West Virginia State Board of Pharmacy

Sterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>. An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Business or Corporation:				Day 1:		Inspector(s)	
Doing Business As (DBA):				Start Time:			
Address:				End Time:			
City:				Day 2:			
State:		Zip Code:		Start Time:			
Telephone number:				End Time:			
	WV Permit#						
	DEA #						
Toll free number:				Pharmacist in Charge			
					License #:		
Fax number:				PIC e-mail			
Email address:				Sterile Compounding Supervisor			
					License #:		
Hours of Sterile Compounding Operation (Check if 24/7) ☐							
eave blank if closed	Sun	Mon	Tues	Wed	Thu	Fri	Sat
Hazardous Compounding Supervisor *(if applicable)*							
License #:							

Revised 7/1/18

	Indicate the areas/rooms of the pharmacy entered to perform the inspection. *If the inspector did not fully garb and enter buffer room(s), indicate reason.*					
	General Operations Information	**Y**	**N**	**?**	**NA**	**Notes**
1.00	Is a copy of USP Chapter 797 and/or Chapter 800 available?					
2.00	Does the pharmacy **dispense** sterile compounded preparations pursuant to a prescription?					
2.01	Are patient profiles complete and DUR performed for each prescription? *View selected files for profile to include allergies, disease states/conditions, other medications taken not dispensed by this pharmacy*					
3.00	Does the pharmacy distribute sterile compounded preparations? *Not pursuant to a prescription, not labeled by the pharmacy with a patient name.*					
3.01	Does the pharmacy distribute sterile compounded preparations to practitioners for office use?					
3.02	Does the pharmacy distribute sterile compounded preparations to hospitals, clinics, or surgery centers?					
3.03	Is the pharmacy registered with the FDA as an Outsourcing Facility?					
4.00	Does the pharmacy provide sterile compounded preparations to other pharmacies for dispensing?					
5.00	Which of the following sterile compounds are prepared?					
5.01	Allergen extracts					
5.02	Parenteral solutions					
5.03	Parenteral *suspensions*					
5.04	Ophthalmic preparations					
5.05	Oral or nasal *inhalation* preparations (not topical sprays)					
5.06	Baths and soaks for live organs and tissues					
5.07	Irrigations for wounds and body cavities					
5.08	Any other sterile preparations (implants, pellets, etc.). *Provide list.*					
6.00	Does the pharmacy compound investigational drugs? *Provide list.*					
7.00	Does the pharmacy only make essential copies of a commercially available drug product on the Drug Shortage List or that is justified by a documented medical need of the individual patient as determined by the prescribing practitioner?					
7.01	If yes, products are verified as appearing on the Drug Shortage List in effect under 506E of the Federal Act at the time of compounding, distribution, and dispensing.					

7.02	If yes, the Drug Shortage List is monitored and when a drug product is no longer on the list, any remaining stock is quarantined and not available for distribution or dispensing. *Note: Per FDA guidance, 503B facilities may continue to distribute for 60 days following drug shortage list removal for existing orders.*					
8.00	Does the pharmacy perform **low-risk** compounding?					
8.01	Are all low-risk compounds assigned BUDs within USP guidelines (48 hours at controlled room temperature, 14 days refrigerated, 45 days frozen)?					
8.02	If extended BUDs are used, list products with Extended BUDs and maximum BUD in notes.					
8.03	If extended BUDs are used, is further testing being performed to justify the use of extended BUDs? *List the types of testing performed (potency, sterility, stability, etc).*					
9.00	Does the pharmacy perform **medium-risk** compounding?					
9.01	Are all medium-risk compounds assigned BUDs within USP guidelines (30 hours at controlled room temperature, 9 days refrigerated, 45 days frozen)?					
9.02	If extended BUDs are used, list products with Extended BUDs and maximum BUD in notes.					
9.03	If extended BUDs are used, is further testing being performed to justify the use of extended BUDs? *List the types of testing performed (potency, sterility, stability, etc).*					
10.00	Does the pharmacy perform **high-risk** compounding?					
10.01	Are all high-risk compounds assigned BUDs within USP guidelines (24 hours at controlled room temperature, 3 days refrigerated, 45 days frozen)?					
10.02	If extended BUDs are used, list products with Extended BUDs and maximum BUD in notes.					
10.03	If extended BUDs are used, is further testing being performed to justify the use of extended BUDs? *List the types of testing performed (potency, sterility, stability, etc).*					
11.00	Does the pharmacy perform compounding for **immediate use?**					
12.00	Does the pharmacy perform compounding with **hazardous drugs**? *NIOSH list of hazardous drugs including chemotherapy, hormones, etc.*					
12.01	Is the pharmacy aware of the more stringent requirements of the					

	proposed USP Chapter <800>?					
12.02	Are hazardous drugs segregated and stored in a room that is negative pressure (at least -0.01" wc) to adjacent areas and with at least 12 ACPH?					
12.03	Is hazardous drug waste quarantined in a designated area and disposed of in compliance with local, state, and federal regulations?					
13.00	Are Safety Data Sheets (SDS) [formerly known as Material Safety Data Sheets (MSDS)] available to personnel for drugs and chemicals used in the pharmacy (including those for compounding, if applicable)? *Verify that personnel can access them and are familiar with the format.*					
14.00	Does the pharmacy perform compounding using **blood products** (or other biological materials)? Such as wound care, autologous eye drops, etc. *Describe.*					
15.00	Does the pharmacy compound using any Federally **controlled substances II-V**?					
16.00	**APIs:** Does the pharmacy make any sterile compounded preparations using bulk powder Active Pharmaceutical Ingredients (APIs)?					
16.01	Does the pharmacy purchase APIs directly from the manufacturer/repackager? *If not, indicate the source of APIs*					
16.02	Does the pharmacy verify that the manufacturer/repackager of the API is an FDA-registered facility? *If so, list how this verified*					
16.03	Does the pharmacy use active ingredients that are not from an FDA facility? *If so, indicate sources.*					
16.04	Does the computer track on-hand quantities of APIs used for compounding?					
17.00	Does the pharmacy use scales/balances for sterile compounding?					
17.01	If the scale/balance is electronic, does the pharmacy use the automatic calibration? *Describe process and indicate frequency.*					
18.00	Does the pharmacy perform any testing in-house (not sent to an outside lab)? *If so, what tests are performed in house?*					
19.00	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*					
20.00	**Quality Assurance/Quality Improvement**: Does the pharmacy continuous quality improvement program include sterile compounding measures?					

	Note: If the facility indicates "yes", please ask each question below to verify.					
20.01	Does the pharmacy continuous quality improvement program include QREs related to the preparation of compounded products?					
20.02	Does the pharmacy continuous quality improvement program include nonviable environmental monitoring and testing?					
20.03	Does the pharmacy continuous quality improvement program include viable environmental testing?					
20.04	Does the pharmacy continuous quality improvement program include personnel testing and verification?					
20.05	Does the pharmacy continuous quality improvement program include equipment calibration, testing, etc?					
20.06	Does the pharmacy continuous quality improvement program include sterilization method testing and validation?					
20.07	Does the pharmacy continuous quality improvement program include end product testing (such as: potency, particulates, sterility, endotoxin, etc.)?					
20.08	Does the pharmacy continuous quality improvement program include patient or prescriber reports or complaints regarding CSPs?					
20.09	Does the facility QA program identify action limits or thresholds and the appropriate follow-up mechanisms when action limits or thresholds are exceeded including a recall system?					
20.10	Does the recall system include communication with both the patient and the physician/prescriber regarding the potentially contaminated CSP administered and the potential risks?					
20.11	Are QREs involving CSPs that may have been contaminated or are recalled reported to the appropriate agency such as the Board of Pharmacy and/or FDA.					
0.12	Are all CFUs detected by any personnel, environmental, or product testing; or any other checks or tests including endotoxin, purity, potency, etc. remediated, appropriately investigated, cause determined, and processes implemented to prevent in the future, where applicable? *Review QA trends.*					
	Component Selection and Use	**C**	**NC**	**?**	**NA**	**Notes**
	Total Non-Compliant (Includes Unknowns)					

21.00	**Active Pharmaceutical Ingredients (APIs), bulk drug substances:** All bulk drug substances (APIs) used are: 1) Compliant with the standards of an applicable USP or NF monograph, if one exists; or 2) A component of an FDA-approved human drug product; or 3) On the list of bulk drug substances for use in compounding developed by the FDA and issued through regulation (note: must comply with (1) or (2) above until the FDA list is issued)					
21.01	Certificates of analysis (COAs) obtained for all bulk APIs used for compounding. *Verify by selecting products from the shelf from different suppliers and ask to see the COAs for those products.* NOTE: The COA for an API should be reviewed upon receipt of the API to verify the quality of the API before being used for compounding.					
21.02	USP- or NF-grade substances used, if available.					
21.03	If compendia quality components are not available, chemically pure, analytical reagent grade or American Chemical Society-certified components are used and are determined to be free from impurities.					
21.04	APIs or other components have labeling indicating use for pharmaceutical compounding or manufacturing. Labels do not indicate "for research purposes only", "not for drug use", or are handwritten labels from other pharmacies. *Photograph and describe if found. Request copies of the invoices for products with questionable labels*					
21.05	If compounding for both humans and animals, APIs or other components that are labeled for veterinary use only are segregated or marked in such a way to prevent them from being used for human compounding.					
21.06	All substances and components have a complete label including a batch control or lot number, and an expiration date.					
21.07	For APIs without an expiration date assigned by the manufacturer or supplier, the pharmacy assigns a conservative expiration date. The expiration date assigned is not greater than one (1) year, unless it is supported with data and/or testing. *Note: purity and quality testing may be performed to extend.*					
21.08	All APIs are labeled with the date they were received.					

21.09	If the pharmacy repackages APIs into smaller containers for ease of use, the expiration date assigned is conservative (typically the lesser of one year or the actual expiration from the original container). Product may be tested to extend the expiration date but may not exceed the original package expiration date.					
21.10	Bulk component containers are labeled with appropriate OSHA hazard communication labels and hazardous substances are segregated (including hormones).					
21.11	Components from foreign sources that are derived from ruminant animals (cow, sheep, goat) have documentation that the component is in compliance with federal laws governing processing, use, and importation. That the animals were free from disease, and that they were born, raised, and slaughtered in locations where bovine spongiform encephalopathy and scrapie are not known to exist.					
22.00	There are no preparations for human use made or ingredients used that appear on the FDA list of drug products withdrawn or removed from the market for safety reasons (facility has a copy of the list or other way to determine).					
23.00	There are no preparations compounded that present demonstrable difficulties for compounding as identified by the FDA. *If so, list the name of the products.*					
24.00	For **animal compounding**, does the compounding meet the same standards as compounding for human patients?					
24.01	The pharmacist is knowledgeable or has the most up-to-date references regarding the individual species' limitations in physiology and metabolic capacity that can result in toxicity when certain drugs or excipients are used.					
24.02	It is determined and documented if the animal is used for food (meat, milk, eggs, etc.) or that the animal is a pet.					
24.03	The pharmacist familiar with, or has the most up-to-date reference regarding drug residues in the food chain and withdrawal times if compounding for food-producing animals.					
24.04	The facility has a list of drugs and components not allowed when compounding for food-producing animals.					

24.05	The pharmacist is familiar with, or has the most up-to-date reference regarding regulations for drug use in performance animals (e.g., race or show horses, racing dogs)					
25.00	If the pharmacy compounds **stock solutions** or components (that are then used to compound a finished product) using APIs, these stock solutions are categorized as high-risk compounding.					
25.01	The stock solutions are assigned BUD based on the USP<797> high-risk compound BUD, OR are assigned on the basis of direct testing or extrapolation from reliable literature sources to support an extended BUD.					
25.02	Compounded preparations using the stock solution are classified as high-risk compounds with appropriate handling with regard to BUD and testing requirements.					
	Environment	**C**	**NC**	**?**	**NA**	**Notes**
	Total Non-Compliant (Includes Unknowns)					
26.00	If the facility performs both sterile and nonsterile compounding, the areas are separated and distinct.					
27.00	If the facility performs compounding using blood products (or other biological materials), this compounding area is separate and distinct from the general compounding areas.					
27.01	Are components used in compounding with blood products restricted to the blood compounding area (not used in other compounding areas)?					
28.00	Entry into the sterile compounding areas is limited to task critical employees (limited to only the pharmacist(s) and other trained and authorized pharmacy personnel).					
29.00	The anteroom has a line of demarcation or other separation of the dirty to the clean side. Note: the line of demarcation may NOT be the doorway between the anteroom and the clean/buffer room.					
29.01	Carts used to bring supplies from the storeroom are kept on the outside of the line of demarcation.					
29.02	Carts used in the clean/buffer room are kept on the clean side of the line of demarcation.					
30.00	All surfaces of the sterile product compounding area carts, shelves, stools, chairs, and other items are resistant to disinfectants, non-permeable, non-carpeted or upholstered, and low particulate generating.					

31.00	Walls painted with epoxy based paint or other impermeable surface, and are seamless or have sealed seams where panels meet and corners with no cracks.					
32.00	The ceiling tiles are composed of a vinyl surface, with the tiles caulked and sealed and the seams where the walls meet the ceiling are caulked and sealed.					
33.00	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 or caulked					
34.00	The clean/buffer room or anteroom does not have dust collecting overhangs (eg ceiling utility pipes, ledges, pneumatic tube stations, sprinkler heads, emergency exit signs, etc).					
35.00	The exposed surfaces of:					
35.01	PEC are free of dirt, rust, chips and particulate matter.					
35.02	Light fixtures are smooth, mounted flush, and sealed.					
36.00	A working sink, located on the clean side of the line of demarcation, is available that enables pharmacy personnel to wash hands and enter the sterile compounding area without contaminating his/her hands and is away from/not adjacent to any PEC(s).					
37.00	There is no sink or drain in the clean/buffer room.					
38.00	Hand drying is with non-linting paper towels, or an electronic or HEPA filtered hand dryer.					
38.01	If using a hand dryer, particle count and smoke testing validation is performed while dryer is in use (while someone is actively using to dry their hands) at certification, and the immediate area around the dryer is part of the viable air and surface testing program performed. *(N/A if only using towels)*					
39.00	All air ducts controlling air flow into the sterile compounding clean/buffer room and anteroom are equipped with High Efficiency Particulate Air filtered air that maintains the cleanroom with an ISO Class 7 or 8 environment.					
40.00	Incoming air ducts through HEPA filters are on or near the ceiling and air return ducts are low on the walls in the anteroom and clean/buffer room.					

41.00	If there are particle generating equipment/appliances in the clean/buffer room or anteroom (e.g. computers, printers, refrigerators, dishwashers, etc), they are located by an air return so air flows over and out of the room taking particles with it, and this air flow has been confirmed by smoke testing while in use.					
42.00	Beverages including drinking water, chewing gum, candy, or food items are prohibited from the clean/buffer room or anteroom.					
43.00	If compounding occurs using nonsterile ingredients, products, components, or devices (for example compounding with non-sterile APIs or using nonsterile vials and closures), the pharmacy has appropriate equipment to sterilize the finished product.					
43.01	Pre-sterilization procedures for high risk level CSPs (such as weighing and mixing) are performed in no worse than an ISO Class 8 environment.					
44.00	Completely enclosed anteroom and clean/buffer room (with a door) are equipped with monitors or gauges to measure differential pressure.					
44.01	Anteroom is at least 0.02" wc positive pressure to general pharmacy areas.					
44.02	Clean/buffer room is at least 0.02" wc positive pressure to general pharmacy areas.					
44.03	Hazardous compounding room and drug storage area is at least 0.01" wc negative pressure to ISO Class 7 anteroom.					
44.04	Pressures are continuously monitored and at a minimum read and recorded each shift (minimum of once daily). *View logs*					
44.05	Plan in place to detect and react to pressure differentials outside of limits.					
45.00	If the clean/buffer room and anteroom are not fully enclosed (open or with plastic strips - no door that closes), the air flow is measured across the openings.					
45.01	The air flow is at least 40 feet per minute across the entire opening.					
45.02	Airflow is read and recorded each shift (minimum of once daily) or continuously recorded. *View logs.*					
45.03	Plan in place to detect and react to air flow measurements outside of limits					
45.04	This area is used only for low- and medium-risk compounding (**High-risk not allowed**).					

46.00	**Temperature:** The temperature of the compounding area is controlled by a thermostat and an air conditioning system is in place.					
46.01	Temperature in the **compounding area** is maintained to provide comfortable working conditions for compounding personnel of 20° C or cooler (68° F or cooler); Temperature can be more restrictive if warranted by specific drug product storage requirements.					
46.02	Temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Temperature records are maintained.					
46.03	Temperature monitoring is also performed in **drug storage areas** (if separate from the compounding areas). Temperature is maintained at controlled room temperature of 20° - 25° C (68° - 77° F) or as specified by FDA approved labeling for drug product storage.					
46.04	Temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Temperature records are maintained.					
46.05	Temperature in the **refrigerator or cooler** is maintained to provide controlled cold temperature of 2° to 8°C (36° to 46°F) or as specified by FDA approved labeling for drug product storage.					
46.06	Temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Temperature records are maintained.					
46.07	Temperature in the **freezer** is maintained to provide controlled frozen temperature of -25° to - 10°C (-13° to 14°F) or as specified by FDA approved labeling for drug product storage.					
46.08	Temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Temperature records are maintained.					
46.09	Action plan in place for any temperature excursions including evaluating excursion effects on drug product integrity for all temperature monitored areas.					

47.00	**Humidity:** If warranted by specific drug products, humidity in the compounding area is maintained to provide humidity within the specified ranges. If drug products require storage in a "dry place", humidity is not to exceed 40%. (*Generally recommended range is 35-60% for performing sterile compounding* .)					
47.01	If applicable, humidity monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Humidity records are maintained.					
47.02	If applicable, excursion action plan in place including evaluating excursion effects on drug product integrity.					
47.03	If applicable, humidity monitoring is also performed in drug storage areas (if separate from the compounding areas).					
48.00	Blowers on ISO 5 PECs are operated continuously during compounding activity, including during interruptions of less than eight hours.					
49.00	When the ISO 5 PEC blower is turned off, and before other personnel enter to perform compounding activities, only one garbed person is 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.					
50.00	The doors into the anteroom from the general pharmacy area and from the anteroom into the clean/buffer room are prevented from both being open at the same time. *By interlocking, training of personnel, or signage.*					
51.00	The inside and outside doors of a pass-through are prevented from both being open at the same time. *By interlocking, training of personnel, or signage.*					
52.00	**BSC or PEC that is NOT located in an ISO Class 7 clean/buffer room**: BSC or PEC has been certified to maintain ISO Class 5 during compounding activities.					
52.01	Used only for low-risk compounded preparations with a 12-hour or less BUD assigned.					
52.02	All garbing requirements are adhered to.					
52.03	Located in an area that is maintained under sanitary conditions and only traveled by persons engaging in the compounding of sterile preparations.					

52.04	Location does not contain any unsealed windows or doors that connect to the outdoors or areas of high traffic flow, and is not adjacent to construction sites, warehouses, or food preparation areas?					
52.05	Has the sink separated from the immediate area of the ISO Class 5 workbench (not adjacent) and an eyewash station.					
53.00	**CAI/CACI that is NOT located in an ISO Class 7 clean/buffer room:** CAI/CACI has been certified to maintain ISO Class 5 under dynamic conditions including transferring of ingredients, components and devices, and during preparation of CSP.					
53.01	The pharmacy has documentation from the manufacturer that the CAI or CACI will meet this standard when located in worse than ISO Class 7 environments.					
53.02	The CAI or CACI is located in an area that is maintained under sanitary conditions and only traveled by persons engaging in the compounding of sterile preparations.					
53.03	There is a sink in the compounding area, not directly adjacent to the CAI or CACI, that enables pharmacy personnel to wash hands and an eyewash station.					
53.04	For NIOSH hazardous compounding in a CACI that is NOT located in a clean/buffer room, the CACI is 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.					
	Cleaning and Disinfection	**C**	**NC**	**?**	**NA**	**Notes**
	Total Non-Compliant (Includes Unknowns)					
54.00	Are all personnel performing cleaning appropriately garbed?					
55.00	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).*					
56.00	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?					

57.00	Are reusable 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.					
58.00	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?					
59.00	Are cleaning and sanitizing agents appropriately labeled including expiration dates? *Verify no expired agents present.*					
60.00	Are appropriate cleaning agents used that are effective for bacteria, viruses, fungi, and spores?					
61.00	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?					
61.01	If heavily soiled, cleaning includes the appropriate agent. *List agent(s) used.*					
62.00	Does sanitizing of the ISO 5 PEC include sanitizing with sterile 70% IPA using a nonlinting wipe?					
63.00	Does daily cleaning and sanitizing include counters and easily cleanable work surfaces?					
64.00	Does daily cleaning include the floors starting from the clean/buffer room and working outwards? Floor cleaning is not to occur during compounding.					
65.00	If fatigue mats are used, are they cleaned daily and let dry on both sides?					
66.00	Is a tacky mat used and if so, is there a procedure in place regarding replacement?					
67.00	Are the ceilings, walls, all shelving, bins, carts, chairs, and the tops and sides of the primary engineering controls (PECs) thoroughly cleaned monthly? (*This includes removing everything from shelves and bins before cleaning, cleaning the undersides of cart surfaces and stools, wheels, etc.)* *Check inside bins and shelving for dust if you are garbed.*					
68.00	Is enough time allocated for cleaning activities, including contact/dwell times for the cleaning/disinfection agents?					
	Training -*Verify records of all compounding personnel (up to 10).*	**C**	**NC**	**?**	**NA**	**Notes**
	Total Non-Compliant (Includes Unknowns)					

69.00	There is documentation that compounding personnel are appropriately trained including policies and procedures, documentation, hazardous drug handling, and aseptic technique. *Note that "compounding personnel" includes personnel performing compounding, supervising compounding, and performing verification of compounding.*					
69.01	All personnel performing compounding are not allowed to compound until training and initial testing is successfully completed.					
69.02	All personnel that SUPERVISE compounding and/or perform verifications of other's compounding are not allowed to supervise or verify compounding until training and initial testing is successfully completed.					
70.00	All personnel of reproductive capability who handle or compound hazardous drugs or chemicals have confirmed in writing that they understand the risks of handling hazardous drugs. *Teratogenicity, carcinogenicity, reproductive issues.*					
71.00	There is documentation, such as an observational checklist, that all personnel (including housekeeping or other outside personnel) that perform cleaning activities in the compounding areas including hazardous compounding areas are appropriately trained in garbing, cleaning and disinfection.					
72.00	There is documentation of training on the operation of any equipment that may be used when preparing compounded sterile products. *Documentation needs to include training on operation, and troubleshooting*					
73.00	If the pharmacy uses relief personnel from outside agencies to perform sterile compounding, training and certifications are verified. *View documentation.*					
74.00	There is documentation that all compounding personnel (including those supervising or performing verifications) have passed an initial written exam, and subsequent annual written exams for the appropriate compounding risk levels and NIOSH hazardous drugs. *Indicate frequency, if testing more than annually*					
75.00	There is documentation that all compounding personnel have passed an initial and subsequent annual competency assessments of aseptic compounding skills using observational audit tools including handling NIOSH hazardous drugs. Compounding skills evaluation to include use of equipment. *Indicate frequency, if testing more than annually.*					

76.00	There is 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 colony-forming units (CFU)/plate on the three initial validations. Indicate frequency, if testing more than annually.*					
77.00	There is documentation that compounding personnel preparing low or medium risk-level products have passed an annual observed gowning procedure and gloved fingertip sampling test. *Action required if the tests yield any garbing deficiencies, or if the fingertip sampling results are >3 CFU (total both hands, all 10 fingers). Documentation to include type of media used, COA on media, incubation time and temperature and interpretation of results. Indicate frequency, if testing more than annually.*					
78.00	There is documentation that a media fill test procedure is performed for each compounding employee prior to first compounding and at least annually for individuals that prepare 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 and include any automation used in compounding. Media-filled vials are incubated and failure is indicated by visible turbidity in the medium on or before 14 days. Indicate frequency, if testing more than annually.*					
79.00	The media-fill testing procedures include:					
79.01	Media selection (including obtaining COAs or growth promotion certificates from suppliers)					
79.02	Fill Volume					
79.03	Incubation time and temperature (30-35°C for a minimum of 14 days)					
79.04	Inspection of filled units					
79.05	Documentation					
79.06	Interpretation of results					
79.07	Action levels set with the corrective actions required					

80.00	**High-Risk Sterile Compounding:** There is documentation that compounding personnel have passed an observed gowning procedure and gloved fingertip sampling test every six (6) months. *Action required if the tests yield any garbing deficiencies, or if the sampling results are >3 CFU on both hands upon revalidation. Documentation to include type of media used, COA on media, incubation time and temperature and interpretation of results. Indicate frequency, if testing more than every 6 months.*					
81.00	**High-Risk Sterile Compounding:** There is documentation that a media fill test procedure is performed for each compounding employee at least every six (6) months for individuals that prepare 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 and include any automation used in compounding. Media-filled vials are incubated and failure is indicated by visible turbidity in the medium on or before 14 days. Indicate frequency, if testing more than every 6 months.*					
82.00	**Failed testing:** Employees who have failed any testing are prohibited from compounding until training is performed/reviewed and subsequent testing is performed successfully.					
82.01	Gloved fingertip tests that have failed have the organisms identified down to the genus to determine the most likely source of the contamination. This data is used to develop plans to prevent contamination.					
82.02	There is a plan to evaluate the sterile compounds prepared by an employee with failed gloved fingertip tests or media fills to detect potential contamination of the sterile preparations compounded.					
	Garbing	**C**	**NC**	**?**	**NA**	**Notes**
	Total Non-Compliant (Includes Unknowns)					
83.00	Personnel are prohibited from compounding, or entering the clean/buffer room or anteroom if they have a rash, sunburn, weeping sores, conjunctivitis, or an active respiratory infection.					

84.00	Personnel are 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.*					
85.00	Personnel are required to remove all hand and wrist jewelry, and all visible jewelry or piercings such as earrings, lip or eyebrow piercings, etc. before entering clean/buffer room.					
86.00	Personnel are prohibited from wearing artificial nails or extenders, and required to keep natural nails neat and trimmed.					
87.00	Garbing 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).					
88.00	Garbing includes head and facial hair covers and masks. *Note that facial hair requires both a facial hair cover AND a mask. Eye shields are optional unless using cleaning agents or preparing hazardous drugs. There is a mirror available to check that all hair is covered.*					
89.00	Hand cleaning is performed in the anteroom and includes 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 with 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.*					
90.00	The gown is nonshedding with sleeves that fit snugly around the wrists and enclosed at the neck.					
91.00	All bare skin is covered on the arms and the legs (no bare ankles, wrists, etc.).					
92.00	Prior to donning sterile gloves, a waterless alcohol based surgical hand scrub with persistent activity is used and hands allowed to dry. *Note: regular Purell Hand Sanitizer is NOT appropriate. Purell or other brand surgical hand scrub is appropriate - must have residual activity.*					
93.00	Upon leaving the sterile product compounding area, gowns are taken off and disposed of, or if used for nonhazardous compounding they are left in the anteroom and not reused for longer than one shift.					

94.00	Pharmacists or other personnel do NOT enter the anteroom and cross the line of demarcation without donning shoe covers or dedicated shoes. *Watch for personnel traversing back and forth across the line of demarcation without doffing and donning new shoe covers or dedicated shoes.*					
95.00	Pharmacists or other personnel do NOT enter the clean/buffer room without fully washing and garbing (wearing just a mask to check technician's work, for example).					
	Environmental Monitoring	**C**	**NC**	**?**	**NA**	**Notes**
	Total Non-Compliant (Includes Unknowns)					
96.00	The most recent PEC and room certification report is available.					
96.01	All ISO Class 7 and 8 SECs (clean/buffer rooms and anterooms) have been certified within the last 6 months. *If non-compliant, record the date of the last certification.*					
96.02	All ISO Class 5 PECs (laminar airflow workbenches or areas, BSCs, CAIs, CACIs, and barrier isolators) have been certified within the last 6 months. *If non-compliant, record the date of the last certification.*					
96.03	Certification is performed at least every six months (view date of previous certification) and whenever a device or room is moved or major work is done to the space. *If non-compliant, record the date of the previous certification.*					
96.04	Certification is performed to the Controlled Environment Testing Association (CETA) guide (USP: CETA CAG-003-2006 Certification Guide for Sterile Compounding Facilities) and is noted on the report.					
96.05	If the certification standard used and noted on the report is NOT CETA CAG-003-2006, the facility has performed a comparison and determined the standard used is the same or better than the CETA CAG-003-2006 guide.					
96.06	The PIC/compounding supervisor is familiar with what testing is required and interpretation of results, ensures all testing is performed appropriately (under dynamic conditions where appropriate), has action levels identified, evaluates results to detect issues or trends, and action levels are further customized based on trended data of performance.					

97.00	The certification report includes information about the equipment used for performing calibration test including: identification of the equipment used by model, serial number, last calibration date (or date when next calibration is due).					
97.01	The equipment used had not exceeded its calibration date at the time of certification.					
98.00	The HEPA filtered air changes per hour (ACPH) were measured for the compounding rooms.					
98.01	ISO Class 7 sterile compounding room is certified as having a minimum of 30 ACPH with at least 15 ACPH from outside air sources. *Recirculated air from the PECs may account for up to 15 ACPH in nonhazardous classified rooms only.*					
98.02	ISO class 7 anteroom is certified as having a minimum of 30 ACPH. *Anteroom must be ISO class 7 if connected to a NIOSH hazardous compounding clean/buffer room.*					
98.04	ISO class 7 hazardous sterile compounding room is certified as having a minimum of 30 ACPH. *Typically, all of the air will be from outside.*					
98.05	If a CACI is used in a non-HEPA filtered room, the room is certified to maintain a minimum of 12 ACPH.					
99.00	Air pattern analysis using smoke testing was performed under dynamic conditions (people working in the PECs and rooms). The smoke flow is described in the report for the various tests such as turbulent, sluggish, smooth, etc.					
99.01	Air pattern analysis was 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 (personnel compounding or simulating compounding in PEC).					
99.02	Air pattern analysis was conducted to confirm positive pressure (and negative pressure into hazardous compounding rooms) at all points around all openings, doorways, and pass-throughs.					
99.03	Air pattern analysis conducted around particle generating equipment *while the equipment was in operation* to confirm air flow.					
100.00	Differential air pressure between rooms was measured.					

100.01	The differential pressure measured was at least 0.02" water column positive from the cleanroom to the anteroom and between the anteroom and all adjacent spaces with the doors closed.					
100.02	The differential pressure measured was at least 0.01" water column negative from the hazardous clean/buffer room to the anteroom with the doors closed.					
101.00	Displacement airflow between rooms or areas was measured. This is for a clean/buffer room without a door that closes to the anteroom - may be an open space or may have plastic strips in doorways.					
101.01	Displacement airflow (for low and medium-risk non-hazardous rooms only) was measured at a minimum differential velocity of 40 feet per minute from the cleanroom to the anteroom. *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.*					
102.00	Particle counts of particles 0.5um and larger were measured under dynamic conditions.					
102.01	ISO Class 5 areas and PECs are certified as having less than 3,520 particles per cubic meter of air (100 particles per cubic foot).					
102.02	ISO Class 7 areas are certified as having less than 352,000 particles per cubic meter of air (10,000 particles per cubic foot).					
102.03	ISO Class 8 areas are certified as having less than 3,520,000 particles per cubic meter of air (100,000 particles per cubic foot).					
103.00	HEPA filter tests were performed.					
103.01	All room HEPA filters were leak tested and if leaks found, they were fixed.					
103.02	All PEC HEPA filters were leak tested and if leaks found, they were fixed.					
104.00	PECs with failed tests are not used for compounding until the conditions are corrected and verified by subsequent testing.					
105.00	Viable air (every six months) and surface sampling (periodically) tests have been conducted as required. *Document frequency.*					
105.01	Appropriate growth media used (containing tryptic soy agar medium with polysorbate and lecithin (TSApl) added to neutralize cleaning agents for surface sampling) with appropriate corresponding incubation time and temperature used. *Required to use media that supports both bacterial and fungal growth for high risk compounding.*					

105.02	Viable air sampling by active impaction using a volumetric air sampling device. *NOTE: Passive air sampling or settling plates are not compliant with USP Chapter <797>.*					
105.03	Air samples were taken in each ISO Class 5 PEC, and in each sterile compounding room and anteroom and the samples are at least 400 liters in volume? *Note: recommendation in ISO 5 PEC is 1000 liters.*					
105.04	Surface samples performed on all direct compounding areas inside of each ISO 5 PEC, in each ISO classified room, inside any pass-throughs, and on surfaces likely to be contaminated due to position relative to doorways, etc.					
105.05	Viable air and surface samples did not exceed USP action levels (or internal action levels if more restrictive). Classification Air Sample Surface Sample ISO Class 5 >1 CFU/m3 >3 CFU/plate ISO Class 7 >10 CFU/m3>5 CFU/plate ISO Class 8 >100 CFU/m3 >100 CFU/plate *CFUs are TOTAL of bacterial plus fungal/mold plates. If air sampling volume is less than 1000 liters (one cubic meter), the number of CFUs found must be multiplied by the appropriate factor.*					
105.06	CFUs detected by any means (viable air or surface sampling, gloved fingertip testing, failed sterility tests, etc.) are 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.*					
105.07	If the number of CFUs detected **in the rooms** exceeds action levels, begin immediate remediation, including recleaning, retraining and retesting; and conduct investigation into the causes.					
105.08	If the number of CFUs detected **in the PECs** exceeds action levels, begin immediate remediation, including recleaning, retraining and retesting; and conduct investigation into the causes.					

105.09	If any highly pathogenic microbes (ie mold, yeast, coagulase positive staphylococcus, or gram- negative rods) were detected **in the PECs** (whether or not the number of CFUs exceeds action levels), begin immediate remediation, including recleaning, retraining and retesting; and conduct investigation into the causes.					
106.00	Facilities performing routine air or surface sampling with internal qualified personnel routinely verify sampling procedures. *Indicate the outside vendor used to verify procedures and frequency of verifications.*					
	Compounding Equipment	**C**	**NC**	**?**	**NA**	**Notes**
	Total Non-Compliant (Includes Unknowns)					
107.00	Appropriate equipment and utensils are available, clean, and in good working order. *Automated, mechanical, or electronic equipment (autoclaves, ovens, etc.) are periodically inspected, and calibrated yearly or in accordance with the equipment manufacturer guidelines.*					
108.00	All environmental monitoring equipment and gauges (differential pressure gauges or probes, air flow and velocity measuring equipment for rooms not fully enclosed, etc.) are periodically inspected, and calibrated yearly or in accordance with the equipment manufacturer guidelines. Calibration is documented.					
109.00	All temperature and humidity (where applicable) monitoring devices (thermometers, hygrometers, probes, etc.) are periodically inspected, and calibrated yearly or in accordance with the equipment manufacturer guidelines. Calibration is documented.					
110.00	Automated Compounding Devices (ACDs) are used for sterile compounding (such as repeater pumps) and there is a P&P for the use and calibration.					
110.01	There is documentation of the ACD tubing being changed or discarded every 24 hours.					
110.02	The ACD is used when performing media fill testing.					
	Compounding Procedures	**C**	**NC**	**?**	**NA**	**Notes**
	Total Non-Compliant (Includes Unknowns)					
111.00	Gloves and critical sites are sanitized with adequate frequency and with an approved disinfectant, such as sterile 70% isopropyl alcohol (IPA) spray and a nonlinting wipe.					

112.00	Objects that shed particles are prohibited in the buffer or clean area, including pencils, cardboard cartons, paper towels, reading material, and cotton items (e.g., gauze pads).					
113.00	Essential paper related products (syringe overwraps, work records contained in a protective plastic sleeve) are wiped down with sterile 70% IPA before being brought into the buffer or clean area.					
114.00	Supplies required for the scheduled operations of the shift are prepared and decontaminated by wiping 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 in a bin or on a movable cart.					
115.00	Compounding employees are using appropriate aseptic technique. *May require inspector to garb and enter clean/buffer room. 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 direct compounding area (DCA).* ***Compounding MUST be observed*** *, if compounding is not being performed at the time of survey mark item as "Non- Compliant".*					
115.01	If compounding is not being performed at the time of survey, ask that a compounding pharmacist or technician prepare a compound for you to observe the compounding process. *If the pharmacy staff refuses or is unable to perform compounding for you to observe, document on the "* ***Denial of Authorization*** *" form. List individual who signs the Denial of Authorization.*					
116.00	Compounding personnel ascertain that ingredients for CSPs are of the correct identity and appropriate quality by reading vendors' labels, and a unit-by-unit physical inspection of the product before use.					
117.00	All rubber stoppers of vials and bottles and the neck of ampules are 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.					

118.00	Single-dose vials exposed to ISO Class 5 or cleaner air are used within six (6) hours of the initial puncture and any remaining contents discarded. *If exposed to less than ISO Class 5 air, used within 1 hour and discarded.*					
119.00	The remaining contents of opened single-dose ampules (or vials where container closure system has been removed) are discarded immediately. *May not be stored for any time period.*					
120.00	Multiple-dose vials formulated for removal of portions on multiple occasions are used within 28 days (or the manufacturer's specific BUD if less) after the initial entry or puncture and any remaining contents discarded.					
121.00	The compounding record is complete. *View several completed compounding records and answer each of the following questions.*					
121.01	Official or assigned name, strength and dosage of the preparation.					
121.02	Names, lot numbers and expiration dates of all components.					
121.03	Total quantity or number of units compounded.					
121.04	Person compounding the preparation.					
121.05	Person performing the quality control procedures.					
121.06	Person who approved the preparation.					
121.07	Date of compounding.					
121.08	Assigned internal identification number or prescription number.					
121.09	Assigned BUD and reference if extended beyond USP guidelines.					
121.10	Duplicate label.					
121.11	Sterilization method (if applicable).					
121.12	Indication of the quality control procedures to perform (testing, filter integrity, etc.) and results of the testing, quality control issues, and investigation/recall if applicable					
122.00	Procedure for in-process checks is followed. *These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists and visual inspection of product. Documentation of the compounding accuracy is **recommended** to be performed by someone other than the compounder to ensure proper measurement, reconstitution, and component usage.*					

123.00	Labels on BATCH preparations include the name and quantity of all contents, date, and time of preparation (or internal code indicating this information), preparer and verification pharmacist identifiers, stability (BUD), and any auxiliary labels indicated including appropriate packaging and labeling of hazardous materials.					
124.00	Labels on PATIENT-SPECIFIC containers, in addition to standard label requirements, also include names and quantity or concentration of active ingredients, BUD, total volume, route of administration, storage conditions and other information for safe use.					
125.00	Inspect several different finished products and look for any particulates. Do any of the finished products inspected show any evidence of particulates? *If so, list the products including lot and expiration date and obtain photos (if possible).* **REQUEST THE PRODUCT BE QUARANTINED AND NOTIFY NABP IMMEDIATELY.**					
126.00	Preparations without additional stability testing or supported by data are assigned BUDs within USP<797> guidelines. **Low Risk:** 48 hours room temp, 14 days refrigerated, 45 days frozen **Medium Risk:** 30 hours room temp, 9 days refrigerated, 45 days frozen **High Risk:** 24 hours room temp, 3 days refrigerated, 45 days frozen					
127.00	If extended BUDs are assigned, are they assigned on the basis of stability data extrapolated from reliable literature sources? *View records, preparation must exactly match the preparation cited in the documentation including concentration of all active ingredients, excipients, etc.*					
128.00	If extended BUDs are assigned, has the facility performed its own stability testing? *View records, preparation must exactly match the preparation tested by the facility including concentration of all active ingredients, excipients, etc. If so, view records for at least three products and list the products reviewed below. List the products reviewed.*					
129.00	Compounded multiple-dose vials with extended BUDs assigned have additional instruction provided that indicates remainder must be discarded 28 days after first puncture or use.					
130.00	**Filter sterilization** in an ISO 5 environment and documentation includes:					

130.01	If the compounded preparation contains large particles, a prefilter is placed upstream from the sterilizing filter.					
130.02	The 0.2 micron sterile microporous membrane filter used to sterilize CSP solutions is chemically and physically compatible with the CSP; and the filter is intended for human-use applications for sterilizing CSPs (labeling does not indicate "research only" or "laboratory only", for example).					
130.03	Is the appropriate capacity filter being used for the volume being filtered?					
130.04	Filtering is completed rapidly without filter replacement.					
130.05	Confirmation of filter integrity/bubble testing is performed and value documented for each filter used with each batch sterilized by filtration. View documentation on compounding records of items sterilized by filtration to confirm.					
131.00	**Steam sterilization** documentation includes:					
131.01	The autoclave has been validated for the exposure time and mass of the items to be sterilized.					
131.02	Ensures live steam contacts all ingredients and surfaces to be sterilized, effectiveness verified with biological indicators and temperature sensing devices.					
131.03	Solutions are passed through a 1.2 micron or smaller filter into the final containers to remove particulates before sterilization.					
131.04	Heated filtered air is evenly distributed throughout the chamber with a blower.					
131.05	That the CSP will not be adversely affected by the steam and heat.					
131.06	The description of steam sterilization includes conditions and duration for specific CSPs.					
131.07	That the effectiveness of steam sterilization is verified each time using appropriate biological indicators.					
132.00	**Dry heat sterilization** documentation includes:					
132.01	Dry heat is only used for those items that cannot be sterilized by steam or would be damaged by moisture.					
132.02	Sufficient space is left between materials to allow for air circulation.					
132.03	The description of dry heat sterilization includes conditions and duration for specific CSPs.					
132.04	That the effectiveness of dry heat sterilization is verified each time using appropriate biological indicators.					

132.05	The oven is equipped with a system for controlling and recording temperature and exposure period.					
133.00	**Depyrogenation by dry heat** documentation includes:					
133.01	Dry heat depyrogenation is used to render glassware and containers (such as vials) free from pyrogens as well as viable microbes.					
133.02	The description of the cycle and duration for specific load items.					
133.03	The effectiveness of the cycle is verified using endotoxin challenge vials (ECVs).					
133.04	Bacterial endotoxin testing is performed on the ECVs to verify the cycle is capable of achieving a three log reduction in endotoxins.					
134.00	Other methods of sterilization are used with documented procedures and validation performed. *Indicate method.*					
	Finished Preparation Release Checks and Tests	**C**	**NC**	**?**	**NA**	**Notes**
	Total Non-Compliant (Includes Unknowns)					
135.00	Are products visually checked for particulates or other foreign matter against both a light and a dark colored background as a condition of release?					
136.00	Are there checks for container, closure integrity and any other apparent visual defects?					
137.00	Is compounding accuracy documented by verification of steps?					
138.00	Is verification of ingredient identity and quantity verified? *Is there a reconciliation of components?*					
139.00	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.*					
140.00	**Sterility testing (USP <71>).** *If testing is performed to a higher standard than the minimums below, describe.*					
140.01	Sterility testing includes both bacterial and fungal testing.					
140.02	Sterility testing is performed for all CSPs that have extended BUDS.					
140.03	Sterility testing is performed for high-risk CSPs prepared in batches of more than 25 identical containers.					

140.04	Sterility testing is performed for CSPs exposed longer than 12 hours at 2°C-8°C or longer than six hours at warmer than 8°C before being sterilized.					
140.05	The appropriate quantities of units are sterility tested. Parenterals, number of units in the batch is: 1. Less than 100, test 10% or four units, whichever is greater 2. 100 up to 500, test 10 units 3. More than 500, test 2% or 20 units, whichever is less For large volume parenterals: 2% or 10 containers, whichever is less. For non-parenterals (eye drops, inhalation, etc.): 1. Less than 200 containers, test 5% or 2 containers, whichever is greater 2. 200 or more containers, test 10 containers 3. If the product is packaged in unit doses, use the parenteral testing above.					
144.06	For products failing testing, product is quarantined, and an investigation is performed including microbial identification and action taken. *View testing records and note any products with failed results and actions taken.*					
144.07	If items are dispensed or distributed prior to sterility testing completion, there is a written procedure requiring daily observation of the incubated media. If there is any evidence of microbial growth, there is an immediate recall and both the patient and the physician/prescriber of the patient to whom a potentially contaminated CSP was administered are notified of the potential risk. *View testing records and note any products with failed results and actions taken.*					
145.00	**Endotoxin testing (USP <85>).** *If testing is performed to a higher standard than the minimums below, describe.*					
145.01	Is endotoxin testing performed for 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).					
145.02	High-risk CSPs prepared in multiple dose vials for administration to multiple patients.					
145.03	High-risk CSPs exposed longer than 12 hours at 2°C-8°C (25°F-46°F) or longer than six (6) hours at warmer than 8°C (46°F) before they are sterilized.					

145.04	For products failing testing, product is quarantined, and an investigation is performed and action taken. *View testing records and note any products with failed results and actions taken.*					
	Patient Counseling and Communication	**C**	**NC**	**?**	**NA**	**Notes**
	Total Non-Compliant (Includes Unknowns)					
146.00	Do patient/caregiver training programs or materials contain information and precautions regarding the handling and disposal of hazardous products such as chemotherapy medications?					
147.00	Are the above required printed drug information materials (drug information, PPI, MedGuides, etc.) provided for the compounded products?					
148.00	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?					
149.00	Product recalls include documentation that both the patient AND the physician/prescriber of the potentially contaminated CSP was administered are notified of the potential risk.					

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>. An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

_____ _____ _____ _____

Pharmacist-in-Charge Signature Date Inspector Signature Date

Revised 7/1/18