Maryland
DEPARTMENT OF HEALTH

Wes Moore, Governor • Aruna Miller, Lt. Governor • Meena Seshamani, M.D., PH.D., Secretary

MARYLAND BOARD OF PHARMACY

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Reset

Sterile Compounding Inspection Form

The Maryland Board of Pharmacy developed this inspection form in coordination with NABP and other state boards of pharmacies in an attempt to apply a uniformed approach to inspection of sterile compounding pharmacies, wherever located, for compliance of USP 797 standards. Thus, this form includes requirements of other states, items related to best practices, and informational questions related to the Board's health oversight functions. These items are highlighted with an asterisk.

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.

1.00 PERMITS AND LICENSES

Corporate Pharmacy Name: _____

Pharmacy Name-Doing Business as (d/b/a) or Trade Name: _____

Address: _____

Business Telephone Number: _____ Business Fax Number: _____

Business Email Contact: _____

Maryland Pharmacy Permit Number: _____ Expiration: _____

CDS Registration Number: _____ Expiration: _____

DEA Registration Number: _____ Expiration: _____

Pharmacy Hours: _____

Inspection Date: _____ Arrival Time: _____ Departure Time: _____

Type of Inspection: Opening ◯ Annual ◯ Follow-up ◯ Previous Date: _____

Name of Inspector: _____

2.00 PERSONNEL (COMAR 10.34.03.05)

Name of Pharmacist/Manager who is charged with ensuring compliance with all applicable laws

_____

Pharmacist Employees	License #	Exp. Date

Registered Technicians	Registration #	Exp. Date

Support Personnel	Title	Duties

General Operations Information

		Y	N	N/A	Follow up ☐
3.00	The pharmacy department provides service 24 hours a day.	◯	◯		COMAR 10.34.05.
4.00	The pharmacy hours of operation are prominently displayed.	◯	◯	◯	COMAR 10.34.05.03B
5.00	All permits, licenses, and registrations are posted conspicuously.	◯	◯		HO §12-311, HO §12-408(b) and HO §12-6B-08
6.00	Does the pharmacy dispense/distribute sterile compounded preparations over state lines	◯	◯		
6.01	States in which Pharmacy is Licensed/Permitted				
7.00	Are patient profiles complete, easily accessible 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.*	◯	◯	◯	COMAR 10.34.19.07A
8.00	Does the pharmacy **dispense** sterile compounded preparations pursuant to a prescription?	◯	◯	◯	HO § 21-220
8.01	The pharmacy fills original prescriptions received via the internet. *If yes, how do pharmacists verify that a relationship exists between the patient and the prescriber?*	◯	◯	◯	HG §21-220; COMAR 10.19.03.02 and .07
8.02	Are sterile compounded prescriptions picked up at the pharmacy?	◯	◯	◯	
8.03	Are sterile compounded prescriptions delivered/mailed to patients in their homes or residential facilities?	◯	◯	◯	
8.03A	Proper in-transit storage is consistent with preparation labeling	◯	◯	◯	COMAR 10.34.19.06(A)(2)
8.04	A reasonable effort to provide tamper-evident packaging if appropriate to setting	◯	◯	◯	COMAR 10.34.19.06(A)(1)
9.00	Does the pharmacy **distribute** sterile compounded preparations? *Not pursuant to a prescription, not labeled by the pharmacy with a patient name.*	◯	◯	◯	COMAR 10.34.37

9.01 Does the pharmacy distribute sterile compounded preparations to practitioners for office-use? COMAR 10.34.37

9.02 Does the pharmacy distribute sterile compounded preparations to hospitals, clinics, or surgery centers? COMAR 10.34.37

9.03 Does the pharmacy distribute sterile compounded preparations to a wholesale distributor? COMAR 10.34.37

9.04 Does the pharmacy have a sales force that distributes samples containing active ingredients? COMAR 10.34.37
List samples provided.

9.05 Does the pharmacy provide sterile compounded preparations to other pharmacies for dispensing?

9.05A Does the pharmacy have central fill/shared services contracts or agreements with these pharmacies for patient specific preparations?

9.06 Proper in-transit storage is consistent with preparation labeling COMAR 10.34.19.06(A)(2)

9.07 A reasonable effort to provide tamper-evident packaging if appropriate to setting COMAR 10.34.19.06(A)(1)

10.00 Is the pharmacy registered with the FDA as an Outsourcing Facility? COMAR 10.34.37

11.00 Which of the following sterile compounds are prepared?

		Y	N			Y	N
11.01	Allergen extracts	◯	◯	11.07	Baths and soaks for live organs and tissues	◯	◯
11.02	Parenteral solutions	◯	◯	11.08	Irrigations for wounds and body cavities	◯	◯
11.03	Parenteral *suspensions*	◯	◯	11.09	Injectables	◯	◯
11.04	Preservative-free parenterals	◯	◯	11.10	Radiopharmaceuticals	◯	◯
11.05	Ophthalmic preparations	◯	◯	11.11	Any other sterile preparations (implants, pellets, etc.). *Provide list.*	◯	◯
11.06	Oral or nasal *inhalation* preparations (not topical sprays)	◯	◯				

12.00 Does the pharmacy prepare medication using proprietary bag and vial systems? (ADD-Vantage, Mini Bag Plus. Etc)

12.01 Are they docked in an ISO 5 environment?

12.02 Are BUDS less than or equal to manufacturers labeling?

13.00 Does the pharmacy outsource medications? *Indicate companies*

13.01 Does the pharmacy act as an outsourcer? *Indicate companies*

14.00 Does the pharmacy compound investigational drugs?

15.00 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? *Indicate name and volume/percent compounded currently.*

15.01 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.

15.02 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 removal from drug shortage list for existing orders.

16.00 Does the pharmacy provide sterile compounded preparations to be administered via an implantable infusion pump?

17.00 Does the pharmacy perform compounding for **immediate use?**
Indicate percentage of immediate use sterile compounding.

18.00 Does the pharmacy perform compounding with **hazardous drugs**?
Indicate percentage of hazardous sterile compounding.
NOTE: NIOSH list of hazardous drugs including chemotherapy, hormones, etc.

18.01 Does pharmacy have a plan to comply with USP Chapter <800> by the implementation date?
Describe plan.

19.00 Does the pharmacy perform compounding using **blood products** (or other biological materials)? Such as wound care, autologous eye drops, etc. *Describe.*

20.00 Does the pharmacy compound using any Federally **controlled substances I-V**?
Indicate controlled substances used and percentage of controlled substance sterile compounding.

21.00 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.

Hazardous Drugs CSPs
COMAR 10.34.07.03(E)

Component Selection and Use

Y N N/A **Follow up ☐**

22.00 **APIs:** Does the pharmacy make any sterile compounded preparations using bulk powder Active Pharmaceutical Ingredients (APIs)?

22.01 Does the pharmacy purchase APIs directly from the manufacturer/repackager?
If not, indicate the source of APIs

22.02 Does the pharmacy verify that the manufacturer/repackager of the API is an FDA-registered facility? *If so, list how this verified*

22.03 Does the pharmacy use active ingredients that are not from an FDA facility?
If so, indicate sources.

22.04 Are on-hand quantities of APIs used for compounding tracked by computer? ***

23.00 If the facility performs both sterile and nonsterile compounding, the areas are separated and distinct.

24.00 If the facility performs compounding using blood products (or other biological materials), this compounding area is separate and distinct from the general compounding areas.

24.01 Are components used in compounding with blood products restricted to the blood compounding area (not used in other compounding areas)?

25.00 **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

Nonsterile Ingredients and Devices

25.01 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.

Nonsterile Ingredients and Devices
Verification of Compounding Accuracy and Sterility

25.02 USP- or NF-grade substances used, if available.

Nonsterile Ingredients and Devices

25.03 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.

High-Risk Level CSPs cross reference to 795, Component Selection Handling and Storage, Item number 4

25.04 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

High-Risk Level CSPs cross reference to 795, Component Selection Handling and Storage, Item number 4

25.05 All substances and components have a complete label including a batch control or lot number, and an expiration date.

Responsibility of Compounding Personnel
Ingredients and Devices
Storage and Beyond-Use Dating cross reference to USP Chapter 795

25.06 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.**

Nonsterile Ingredients and Devices

25.07	All APIs are labeled with the date they were received.		Nonsterile Ingredients and Devices
25.08	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.		Nonsterile Ingredients and Devices Determining BUD cross reference to USP Chapter 795
25.09	Bulk component containers are labeled with appropriate OSHA hazard communication labels and hazardous substances are segregated (including hormones). ***		Hazardous Drugs CSPs
26.00	The Pharmacy is free of 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).		U.S. Food, Drug and Cosmetic Act List 21CFR216.64 COMAR 10.34.19.04
27.00	When manufactured products are used for compounding, all the other excipients (in addition to the active ingredient) in the manufactured product are considered relative to the use, effectiveness, and stability of the compounded preparation to be made.		Introduction Ingredients and Devices
28.00	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. ***		High-Risk Level CSPs
28.01	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.***		High-Risk Level CSPs
28.02	Compounded preparations using the stock solution are classified as high-risk compounds with appropriate handling with regard to BUD and testing requirements. ***		High-Risk Level CSPs
29.00	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.***		
29.01	For **animal compounding**, does the compounding meet the same standards as compounding for human patients? ***		Cross reference USP Chapter 795
29.02	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. ***		Cross reference USP Chapter 795
29.03	It is determined and documented if the animal is used for food (meat, milk, eggs, etc.) or that the animal is a pet. ***		Cross reference USP Chapter 795
29.04	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. ***		Cross reference USP Chapter 795

29.05	The facility has a list of drugs and components not allowed when compounding for food-producing animals. ***	◯◯◯	Cross reference USP Chapter 795
29.06	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)***	◯◯◯	Cross reference USP Chapter 795

Environment

		Y N N/A	Follow up ☐
30.00	The anteroom contains an eyewash station or sink design suitable for flushing an eye injury.	◯◯	COMAR 10.34.19.09(C)(2)(c)
31.00	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).	◯◯	
32.00	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.	◯◯	
32.01	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.	◯◯◯	
33.00	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. *** **	◯◯◯	Additional Personnel Requirements
33.01	Carts used to bring supplies from the storeroom are kept on the outside of the line of demarcation. ***	◯◯◯	Suggested SOPs
33.02	Carts used in the clean/buffer room are kept on the clean side of the line of demarcation. ***	◯◯◯	Suggested SOPs
34.00	Hand drying is with lint-free disposable towels, or an electronic or HEPA filtered hand dryer.	◯◯◯	Personnel Cleansing and Garbing COMAR 10.34.19.11(D)
34.01	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. ***	◯◯◯	Environmental Viable Airborne Particle Testing Program
35.00	Beverages including drinking water, chewing gum, candy, or food items are prohibited from the clean/buffer room or anteroom.	◯◯◯	Additional Personnel Requirements Suggested SOPs (Item 13) COMAR 10.34.19.09
36.00	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.	◯◯◯	Facility Design and Environmental Controls 10.34.19.09(B)(3)
37.00	Walls are constructed of durable material, which is cleanable, such as epoxy-coated or heavy-gauge polymer material. *If panels are used, they are locked together and sealed.*	◯◯◯	Facility Design and Environmental Controls 10.34.19.09(B)(3)

38.00	The ceiling surface shall be impervious and hydrophobic. *If tiles are used, they shall be locked and the seams (between tiles and where the tiles meet with the walls) shall be caulked and sealed.*		Facility Design and Environmental Controls 10.34.19.09(B)(3)
39.00	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.		Facility Design and Environmental Controls 10.34.19.09(B)(3)
40.00	The clean/buffer room or anteroom does not have dust collecting overhangs. ***		Facility Design and Environmental Controls
41.00	The exposed surfaces of:		
41.01	PEC are free of dirt, rust, chips and particulate matter.		Cleaning and Disinfecting the Compounding Area COMAR 10.34.19.09(B)(3)
41.02	Light fixtures are smooth, mounted flush, and sealed.		Facility Design and Environmental Controls COMAR 10.34.19.09(B)(3)
42.00	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).		Additional Personnel Requirements COMAR 10.34.19.09(C)(2)
43.00	The permit holder shall ensure that the clean room in the controlled environment contains no sinks or floor drains;		Facility Design and Environmental Controls Appendix 1 COMAR 10.34.19.09(B)(2)
44.00	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 environment and the anteroom with an ISO Class 7 (when adjacent to HD cleanroom) or ISO Class 8 environment.		ISO Class 5 Air Sources, Buffer Areas, and Ante-Areas
45.00	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.***		Facility Design and Environmental Controls
46.00	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. ***		ISO Class 5 Air Sources, Buffer Areas, and Ante-Areas
47.00	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.		Verification of Compounding Accuracy and Sterility
47.01	Pre-sterilization procedures for high-risk level CSPs (such as weighing and mixing) are performed in no worse than an ISO Class 8 environment.		Placement of Primary Engineering Controls Appendix 1
48.00	Completely enclosed anteroom and clean/buffer room (with a door) are equipped with monitors or gauges to measure differential pressure.		Pressure Differential Monitoring Facility Design and Environmental Controls

48.01	Anteroom is at least 0.02" wc positive pressure to general pharmacy areas.		Facility Design and Environment Controls
48.02	Clean/buffer room is at least 0.02" wc positive pressure to Anteroom.		Facility Design and Environment Controls
48.03	Hazardous compounding room and drug storage area is at least 0.01" wc negative pressure to ISO Class 7 anteroom.		Hazardous Drugs CSPs
48.04	Pressures are reviewed and documented on a log at least every work shift (minimum of once daily) or monitored by a continuous recording device. *View logs*		Pressure Differential Monitoring
48.05	Written plan in place to detect and react to pressure differentials outside of limits.		Facility Design and Environmental Controls Equipment
49.00	Is the clean/buffer room and anteroom not fully enclosed (open or with plastic strips - no door that closes):		Facility Design and Environment Controls
49.01	Airflow is measured across the openings.		
49.02	Airflow is at least 40 feet per minute across the entire opening.		Facility Design and Environment Controls
49.03	Airflow is read and recorded each shift (minimum of once daily) or continuously recorded. *View logs.*		Pressure Differential Monitoring
49.04	Written plan in place to detect and react to airflow measurements outside of limits		Facility Design and Environmental Controls Equipment
49.05	This area is used only for low- and medium-risk compounding **NOTE: HD and high-risk not allowed**.		Facility Design and Environment Controls
50.00	**Temperature:** The temperature of all compounding and drug storage areas shall be maintained in accordance with standards, and a written plan shall be in place and followed to address any excursions.		Facility Design and Environment Controls Monitoring Controlled Storage Areas USP Chapter 659 COMAR 10.34.19.09(3)(b)
50.01	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. *Temperature records are maintained.* ***		Facility Design and Environment Controls
50.02	If drugs are stored in the compounding area, temperature monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. *Temperature records are maintained.* ***		Monitoring Controlled Storage Areas

50.03	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.		Nonsterile Ingredients and Devices COMAR 10.34.19.09(A), 10.34.19.15(A), 10.34.19.12(B),
50.04	Temperature monitoring in the **drug storage area** is performed at least once daily and documented. *Temperature records are maintained for at least 5 years.*		Monitoring Controlled Storage Areas
50.05	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.		Monitoring Controlled Storage Areas COMAR 10.34.19.10(A)
50.06	Temperature monitoring in the **refrigerator** is performed at least once daily and documented. Additionally, compounding personnel shall note the storage temperature when placing the product into or removing the product from the storage unit in order to monitor any temperature aberration. Alternatively, continuous monitoring or retroactive detection using min/max may be used. *Temperature records are maintained for at least 5 years.*		Monitoring Controlled Storage Areas COMAR 10.34.19.10(A), 10.34.19.15(B), 10.34.19.07(B)(1)(b)
50.07	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.		Monitoring Controlled Storage Areas
50.08	Temperature monitoring in the **freezer** is performed at least once daily and documented. Additionally, compounding personnel shall note the storage temperature when placing the product into or removing the product from the storage unit in order to monitor any temperature aberration. *Temperature records are maintained for at least 5 years.*		Monitoring Controlled Storage Areas COMAR 10.34.19.07(B)(1)(b), 10.34.19.10(A), 10.34.19.15(B)
50.09	Action plan in place for any temperature excursions including evaluating excursion effects on drug product integrity for all temperature-monitored areas. ***		Monitoring Controlled Storage Areas
51.00	**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%. (*General <u>recommended</u> range is 35-60% for performing sterile compounding*.) ***		Nonsterile Ingredients and Devices USP Chapter 659 (definition of dry place)
51.01	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. ***		Nonsterile Ingredients and Devices
51.02	If applicable, excursion action plan in place including evaluating excursion effects on drug product integrity. ***		Nonsterile Ingredients and Devices
51.03	If applicable, humidity monitoring is also performed in drug storage areas (if separate from the compounding areas). ***		Nonsterile Ingredients and Devices
52.00	Blowers on ISO 5 PECs are operated continuously during compounding activity, including during interruptions of less than eight hours. ***		Suggested SOPs
53.00	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. ***		Suggested SOPs

54.00	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.*		Facility Design and Environmental Controls
55.00	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.*		Facility Design and Environmental Controls
56.00	**If the PEC is a BSC or LAFW that is NOT located in an ISO Class 7 clean/buffer room**:		
56.01	BSC or LAFW has been certified to maintain ISO Class 5 during compounding activities.		Low-Risk Level CSPs COMAR 10.34.19.15(D)
56.02	Used only for low-risk compounded preparations with a 12-hour or less BUD assigned. *If yes, list percentage.*		Low-Risk Level CSPs
56.03	All garbing requirements are adhered too.		Low-Risk Level CSPs
56.04	Located in an area that is maintained under sanitary conditions and only traveled by persons engaging in the compounding of sterile preparations.		Low-Risk Level CSPs
56.05	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.		Low-Risk Level CSPs
56.06	The sink is separated from the immediate area of the ISO Class 5 BSC or LAFW (not adjacent).		Low-Risk Level CSPs
57.00	**If the PEC is a CAI/CACI that is NOT located in an ISO Class 7 clean/buffer room:**		
57.01	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.		Placement of Primary Engineering Controls Low-Risk Level CSPs COMAR 10.34.19.15(D)
57.02	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.		Placement of Primary Engineering Controls Low-Risk Level CSPs
57.03	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.		Placement of Primary Engineering Controls Low-Risk Level CSPs
57.04	The sink is separated from the immediate area of the CAI or CACI (not adjacent).		Placement of Primary Engineering Controls Low-Risk Level CSPs
57.05	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.		Hazardous Drugs as CSPs

58.00	Supplies are stored in a manner that maintains integrity of an aseptic environment.	◯	◯	◯
59.00	The facility must contain appropriate waste containers to isolate sharps, hazardous waste, biological, and chemotherapy waste.	◯	◯	◯ COMAR 10.34.19.09(B)(6), 10.34.19.15(F), 10.34.19.10(A)(3)

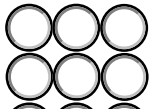
Cleaning and Disinfection

		Y	N	N/A	Follow up ☐
60.00	Are all personnel performing cleaning appropriately garbed?	◯	◯	◯	Personnel Cleansing and Garbing
61.00	The sterile compounding area is 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).*	◯	◯	◯	Cleaning and Disinfecting the Compounding Area Appendix 2 USP General Chapter 1072 COMAR 10.34.19.13(3)
62.00	If cleaning tools are reused, is there a procedure to rinse and sanitize the tools and an appropriate clean storage area?	◯	◯	◯	Cleaning and Disinfecting the Compounding Area
63.00	Reusable tools are appropriately labeled to prevent them from being used inappropriately. ***	◯	◯	◯	Cleaning and Disinfecting the Compounding Area
64.00	For cleaning and sanitizing agents that are not "ready-to-use" formulations, are there formulas and instructions for mixing or diluting the agents prior to use and is the preparation documented? ***	◯	◯	◯	Cleaning and Disinfecting the Compounding Area Appendix 2 USP General Chapter 1072
65.00	Cleaning and sanitizing agents are appropriately labeled including expiration dates. *** *Verify no expired agents present.*	◯	◯	◯	Cleaning and Disinfecting the Compounding Area Appendix 2 USP General Chapter 1072
66.00	Appropriate cleaning agents are used that are effective for bacteria, viruses, fungi, and spores.	◯	◯	◯	Cleaning and Disinfecting the Compounding Area Appendix 2 USP General Chapter 1072 COMAR 10.34.19.11(C), 10.34.19.12(4)
67.00	Are 3rd party cleaners and/or cleaning staff utilized to perform cleaning of rooms? List company/unit and frequency they perform cleaning.	◯	◯	◯	Cleaning and Disinfecting the Compounding Area Appendix 2 USP General Chapter 1072
6701	Are they trained to enter the cleanroom and perform cleaning? *Review training documents.*	◯	◯	◯	COMAR 10.34.19.07B(1)(d)
68.00	The ISO 5 PEC is cleaned at the beginning of each shift, between compounding activities, at least every 30 minutes while compounding and after spills or suspected surface contamination.	◯	◯	◯	Cleaning and Disinfecting the Compounding Area Appendix 2 USP General Chapter 1072
68.01	If heavily soiled, cleaning includes the appropriate agent. *List agent(s) used.*				

69.00	Sanitizing of the ISO 5 PEC includes sanitizing with sterile 70% IPA using a non-linting wipe.	○○○	Cleaning and Disinfecting the Compounding Area Appendix 2 USP General Chapter 1072 COMAR 10.34.19.11(C)
70.00	Daily cleaning and sanitizing include counters and easily cleanable work surfaces.	○○○	Cleaning and Disinfecting the Compounding Area COMAR 10.34.19.15(e)
71.00	Daily cleaning includes the floors starting from the clean/buffer room and working outwards. *Floor cleaning is not to occur during compounding.*	○○○	Cleaning and Disinfecting the Compounding Area COMAR 10.34.19.15(e)
72.00	If fatigue mats are used, are they cleaned daily and allowed to dry on both sides?	○○○	Cleaning and Disinfecting the Compounding Area
73.00	Is a tacky mat used, and if so, is there a procedure in place regarding replacement?	○○○	Cleaning and Disinfecting the Compounding Area
74.00	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.*	○○○	Cleaning and Disinfecting the Compounding Area COMAR 10.34.19.15(e)
75.00	Enough time is allocated for cleaning activities, including contact/dwell times for the cleaning/disinfection agents.	○○○	Cleaning and Disinfecting the Compounding Area Appendix 2 USP General Chapter 1072
76.00	Cleaning is documented and retained for 5 years	○○○	COMAR 10.34.19.07B()(1)(d)

Training

		Y N NA	Follow up ☐
77.00	Pharmacies must establish and follow a written program of training performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly.	○○○	COMAR 10.34.19.14E(1)
77.01	Personnel competency must be re-verified at least every 12 months (every 6 months for high-risk), whenever the quality assurance program yields an unacceptable result, or whenever improper aseptic technique is observed.	○○○	COMAR 10.34.19.14E(1)(a)
77.02	Records of training and demonstrated competence shall be available for each individual and shall be retained for five (5) years beyond the period of employment.	○○○	COMAR 10.34.19.14(c), COMAR 10.34.19.07(B)(1)(a)
78.00	There is documentation that compounding personnel are appropriately trained including policies and procedures, documentation, cleaning/disinfection/spills, garbing/gowning/hand hygiene, aseptic technique, and general conduct in the controlled area. **NOTE: "Compounding personnel" includes personnel performing compounding, supervising compounding, and performing verification of compounding.** *List number of personnel training files viewed.*	○○○	Responsibility of Compounding Personnel Personnel Training and Evaluation in Aseptic Manipulation Skills Hazardous Drugs as CSPs Personnel Cleansing and Garbing Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and

			Cleaning/Disinfection Procedures Appendices 3, 4, & 5 COMAR 10.34.19.14E(1)
78.01	Equipment and closure system selection if applicable		COMAR 10.34.19.14E(1)(j)
78.02	Hazardous drug handling if applicable		
78.03	Sterilization techniques if applicable		COMAR 10.34.19.14E(1)(i)
79.00	No personnel performing compounding are allowed to compound until training and initial testing is successfully completed.		Personnel Training and Evaluation in Aseptic Manipulation Skills Personnel Cleansing and Garbing Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures Appendices 3, 4, & 5 COMAR 10.34.19.14(B)
80.00	No personnel that SUPERVISE compounding and/or perform verifications of other's compounding are allowed to supervise or verify compounding until training and initial testing is successfully completed.		Personnel Training and Evaluation in Aseptic Manipulation Skills Personnel Cleansing and Garbing Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures Appendices 3, 4, & 5 COMAR 10.34.19.14(B)
81.00	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.* ***		Hazardous Drugs as CSPs
82.00	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.		Personnel Training and Evaluation in Aseptic Manipulation Skills Hazardous Drugs as CSPs Personnel Cleansing and Garbing Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures Appendices 3, & 5 COMAR 10.34.19.14(E)(1)(f), 10.34.19.14(E)(2)

83.00 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

Personnel Training and Evaluation in Aseptic Manipulation Skills
Personnel Cleansing and Garbing
Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures
Appendices 3, 4, & 5
COMAR 10.34.19.14E(1)(h) & (j)

84.00 If the pharmacy uses relief personnel from outside agencies to perform sterile compounding, training and certifications are verified.
View documentation.

Personnel Training and Evaluation in Aseptic Manipulation Skills
Personnel Cleansing and Garbing
Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures
Appendices 3, 4, & 5

85.00 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 when applicable. *Indicate frequency, if testing more than annually*

Personnel Training and Evaluation in Aseptic Manipulation Skills
Hazardous Drugs as CSPs
Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures
Appendix 1
COMAR 10.34.19.14(B), COMAR 10.34.19.14E(3)

85.01 There is documentation that all compounding personnel (including those supervising or performing verifications) have passed an initial pharmaceutical calculation exam, and subsequent annual pharmaceutical calculation exams.

COMAR 10.34.19.14E(1)(b)

86.00 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 when applicable. Compounding skills evaluation to include use of equipment. *Indicate frequency, if testing more than annually.*

Personnel Training and Evaluation in Aseptic Manipulation Skills
Hazardous Drugs as CSPs
Personnel Cleansing and Garbing
Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures
Appendices 3, 4, & 5
COMAR 10.34.19.14(B)

87.00 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.*

Personnel Training and Evaluation in Aseptic Manipulation Skills
Personnel Cleansing and Garbing
Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures
Action Levels, Documentation, and Data Evaluation
Appendices 1, 3, 4, & 5

88.00 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.

Low-Risk Level CSPs
Medium-Risk Level CSPs
Personnel Training and Evaluation in Aseptic Manipulation Skills
Hazardous Drugs as CSPs
Personnel Cleansing and Garbing
Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures
Appendices 3, 4, & 5

89.00 There is documentation that a media fill test procedure is performed for each compounding employee 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.*

Low-Risk Level CSPs
Medium-Risk Level CSPs
Personnel Training and Evaluation in Aseptic Manipulation Skills
Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedure (includes all sub-headings)
COMAR 10.34.19.12(C)(11), 10.34.19.15(C)

90.00 The media-fill testing procedures include:

Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning /Disinfection Procedure (includes all subheadings)

90.01 Media selection (including obtaining COAs or growth promotion certificates from suppliers)

Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning /Disinfection Procedure (includes all subheadings)
NABP 80.01

90.02 Fill Volume

Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning /Disinfection Procedure (includes all subheadings)
NABP 80.02

90.03	Incubation time and temperature (Media-filled vials are generally incubated at 20° to 25° or at 30° to 35° for a minimum of 14 days. If two temperatures are used for incubation of media-filled samples, then these filled containers should be incubated for at least 7 days at each temperature.)		Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning /Disinfection Procedure (includes all subheadings) COMAR 10.34.19.15(c)
90.04	Inspection of filled units		Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning /Disinfection Procedure (includes all subheadings)
90.05	Documentation		Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning /Disinfection Procedure (includes all subheadings)
90.06	Interpretation of results		Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning /Disinfection Procedure (includes all subheadings)
90.07	Action levels set with the corrective actions required		Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning /Disinfection Procedure (includes all subheadings)
91.00	**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.*		High-Risk Level CSPs Appendix I COMAR 10.34.19.14(E)(1)(a)
91.01	**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 generally incubated at 20° to 25° or at 30° to 35° for a minimum of 14 days. If two temperatures are used for incubation of media-filled samples, then these filled containers should be incubated for at least 7 days at each temperature.*		High-Risk Level CSPs Appendix I COMAR 10.34.19.14(E)(1)(a)

92.00	**Failed testing:** Employees who have failed any testing are prohibited from compounding until training is performed/reviewed and subsequent testing is performed successfully.	◯◯◯	Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning /Disinfection Procedure (includes all subheadings)
92.01	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. ***	◯◯◯	Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning /Disinfection Procedure (includes all subheadings) Action Levels, Documentation, and Data Evaluation
92.02	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.	◯◯◯	Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning /Disinfection Procedure (includes all subheadings) Action Levels, Documentation, and Data Evaluation

Garbing

		Y N N/A	Follow up ☐
93.00	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.	◯◯◯	Personnel Cleansing and Garbing
94.00	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.*	◯◯◯	Personnel Cleansing and Garbing COMAR 10.34.19.13(A)(7)
95.00	Personnel are required to remove all jewelry	◯◯◯	Personnel Cleansing and Garbing COMAR 10.34.19.13(A)(5)
96.00	Personnel are prohibited from wearing artificial nails or extenders, and required to keep natural nails neat and trimmed.	◯◯◯	Personnel Cleansing and Garbing
97.00	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). ***	◯◯◯	Personnel Cleansing and Garbing COMAR 10.34.19.13(A)(3), 10.34.19.13(A)(4)
98.00	Garbing includes head and facial hair covers and masks. **NOTE: 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 method available to assure that all hair is covered.**	◯◯◯	Personnel Cleansing and Garbing COMAR 10.34.19.13(A)(3)(b), 10.34.19.13(3)(c)
99.00	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.*	◯◯◯	Personnel Cleansing and Garbing COMAR 10.34.19.13(2)
100.00	The gown is non-shedding with sleeves that fit snugly around the wrists and enclosed at the neck.	◯◯◯	Personnel Cleansing and Garbing COMAR 10.34.19.13(A)(3)

101.00	The gloves are sterile and made of non-shedding materials.	◯◯◯	COMAR 10.34.19.11(A)
102.00	All bare skin is covered on the arms and the legs (no bare ankles, wrists, etc.).	◯◯◯	Personnel Cleansing and Garbing
103.00	Prior to donning sterile gloves, a waterless alcohol based surgical hand scrub with persistent activity is used and hands are allowed to dry.	◯◯◯	Personnel Cleansing and Garbing
104.00	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.	◯◯◯	Personnel Cleansing and Garbing COMAR 10.34.19.13(A)(4)
105.00	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.***	◯◯◯	Personnel Cleansing and Garbing 10.34.19.13A(4)
106.00	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)	◯◯◯	Personnel Cleansing and Garbing COMAR 10.34.19.13(A)
107.00	When preparing cytotoxic agents, appropriate personal protective equipment including gowns and gloves are worn.	◯◯◯	COMAR 10.34.19.12(C)(17), 10.34.19.14(B)
108.00	When working in a CAI/CACI are sterile gloves donned over the CAI/CACI gloves prior to compounding and changed in accordance with USP 797 or manufacturers recomendations	◯◯◯	Personnel Cleansing and Garbing

Environmental Monitoring

		Y N N/A	Follow up ☐
109.00	The most recent PEC and room certification report is available.	◯◯◯	Viable and Nonviable Environmental Sampling (ES) Testing
109.01	All ISO Class 7 and 8 SECs (clean/buffer rooms and anterooms) have been certified within the last 6 months.	◯◯◯	Viable and Nonviable ES Testing
109.02	All ISO Class 5 PECs (laminar airflow workbenches or areas, BSCs, CAIs, CACIs, and barrier isolators) have been certified within the last 6 months.	◯◯◯	Viable and Nonviable ES Testing COMAR 10.34.19.03(B)(5) & (10), 10.34.19.15(D)
109.03	Certification is performed at least every six months (view date of previous certification) and whenever a device or room is relocated, altered, or major service to the facility is performed. *Record the date of the previous certification.*	◯◯◯	Viable and Nonviable ES Testing COMAR 10.34.19.03(B)(5), 10.34.19.15(e)
110.00	Certification of the testing of the sterile compounding environment is retained for 5 years	◯◯◯	COMAR 10.34.19.07(B)(1)(c)
111.00	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.	◯◯◯	Viable and Nonviable ES Testing COMAR 10.34.19.07(B)(1)

112.00	The certification report includes information about the equipment used for performing each test including, identification of the equipment used by model, serial number, last calibration date (or date when next calibration is due).		Viable and Nonviable ES Testing cross reference CETA guide
112.01	The equipment used had not exceeded its calibration date at the time of certification.		Viable and Nonviable ES Testing cross reference CETA guide
113.00	The HEPA filtered air changes per hour (ACPH) were measured for the compounding rooms.		Facility Design and Environmental Controls
113.01	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.*		Facility Design and Environmental Controls
113.02	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.*		Facility Design and Environmental Controls
113.03	ISO class 7 <u>hazardous</u> sterile compounding room is certified as having a minimum of 30 ACPH. *Typically all of the air will be from outside.*		Hazardous Drugs CSPs
113.04	If a CACI is used in a non-HEPA filtered room, the room is certified to maintain a minimum of 12 ACPH.		Hazardous Drugs CSPs
114.00	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.		Facility Design and Environmental Controls
114.01	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).		Facility Design and Environmental Controls
114.02	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 ***		Facility Design and Environmental Controls Hazardous Drugs CSPs
114.03	Air pattern analysis conducted around particle generating equipment *while the equipment was in operation* to confirm airflow. ***		Facility Design and Environmental Controls Viable and Nonviable ES Testing
115.00	Differential air pressure between rooms was measured.		Facility Design and Environmental Controls
115.01	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.		Facility Design and Environmental Controls
115.02	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.		Facility Design and Environmental Controls

116.00	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.	Facility Design and Environmental Controls
116.01	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: It is very important to maintain this velocity across the entire opening and the report should indicate multiple points of measure across all openings.**	Facility Design and Environmental Controls
117.00	Particle counts of particles 0.5um and larger were measured under dynamic conditions.	Facility Design and Environmental Controls
117.01	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).	Facility Design and Environmental Controls Table 1
117.02	ISO Class 7 areas are certified as having less than 352,000 particles per cubic meter of air (10,000 particles per cubic foot).	Facility Design and Environmental Controls Table 2
117.03	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).	Facility Design and Environmental Controls Table 3
118.00	HEPA filter tests were performed.	Facility Design and Environmental Controls
118.01	All room HEPA filters were leak tested and if leaks found, they were fixed	Facility Design and Environmental Controls
118.02	All PEC HEPA filters were leak tested and if leaks found, they were fixed	Facility Design and Environmental Controls
119.00	PECs with failed tests are not used for compounding until the conditions are corrected and verified by subsequent testing.	Viable and Nonviable ES Testing (includes all subheadings)
120.00	Viable air (every six months) and surface sampling (periodically) tests have been conducted as required. *Document frequency.*	Viable and Nonviable ES Testing (includes all subheadings) Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/ Disinfection Procedures (includes subheadings) COMAR 10.34.19.15(C)
120.01	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.*	Competency Evaluation of Garbing and Aseptic Work Practice Cross reference USP Chapter 1116 COMAR 10.34.19.15(C)

120.02 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>.

Environmental Viable Airborne Particle Testing Program
COMAR 10.34.19.15(C)

120.03 Air samples were taken in each ISO Class 5 PEC and in each sterile compounding room and anteroom and volume sufficient volume of air (400-1000L) was collected.
NOTE: 1000L must be collected in ISO Class 5 PECs to be able to detect the action level. Room samples can be 400-1000L.

Environmental Viable Airborne Particle Testing Program
10.34.19.15(C)

120.04 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.

Environmental Viable Airborne Particle Testing Program
COMAR 10.34.19.15(C)

120.05 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/m^3	>3 CFU/plate
ISO Class 7	>10 CFU/m^3	>5 CFU/plate
ISO Class 8	>100 CFU/m^3	>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 raw total microbial count must be multiplied by the appropriate factor to determine the number of CFU/cubic meter.

Environmental Viable Airborne Particle Testing Program, Table 2
Action Levels, Documentation, and Data Evaluation, Table 4
COMAR 10.34.19.15(C)

120.06 CFUs detected (viable air or surface sampling failed sterility tests, etc.) are identified to the genus level. *All CFUs detected must be identified even if the number of CFUs does not exceed an action level.*

Environmental Viable Airborne Particle Testing Program
COMAR 10.34.19.15(C)

120.07 If the number of CFUs detected **in the rooms** exceeds action levels, begin immediate remediation (e.g. recleaning and retesting); and conduct investigation into the source(s) of the contamination.

Environmental Viable Airborne Particle Testing Program
COMAR 10.34.19.15(C)

120.08 If the number of CFUs detected **in the PECs** exceeds action levels, begin immediate remediation, (e.g. recleaning and retesting); and conduct investigation into the source(s) of the contamination.

Environmental Viable Airborne Particle Testing Program
COMAR 10.34.19.15(C)

120.09 If any highly pathogenic microbes (e.g. mold, yeast, coagulase positive staphylococcus, or gram-negative rods) were detected (whether or not the number of CFUs exceeds action levels), begin immediate remediation (e.g. recleaning and retesting); and conduct investigation into the source(s) of the contamination.

Environmental Viable Airborne Particle Testing Program

121.00 Samples that exceed USP action levels (or internal action levels if more restrictive) or have highly pathogenic microbes detected have been reported to the Board within 5 days of receiving report.

COMAR 10.34.19.18(B)

122.00	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.* ***	◯◯◯	Viable and Nonviable ES Testing (includes all subheadings)

Equipment

		Y N N/A	Follow up ☐
123.00	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.*	◯◯◯	Equipment USP Chapter 1176 COMAR 10.34.19.10(B)
124.00	All environmental monitoring equipment and gauges (differential pressure gauges or probes, airflow 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.	◯◯◯	Equipment
125.00	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	◯◯◯	Equipment USP Chapter 659; USP Chapter 1079 COMAR 10.34.19.10(B)(5)
126.00	Does the pharmacy use scales/balances for sterile compounding?	◯◯	Accuracy
126.01	If so, what type of scale/balanced is used? *List manufacturer and model number.*		
126.02	If the scale/balance is electronic, does the pharmacy use the automatic calibration? *Describe process and indicate frequency.*	◯◯◯	
127.00	Does the pharmacy have a **lyophilizer**?	◯◯	
127.01	Where is the lyophilizer located? *Indicate location and ISO class of room.*		
127.02	Note the products lyophilized, and the volume or percent of products per week produced using the lyophilizer.		
127.03	The lyophilizer is part of the viable air and surface sampling; media fill testing procedures, and cleaning schedules and procedures.	◯◯◯	
128.00	Automated Compounding Devices (ACDs) are used for sterile compounding and there is a P&P for the use and calibration. (TPN Preparations, Repeater Pumps, Robots, HD Preparations [Diana ACS], etc.)	◯◯	Equipment; Verification of Automated Compounding Devices for Parenteral Nutrition Compounding (and subsections) COMAR 10.34.19.10(B)

128.01 There is documentation of the ACD tubing being changed or discarded every 24 hours

Equipment;
Verification of Automated Compounding Devices for Parenteral Nutrition Compounding (and subsections)
manufacturer's guidance for tubing

128.02 The ACD is used when performing media fill testing.

Equipment;
Verification of Automated Compounding Devices for Parenteral Nutrition Compounding (and subsections)

129.00 Does the pharmacy have an **incubator**?

129.01 The temperature is documented at least daily when in use

COMAR 10.34.19.10(B)(6)

Compounding Procedures

Y N N/A **Follow up ☐**

130.00 Does the pharmacy perform **low-risk** compounding?
Indicate percentage of low-risk sterile compounding.

Low-Risk Level CSPs

130.01 All low-risk compounds are assigned BUDs within USP guidelines (48 hours at controlled room temperature, 14 days refrigerated, 45 days frozen).

COMAR 10.34.19.06(D)

130.02 If low-risk, the compounds located in segregated area are BUD 12 hours or less.

130.03 If extended BUDs are used, list products with Extended BUDs and maximum BUD in notes.

130.04 If extended BUDs are used, further testing is being performed to justify the use of extended BUDs. *List the types of testing performed (potency, sterility, stability, etc.).*

131.00 Does the pharmacy perform **medium-risk** compounding?
Indicate percentage of medium-risk sterile compounding.

Medium-Risk Level CSPs

131.01 All medium-risk compounds are assigned BUDs within USP guidelines (30 hours at controlled room temperature, 9 days refrigerated, 45 days frozen).

COMAR 10.34.19.06(D)

131.02 If extended BUDs are used, list products with Extended BUDs and maximum BUD in notes.

131.03 If extended BUDs are used, further testing is being performed to justify the use of extended BUDS. *List the types of testing performed (potency, sterility, stability, etc.).*

132.00 Does the pharmacy perform **high-risk** compounding?
Indicate percentage of high-risk sterile compounding.

High-Risk Level CSPs

132.01 All high-risk compounds are assigned BUDs within USP guidelines (24 hours at controlled room temperature, 3 days refrigerated, 45 days frozen).

COMAR 10.34.19.06 (D)

132.02 If extended BUDs are used, list products with Extended BUDs and maximum BUD in notes.

132.03 If extended BUDs are used, further testing is being performed to justify the use of extended BUDs. *List the types of testing performed (potency, sterility, stability, etc.).*

133.00 Hazardous drugs are segregated and stored in a room that is negative pressure (at least -0.01" wc) to adjacent areas and with at least 12 ACPH. ***

133.01 Hazardous drug waste is quarantined in a designated area and disposed of in compliance with local, state, and federal regulations.

COMAR 10.34.19.12C(18), 10.34.19.09B(6) 10.34.19.15(F), 10.34.19.10(A)(3)

134.00 Closed system vial transfer devices (CSTD) are employed when handling cytotoxic drugs.

COMAR 10.34.19.12(17)

135.00 Gloves are disinfected with adequate frequency with an approved disinfectant, such as sterile 70% isopropyl alcohol (IPA).

Suggested SOPs

Exposure of Critical Sites

136.00 Nonessential 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).

Suggested SOPs

137.00 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.

Suggested SOPs

138.00 Supplies required for the scheduled operations of the shift are prepared 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.

Suggested SOPs

139.00 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).

Responsibility of Compounding Personnel
Competency Evaluation of Garbing and Aseptic

140.00 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.

Responsibility of Compounding Personnel
Identity and Strength Verification of Ingredients and Devices (and subsections)

141.00 All rubber stoppers, of vials and bottles and the necks of ampules are disinfected with sterile 70% IPA waiting for at least 10 seconds before they are used to prepare CSPs.

Suggested SOPs
Exposure of Critical Sites

142.00 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.*

Single Dose and Multiple Dose Containers

143.00 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 period of time.*

Single Dose and Multiple Dose Containers

144.00 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.

Single Dose and Multiple Dose Containers Determining BUD

145.00 The compounding record is complete.
View several completed compounding records and answer each of the following questions. List records reviewed.

Inspection of Solution Dosage Forms and Review of Compounding Procedures
Compounding Accuracy Checks
COMAR 10.34.19.07(B)(1)

145.01 Official or assigned name, strength and dosage of the preparation

Inspection of Solution Dosage Forms and Review of Compounding Procedures
COMAR 10.34.19.07(B)(1)

145.02 Names, lot numbers and expiration dates of all components
(lot numbers for high risk and batch compounding)

Inspection of Solution Dosage Forms and Review of Compounding Procedures
COMAR 10.34.19.07(B)(1)

145.03 Total quantity or number of units compounded

Inspection of Solution Dosage Forms and Review of Compounding Procedures

145.04 Person compounding the preparation

Inspection of Solution Dosage Forms and Review of Compounding Procedures
Compounding Accuracy Checks

145.05 Person performing the quality control procedures

Inspection of Solution Dosage Forms and Review of Compounding Procedures
Compounding Accuracy Checks

145.06 Person who approved the preparation

Inspection of Solution Dosage Forms and Review of Compounding Procedures
Compounding Accuracy Checks
COMAR 10.34.19.07(B)(1)(f) & (g)

145.07 Date of compounding

Inspection of Solution Dosage Forms and Review of Compounding Procedures

145.08 Assigned internal identification number or prescription number

Inspection of Solution Dosage Forms and Review of Compounding Procedures

145.09	Assigned BUD and reference if extended beyond USP guidelines	◯◯◯	Inspection of Solution Dosage Forms and Review of Compounding ProceduresCOMAR 10.34.19.07(B)(1)
145.10	Duplicate label ***	◯◯◯	Responsibility of Compounding Personnel Inspection of Solution Dosage Forms and Review of Compounding Procedures Identity and Strength Verification of Ingredients
145.11	Sterilization method (if applicable)	◯◯◯	Inspection of Solution Dosage Forms and Review of Compounding Procedures Sterility Testing
145.12	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	◯◯◯	Inspection of Solution Dosage Forms and Review of Compounding Procedures Elements of Quality Control (and subparagraphs) COMAR 10.34.19.12C(6)(h)
146.00	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.*	◯◯◯	Responsibility of Compounding Personnel Verification of Automat4ed Compounding Devices for Parenteral Nutrition Compounding
147.00	Preparation records including the master work sheet, the preparation work sheet and records of end-product evaluation, if applicable. (Documentation to be retained for 5 years)	◯◯◯	COMAR 10.34.19.07(B)(1)(f)
148.00	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.	◯◯◯	Responsibility of Compounding Personnel Inspection of Solution Dosage Forms and Review of Compounding Procedures Compounding Accuracy Checks Identity and Strength Verification of Ingredients COMAR 10.34.19.07(B)(2)
149.00	Labels on PATIENT-SPECIFIC compounded sterile preparations contain the following: **NOTE: Some requirements may not be applicable if items are dispensed for inpatient use only.**		Responsibility of Compounding Personnel Inspection of Solution Dosage Forms and Review of Compounding Procedures Compounding Accuracy Checks Identity and Strength Verification of Ingredients COMAR 10.34.19.06(B)
149.01	Date of preparation unless otherwise readily retrievable from prescription records	◯◯◯	COMAR 10.34.19.06(B)(1)
149.02	Serial number of the prescription	◯◯◯	HG § 21-221(a)(2)

149.03	Pertinent requirements for proper storage	COMAR 10.34.19.06(B)(3)
149.04	Name of the prescriber, unless in an inpatient hospital setting	COMAR 10.34.19.06(B)(4)
149.05	Name of the patient	COMAR 10.34.19.06(B)(5)
149.06	Directions for use	COMAR 10.34.19.06(B)(6)
149.07	Name of the base solution for infusion preparations	COMAR 10.34.19.06(B)(7)
149.08	Name and concentration or amount of active drugs contained in the final sterile preparation	COMAR 10.34.19.06(B)(8)
149.09	Reviewing pharmacist and data-entry technician initials	COMAR 10.34.08.01
149.10	Name or identifying initials of the pharmacist who checked or prepared the compounded sterile preparation unless otherwise readily retrievable from prescription records	COMAR 10.34.19.06(B)(9)
149.11	Name, address, and telephone number of the pharmacy unless in an inpatient hospital facility	COMAR 10.34.19.06(B)(10)
149.12	Beyond-use/expiration dating and time of the compounded sterile preparation	COMAR 10.34.19.06(B)(11)
149.13	Ancillary and cautionary instructions as needed	COMAR 10.34.19.06(B)(12)
149.13A	Cytotoxic agents include a special label, which states: "Chemotherapy-Dispose of Properly."	COMAR 10.34.19.06(B)(13)
149.13B	Short dated preparations labeling must include: Time and Cautionary Label	COMAR 10.34.19.06(B)(2)

150.00	Inspect several different finished products and look for any particulates. Are the inspected finished products free of particulates? *If so, list the products including lot and expiration date and obtain photos (if possible).* **REQUEST THE PRODUCT BE QUARANTINED**	Responsibility of Compounding Personnel Inspection of Solution Dosage Forms and Review of Compounding Procedures
151.00	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	CSP Microbial Contamination Risk Levels (and subsections) Determining BUD COMAR 10.34.19.06(D)
152.00	There must be current and appropriate reference materials regarding the compounding of sterile preparations located in or immediately available to the pharmacy.	COMAR 10.34.19.16
153.00	If extended BUDs are assigned, are they assigned based on 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.*	Determining BUD COMAR 10.34.19.12(C)(5)(e)

154.00	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.* ***	◯◯◯	Determining BUD
155.00	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.	◯◯◯	Single-Dose and Multiple-Dose Containers

Sterilization

		Y N N/A	Follow up ☐
156.00	**Is Filter sterilization performed** in an ISO 5 environment? Documentation includes:	◯◯◯	Verification of Compounding Accuracy and Sterility Sterilization of High-Risk Level CSPs by Filtration Appendix I
156.01	If the compounded preparation contains large particles, a prefilter is placed upstream from the sterilizing filter.	◯◯◯	Sterilization of High-Risk Level CSPs by Filtration Appendix I
156.02	The 0.2micron 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 on the filter does not indicate "research only" or "laboratory only", for example).	◯◯◯	Sterilization Methods Sterilization of High-Risk Level CSPs by Filtration Appendix I
156.03	Is the appropriate capacity filter being used for the volume being filtered?	◯◯◯	Sterilization of High-Risk Level CSPs by Filtration Appendix I
156.04	Filtering is completed rapidly without filter replacement.	◯◯◯	Sterilization of High-Risk Level CSPs by Filtration Appendix I
156.05	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.	◯◯◯	Sterilization of High-Risk Level CSPs by Filtration Appendix I
157.00	**Is steam sterilization performed?** Documentation includes:	◯◯	Verification of Compounding Accuracy and Sterility Sterilization of High-Risk Level CSPs by Steam
157.01	The autoclave has been verified for the exposure time and mass of the items to be sterilized	◯◯◯	Sterilization of High-Risk Level CSPs by Steam Equipment
157.02	Ensures live steam contacts all ingredients and surfaces to be sterilized, effectiveness verified with biological indicators and temperature sensing devices	◯◯◯	Sterilization of High-Risk Level CSPs by Steam
157.03	Solutions are passed through a 1.2 micron or smaller filter into the final containers to remove particulates before sterilization	◯◯◯	Sterilization of High-Risk Level CSPs by Steam

157.04	That the CSP will not be adversely affected by the steam and heat	Sterilization of High-Risk Level CSPs by Steam
157.05	The description of steam sterilization includes conditions and duration for specific CSPs	Sterilization of High-Risk Level CSPs by Steam
157.06	That the effectiveness of steam sterilization is verified each time using appropriate biological indicators of Bacillus stearothermophilus and other confirmation methods such as temperature-sensing devices.	Sterilization of High-Risk Level CSPs by Steam
158.00	**Is dry heat sterilization performed?** Documentation includes:	Verification of Compounding Accuracy and Sterility Sterilization Methods Sterilization of High-Risk Level CSPs by Dry Heat
158.01	Dry heat is only used for those items that cannot be sterilized by steam or would be damaged by moisture	Sterilization Methods Sterilization of High-Risk Level CSPs by Dry Heat
158.02	Sufficient space is left between materials to allow for air circulation	Sterilization Methods Sterilization of High-Risk Level CSPs by Dry Heat
158.03	The description of dry heat sterilization includes conditions and duration for specific CSPs	Sterilization Methods Sterilization of High-Risk Level CSPs by Dry Heat
158.04	That the effectiveness of dry heat sterilization is verified each time using appropriate biological indicators of Bacillus subtilis and other confirmation methods such as temperature-sensing devices.	Sterilization Methods Sterilization of High-Risk Level CSPs by Dry Heat
158.05	Heated filtered air is evenly distributed throughout the chamber with a blower and the oven is equipped with a system for controlling and recording temperature and exposure period.	Sterilization of High-Risk Level CSPs by Dry Heat Equipment
159.00	**Is depyrogenation by dry heat performed?** Documentation includes:	Verification of Compounding Accuracy and Sterility Sterilization Methods Depyrogenation by Dry Heat
159.01	Dry heat depyrogenation is used to render glassware and containers (such as vials) free from pyrogens as well as viable microbes	Sterilization Methods Depyrogenation by Dry Heat
159.02	The description of the cycle and duration for specific load items	Sterilization Methods Depyrogenation by Dry Heat
159.03	The effectiveness of the cycle is verified using endotoxin challenge vials (ECVs)	Sterilization Methods Depyrogenation by Dry Heat Equipment

159.04	Bacterial endotoxin testing is performed on the ECVs to verify the cycle is capable of achieving a 3-log reduction in endotoxins	◯◯◯	Sterilization Methods Depyrogenation by Dry Heat
160.00	Other methods of sterilization are used with documented procedures and validation performed. *Indicate method.*	◯◯◯	Verification of Compounding Accuracy and Sterility Equipment Appendix I

Finished Preparation Release Checks and Tests

		Y N N/A	Follow up ☐
161.00	The verification and re-verification process must be documented to be retained for 5 years	◯◯◯	COMAR 10.34.19.07B(3)
162.00	Products are visually checked for particulates or other foreign matter against both a light and a dark colored background as a condition of release. *To be enforced FY2023*	◯◯◯	Physical Inspection COMAR 10.34.19.10(A)(7)
163.00	Are there checks for container, closure integrity and any other apparent visual defects?	◯◯◯	Physical Inspection
164.00	Compounding accuracy is documented by verification of steps.	◯◯◯	Compounding Accuracy Checks
165.00	Ingredient identity and quantity is verified. *Is there a reconciliation of components?*	◯◯◯	Identity and strength Verification of Ingredients
166.00	Labels are verified as being correct and is a copy of the label included in the record. *Complies with regulation, contains the correct names and amounts or concentrations of ingredients, total volumes, BUDs, storage conditions, and route of administration.*	◯◯◯	Responsibility of Compounding Personnel Inspection of Solution Dosage Forms and Review of Compounding Procedures Identity and Strength Verification of Ingredients
167.00	Does the pharmacy perform any testing in-house (not sent to an outside lab)? *If so, what tests are performed in house?*	◯◯◯	
168.00	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*	◯◯◯	
169.00	**Is sterility testing performed(USP <71>)?** *If testing is performed to a higher standard than the minimums below, describe.*	◯◯	Sterility Testing COMAR 10.34.19.15(H)
169.01	Sterility testing includes both bacterial and fungal testing.	◯◯◯	Sterility Testing
169.02	Sterility testing is performed for all CSPs that have extended BUDS.	◯◯◯	Sterility Testing

169.03 Sterility testing is performed for high-risk CSPs prepared in batches of more than 25 identical containers.

Sterility Testing

169.04 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.

Sterility Testing

169.05 The appropriate quantities of units are sterility tested.
Parenterals, number of units in the batch is:

1. Not more than 100, test 10% or four units, whichever is greater
2. More than 100 but more than 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.):
4. Not more than 200 containers test 5% or 2 containers, whichever is greater
5. More than 200, test 10 containers
6. If the product is packaged in unit doses, use the parenteral testing above.

Sterility Testing
cross reference USP Chapter 71

169.06 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.

Sterility Testing

169.07 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.

Sterility Testing

170.00 **Is endotoxin testing performed (USP <85>)?**
If testing is performed to a higher standard than the minimums below, describe.

Bacterial Endotoxin (Pyrogen) Testing
COMAR 10.34.19.15(H)

170.01 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)

Bacterial Endotoxin (Pyrogen) Testing

170.02 High-risk CSPs prepared in multiple dose vials for administration to multiple patients

Bacterial Endotoxin (Pyrogen) Testing

170.03 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

Bacterial Endotoxin (Pyrogen) Testing

170.04 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.*

Sterility Testing

Standard Operating Procedures

Y N N/A **Follow up** ☐

171.00 The pharmacy has policies/procedures on:

171.01	The compounding, filling, and labeling of sterile compounds.	◯◯◯	COMAR 10.34.19.12(C)(6)(a), (c) and (d)
171.02	Proper labeling of the compounded sterile preparation including the intended route of administration and recommended rate of administration.	◯◯◯	COMAR 10.34.19.12(C)(6)(d)
171.03	Availability of equipment and supplies.	◯◯◯	COMAR 10.34.19.12(C)(3), 10.34.19.12(C)(17)(a)
171.04	The training of staff in the preparation of compounded sterile preparations.	◯◯◯	COMAR 10.34.19.12(C)(10), 10.34.19.14(B)
171.05	Staff competency evaluations.	◯◯◯	COMAR 10.34.19.14(E)
171.06	The Quality Assurance Program.	◯◯◯	COMAR 10.34.19.12(C)(9), 10.34.19.15
171.07	All record keeping requirements.	◯◯◯	COMAR 10.34.19.12(C)(7)
171.08	A written process, verified by a pharmacist, describing ingredients and the compounding process for each preparation.	◯◯◯	COMAR 10.34.19.05(B)(4), 10.34.19.07(B)(1) & (2)
171.09	Written policies and procedures for implementing the immediate use exemption for admixtures.	◯◯◯	
171.10	Documentation demonstrating that all personnel involved have read the policies and procedures.	◯◯◯	COMAR 10.34.19.12B
171.11	Documentation of communication of policy and procedure for additions and deletions.	◯◯◯	
171.12	The storage and handling of products and supplies.	◯◯◯	COMAR 10.34.19.12(C)(6)(b)
171.13	The storage and delivery of final preparation.	◯◯◯	COMAR 10.34.19.12(6)(b) & (f)
171.14	Media fill process verification testing.	◯◯◯	COMAR 10.34.19.12(C)(11)
171.15	The criteria for Beyond Use Dating (BUD).	◯◯◯	COMAR 10.34.19.12(C)(6)(e)
171.16	Personnel access and movement of materials into and near the compounding area.	◯◯◯	COMAR 10.34.19.12(C)(2)
171.17	The use and maintenance of environmental control devices used to create the critical area for manipulation of sterile preparations (e.g. laminar airflow workstations, biological safety cabinet, ISO Class 7 clean room, and/or CAIs.	◯◯◯	COMAR 10.34.19.12(C)(3)
171.18	A regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants (pharmacies subject to an institutional infection control policy may follow that policy).	◯◯◯	
171.19	The method used to monitor the environment for bacterial microorganisms.	◯◯◯	COMAR 10.34.19.12(C)(4)
171.20	The disposal of packaging materials, used syringes, containers, and needles to avoid accumulation and maintain sanitation in the controlled area.	◯◯◯	COMAR 10.34.19.12(C)(18), 10.34.19.15(F)
171.21	Written policies and procedures for the use of established master formulas and worksheets for sterile batch compounding, if applicable.	◯◯◯	
171.22	Procedures must include cleanup of spills and shall be in conformance with local health jurisdictions.	◯◯◯	COMAR 10.34.19.12(C)(4)

171.23	Pharmacies compounding sterile preparations shall have written policies and procedures for disposal of infectious materials and/or materials containing cytotoxic residue or hazardous waste.	◯◯◯	COMAR 10.34.19.12(C)(18)
171.24	Established sterilization procedures including documentation of results, if applicable.	◯◯◯	COMAR 10.34.19.12(C)(4)
171.25	End-product evaluation and testing, if applicable.	◯◯◯	COMAR 10.34.19.12(C)(11), 10.34.19.15(H)

Quality Assurance and Patient Counseling

		Y N N/A	Follow up ☐
172.00	**Quality Assurance/Quality Improvement**: Does the pharmacy continuous quality improvement program include sterile compounding measures?	◯◯◯	Quality Assurance Program COMAR 10.34.19.12(C), 10.34.19.15
172.01	Does the pharmacy continuous quality improvement program include QREs related to the preparation of compounded products?	◯◯◯	COMAR 10.34.19.14(E)(1), 10.34.19.12C(9), 10.34.19.17(B)(1)
172.02	Does the pharmacy continuous quality improvement program include nonviable environmental monitoring and testing?	◯◯◯	
172.03	Does the pharmacy continuous quality improvement program include viable environmental testing?	◯◯◯	COMAR 10.34.19.15(C)
172.04	Does the pharmacy continuous quality improvement program include personnel testing and verification?	◯◯◯	COMAR 10.34.19.14
172.05	Does the pharmacy continuous quality improvement program include equipment calibration, testing, etc.?	◯◯◯	COMAR 10.34.19.15(D), 10.34.19.10(B)
172.06	Does the pharmacy continuous quality improvement program include sterilization method testing and validation?	◯◯◯	
172.07	Does the pharmacy continuous quality improvement program include end-product testing (such as potency, particulates, sterility, endotoxin, etc.)? Written documentation that the end-product has been tested on a periodic sampling basis for microbial contamination and steps taken in the event that testing for contamination proves positive, if applicable.	◯◯◯	COMAR 10.34.19.15C
172.08	Does the pharmacy continuous quality improvement program include patient or prescriber reports or complaints regarding CSPs?	◯◯◯	COMAR 10.34.26.04(A), 10.34.19.12(C)(9), 10.34.19.17(B)(1)
172.09	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?	◯◯◯	COMAR 10.34.19.12(C)(6)(h)
172.10	Does the recall system include communication with both the patient and the physician/prescriber regarding the potentially contaminated CSP administered and the potential risks?	◯◯◯	COMAR 10.34.19.12(C)(6)(h)
172.11	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?	◯◯◯	COMAR 10.34.19.12C(6)(h)
172.12	Records documenting inspection for expired or recalled pharmaceutical preparations or raw ingredients(Documentation to be retained for 5 years)	◯◯◯	COMAR 10.34.19.07(B)(1)(e)

172.13	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.*		
172.14	A 24-hour telephone number is provided to allow its patients or other health care providers who may be administering its prescriptions to contact its pharmacists		COMAR 10.34.19.06(C)
173.00	Do patient/caregiver training programs or materials contain information and precautions regarding the handling and disposal of hazardous products such as chemotherapy medications?		Patient or Caregiver Training COMAR 10.34.19.14(A)
174.00	Are the above required printed drug information materials (drug information, PPI, MedGuides, etc.) provided for the compounded products?		Patient or Caregiver Training COMAR 10.34.19.14(A)
175.00	Patients are 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.		Patient or Caregiver Training COMAR 10.34.19.14(A)
176.00	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.		Patient Monitoring and Adverse Events Reporting COMAR 10.34.19.12(C)(6)(h)

Final Comments:

Inspector
Signature:

Pharmacist
Name

Signature:

Received a copy
of this inspection
report: