic and inhalation preparations), prepared in batches of 25 or more identical containers, or are exposed longer than 12 hours at 2-8°C or longer than six hours at warmer than 8°C before being sterilized?									
343	231.0 P23	Are products appropriately tested for purity and potency? *How are the products selected for testing?*									
344	232.0 P21	View testing records. Have products that failed sterility, endotoxin, purity or potency testing been recalled? *How are 'inconclusive' results handled?*									
345	233.0	Sterile Compounding: Does the pharmacy have its own lab to perform testing? If so, what testing is performed in house?									

	A	B	C	D	E	F	G	H	I	J	K
346	234.0	Sterile Compounding: Does the pharmacy send samples to an outside lab to perform testing? *If so, provide the name of the lab performing testing for the pharmacy and what testing is performed.*									
347		Inspector Notes:									
348	PACKING AND TRANSPORTING						Y/N/NA	Note			
349	***If any part of a question is no, answer the whole question "no" and explain the observation.***										
350	235.0 P24	Are packing materials designed to maintain the physical integrity, sterility, stability, and purity of CSPs in transport? *Are packages tamper-evident?*									
351	236.0	Does the pharmacy have testing data from the packaging supplier? *View documentation.*									
352	237.0	Does the pharmacy conduct its own testing of packing materials? *View documentation.*									
353	238.0	Does the pharmacy ship overnight?									
354	239.0	Do shipments go out on Fridays or weekends where they might sit in a truck for a period of time?									
355	240.0 P25	Does the pharmacy obtain information from carriers regarding shipping conditions to maintain appropriate temperatures of the products?									
356		Inspector Notes:									
357	PATIENT TRAINING AND ADVERSE EVENT REPORTING						Y/N/NA	Note			
358	***If any part of a question is no, answer the whole question "no" and explain the observation.***										
359	241.0 P25	Do patient/caregiver training programs include a hands-on and reverse demonstration with actual items that the patient or caregiver is expected to use, such as CSP containers, devices, and equipment?									
360	242.0 P25	Does the training program include proper storage, handling, use, and disposal if CSPs and administration equipment?									
361	243.0 P25	Do patient/caregiver training programs or materials contain information regarding how the product is to be used including any precautions if the product is hazardous?									
362	244.0 P25	Are required printed drug information materials (PPI, MedGuides, etc.) provided for the compounded products?									
363	245.0 P24	Do patients receive instruction and directions on reporting any adverse reaction or event? *View complaints or reports from patients or caregivers, verify investigation, and action taken.*									

	A	B	C	D	E	F	G	H	I	J	K
364	246.0 P25	Are patients instructed on the signs of product instability or contamination (as appropriate) and to report any changes in the physical characteristics of the product to the pharmacy?									
365		Inspector Notes:									
366	QA PROGRAM						Y/N/NA	Note			
367	***If any part of a question is no, answer the whole question "no" and explain the observation.***										
368	247.0 P34	Are reports of adverse events with CSPs documented and reviewed promptly and thoroughly by compounding supervisors to correct and prevent future occurrences?									
369	248.0 P34	Are adverse events and defects with CSPs reported to FDA's MedWatch and to USP's MEDMARX programs?									
370	249.0 P26	Does the quality assurance (QA) program measure all aspects of the preparation and dispensing of compounded products including environmental testing, validation results, etc.									
371	250.0 P26	Does the facility QA program identify the appropriate follow-up mechanisms when action limits or thresholds are exceeded?									
372	251.0 P26	Does the QA program address how data is collected or reported, tabulated, and analyzed?									
373	252.0 P26	Are deficiencies in compounding, labeling, packaging, and quality testing and inspection identified and corrected?									
374	253.0 P26	Are there regular QA meetings to discuss analysis and findings, implementation of improvements and evaluation of the success of the improvements?									
375		Inspector Notes:									
376											

	A	B	C	D	E	F	G	H	I	J	K
377		Inspector Overall Notes and General Impressions:									