The Virginia Board of Pharmacy
Universal Pharmacy Inspection Form

NOTE: VA-n refers to the corresponding numeric deficiency on Virginia Guidance Document 110-9 Pharmacy Inspection Deficiency Monetary Penalty Guide

1.00 General & Simple Compounding Pharmacy Inspection

Pharmacy License number							
Pharmacy Name				Day 1:		Inspector name(s):	
Address:				Start Time			
Address 2:				End Time:			
City:				Day 2 (if applicable):			
State:		Zip Code:		Start Time			
Telephone number:				End Time:			
Toll-Free number:				Pharmacist-in-Charge Name			
Fax number:				PIC License number			
Email:				Website:			

Hours of Operation - *leave blank if closed.*						
Sun	Mon	Tues	Wed	Thu	Fri	Sat

Pharmacist on Duty if PIC not present:					
Pharmacist on Duty License Number					

		Y	N	Notes
2.00	Are there any other businesses located at this address? *If so, note type of business and name.*			

3.00	Other License Information: (Resident State Controlled Substances, DEA, FDA, other, if applicable)			
	License/Registration Agency:	**Business Name on License/Registration:**	**License/ Registration Number:**	**Expiration Date:**
	State CSR			
	DEA			
	FDA			
	other			
	Pharmacy licensed and distributes CSPs to other states? *If so, indicates states.*			

4.00	Type(s) of practice **Type "X" for all that apply**										
	Traditional retail		Hospital		Manufacturer		Outsourcing Facility		Nonsterile Compounding		
	Open to the Public		Other Institutional		Wholesale Distributor		Nuclear Pharmacy		Hazardous Drug Compounding-Nonsterile		
	Closed Door		HMO/PBM only		Mail/Deliver (out-of-state)		Investigational Drugs, Clinical Trials, Research		Sterile Compounding		
	Long Term Care		Internet Pharmacy		Veterinary Pharmacy		Handles Medical Marijuana		Hazardous Drug Compounding-Sterile		
	Mail/Deliver (in state)		Telepharmacy		Central or Remote Fill/Processing/ Shared Services		Substance/Opioid Treatment Center		Distribute compounded products for		
	Specialty Pharmacy										

			Y	N	Need Info	N/A	Notes	
Types of Practice Additional Questions								
5.00	Does the pharmacy mail or deliver filled prescriptions (patient specific, labeled with patient name when it leaves the pharmacy) to a provider or facility for administration to the patient?							
6.00	Does the pharmacy provide prescription products to a provider or facility within the resident state for "office use" (not pursuant to a prescription received prior to delivery, not patient specific, not labeled with the patient name)? If yes, indicate if in compliance with state law.							
6.01		Does the pharmacy provide prescription products for office use to other states. *If so, list states.*						
7.00	Does the pharmacy provide prescription products to providers or facilities (including other pharmacies) as a wholesale distributer (sold to the provider or facility for their use, administration, or providing/dispensing to patients)?							
General Operations and Licensure								
								Virginia Deficiency
8.00	Are pharmacy and pharmacy personnel licenses, permits, and registrations posted in customers' view (if required) and current? *Provide relevant information if "no", such as closed-door pharmacy.*							
9.00	Is the pharmacy operating under any exemption, restriction, waiver, or variance granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the exemption or restriction.*	**VA-102**						
9.01		Is pharmacy operating within the scope of any exemption, restriction, waiver or variance? *If no, describe activities outside the scope.* **VA-102**						
10.00	Does the pharmacy hold any relevant accreditations or certifications? *If so, indicate which in notes.*							
11.00	Has the pharmacy held any accreditations or certifications in the past that have been rescinded or suspended? *If yes, list and the reasons for discontinuation.*							

			Y	N	Need Info	N/A	Notes	
Personnel								
12.00	Are all pharmacist, pharmacy intern, and pharmacy technician (if applicable) licenses or registrations posted or on file with the pharmacy current and in good standing/active?							
13.00	**Personnel present at the time of the inspection:**							
	Number of Pharmacists							
	Number of Technicians							
		Y	**N**	Notes if no:				
	Ratio in compliance, if applicable							
								Virginia Deficiency
	Are all pharmacists, pharmacy interns, and pharmacy technicians on duty at the time of the inspection current and in good standing/active? (i.e. may be relief personnel not checked on posted licenses)	**VA-3 VA-4**						
14.00	Is the PIC in full and actual charge and actively engaged in the practice of pharmacy at the location in compliance with resident state law?	**VA-1**						
15.00	Are acts restricted to pharmacists being only performed by pharmacists or pharmacy interns as allowed by state law?	**VA-5**						
16.00	Are pharmacists supervising pharmacy technicians and pharmacy interns as required by state law?	**VA-5**						
17.00	Are only pharmacy technicians, licensed, registered, or certified in compliance with state law, performing those acts that require such licensure. i.e. no unlicensed persons engaged in activities requiring a license?	**VA-3 VA-4**						
18.00	Is there a process for periodic verification of validity of licenses?							
19.00	Are pharmacists providing patient services that require additional training or certification appropriately trained and certified? *Are the certifications current? (Immunization, CPR, MTM, etc.)*							
20.00	Does the pharmacy maintain the proper technician-to-pharmacist ratio, if applicable?	**VA-6 VA-143**						

			Y	N	Need Info	N/A	Notes
Facility General and Security							
21.00	Does the pharmacy have a working security/alarm system in place that is in compliance with the laws and regulations of the resident state? **(VIRGINIA - Includes Emergency Key)**	**VA-9 VA-9A VA-108 VA-144**					
21.01	Is the ability to disable the alarm system restricted to pharmacists practicing at the location or other persons authorized by state law?	**VA-10**					
22.00	Are all prescription drugs stored within an enclosure that is lockable and protects the drug stock against unauthorized access at all times? *If no, describe issue.*	**VA-11 VA-12 VA-145**					
22.01	Is the means to unlock the enclosure limited to pharmacists practicing at the pharmacy and any other person authorized by state law?	**VA-11 VA-145**					
22.02	Is the enclosure locked and the alarm system activated whenever the pharmacy is closed for business and a pharmacist is not on the premises?	**VA-9 VA-9A**					
23.00	Are Schedule II controlled substances secured in a locked cabinet or safe or dispersed in accordance with state and federal law? *If no, describe.*	**VA-12A VA-146**					
24.00	Is the pharmacy clean and sanitary, in good repair, and is there appropriate space for the prescription volume?	**VA-106**					
25.00	Does the pharmacy have a sink with hot and cold running water available within the prescription department?	**VA-104**					
26.00	Does the pharmacy have a private area for patient counseling and providing patient services?						
27.00	Is temperature in the drug storage area monitored and in compliance? *If no, describe.*						
27.01	Is the temperature in the drug storage area within the USP range for controlled room temperature (20°-25°C or 68°-77 °F)? *Record the temperature at the time of inspection.*						

				Y	N	Need Info	N/A	Notes	
28.00	Are the refrigerator and freezer restricted to drug products only (no food)?								
29.00	The pharmacy has a process for how the refrigerator temperature is monitored for excursions 24/7.								
29.01		Is the temperature in the refrigerator within the USP range (2°-8°C or 36°-46 °F)? *Record the temperature of the refrigerator at the time of inspection.*	**VA-8 VA-105**						
30.00	The pharmacy has a process for how the freezer temperature is monitored for excursions 24/7.								
30.01		Is the temperature in the freezer within the USP range (between −25° to −10°C or −13° to 14 °F)? *Record the temperature of the freezer at the time of inspection.*	**VA-8 VA-105**						
32.00	Is there a plan of action if there are any temperature or humidity excursions to determine if the integrity of the products has been compromised?								
33.00	Does the pharmacy have adequate reference materials consistent with scope of practice of otherwise required by state law?		**VA-107**						
Facility and Security: *VIRGINIA State Specific Questions*									
VG1.00	Has pharmacy performed a change of location or remodel without submitting application to Board or receiving Board approval?		**VA-7**						
VG2.00	Does the pharmacy have sufficient enclosures and locking devices?		**VA-11 VA-145**						
VG3.00	Is the security and access of the after-hours stock in the hospital in compliance with law and regulation?		**VA-30 VA-136**						
VG4.00	Are policies and procedures for proper storage, security and dispensing of drugs established and assured in the hospital?		**VA-134**						

				Y	N	Need Info	N/A	Notes	
Records									
	Inventory and Miscellaneous Records								
34.00	Are the past two years of complete inventories of controlled substances available for review? *Indicate the date of the last inventory.*		**VA-13 VA-112 VA-113**						
34.01		Is the inventory signed and dated by the responsible party, and indicate whether taken at open or close of business?	**VA-113**						
34.01		Are the Schedule I and II drugs separated from other controlled substances schedules?	**VA-113**						
35.00	Does the pharmacy keep a perpetual inventory log of all Schedule II controlled substances (including APIs, if applicable)?		**VA-15**						
36.00	Is the Schedule II perpetual inventory log reconciled regularly in accordance with state law frequency? *View the perpetual log and verify that reconciliation is taking place.*		**VA-15**						
37.00	Does the pharmacy maintain other required inventories (such as change in PIC, theft/loss, etc.)? Report as required to board?		**VA-2 VA-14 VA-16 VA-113**						
	Records of Product Receipt								
38.00	Does the pharmacy restrict ordering to only approved wholesale distributors**, outsourcing facilities,** or manufacturers licensed as required by state or federal law?		**VA-35**						
38.01		Does the pharmacy ensure transaction data (transaction history, transaction information, transaction statement) is received at the same time or before the product is received? *Explain procedure if transaction data not received.*							
38.02		Does the pharmacy have a procedure to verify product (suspect or illegitimate) including quarantine of product and reporting?							

			Y	N	Need Info	N/A	Notes
39.00	Is the receipt of Schedule II orders documented appropriately? *DEA-222 has the quantity and date on each line of product received, the CSOS record (electronic or paper printout) indicates verification of receipt and staff performing verification.*						
40.00	Are invoices for controlled substances (Schedules I-V) that are received filed separately and are the invoices dated upon receipt?	**VA-114**					
41.00	Are other invoices for receipt of prescription drugs (other than DEA controlled substances) maintained in accordance with state law?	**VA-114**					
42.00	Are records of returns to wholesale distributor, destruction of drugs on site if applicable, or of distributions to reverse distributors/drug destruction companies maintained.	**VA-115**					
	Prescription or Other Records of Dispensing or Distribution						
43.00	Does the pharmacy maintain all required dispensing history including but not limited to prescription files on site? *How long are records kept? If not on site, where?*	**VA-17 VA-18 VA-114 VA-115**					
43.01	Other than electronic prescriptions, are hard copies of prescriptions, or for non-controlled substances electronic images, maintained at least two years from date of last dispensing for controlled substances, and in accordance with state law for other prescription drugs?	**VA-17 VA-18 VA-114 VA-115**					
43.02	Are electronic prescriptions maintained in accordance with state law and federal law for EPCS for the entire retention period and available on site or upon request by timelines established in law?	**VA-17 VA-18 VA-114 VA-115**					
43.03	Are all dispensing records retrievable on site, on paper, or if automated, via computer monitor display, printout, or other data format, for the entire retention period required by state and federal law?	**VA-17 VA-18 VA-114 VA-115**					

			Y	N	Need Info	N/A	Notes	
43.04	Are partial dispensing records maintained in accordance with state and federal law?	VA-17 VA-18 VA-114 VA-115						
44.00	Does the pharmacy maintain logs of OTC sales of restricted products in accordance with state and federal law, such as CV sales.	VA-110						
45.00	Are other records of distribution of prescription drugs maintained for distributions for office use, other pharmacies, etc.	VA-18						
46.00	**PDMP:** Does the pharmacy report dispensing of controlled substances to this state prescription drug monitoring program as required by state law?							
46.01	Does the pharmacy report dispensing of controlled substances shipped into other states in accordance with those states' PDMP requirements.							
47.00	Are all required records related to drugs distributed to and dispensed from automated dispensing devices maintained as required by state law documenting any required checks for accuracy of filling?	VA-20 VA-109 VA-129 VA-138						
48.00	Are all required records related to repackaging of drugs from manufacturer's containers into automated counting or dispensing devices, unit dose packaging, unit of use packaging, or other containers maintained in accordance with state law documenting personnel performing and checking the repackaging	VA-20 VA-20A VA-109 VA-124 VA-127 VA-128 VA-129						
Records-*State Specific Questions*								
VG5.00	If the pharmacy does not report to the PMP, does it have an approved waver? *Notify the PMP program if not reporting and no approved waiver at PMP@DHP.VIRGINIA.GOV*	REPORT						
Product Receiving and Handling								
49.00	Are all orders received when the pharmacy is open?							
50.00	Does the pharmacy purchase any compounded products from other entities for dispensing to patients? *If yes, describe.*	VA-35						

			Y	N	Need Info	N/A	Notes
51.00	Does the pharmacy have a system in place to track prescription drug products in order to detect diversion or theft? *(for example, inventory or shrink report tools used, perpetual inventory in computer, etc.)*						
51.01	Are incidents of diversion or resignation/termination of personnel for cause appropriately investigated and reported?						
52.00	Are outdated, damaged, recalled or otherwise suspicious products segregated? *(conduct a random check of shelves for outdated product)*	**VA-109**					
52.01	Does the pharmacy use a reverse distributor? *If so, indicate name of reverse distributor used.*						
53.00	Does the pharmacy **repackage** bulk containers of prescription medications into smaller containers for ease of use?	**VA-20 VA-127**					
53.01	Does the labeling indicate a beyond use date consistent with USP standards?	**VA-124 VA-130A**					
54.00	Does the pharmacy **prepack** bulk containers of prescription medications into unit-of-use quantities?	**VA-20 VA-127**					
54.01	Does the labeling indicate a beyond use date consistent with USP standards?	**VA-124 VA-130A**					
55.00	Does the pharmacy return to stock prescription drugs that were filled but never picked up?	**VA-109**					
55.01	Is the return maintained in the prescription vial, i.e. not returned to a stock bottle?	**VA-109**					
55.02	Does labeling indicate an appropriate beyond use date	**VA-109**					
53.00	Are processes in place to handle a drug recall?						
54.00	Does the pharmacy accept prescription drugs back for destruction as part of a drug take-back program?						
54.01	Does the take-back program include controlled substances?						
54.02	Does the pharmacy have a modified DEA registration for controlled substance take-back?						

				Y	N	Need Info	N/A	Notes	
Product Receiving and Handling: ***VIRGINIA State Specific Questions***									
VG6.00	Are prescriptions awaiting delivery that are located outside of the prescription department stored in compliance?		**VA-111**						
VG7.00	Are unit dose procedures or records in compliance?		**VA-128**						
VG8.00	Are floor stock records in compliance, is the pharmacist appropriately checking floor stock, and are required reconciliations being completed?		**VA-137**						
Prescription Processing									
	Receipt and Review of Prescriptions								
55.00	Is patient profile data obtained and readily accessible to facilitate prospective drug utilization review prior to dispensing and for consultation with the prescriber, patient, or caregiver?		**VA-121**						
55.01		Is the accuracy of the information entered into the computer system checked and verified by a pharmacist?	**VA-19**						
55.02		Prospective drug utilization review is conducted prior to dispensing a new prescription or a refill in accordance with state and federal law.	**VA-121**						
55.03		Are DUR overrides/bypasses documented?							
56.00	Are adequate processes in place to assure the integrity, legitimacy, and authenticity of prescription orders?								
56.01		The prescription is evaluated for legitimacy and there is a procedure followed when a prescription is suspected of being (or actually is) fraudulent?							
56.02		Prescriptions dispensed appear to be pursuant to a valid patient-prescriber relationship.							
56.03		Do pharmacists have access to the state prescription monitoring program?							

			Y	N	Need Info	N/A	Notes
57.00	Has the pharmacy dispensing system been approved/certified to receive electronic prescriptions for controlled substances?						
57.01	If no, does the pharmacy receive electronic prescriptions for non-controlled substances? *Note how they are received/recorded, i.e. converted to fax, otherwise reduced to writing, image maintained?*						
	Prescription Processing						
58.00	Are filled prescriptions verified for accuracy by a pharmacist, and verification documented, unless otherwise excepted by state law, prior to dispensing?	**VA-19 VA-20A VA-20B**					
59.00	Are filled prescriptions appropriately labeled?	**VA-124 VA-125 VA-130A**					
59.01	Do drugs dispensed in customized patient compliance packaging meet USP or state requirements for packaging and labeling?	**VA-125**					
60.00	Are prescriptions dispensed in child-resistant packaging unless a documented patient request or other exemption?	**VA-126**					
61.00	**Confidentiality:** Is access to the pharmacy computer system limited to appropriate personnel? *Password protected, in a secured location, access limited by job type, access revoked as appropriate such as upon termination.*						
61.01	Does the pharmacy appropriately destroy PHI including labeled prescription vials?						
62.00	**Mail/Delivery:** If applicable, are packing materials designed to maintain the physical integrity, stability, and purity of prescription medications and compounded preparations in transport?						
63.00	**Off-Site Processes** (central/remote fill/processing): Are any portions of the prescription processing (in the questions below) performed at a different location?	**VA-123**					
63.01	Is patient information (demographics and contact information) and profile information (allergies, disease states, etc.) entered into the computer at another location?	**VA-123**					

				Y	N	Need Info	N/A	Notes	
63.02		Are prescriptions received by another location (including written, telephone, fax, electronic)?	VA-123						
63.03		Is prescription information entered into the computer system at another location?	VA-123						
63.04		Is the accuracy of the prescription information entered into the computer verified at another	VA-123						
63.05		Is any part of the DUR process (including assessing and acting on DUR alerts and warnings) performed at another location?	VA-123						
63.06		Are any prescriptions dispensed or sold from this facility filled at another location? *If so, explain how the prescriptions are labeled including any identifier indicating it was filled at the other location.*	VA-123						
63.07		If any of the above functions are performed at another location, is the other location under common ownership? *If not commonly owned, explain if there is a central fill or other agreement in place.*	VA-123						
63.08		If any of the above functions are performed at another location, is that location in a different state than this facility? *If so, explain.*	VA-123						
63.09		If any of the above functions are performed at another location, are there policies and procedures for the function that include maintaining records of the person(s) performing the function and accountability?	VA-123						
63.10		Is the other pharmacy and any personnel at another location licensed in this state? *If so, place info into notes section*	VA-123						

			Y	N	Need Info	N/A	Notes	
64.00	Off-Site Inventory: Does the pharmacy maintain any emergency kits in nursing homes, long-term care facilities, or other entities (such as hospice, EMTs, ambulances)? Note name(s) of facilities or entities.	VA-140						
64.01	Do the emergency kits contain any compounded sterile products? If so, list.							
65.00	**Off-Site Inventory:** Does the pharmacy maintain any automated prescription dispensing devices outside the pharmacy such as Pyxis in a nursing home, or a secure mailbox device that patients access after hours, etc.? *Note types and locations.*	VA-131 VA-138						
65.01	If so, are the automated devices appropriately licensed, registered, or approved by the board of pharmacy? *Provide details.*	VA-138						
65.02	Do the automated dispensing devices contain any compounded sterile products? If so, list.							
Prescription Processing: ***VIRGINIA State Specific Questions***								
VG9.00	Are records of dispensing appropriately maintained as required?	VA-18						
VG10.00	Do prescriptions include required information and are they transmitted as required?	VA-116						
VG11.00	Are Schedule II emergency prescriptions dispensed in compliance?	VA-118						
VG12.00	Is alternate delivery being performed in compliance?	VA-122						
VG13.00	Are policies and procedures for drug therapy reviews within the hospital being maintained and followed?	VA-135						
VG14.00	Are emergency medical services procedures and records in compliance?	VA-139						
VG15.00	Are emergency kit or stat-drug box procedures and records in compliance?	VA-140						
VG16.00	Is the pharmacy providing long-term care facilities with floor stock only when authorized?	VA-141						

				Y	N	Need Info	N/A	Notes
Patient Counseling and Communication								
66.00	Does the pharmacist provide counseling for all new prescriptions picked up at the pharmacy (proactively, not just an offer)?							
66.01		Is an "offer" to counsel made for all new prescriptions picked up at the pharmacy?	VA-120					
67.00	Does the pharmacist provide counseling for all refilled prescriptions picked up at the pharmacy (proactively, not just an offer)?							
67.01		Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy?	VA-120					
68.00	Is there a mechanism for providing patient counseling for mailed or delivered prescriptions?		VA-120					
69.00	Is patient counseling, the offer to counsel, or the refusal of patient counseling documented in compliance with state law?		VA-120					
Quality Assurance/Quality Improvement Program								
70.00	Is there a documented continuous quality improvement (CQI) Program for the purpose of detecting, documenting, assessing, and preventing quality related events (QREs)?		VA-142					
70.01		Policies and procedures for the program are maintained in the pharmacy in an immediately retrievable form.						
71.00	Data collected is analyzed to assess causes and any contributing factors (root cause). *Indicate who performs the analysis and frequency (with each event, weekly, monthly, quarterly, etc.)*							
71.01		The pharmacy uses the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs and increase good outcomes for patients.						

			Y	N	Need Info	N/A	Notes	
72.00	Quality meetings are held at least annually by staff members of the Pharmacy to consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.							
72.01		The meeting reviews data showing evidence of the quality of care for patients and develops plans for improvements to increase good outcomes for patients.						
72.02		Improvements or changes made are evaluated for performance to measure the effectiveness of the CQI program.						
73.00	**Reporting:** Incidents of QREs are reported to a nationally recognized error reporting program, an outside peer review committee, or a patient safety organization.							
73.01		Adverse events are reported to the appropriate entities such as the board of pharmacy, MedWatch, FDA, VAERS, etc.?						
73.02		Incidents involving malfunctioning or defective medical equipment or devices (blood glucose meters, DME, injection devices, etc.) are documented and reported to the manufacturer or distributor.						
74.00	**Quality Self-Audits** are performed by the pharmacy at least quarterly (and upon change in PIC) to determine whether the occurrence of QREs has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the CQI program in the future.							
75.00	**Patient Complaints** are documented, tracked, and investigated as appropriate and the information is used as part of the CQI program.							

			Y	N	Need Info	N/A	Notes	
Quality Assurance/Quality Improvement Program: ***VIRGINIA State Specific Questions***								
VG17.00	If reporting to a PSO, a record indicating the date a report was submitted to a patient safety organization is maintained for 12 months from the date of reporting. If no dispensing errors have occurred within the past 30 days, a zero report with date shall be recorded on the record.	**VA-142**						
VG18.00	if not reporting to a PS), a separate record is maintained and available for inspection for 12 months from the date of the analysis of dispensing errors and includes the following information: (1) Dates the analysis was initiated and completed; (2) Names of the participants in the analysis; (3) General description of remedial action taken to prevent or reduce future errors; and (4) A zero report with date shall be recorded on the record if no dispensing errors have occurred within the past 30 days.	**VA-142**						
76.00	Were any uncorrected deficiencies from a prior state inspection noted? *If yes, indicate the repeat deficiencies. Attach to form if need additional documentation*							
77.00	Did this pharmacy have any uncorrected deficiencies from an inspection by another state or federal regulatory authority? *If yes, indicate the repeat deficiencies. Attach to form if need additional documentation.*							
78.00	Has this pharmacy been inspected as part of the NABP Verified Pharmacy Program? *If so, note any uncorrected deficiencies identified by NABP.*							
79.00	Has this pharmacy been inspected by any federal agency or another state? *If so, please list inspecting agency and date, and any uncorrected deficiencies noted.*							

				Y	N	Need Info	N/A	Notes	
Non-Sterile Compounding - Simple **Complete if only SIMPLE non-sterile compounding is performed. Do not complete non-sterile compounding report.**									
									Virginia Deficiency
1.00	Does the pharmacy **dispense** nonsterile compounded preparations pursuant to a prescription?								
1.01		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.*							
1.02		Do the compounded prescriptions produce a significant difference from a commercially available drug that is justified by a documented medical need of the individual patient as determined by the prescribing practitioner?	VA-28						
1.03		Are nonsterile compounded prescriptions picked up at the pharmacy?							
1.04		Are nonsterile compounded prescriptions delivered to patients in their homes or residential facilities?							
1.05		Are nonsterile compounded prescriptions delivered to the practitioner for administration to the patient in the office, clinic, or facility?							
2.00	Does the pharmacy **distribute** nonsterile compounded preparations? *Not pursuant to a prescription, not labeled by the pharmacy with a patient name.*		VA-29						
2.01		Does the pharmacy distribute nonsterile compounded preparations to practitioners for office use?	VA-29						

				Y	N	Need Info	N/A	Notes	
2.02		Does the pharmacy distribute nonsterile compounded preparations to hospitals, clinics, or surgery centers?	**VA-29**						
2.03		Does the pharmacy have a sales force that distributes samples containing active ingredients? *List samples provided.*							
3.00	Does the pharmacy provide nonsterile compounded preparations to other pharmacies for dispensing? **(Virginia - Other than for alternate delivery)**		**VA-29**						
3.01		If so, does the pharmacy have central fill contracts or agreements with these pharmacies for patient specific preparations?							
4.00	Does the pharmacy compound oral preparations (tablets, capsules, liquids, lozenges, etc.)? *Indicate which in Notes*								
5.00	Does the pharmacy compound topicals (creams, ointments, inserts, suppositories, patches, sprays including nasal sprays, etc.)? *Indicate which in Notes*								
6.00	Does the pharmacy compound vitamin or nutritional supplements?								
7.00	Does the pharmacy compound investigational drugs? *If so, provide list.*								
8.00	Does the pharmacy make a copy of an approved commercial product? *Indicate volume or percent compounded currently in note.*		**VA-28**						
8.01		Products are verified as not available via FDA list and/or the manufacturer and documented **§54.1-**	**VA-28**						

			Y	N	Need Info	N/A	Notes	
8.02		FDA list is monitored (and manufacturer) and when item is taken off the list or becomes available, any remaining stock is quarantined for destruction and not dispensed or distributed						
9.00	Does the pharmacy perform compounding identified as **simple?** *Indicate percentage of simple compounding in Notes* 1. Making a preparation that has a USP compounding monograph or that appears in a peer-reviewed journal article that contains specific quantities of all components, compounding procedure and equipment, and stability data for that formulation with appropriate beyond-use dates (BUD)s. 2. Reconstituting or manipulating commercial products that may require the addition of one or more ingredients as directed by the manufacturer.							
10.00	Does the pharmacy perform compounding identified as **moderate?** *Indicate percentage of moderate compounding in Notes* 1. Making a preparation that requires special calculations or procedures (such as calibration of dosage unit mold cavities) to determine quantities of components per preparation or per individualized dosage units. 2. Making a preparation for which stability data for that specific formula is not available.							

Beyond Use Dating (BUD)		Total Non-Compliant (includes Unknowns)	Non-Compliant		Compliant	
			N/A	Unknown		
25.00	BUDs are assigned from the day of preparation.					
26.00	BUDs for nonaqueous formulations are not later than the remaining time until the earliest expiration date of any API and not later than six (6) months.					
27.00	BUDs for water-containing oral formulations are not later than 14 days when stored at controlled cold temperatures (refrigerated).					
28.00	BUDs for water-containing topical/dermal and mucosal liquid and semisolid formulations not later than 30 days.					

		Y	N	Need Info	N/A	Notes
29.00	BUDs are assigned based on dispensing in tight, light-resistant containers/overpacks.					
30.00	Extended BUDs are supported by testing data. *View documentation used, preparation must exactly match formulation upon which data was obtained.*					
Notes (refer to question number above)						

Environment		Total Non-Compliant (includes Unknowns)		Non-Compliant	Compliant	Unknown	N/A
31.00	The non-sterile compounding area is a controlled environment and separate from the general pharmacy.	VA-133					
32.00	There sufficient space available for the type and amount of compounding performed and the space is orderly to prevent mix-ups between ingredients, containers, labels, in-process materials, and finished preparations.						
33.00	Only one preparation compounded at a time.	VA-133					
34.00	Procedures are implemented to prevent cross-contamination, especially when compounding with drugs such as hazardous drugs and known allergens like penicillin that require special precautions.	VA-133					
35.00	The compounding area is well lit.						

		Y	N	Need Info	N/A	Notes
Training *Verify records of all compounding personnel (up to 10). Indicate number of records viewed in Notes.*						
50.00	There is documentation that all personnel that perform compounding are appropriately trained including policies and procedures, documentation, hazardous drug handling, and compounding technique and not allowed to compound or supervise compounding until training is successfully completed.					
51.00	There is documentation that the training process for the preparation of compounds includes demonstration of the compounding procedure first, followed by the trainee performing the procedure under supervision successfully before being allowed to perform compounding.					
52.00	There is documentation that training includes the operation of any equipment that may be used when preparing compounded products. *Documentation includes operation and troubleshooting*					
53.00	There is documentation available showing employees performing non-sterile compounding are evaluated at least annually (including hazardous drug handling).					
54.00	If the pharmacy uses relief personnel from outside agencies to perform non-sterile compounding there is documentation that training is verified.					
Notes (refer to question number above)						
Number of personnel training files viewed:						

		Total Non-Compliant (includes Unknowns)	Non-Compliant		Compliant	
			N/A	Unknown		
Compounding Equipment						
55.00	Appropriate equipment and utensils are available, clean, and in good working order. *Automated, mechanical, or electronic equipment (including capsule machines, autoclaves, ovens, etc.) are periodically inspected and calibrated.*					

		Y	N	Need Info	N/A	Notes			
56.00	Scales, balances, or other equipment used for measurement is validated and calibrated at least annually. *If scales are NOT validated and sealed by a state or local weights and measures agency, describe procedure used below in notes.*								
57.00	Powder hoods used for nonsterile compounding are certified or tested periodically to ensure proper function. Hood filters are checked regularly and replaced when necessary.								
58.00	All equipment is cleaned promptly after each use. *Equipment and utensils washed using potable water with a soap or detergent, and rinsed.* ***Recommended*** *rinsed with purified water.*					VA-133			
Notes (refer to question number above)									

Documentation			Total Non-Compliant (includes Unknowns)	Non-Compliant	Compliant	Unknown	N/A
60.00	The pharmacy creates a master formulation record the first time before compounding a new preparation						
60.01		Every formulation is evaluated for incompatibilities and the potential for being ineffective or toxic.					
60.02		The master formulation record contains: 1. Official or assigned name, strength, and dosage form 2. All necessary calculations 3. Description of all ingredients and their quantities 4. Compatibility and stability information including references (when available) 5. Equipment used for the preparation 6. Mixing instructions (order of mixing, temperatures, duration of mixing, and other pertinent factors) 7. Container used and packaging requirements 8. Assigned BUD information 9. Labeling information including the name of and quantity or concentration of each active ingredient 10. Description of the finished preparation 11. Storage requirements 12. Quality control procedures and expected results (e.g. dose measurement of capsule in the dose calibrator).					

		Y	N	Need Info	N/A	Notes				
61.00	The pharmacy creates a compounding record for each compound prepared.					VA-130 §54.1-3410.2 (I)				
61.01	The compounding record includes: 1. Official or assigned name, strength and dosage of the preparation 2. Master Formulation Record reference 3. Sources, lot numbers, and expiration dates of all components 4. Total quantity or number of dosage units compounded 5. Person compounding the preparation 6. Person performing the quality control procedures 7. Person who approved the preparation 8. Date of compounding 9. Assigned internal identification number or prescription number 10. Description of the final preparation 11. Assigned BUD 12. Duplicate label 13. Results of quality control procedures (weight range of filled capsules, pH of aqueous liquids, etc.)? 14. Documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver including investigation and recall, if appropriate									
Notes (refer to question number above)							N/A	Unknown	Compliant	Non-Complaint

Compounding Procedures		Total Non-Compliant (includes Unknowns)	Non-Compliant			
			N/A	Unknown	Compliant	
62.00	The Master Formulation Record and the Compounding Record has been reviewed by the compounder to ensure it is error free.					
63.00	Compounding personnel ascertain that ingredients for compounded preparations are of the correct identity and appropriate quality including a unit-by-unit inspection of the components.					
64.00	The containers and closures selected meet USP standards (from container supplier).					

		Y	N	Need Info	N/A	Notes			
65.00	Container selection determined by physical and chemical properties of the preparation.								
66.00	Compounding personnel maintain good hand hygiene and wear clean and appropriate clothing for the compounding being performed.								
68.00	Routine compounding procedures for batch preparation completed and verified according to written procedures. Including: *Calculations correct, weighing and measuring performed correctly, order of mixing correct, compounding techniques performed correctly*								
69.00	Procedures for in-process checks followed. *These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists that includes visual inspection of product, and documentation of the compounding accuracy is performed to ensure proper measurement, reconstitution and component usage.* ***Recommended:*** *compounding accuracy checked by a person other than the compounder.*								
70.00	If there are any deviations from the master formulation record, these deviations are recorded.								
71.00	There is a plan for cleaning. *After each preparation, daily tasks, monthly tasks, etc.*								
72.00	Personnel are appropriately garbed for protection when cleaning.								
72.01	Compounding employees are using appropriate techniques. *Inspector to observe compounding procedures, documentation, appropriate garb, cleanliness of compounding area and equipment. Compounding MUST be observed, 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 and mark item as "Non-Compliant".*								
Notes (refer to question number above)									

Finished Preparation Release Checks and Tests		**Total Non-Compliant (includes Unknowns)**	**Non-Compliant**	**Compliant**	**Unknown**	**N/A**
73.00	The finished preparation is observed to appear as expected in the master formulation record and documented.					

		Y	N	Need Info	N/A	Notes			
74.00	As appropriate, the final completed preparation assessed for weight, mixing, clarity, odor, color, consistency, pH, and strength and is documented.								
78.00	Labels on immediate patient-specific containers include identifiers for the persons preparing the compound and performing the final verification, BUD, an indication that this is a compounded preparation, special requirements for storage, and appropriate packaging and labeling of hazardous materials.								
79.00	Batch preparations (in anticipation of prescriptions) are of an appropriate volume and batch products in stock are all within their BUD (not outdated).								
80.00	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.								
81.00	Preparations are stored properly prior to dispensing based upon conditions upon which BUD was assigned.								
82.00	Preparations are examined immediately after preparation AND again immediately prior to dispensing for any signs of instability.								
Notes (refer to question number above)									

Patient Counseling and Communication		**Total Non-Compliant (includes Unknowns)**	**Non-Compliant**	**Compliant**	**Unknown**	**N/A**
	Do patient/caregiver training programs or materials contain information and precautions regarding the handling and disposal of hazardous products such as chemotherapy medications?					
	Are the required printed drug information materials (drug information sheets, Patient Package Inserts, MedGuides, etc.) provided for the compounded products?					
	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?					
	Product recalls include documentation that both the patient AND the physician/prescriber of the potentially contaminated compounded product are notified of the potential risk.					

	Y	N	Need Info	N/A	Notes
Notes (refer to question number above)					

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.

The Virginia Board of Pharmacy
Universal Pharmacy Inspection Form

NOTE: VA-n refers to the corresponding numeric deficiency on Virginia Guidance Document 110-9 Pharmacy Inspection Deficiency Monetary Penalty Guide

1.00 General Pharmacy Inspection

Pharmacy License number							
Pharmacy Name				Day 1:		Inspector name(s):	
Address:				Start Time			
Address 2:				End Time:			
City:				Day 2 (if applicable):			
State:		Zip Code:		Start Time			
Telephone number:				End Time:			
Toll-Free number:				Pharmacist-in-Charge Name			
Fax number:				PIC License number			
Email:				Website:			

Hours of Operation - *leave blank if closed.*							Pharmacist on Duty if PIC not present:	
Sun	Mon	Tues	Wed	Thu	Fri	Sat		
							Pharmacist on Duty License Number	

		Y	N	Notes
2.00	Are there any other businesses located at this address? *If so, note type of business and name.*			

3.00	Other License Information: (Resident State Controlled Substances, DEA, FDA, other, if applicable)			
	License/Registration Agency:	**Business Name on License/Registration:**	**License/ Registration Number:**	**Expiration Date:**
	State CSR			
	DEA			
	FDA			
	other			
	Pharmacy licensed and distributes CSPs to other states? *If so, indicates states.*			

4.00	Type(s) of practice Type "X" for all that apply										
	Traditional retail		Hospital		Manufacturer		Outsourcing Facility		Nonsterile Compounding		
	Open to the Public		Other Institutional		Wholesale Distributor		Nuclear Pharmacy		Hazardous Drug Compounding-Nonsterile		
	Closed Door		HMO/PBM only		Mail/Deliver (out-of-state)		Investigational Drugs, Clinical Trials, Research		Sterile Compounding		
	Long Term Care		Internet Pharmacy		Veterinary Pharmacy		Handles Medical Marijuana		Hazardous Drug Compounding-Sterile		
	Mail/Deliver (in state)		Telepharmacy		Central or Remote Fill/Processing/ Shared Services		Substance/Opioid Treatment Center		Distribute compounded products for		
	Specialty Pharmacy										

			Y	N	Need Info	N/A	Notes	
Types of Practice Additional Questions								
5.00	Does the pharmacy mail or deliver filled prescriptions (patient specific, labeled with patient name when it leaves the pharmacy) to a provider or facility for administration to the patient?							
6.00	Does the pharmacy provide prescription products to a provider or facility within the resident state for "office use" (not pursuant to a prescription received prior to delivery, not patient specific, not labeled with the patient name)? If yes, indicate if in compliance with state law.							
6.01		Does the pharmacy provide prescription products for office use to other states. *If so, list states.*						
7.00	Does the pharmacy provide prescription products to providers or facilities (including other pharmacies) as a wholesale distributer (sold to the provider or facility for their use, administration, or providing/dispensing to patients)?							
General Operations and Licensure								
								Virginia Deficiency
8.00	Are pharmacy and pharmacy personnel licenses, permits, and registrations posted in customers' view (if required) and current? *Provide relevant information if "no", such as closed-door pharmacy.*							
9.00	Is the pharmacy operating under any exemption, restriction, waiver, or variance granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the exemption or restriction.*	**VA-102**						
9.01		Is pharmacy operating within the scope of any exemption, restriction, waiver or variance? *If no, describe activities outside the scope.* **VA-102**						
10.00	Does the pharmacy hold any relevant accreditations or certifications? *If so, indicate which in notes.*							
11.00	Has the pharmacy held any accreditations or certifications in the past that have been rescinded or suspended? *If yes, list and the reasons for discontinuation.*							

			Y	N	Need Info	N/A	Notes
Personnel							
12.00	Are all pharmacist, pharmacy intern, and pharmacy technician (if applicable) licenses or registrations posted or on file with the pharmacy current and in good standing/active?						
13.00	**Personnel present at the time of the inspection:**						
	Number of Pharmacists						
	Number of Technicians						
		Y	**N**	Notes if no:			
	Ratio in compliance, if applicable						
							Virginia Deficiency
	Are all pharmacists, pharmacy interns, and pharmacy technicians on duty at the time of the inspection current and in good standing/active? (i.e. may be relief personnel not checked on posted licenses)	**VA-3 VA-4**					
14.00	Is the PIC in full and actual charge and actively engaged in the practice of pharmacy at the location in compliance with resident state law?	**VA-1**					
15.00	Are acts restricted to pharmacists being only performed by pharmacists or pharmacy interns as allowed by state law?	**VA-5**					
16.00	Are pharmacists supervising pharmacy technicians and pharmacy interns as required by state law?	**VA-5**					
17.00	Are only pharmacy technicians, licensed, registered, or certified in compliance with state law, performing those acts that require such licensure. i.e. no unlicensed persons engaged in activities requiring a license?	**VA-3 VA-4**					
18.00	Is there a process for periodic verification of validity of licenses?						
19.00	Are pharmacists providing patient services that require additional training or certification appropriately trained and certified? *Are the certifications current? (Immunization, CPR, MTM, etc.)*						
20.00	Does the pharmacy maintain the proper technician-to-pharmacist ratio, if applicable?	**VA-6 VA-143**					

			Y	N	Need Info	N/A	Notes	
Facility General and Security								
21.00	Does the pharmacy have a working security/alarm system in place that is in compliance with the laws and regulations of the resident state? **(VIRGINIA - Includes Emergency Key)**	**VA-9 VA-9A VA-108 VA-144**						
21.01	Is the ability to disable the alarm system restricted to pharmacists practicing at the location or other persons authorized by state law?	**VA-10**						
22.00	Are all prescription drugs stored within an enclosure that is lockable and protects the drug stock against unauthorized access at all times? *If no, describe issue.*	**VA-11 VA-12 VA-145**						
22.01	Is the means to unlock the enclosure limited to pharmacists practicing at the pharmacy and any other person authorized by state law?	**VA-11 VA-145**						
22.02	Is the enclosure locked and the alarm system activated whenever the pharmacy is closed for business and a pharmacist is not on the premises?	**VA-9 VA-9A**						
23.00	Are Schedule II controlled substances secured in a locked cabinet or safe or dispersed in accordance with state and federal law? *If no, describe.*	**VA-12A VA-146**						
24.00	Is the pharmacy clean and sanitary, in good repair, and is there appropriate space for the prescription volume?	**VA-106**						
25.00	Does the pharmacy have a sink with hot and cold running water available within the prescription department?	**VA-104**						
26.00	Does the pharmacy have a private area for patient counseling and providing patient services?							

			Y	N	Need Info	N/A	Notes	
27.00	Is temperature in the drug storage area monitored and in compliance? *If no, describe.*							
27.01		Is the temperature in the drug storage area within the USP range for controlled room temperature (20°-25°C or 68°-77 °F)? *Record the temperature at the time of inspection.*						

			Y	N	Need Info	N/A	Notes	
28.00	Are the refrigerator and freezer restricted to drug products only (no food)?							
29.00	The pharmacy has a process for how the refrigerator temperature is monitored for excursions 24/7.							
29.01	Is the temperature in the refrigerator within the USP range (2°-8°C or 36°-46 °F)? *Record the temperature of the refrigerator at the time of inspection.*	**VA-8 VA-105**						
30.00	The pharmacy has a process for how the freezer temperature is monitored for excursions 24/7.							
30.01	Is the temperature in the freezer within the USP range (between −25° to −10°C or −13° to 14 °F)? *Record the temperature of the freezer at the time of inspection.*	**VA-8 VA-105**						
32.00	Is there a plan of action if there are any temperature or humidity excursions to determine if the integrity of the products has been compromised?							
33.00	Does the pharmacy have adequate reference materials consistent with scope of practice of otherwise required by state law?	**VA-107**						
Facility and Security: *VIRGINIA State Specific Questions*								
VG1.00	Has pharmacy performed a change of location or remodel without submitting application to Board or receiving Board approval?	**VA-7**						
VG2.00	Does the pharmacy have sufficient enclosures and locking devices?	**VA-11 VA-145**						
VG3.00	Is the security and access of the after-hours stock in the hospital in compliance with law and regulation?	**VA-30 VA-136**						
VG4.00	Are policies and procedures for proper storage, security and dispensing of drugs established and assured in the hospital?	**VA-134**						

				Y	N	Need Info	N/A	Notes	
Records									
	Inventory and Miscellaneous Records								
34.00	Are the past two years of complete inventories of controlled substances available for review? *Indicate the date of the last inventory.*		**VA-13 VA-112 VA-113**						
34.01		Is the inventory signed and dated by the responsible party, and indicate whether taken at open or close of business?	**VA-113**						
34.01		Are the Schedule I and II drugs separated from other controlled substances schedules?	**VA-113**						
35.00	Does the pharmacy keep a perpetual inventory log of all Schedule II controlled substances (including APIs, if applicable)?		**VA-15**						
36.00	Is the Schedule II perpetual inventory log reconciled regularly in accordance with state law frequency? *View the perpetual log and verify that reconciliation is taking place.*		**VA-15**						
37.00	Does the pharmacy maintain other required inventories (such as change in PIC, theft/loss, etc.)? Report as required to board?		**VA-2 VA-14 VA-16 VA-113**						
	Records of Product Receipt								
38.00	Does the pharmacy restrict ordering to only approved wholesale distributors**, outsourcing facilities,** or manufacturers licensed as required by state or federal law?		**VA-35**						
38.01		Does the pharmacy ensure transaction data (transaction history, transaction information, transaction statement) is received at the same time or before the product is received? *Explain procedure if transaction data not received.*							
38.02		Does the pharmacy have a procedure to verify product (suspect or illegitimate) including quarantine of product and reporting?							

			Y	N	Need Info	N/A	Notes	
39.00	Is the receipt of Schedule II orders documented appropriately? *DEA-222 has the quantity and date on each line of product received, the CSOS record (electronic or paper printout) indicates verification of receipt and staff performing verification.*							
40.00	Are invoices for controlled substances (Schedules I-V) that are received filed separately and are the invoices dated upon receipt?	**VA-114**						
41.00	Are other invoices for receipt of prescription drugs (other than DEA controlled substances) maintained in accordance with state law?	**VA-114**						
42.00	Are records of returns to wholesale distributor, destruction of drugs on site if applicable, or of distributions to reverse distributors/drug destruction companies maintained.	**VA-115**						
	Prescription or Other Records of Dispensing or Distribution							
43.00	Does the pharmacy maintain all required dispensing history including but not limited to prescription files on site? *How long are records kept? If not on site, where?*	**VA-17 VA-18 VA-114 VA-115**						
43.01	Other than electronic prescriptions, are hard copies of prescriptions, or for non-controlled substances electronic images, maintained at least two years from date of last dispensing for controlled substances, and in accordance with state law for other prescription	**VA-17 VA-18 VA-114 VA-115**						
43.02	Are electronic prescriptions maintained in accordance with state law and federal law for EPCS for the entire retention period and available on site or upon request by timelines established in law?	**VA-17 VA-18 VA-114 VA-115**						
43.03	Are all dispensing records retrievable on site, on paper, or if automated, via computer monitor display, printout, or other data format, for the entire retention period required by state and federal law?	**VA-17 VA-18 VA-114 VA-115**						

				Y	N	Need Info	N/A	Notes	
43.04		Are partial dispensing records maintained in accordance with state and federal law?	VA-17 VA-18 VA-114 VA-115						
44.00	Does the pharmacy maintain logs of OTC sales of restricted products in accordance with state and federal law, such as CV sales.		VA-110						
45.00	Are other records of distribution of prescription drugs maintained for distributions for office use, other pharmacies, etc.		VA-18						
46.00	**PDMP:** Does the pharmacy report dispensing of controlled substances to this state prescription drug monitoring program as required by state law?								
46.01		Does the pharmacy report dispensing of controlled substances shipped into other states in accordance with those states' PDMP requirements.							
47.00	Are all required records related to drugs distributed to and dispensed from automated dispensing devices maintained as required by state law documenting any required checks for accuracy of filling?		VA-20 VA-109 VA-129 VA-138						
48.00	Are all required records related to repackaging of drugs from manufacturer's containers into automated counting or dispensing devices, unit dose packaging, unit of use packaging, or other containers maintained in accordance with state law documenting personnel performing and checking the repackaging		VA-20 VA-20A VA-109 VA-124 VA-127 VA-128 VA-129						
Records-*State Specific Questions*									
VG5.00	If the pharmacy does not report to the PMP, does it have an approved waver? *Notify the PMP program if not reporting and no approved waiver at PMP@DHP.VIRGINIA.GOV*		REPORT						
Product Receiving and Handling									
49.00	Are all orders received when the pharmacy is open?								

			Y	N	Need Info	N/A	Notes	
50.00	Does the pharmacy purchase any compounded products from other entities for dispensing to patients? *If yes, describe.*	**VA-35**						
51.00	Does the pharmacy have a system in place to track prescription drug products in order to detect diversion or theft? *(for example, inventory or shrink report tools used, perpetual inventory in computer, etc.)*							
51.01	Are incidents of diversion or resignation/termination of personnel for cause appropriately investigated and reported?							
52.00	Are outdated, damaged, recalled or otherwise suspicious products segregated? *(conduct a random check of shelves for outdated product)*	**VA-109**						
52.01	Does the pharmacy use a reverse distributor? *If so, indicate name of reverse distributor used.*							
53.00	Does the pharmacy **repackage** bulk containers of prescription medications into smaller containers for ease of use?	**VA-20 VA-127**						
53.01	Does the labeling indicate a beyond use date consistent with USP standards?	**VA-124 VA-130A**						
54.00	Does the pharmacy **prepack** bulk containers of prescription medications into unit-of-use quantities?	**VA-20 VA-127**						
54.01	Does the labeling indicate a beyond use date consistent with USP standards?	**VA-124 VA-130A**						
55.00	Does the pharmacy return to stock prescription drugs that were filled but never picked up?	**VA-109**						
55.01	Is the return maintained in the prescription vial, i.e. not returned to a stock bottle?	**VA-109**						
55.02	Does labeling indicate an appropriate beyond use date	**VA-109**						
53.00	Are processes in place to handle a drug recall?							

				Y	N	Need Info	N/A	Notes	
54.00	Does the pharmacy accept prescription drugs back for destruction as part of a drug take-back program?								
54.01		Does the take-back program include controlled substances?							
54.02		Does the pharmacy have a modified DEA registration for controlled substance take-back?							
Product Receiving and Handling: ***VIRGINIA State Specific Questions***									
VG6.00	Are prescriptions awaiting delivery that are located outside of the prescription department stored in compliance?		**VA-111**						
VG7.00	Are unit dose procedures or records in compliance?		**VA-128**						
VG8.00	Are floor stock records in compliance, is the pharmacist appropriately checking floor stock, and are required reconciliations being completed?		**VA-137**						
Prescription Processing									
	Receipt and Review of Prescriptions								
55.00	Is patient profile data obtained and readily accessible to facilitate prospective drug utilization review prior to dispensing and for consultation with the prescriber, patient, or caregiver?		**VA-121**						
55.01		Is the accuracy of the information entered into the computer system checked and verified by a pharmacist?	**VA-19**						
55.02		Prospective drug utilization review is conducted prior to dispensing a new prescription or a refill in accordance with state and federal law.	**VA-121**						
55.03		Are DUR overrides/bypasses documented?							
56.00	Are adequate processes in place to assure the integrity, legitimacy, and authenticity of prescription orders?								
56.01		The prescription is evaluated for legitimacy and there is a procedure followed when a prescription is suspected of being (or actually is) fraudulent?							

				Y	N	Need Info	N/A	Notes	
56.02		Prescriptions dispensed appear to be pursuant to a valid patient-prescriber relationship.							
56.03		Do pharmacists have access to the state prescription monitoring program?							
57.00	Has the pharmacy dispensing system been approved/certified to receive electronic prescriptions for controlled substances?								
57.01		If no, does the pharmacy receive electronic prescriptions for non-controlled substances? *Note how they are received/recorded, i.e. converted to fax, otherwise reduced to writing, image maintained?*							
	Prescription Processing								
58.00	Are filled prescriptions verified for accuracy by a pharmacist, and verification documented, unless otherwise excepted by state law, prior to dispensing?		**VA-19 VA-20A VA-20B**						
59.00	Are filled prescriptions appropriately labeled?		**VA-124 VA-125 VA-130A**						
59.01		Do drugs dispensed in customized patient compliance packaging meet USP or state requirements for packaging and labeling?	**VA-125**						
60.00	Are prescriptions dispensed in child-resistant packaging unless a documented patient request or other exemption?		**VA-126**						
61.00	**Confidentiality:** Is access to the pharmacy computer system limited to appropriate personnel? *Password protected, in a secured location, access limited by job type, access revoked as appropriate such as upon termination.*								
61.01		Does the pharmacy appropriately destroy PHI including labeled prescription vials?							
62.00	**Mail/Delivery:** If applicable, are packing materials designed to maintain the physical integrity, stability, and purity of prescription medications and compounded preparations in transport?								

				Y	N	Need Info	N/A	Notes	
63.00	**Off-Site Processes** (central/remote fill/processing): Are any portions of the prescription processing (in the questions below) performed at a different location?		VA-123						
63.01		Is patient information (demographics and contact information) and profile information (allergies, disease states, etc.) entered into the computer at another location?	VA-123						
63.02		Are prescriptions received by another location (including written, telephone, fax, electronic)?	VA-123						
63.03		Is prescription information entered into the computer system at another location?	VA-123						
63.04		Is the accuracy of the prescription information entered into the computer verified at another	VA-123						
63.05		Is any part of the DUR process (including assessing and acting on DUR alerts and warnings) performed at another location?	VA-123						
63.06		Are any prescriptions dispensed or sold from this facility filled at another location? *If so, explain how the prescriptions are labeled including any identifier indicating it was filled at the other location.*	VA-123						
63.07		If any of the above functions are performed at another location, is the other location under common ownership? *If not commonly owned, explain if there is a central fill or other agreement in place.*	VA-123						
63.08		If any of the above functions are performed at another location, is that location in a different state than this facility? *If so, explain.*	VA-123						
63.09		If any of the above functions are performed at another location, are there policies and procedures for the function that include maintaining records of the person(s) performing the function and accountability?	VA-123						
63.10		Is the other pharmacy and any personnel at another location licensed in this state? *If so, place info into notes section*	VA-123						

			Y	N	Need Info	N/A	Notes	
64.00	Off-Site Inventory: Does the pharmacy maintain any emergency kits in nursing homes, long-term care facilities, or other entities (such as hospice, EMTs, ambulances)? Note name(s) of facilities or entities.	VA-140						
64.01	Do the emergency kits contain any compounded sterile products? If so, list.							
65.00	**Off-Site Inventory:** Does the pharmacy maintain any automated prescription dispensing devices outside the pharmacy such as Pyxis in a nursing home, or a secure mailbox device that patients access after hours, etc.? *Note types and locations.*	VA-131 VA-138						
65.01	If so, are the automated devices appropriately licensed, registered, or approved by the board of pharmacy? *Provide details.*	VA-138						
65.02	Do the automated dispensing devices contain any compounded sterile products? If so, list.							
Prescription Processing: ***VIRGINIA State Specific Questions***								
VG9.00	Are records of dispensing appropriately maintained as required?	VA-18						
VG10.00	Do prescriptions include required information and are they transmitted as required?	VA-116						
VG11.00	Are Schedule II emergency prescriptions dispensed in compliance?	VA-118						
VG12.00	Is alternate delivery being performed in compliance?	VA-122						
VG13.00	Are policies and procedures for drug therapy reviews within the hospital being maintained and followed?	VA-135						
VG14.00	Are emergency medical services procedures and records in compliance?	VA-139						
VG15.00	Are emergency kit or stat-drug box procedures and records in compliance?	VA-140						
VG16.00	Is the pharmacy providing long-term care facilities with floor stock only when authorized?	VA-141						

				Y	N	Need Info	N/A	Notes
Patient Counseling and Communication								
66.00	Does the pharmacist provide counseling for all new prescriptions picked up at the pharmacy (proactively, not just an offer)?							
66.01		Is an "offer" to counsel made for all new prescriptions picked up at the pharmacy?	VA-120					
67.00	Does the pharmacist provide counseling for all refilled prescriptions picked up at the pharmacy (proactively, not just an offer)?							
67.01		Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy?	VA-120					
68.00	Is there a mechanism for providing patient counseling for mailed or delivered prescriptions?		VA-120					
69.00	Is patient counseling, the offer to counsel, or the refusal of patient counseling documented in compliance with state law?		VA-120					
Quality Assurance/Quality Improvement Program								
70.00	Is there a documented continuous quality improvement (CQI) Program for the purpose of detecting, documenting, assessing, and preventing quality related events (QREs)?		VA-142					
70.01		Policies and procedures for the program are maintained in the pharmacy in an immediately retrievable form.						
71.00	Data collected is analyzed to assess causes and any contributing factors (root cause). *Indicate who performs the analysis and frequency (with each event, weekly, monthly, quarterly, etc.)*							
71.01		The pharmacy uses the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs and increase good outcomes for patients.						

			Y	N	Need Info	N/A	Notes	
72.00	Quality meetings are held at least annually by staff members of the Pharmacy to consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.							
72.01		The meeting reviews data showing evidence of the quality of care for patients and develops plans for improvements to increase good outcomes for patients.						
72.02		Improvements or changes made are evaluated for performance to measure the effectiveness of the CQI program.						
73.00	**Reporting:** Incidents of QREs are reported to a nationally recognized error reporting program, an outside peer review committee, or a patient safety organization.							
73.01		Adverse events are reported to the appropriate entities such as the board of pharmacy, MedWatch, FDA, VAERS, etc.?						
73.02		Incidents involving malfunctioning or defective medical equipment or devices (blood glucose meters, DME, injection devices, etc.) are documented and reported to the manufacturer or distributor.						
74.00	**Quality Self-Audits** are performed by the pharmacy at least quarterly (and upon change in PIC) to determine whether the occurrence of QREs has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the CQI program in the future.							
75.00	**Patient Complaints** are documented, tracked, and investigated as appropriate and the information is used as part of the CQI program.							

			Y	N	Need Info	N/A	Notes	
Quality Assurance/Quality Improvement Program: ***VIRGINIA State Specific Questions***								
VG17.00	If reporting to a PSO, a record indicating the date a report was submitted to a patient safety organization is maintained for 12 months from the date of reporting. If no dispensing errors have occurred within the past 30 days, a zero report with date shall be recorded on the record.	**VA-142**						
VG18.00	if not reporting to a PS), a separate record is maintained and available for inspection for 12 months from the date of the analysis of dispensing errors and includes the following information: (1) Dates the analysis was initiated and completed; (2) Names of the participants in the analysis; (3) General description of remedial action taken to prevent or reduce future errors; and (4) A zero report with date shall be recorded on the record if no dispensing errors have occurred within the past 30 days.	**VA-142**						
76.00	Were any uncorrected deficiencies from a prior state inspection noted? *If yes, indicate the repeat deficiencies. Attach to form if need additional documentation*							
77.00	Did this pharmacy have any uncorrected deficiencies from an inspection by another state or federal regulatory authority? *If yes, indicate the repeat deficiencies. Attach to form if need additional documentation.*							
78.00	Has this pharmacy been inspected as part of the NABP Verified Pharmacy Program? *If so, note any uncorrected deficiencies identified by NABP.*							
79.00	Has this pharmacy been inspected by any federal agency or another state? *If so, please list inspecting agency and date, and any uncorrected deficiencies noted.*							

The Virginia Board of Pharmacy
Universal Pharmacy Inspection Form

Nonsterile Compounding Inspection

NOTE: VA-n refers to the corresponding numeric deficiency on Virginia Guidance Document 110-9 Pharmacy Inspection Deficiency Monetary Penalty Guide

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.

Business or Corporation:	0			Day 1:		Inspector(s) and Affiliation	
Doing Business As (DBA):				Start Time:			
Address:	0			End Time:			
City:	0			Day 2:			
State:	0	Zip Code:		Start Time:			
Telephone number:	0			End Time:			
Toll free number:	0			Pharmacist in Charge	0		
Fax number:	0			PIC e-mail			
Website:				Nonsterile Compounding Manager			

Hours of Operation						
Sun	Mon	Tues	Wed	Thu	Fri	Sat
0:00	0:00	0:00	0:00	0:00	0:00	0:00
0:00	0:00	0:00	0:00	0:00	0:00	0:00

Sterile Compounding Manager	
Hazardous Compounding Supervisor	

Note if nonsterile compounding hours of operation differ from the facility hours above:

General Operations and Information				Y	N	?	NA	Notes	
									Virginia Deficiency
1.00	Does the pharmacy **dispense** nonsterile compounded preparations pursuant to a prescription?								
1.01		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.*							
1.02		Do the compounded prescriptions produce a significant difference from a commercially available drug that is justified by a documented medical need of the individual patient as determined by the prescribing practitioner?	**VA-28**						
1.03		Are nonsterile compounded prescriptions picked up at the pharmacy?							
1.04		Are nonsterile compounded prescriptions delivered to patients in their homes or residential facilities?							
1.05		Are nonsterile compounded prescriptions delivered to the practitioner for administration to the patient in the office, clinic, or facility?							
2.00	Does the pharmacy **distribute** nonsterile compounded preparations? *Not pursuant to a prescription, not labeled by the pharmacy with a patient name.*		**VA-29**						
2.01		Does the pharmacy distribute nonsterile compounded preparations to practitioners for office use?	**VA-29**						
2.02		Does the pharmacy distribute nonsterile compounded preparations to hospitals, clinics, or surgery centers?	**VA-29**						

2.03		Does the pharmacy have a sales force that distributes samples containing active ingredients? *List samples provided.*						
3.00	Does the pharmacy provide nonsterile compounded preparations to other pharmacies for dispensing? **(Virginia - Other than for alternate delivery)**	**VA-29**						
3.01		If so, does the pharmacy have central fill contracts or agreements with these pharmacies for patient specific preparations?						
4.00	Does the pharmacy compound oral preparations (tablets, capsules, liquids, lozenges, etc.)? *Indicate which in Notes*							
5.00	Does the pharmacy compound topicals (creams, ointments, inserts, suppositories, patches, sprays including nasal sprays, etc.)? *Indicate which in Notes*							
6.00	Does the pharmacy compound vitamin or nutritional supplements?							
7.00	Does the pharmacy compound investigational drugs? *If so, provide list.*							
8.00	Does the pharmacy make a copy of an approved commercial product? *Indicate volume or percent compounded currently in note.*	**VA-28**						
8.01		Products are verified as not available via FDA list and/or the manufacturer and documented **§54.1-**	**VA-28**					
8.02		FDA list is monitored (and manufacturer) and when item is taken off the list or becomes available, any remaining stock is quarantined for destruction and not dispensed or distributed						

9.00	Does the pharmacy perform compounding identified as **simple?** *Indicate percentage of simple compounding in Notes* 1. Making a preparation that has a USP compounding monograph or that appears in a peer-reviewed journal article that contains specific quantities of all components, compounding procedure and equipment, and stability data for that formulation with appropriate beyond-use dates (BUD)s. 2. Reconstituting or manipulating commercial products that may require the addition of one or more ingredients as directed by the manufacturer.						
10.00	Does the pharmacy perform compounding identified as **moderate?** *Indicate percentage of moderate compounding in Notes* 1. Making a preparation that requires special calculations or procedures (such as calibration of dosage unit mold cavities) to determine quantities of components per preparation or per individualized dosage units. 2. Making a preparation for which stability data for that specific formula is not available.						
11.00	Does the pharmacy perform compounding identified as **complex**? *Indicate percentage of complex compounding in Notes* Making a preparation that requires special training, environment, facilities, equipment, and procedures to ensure appropriate therapeutic outcomes.						
12.00	Does the pharmacy perform compounding with **hazardous drugs**? *Indicate percentage of hazardous nonsterile compounding in Notes* 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		Does the pharmacy have a hazardous waste handling and collection system? For example, empty bottles that contained chemotherapy medications or warfarin, hazardous drug compounding waste. *Indicate how often the bin is emptied/collected and the vendor used.*						

12.03		Do patient/caregiver training programs or materials contain information and precautions regarding the handling and disposal of hazardous products such as chemotherapy medications?						
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 compound using any **controlled substances**? *Indicate percentage of controlled substance nonsterile compounding in Notes*							
15.00	**APIs:** Does the pharmacy make any nonsterile compounded preparations using bulk powder Active Pharmaceutical Ingredients (APIs)?							
15.01		Does the pharmacy purchase APIs directly from the manufacturer? *If not, indicate the source of APIs.*						
15.02		Does the pharmacy verify that the manufacturer of the API is an FDA-registered facility? *How? If not, indicate how the pharmacy ensures quality.*						
15.03		Does the pharmacy use active ingredients that are not from an FDA facility? *If so, indicate sources*						
15.04		Does the computer track on-hand quantities of APIs used for compounding?						
16.00	Does the pharmacy perform any testing in-house (not sent to an outside lab)? *If so, what tests are performed in house?*							
17.00	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.*							

18.00	**Quality Assurance/Quality Improvement:** Does the pharmacy continuous quality improvement program include nonsterile compounding measures? • QREs related to the preparation of compounded products • Personnel testing and validation • Equipment calibration, testing and validation • End product testing (such as: potency, particulates, consistency, etc.) • Patient or prescriber reports or complaints regarding nonsterile compounded products.							
18.01		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?						
18.02		Does the recall system include communication with both the patient and the physician/prescriber regarding the affected nonsterile compounded preparation?						
18.03		Are QREs involving nonsterile compounded preparations or are recalled by the pharmacy reported to the Board of Pharmacy?						

Component Selection and Use		**Total Non-Compliant (includes Unknowns)**	**Non-Compliant**	**Compliant**	**Unknown**	**N/A**
19.00	**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)	VA-27				

19.01		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 using to compound.				
19.02		USP- or NF-grade substances used, if available				
19.03		If compendial 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.				
19.04		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 in notes below if found. Request copies of the invoices for products with questionable labels.*				
19.05		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				
19.06		All substances and components have a complete label including a batch control or lot number, and an expiration date.				
19.07		For APIs without an expiration date assigned by the manufacturer or supplier, the pharmacy assigns a conservative expiration date. The expiration date assigned does not exceed three (3) years for ingredients used for non-sterile compounding and does not exceed one (1) year for ingredients used for sterile compounding. *Note: purity and quality testing may be performed to extend.*				
19.08		All APIs and components received without an expiration date are labeled with the date they were received.				
19.09		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.				

19.10		Bulk component containers are labeled with appropriate OSHA hazard communication labels and hazardous substances are segregated (including hormones).					
19.11		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.					
20.00	Where water is an ingredient, purified or distilled water is used.						
21.00	Ingredients used for dietary or nutritional supplements meet USP, Food Chemicals Codex (FCC), or NF standards, or the pharmacy has alternate means to determine if the ingredients meet food-grade quality.						
22.00	There are no preparations 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).		**VA-27 §54.1-3410.2 (H)**				
23.00	When manufactured products are used for compounding, all the other excipients in the product are considered relative to the use, effectiveness, and stability of the compounded preparation to be made.						
24.00	For **animal compounding:** The compounding meets the same standards as compounding for human patients.						
24.01		The pharmacist is knowledgeable or has references regarding the individual species' limitations in physiology and metabolic capacity that can result in toxicity when certain drugs or excipients are used.	**VA-107**				
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 a 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 a reference regarding regulations for drug use in performance animals (e.g., race or show horses, racing dogs)					

Notes (refer to question number above)				

Beyond Use Dating (BUD)		Total Non-Compliant (includes Unknowns)	N/A	Unknown	Compliant	Non-Compliant
25.00	BUDs are assigned from the day of preparation.					
26.00	BUDs for nonaqueous formulations are not later than the remaining time until the earliest expiration date of any API and not later than six (6) months.					
27.00	BUDs for water-containing oral formulations are not later than 14 days when stored at controlled cold temperatures (refrigerated).					
28.00	BUDs for water-containing topical/dermal and mucosal liquid and semisolid formulations not later than 30 days.					
29.00	BUDs are assigned based on dispensing in tight, light-resistant containers/overpacks.					
30.00	Extended BUDs are supported by testing data. *View documentation used, preparation must exactly match formulation upon which data was obtained.*					
Notes (refer to question number above)						

Environment			Total Non-Compliant (includes Unknowns)	N/A	Unknown	Compliant	Non-Compliant
31.00	The non-sterile compounding area is a controlled environment and separate from the general pharmacy.	VA-133					
32.00	There sufficient space available for the type and amount of compounding performed and the space is orderly to prevent mix-ups between ingredients, containers, labels, in-process materials, and finished preparations.						

33.00	Only one preparation compounded at a time.		VA-133				
34.00	Procedures are implemented to prevent cross-contamination, especially when compounding with drugs such as hazardous drugs and known allergens like penicillin that require special precautions.		VA-133				
35.00	The compounding area is well lit.						
36.00	The pharmacy performs **hazardous** non-sterile compounding a ventilated cabinet such as a BSC, CAI, or CACI. *Note: CAI may not be used for hazardous drugs that may volatilize.(NIOSH requirement referenced in USP<795>. Note that proposed USP Chapter <800> will change hazardous drug compounding requirements.)*						
36.01		Ventilated cabinets (BSC, CAI, CACI) used for hazardous compounding are certified or tested periodically.					
36.02		RECOMMENDED: Hood prefilters are checked and replaced regularly.					
36.03		If the hoods or isolators are not located in a closed, controlled room environment, there is documentation from the manufacturer and site testing to verify proper functioning of equipment under dynamic conditions for the safety of personnel.					
37.00	Appropriate protective attire (gowns, gloves, masks, etc.) is available including appropriate PPE for hazardous drug compounding, if hazardous drugs are used.						
38.00	There is a sink in the compounding area with hot and cold potable water, soap or detergent, and air-driers or single-use towels.						
39.00	There is adequate space to wash equipment and utensils including access to water for rinsing. *(Purified water is **recommended -** not required)*						
40.00	The temperature of the compounding area is controlled by a thermostat and an air conditioning system is in place.						

41.00	**Temperature** in the compounding area is maintained to provide controlled room temperature storage of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements.					
41.01		Temperature monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Temperature records are maintained.				
41.02		Excursion action plan in place including evaluating excursion effects on drug product integrity.				
41.03		Temperature monitoring is also performed in drug storage areas (if separate from the compounding areas).				
42.00	**Humidity** in the compounding area is maintained to provide humidity in the ranges warranted by specific drug product storage requirements. If drug products require storage in a "dry place", humidity is not to exceed 40%. Generally **recommended** range is 35-60%.					
42.01		Humidity monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Humidity records are maintained.				
42.02		Excursion action plan in place including evaluating excursion effects on drug product integrity.				
42.03		Humidity monitoring is also performed in drug storage areas (if separate from the compounding areas).				
43.00	The bulk component storage area is adequately arranged and maintained in a clean and sanitary condition.					
44.00	All components, equipment, and containers are stored off the floor, and handled and stored to prevent contamination.					
45.00	All components and packaging containers and closures are properly rotated to use oldest first.					
46.00	Hazardous drugs are appropriately identified and marked, received, handled and stored by appropriately trained personnel. (OSHA regulations and NIOSH Alerts)					
47.00	Trash is disposed of in a safe, sanitary, and timely manner including hazardous waste.					

48.00	**Recommended:** Environmental testing is performed to detect contamination by drug residue in the pharmacy areas or areas served by the same ventilation system? *Drug residue may cause cross contamination to other products and expose staff. Not required but is recommended if compounding with hazardous materials or known allergens such as penicillin, not using a hood, or the compounding room not segregated.*				
Notes (refer to question number above)					

Training *Verify records of all compounding personnel (up to 10). Indicate number of records viewed in Notes.*		**Total Non-Compliant (includes Unknowns)**	**Non-Compliant**			
			N/A	**Unknown**	**Compliant**	
49.00	Have all personnel of reproductive capability who handle or compound hazardous drugs or chemicals confirmed in writing that they understand the risks of handling hazardous drugs? Teratogenicity, carcinogenicity, reproductive issues.					
50.00	There is documentation that all personnel that perform compounding are appropriately trained including policies and procedures, documentation, hazardous drug handling, and compounding technique and not allowed to compound or supervise compounding until training is successfully completed.					
51.00	There is documentation that the training process for the preparation of compounds includes demonstration of the compounding procedure first, followed by the trainee performing the procedure under supervision successfully before being allowed to perform compounding.					
52.00	There is documentation that training includes the operation of any equipment that may be used when preparing compounded products. *Documentation includes operation and troubleshooting*					
53.00	There is documentation available showing employees performing non-sterile compounding are evaluated at least annually (including hazardous drug handling).					
54.00	If the pharmacy uses relief personnel from outside agencies to perform non-sterile compounding there is documentation that training is verified.					

Notes (refer to question number above)				
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Compounding Equipment		Total Non-Compliant (includes Unknowns)	N/A	Unknown	Compliant	Non-Compliant
55.00	Appropriate equipment and utensils are available, clean, and in good working order. *Automated, mechanical, or electronic equipment (including capsule machines, autoclaves, ovens, etc.) are periodically inspected and calibrated.*					
56.00	Scales, balances, or other equipment used for measurement is validated and calibrated at least annually. *If scales are NOT validated and sealed by a state or local weights and measures agency, describe procedure used below in notes.*					
57.00	Powder hoods used for nonsterile compounding are certified or tested periodically to ensure proper function. Hood filters are checked regularly and replaced when necessary.					
58.00	All equipment is cleaned promptly after each use. *Equipment and utensils washed using potable water with a soap or detergent, and rinsed.* ***Recommended*** *rinsed with purified water.* **VA-133**					
59.00	The pharmacy uses separate equipment and utensils to compound allergenic, cytotoxic, or hazardous products, or has detailed procedures for meticulous cleaning of equipment and utensils immediately after use to prevent cross-contamination or exposure.					
Notes (refer to question number above)						

Documentation			Total Non-Compliant (includes Unknowns)	Non-Compliant			
				N/A	Unknown	Compliant	
60.00	The pharmacy creates a master formulation record the first time before compounding a new preparation						
60.01		Every formulation is evaluated for incompatibilities and the potential for being ineffective or toxic.					
60.02		The master formulation record contains: 1. Official or assigned name, strength, and dosage form 2. All necessary calculations 3. Description of all ingredients and their quantities 4. Compatibility and stability information including references (when available) 5. Equipment used for the preparation 6. Mixing instructions (order of mixing, temperatures, duration of mixing, and other pertinent factors) 7. Container used and packaging requirements 8. Assigned BUD information 9. Labeling information including the name of and quantity or concentration of each active ingredient 10. Description of the finished preparation 11. Storage requirements 12. Quality control procedures and expected results (e.g. dose measurement of capsule in the dose calibrator).					

61.00	The pharmacy creates a compounding record for each compound prepared.	VA-130 §54.1-3410.2 (I)				
61.01	The compounding record includes: 1. Official or assigned name, strength and dosage of the preparation 2. Master Formulation Record reference 3. Sources, lot numbers, and expiration dates of all components 4. Total quantity or number of dosage units compounded 5. Person compounding the preparation 6. Person performing the quality control procedures 7. Person who approved the preparation 8. Date of compounding 9. Assigned internal identification number or prescription number 10. Description of the final preparation 11. Assigned BUD 12. Duplicate label 13. Results of quality control procedures (weight range of filled capsules, pH of aqueous liquids, etc.)? 14. Documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver including investigation and recall, if appropriate					
Notes (refer to question number above)			N/A	Unknown	Compliant	Non-Complaint

Compounding Procedures		**Total Non-Compliant (includes Unknowns)**	**Non-Compliant**			
			N/A	**Unknown**	**Compliant**	
62.00	The Master Formulation Record and the Compounding Record has been reviewed by the compounder to ensure it is error free.					
63.00	Compounding personnel ascertain that ingredients for compounded preparations are of the correct identity and appropriate quality including a unit-by-unit inspection of the components.					

64.00	The containers and closures selected meet USP standards (from container supplier).				
65.00	Container selection determined by physical and chemical properties of the preparation.				
66.00	Compounding personnel maintain good hand hygiene and wear clean and appropriate clothing for the compounding being performed.				
67.00	Personnel don appropriate protective garb when performing compounding including hazardous compounding.				
68.00	Routine compounding procedures for batch preparation completed and verified according to written procedures. Including: *Calculations correct, weighing and measuring performed correctly, order of mixing correct, compounding techniques performed correctly*				
69.00	Procedures for in-process checks followed. *These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists that includes visual inspection of product, and documentation of the compounding accuracy is performed to ensure proper measurement, reconstitution and component usage.* ***Recommended:*** *compounding accuracy checked by a person other than the compounder.*				
70.00	If there are any deviations from the master formulation record, these deviations are recorded.				
71.00	There is a plan for cleaning. *After each preparation, daily tasks, monthly tasks, etc.*				
72.00	Personnel are appropriately garbed for protection when cleaning.				
72.01	Compounding employees are using appropriate techniques. *Inspector to observe compounding procedures, documentation, appropriate garb, cleanliness of compounding area and equipment. Compounding MUST be observed, 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 and mark item as "Non-Compliant".*				
Notes (refer to question number above)					

Finished Preparation Release Checks and Tests			Total Non-Compliant (includes Unknowns)	Non-Compliant			
						Compliant	
					Unknown		
				N/A			
73.00	The finished preparation is observed to appear as expected in the master formulation record and documented.						
74.00	As appropriate, the final completed preparation assessed for weight, mixing, clarity, odor, color, consistency, pH, and strength and is documented.						
75.00	There are established written processes that describe test or examinations conducted on the compounded preparation (degree of weight variation in capsules, for example) to ensure uniformity and integrity.						
76.00	Preparations with extended BUDs that are not supported by testing data are sampled and tested for physical, chemical, and microbiological characteristics.						
76.01		If any failed tests or discrepancies are observed, there an investigation and appropriate corrective actions taken before dispensing to patient					
76.02		If products being tested are dispensed or distributed before the test results are obtained, there is a recall procedure if the test results indicate an issue.					
77.00	There are appropriate control procedures to monitor the output and to verify the performance of compounding processes and equipment that may be responsible for causing variability in the final compounded preparations. *Validation of equipment and personnel performance documentation*						
78.00	Labels on immediate patient-specific containers include identifiers for the persons preparing the compound and performing the final verification, BUD, an indication that this is a compounded preparation, special requirements for storage, and appropriate packaging and labeling of hazardous materials.						
79.00	Batch preparations (in anticipation of prescriptions) are of an appropriate volume and batch products in stock are all within their BUD (not outdated).						
80.00	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.						

81.00	Preparations are stored properly prior to dispensing based upon conditions upon which BUD was assigned.				
82.00	Preparations are examined immediately after preparation AND again immediately prior to dispensing for any signs of instability.				
Notes (refer to question number above)					

Patient Counseling and Communication		**Total Non-Compliant (includes Unknowns)**	**Non-Compliant**	**Compliant**	**Unknown**	**N/A**
	Do patient/caregiver training programs or materials contain information and precautions regarding the handling and disposal of hazardous products such as chemotherapy medications?					
	Are the required printed drug information materials (drug information sheets, Patient Package Inserts, MedGuides, etc.) provided for the compounded products?					
	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?					
	Product recalls include documentation that both the patient AND the physician/prescriber of the potentially contaminated compounded product are notified of the potential risk.					
Notes (refer to question number above)						

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.

The Virginia Board of Pharmacy
Universal Pharmacy Inspection Form
Sterile Compounding Inspection

NOTE: VA-n refers to the corresponding numeric deficiency on Virginia Guidance Document 110-9 Pharmacy Inspection Deficiency Monetary Penalty Guide

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.

Business or Corporation:	0			Day 1:		Inspector(s) and Affiliation	
Doing Business As (DBA):				Start Time:			
Address:	0			End Time:			
City:	0			Day 2:			
State:	0	Zip Code:		Start Time:			
Telephone number:	0			End Time:			
Toll free number:	0			Pharmacist in Charge	0		
Fax number:	0			PIC Email			
Email Address:							

Hours of Sterile Compounding Operation (Check if 24/7)						
Sun	Mon	Tues	Wed	Thu	Fri	Sat
0:00	0:00	0:00	0:00	0:00	0:00	0:00
0:00	0:00	0:00	0:00	0:00	0:00	0:00

Sterile Compounding Manager	
Hazardous Compounding Supervisor	

Note if differ from regular facility hours

	Indicate the drug name, dosage or strength, and the size of the sample obtained for testing. (*NA if no sample)*	
	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	
									Virginia Deficiency
1.00	Does the pharmacy **dispense** sterile compounded preparations pursuant to a prescription?								
1.01		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.*							
1.02		Are sterile compounded prescriptions picked up at the pharmacy?							
1.03		Are sterile compounded prescriptions delivered/mailed to patients in their homes or residential facilities?							
1.04		Are sterile compounded prescriptions delivered/mailed to the practitioner for administration to the patient in the office, clinic, or facility?							
2.00	Does the pharmacy **distribute** sterile compounded preparations? *Not pursuant to a prescription, not labeled by the pharmacy with a patient name.*								
2.01		Does the pharmacy distribute sterile compounded preparations to practitioners for office use?	**VA-29**						

2.02		Does the pharmacy distribute sterile compounded preparations to hospitals, clinics, or surgery centers?	VA-29						
2.03		Is the pharmacy registered with the FDA as an Outsourcing Facility?							
2.04		Does the pharmacy have a sales force that distributes samples containing active ingredients? *List samples provided.*							
3.00	Does the pharmacy provide sterile compounded preparations to other pharmacies for dispensing?		VA-29						
3.01		If so, does the pharmacy have central fill contracts or agreements with these pharmacies for patient specific preparations?							
				Y	**N**	**?**	**NA**	**Notes**	
								Virginia Deficiency	
4.01		Allergen extracts							
4.02		Parenteral solutions							
4.03		Parenteral *suspensions*							
4.04		Preservative-free parenterals							
4.05		Ophthalmic preparations							
4.06		Oral or nasal *inhalation* preparations (not topical sprays)							
4.07		Baths and soaks for live organs and tissues							
4.08		Irrigations for wounds and body cavities							
4.09		Any other sterile preparations (implants, pellets, etc.) *List in Notes.*							
5.00	Does the pharmacy compound investigational drugs? *If so, provide list.*								

6.00	Does the pharmacy make a copy of an approved commercial product? *Indicate volume/percent compounded currently in Notes .*		**VA-28**						
6.01		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.	**VA-28 §54.1-3410.2 (H)**						
6.02		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.							
6.03		If the essential copy is not on the Drug Shortage List, the compounded preparation produces a clinical difference from a commercially available drug that is justified by a documented medical need of the individual patient as determined by the prescribing practitioner.	**VA-28**						
				Y	**N**	**?**	**NA**	**Notes**	
								Virginia Deficiency	
7.01		Are all low-risk compounds assigned BUDs within USP guidelines (48 hours at controlled room temperature, 14 days refrigerated, 45 days frozen)? *If no, indicate maximum BUD assigned in Notes.*	**VA-33**						
8.00	Does the pharmacy perform **medium-risk** compounding? *Indicate percentage of medium-risk sterile compounding in Notes*								
8.01		Are all medium-risk compounds assigned BUDs within USP guidelines (30 hours at controlled room temperature, 9 days refrigerated, 45 days frozen)? *If no, indicate maximum BUD assigned in Notes.*	**VA-33**						

9.00	Does the pharmacy perform **high-risk** compounding? *Indicate percentage of high-risk sterile compounding in Notes*							
9.01		Are all high-risk compounds assigned BUDs within USP guidelines (24 hours at controlled room temperature, 3 days refrigerated, 45 days frozen)? *If no, indicate maximum BUD assigned in Notes.*	**VA-25**					
10.00	Does the pharmacy provide sterile compounded preparations to be administered via an implantable infusion pump?							
10.01		Are BUDs assigned to include the full length of time during which the CSP will be administered or present in the reservoir of the pump? *If not, indicate in "Notes" the maximum length of time of administration that may be beyond the BUD assigned*						
11.00	Does the pharmacy perform compounding for **immediate use?** *Indicate percentage of immediate use sterile compounding in Notes*							
12.00	Does the pharmacy perform compounding with **hazardous drugs**? *Indicate percentage of hazardous sterile compounding in Notes*							
12.01		Is the pharmacy aware of the more stringent requirements of the proposed USP Chapter <800>?						
							Notes	
								Virginia Deficiency
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 I-V**? *Indicate controlled substances used and percentage of controlled substance sterile compounding in Notes*							
16.00	**APIs:** Does the pharmacy make any sterile or nonsterile compounded preparations using bulk powder Active Pharmaceutical Ingredients (APIs)?							
16.01		Does the pharmacy purchase APIs directly from the manufacturer? *If not, indicate the source of APIs.*						
16.02		Does the pharmacy verify that the source of the API is an FDA-registered facility? *How?*						
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 have a **lyophilizer**?							
17.01		Where is the lyophilizer located? *Indicate ISO class of room.*						
17.02		Note the products lyophilized, and the volume or percent of products per week produced using the lyophilizer						
							Notes	

									Virginia Deficiency
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?		**VA-131**						
20.01		Nonviable environmental monitoring and testing	**VA-131**						
20.01		Viable environmental testing	**VA-131**						
20.03		Personnel testing and validation	**VA-131**						
20.04		Equipment calibration, testing, validation	**VA-131**						
20.05		Sterilization method testing validation	**VA-131**						
20.06		End product testing (such as: potency, particulates, sterility, endotoxin, etc.	**VA-131**						
20.07		Patient or prescriber reports or complaints regarding CSPs	**VA-131**						
20.08		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?							
20.09		Does the recall system include communication with both the patient and the physician/prescriber regarding the potentially contaminated CSP administered and the potential risks?							

20.10		Are QREs involving CSPs that may have been contaminated or are recalled reported to the Board of Pharmacy?						
20.11		Are all incidents (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?						

Component Selection and Use			Total Non-Compliant (includes Unknowns)	Non-Compliant		Compliant	
				N/A	Unknown		
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)	VA-27					
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 compendial 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 in notes below 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, 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	No preparations are 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).		**VA-27 §54.1-3410.2 (H)**				
23.00	There are no preparations compounded that present demonstrable difficulties for compounding as identified by the FDA.						
24.00	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.						

25.00	For **animal compounding**, does the compounding meet the same standards as compounding for human patients?						
25.01		The pharmacist is knowledgeable or has references regarding the individual species' limitations in physiology and metabolic capacity that can result in toxicity when certain drugs or excipients are used.	VA-107				
25.02		It is determined and documented if the animal is used for food (meat, milk, eggs, etc.) or that the animal is a pet.					
25.03		The pharmacist familiar with, or has a reference regarding drug residues in the food chain and withdrawal times if compounding for food-producing animals.					
25.04		The facility has a list of drugs and components not allowed when compounding for food-producing animals.					
25.05		The pharmacist is familiar with, or has a reference regarding regulations for drug use in performance animals (e.g., race or show horses, racing dogs)					
26.00	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.						
26.01		The stock solutions are assigned BUD based on the USP<797> high-risk compound BUD, OR there is documentation of stability or testing to support an extended BUD.	VA-25				
26.02		Sterility testing is performed on stock solutions.	VA-25				
26.03		Endotoxin testing is performed after sterilization on stock solutions to be used for parenteral preparations.	VA-25				
26.04		Once punctured, the stock solution is discarded after 6 hours if kept in ISO Class 5 (or 1 hour if in less than ISO Class 5).					
26.05		Compounded preparations using the stock solution are classified as high-risk compounds with appropriate handling with regard to BUD and testing requirements.	VA-25				
Notes (refer to question number above)							

Environment			Total Non-Compliant (includes Unknowns)	Non-Compliant		Compliant	
				N/A	Unknown		
27.00	If the facility performs both sterile and nonsterile compounding, the areas are separated and distinct.		VA-21 VA-21A				
28.00	If the facility performs compounding using blood products (or other biological materials), this compounding area is separate and distinct from the general compounding areas.						
28.01		Are components used in compounding with blood products restricted to the blood compounding area (not used in other compounding areas)?					
29.00	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).						
30.00	The ante-room 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 ante room and the clean/buffer room.*		VA-32				
30.01		Carts used to bring supplies from the storeroom are kept on the outside of the line of demarcation.					
30.02		Carts used in the clean room/buffer room are kept on the clean side of the line of demarcation.					
31.00	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.		VA-32				
32.00	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.		VA-32				
33.00	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.		VA-32				
34.00	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.		VA-32				

35.00	The clean room or ante-room does not have dust collecting overhangs, such as ceiling utility pipes, or ledges; and sprinkler heads are flush with the ceiling.		VA-32				
36.00	The exposed surfaces of the light fixtures are smooth, mounted flush, and sealed.		VA-32				
37.00	A sink with hot and cold running water is located on the clean side of the line of demarcation **in the ante room** that enables pharmacy personnel to wash hands and enter the sterile compounding area without contaminating his/her hands, and an eyewash station.		VA-32				
37.01		RECOMMENDED: The sink and the soap dispenser(s) are hands-free.					
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	There is no sink or drain in the clean room/buffer room.		VA-32				
40.00	All air ducts controlling air flow into the sterile compounding clean/buffer room and ante room are equipped with High Efficiency Particulate Air filtered air that maintains the cleanroom with an ISO Class 7 environment.						
41.00	Incoming air ducts through HEPA filters are on or near the ceiling and air return ducts are low on the walls in the ante-room and clean room.						
42.00	If there is particle generating equipment in the clean room or ante-room (such as computers and printers), the equipment is 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 the equipment was in use.						
43.00	If there are particle generating appliances in the clean room or ante-room (such as refrigerators, dishwashers, etc.), the equipment 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 the equipment was in use and appliances are also part of the viable surface sampling program.						
44.00	Beverages including drinking water, chewing gum, candy, or food items are prohibited from the clean room/buffer area or ante-room.						

45.00	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.						
45.01		RECOMMENDED: Pre-sterilization procedures for high risk level CSPs (such as weighing and mixing) are performed in no worse than an ISO Class 8 environment					
46.00	Completely enclosed ante room and clean room (with a door) are equipped with monitors or gauges to measure differential pressure		**VA-32**				
46.01		Ante room is at least 0.02" w.c. positive pressure to general pharmacy areas	**VA-32**				
46.02		Clean room/buffer room is at least 0.02" w.c. positive pressure to the ante room	**VA-32**				
46.03		Hazardous compounding room and drug storage area is at least 0.01" w.c. negative pressure to ISO Class 7 ante room	**VA-32**				
46.04		Pressures are read and recorded each shift (minimum of once daily) or are continuously recorded. *View logs*					
46.05		Plan in place to detect and react to pressure differentials outside of limits					
47.00	If the clean room and anteroom are not fully enclosed (open or with plastic strips - no door that closes), the air flow is measured across the openings.						
47.01		The air flow is at least 40 feet per minute across the entire opening					
47.02		Airflow is read and recorded each shift (minimum of once daily) or continuously recorded. *View logs.*					
47.03		Plan in place to detect and react to air flow measurements outside of limits					
47.04		This area is used only for low- and medium-risk compounding. (High-risk not allowed)					

48.00	**Temperature:** The temperature of the compounding area is controlled by a thermostat and an air conditioning system is in place.						
48.01		Temperature in the **compounding area** is maintained to provide controlled room temperature of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements. Recommended temperature range for performing sterile compounding while garbed is between 64-72°F (18-22°C).	**VA-32**				
48.02		Temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Temperature records are maintained.					
48.03		Temperature monitoring is also performed in **drug storage areas** (if separate from the compounding areas).	**VA-32**				
48.04		Temperature in the **refrigerator or cooler** is maintained to provide controlled cold temperature of 2° to 8°C (36° to 46°F).	**VA-8 VA-104**				
48.05		Temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Temperature records are maintained.	**VA-131**				
48.06		Temperature in the **freezer** is maintained to provide controlled frozen temperature of -10° to -25°C (-13° to 14°F).	**VA-8 VA-105**				
48.07		Temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Temperature records are maintained.	**VA-131**				
48.08		Action plan in place for temperature excursions including evaluating excursion effects on drug product integrity.					

49.00	**Humidity:** Humidity in the compounding area is maintained to provide humidity in the ranges warranted by specific drug product storage requirements. 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.					
49.01		Humidity monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Humidity records are maintained.				
49.02		Excursion action plan in place including evaluating excursion effects on drug product integrity.				
49.03		Humidity monitoring is also performed in drug storage areas (if separate from the compounding areas).				
50.00	Blowers on ISO 5 PECs are operated continuously during compounding activity, including during interruptions of less than eight hours.					
51.00	When the ISO 5 LAFW 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					
52.00	The doors into the ante-room from the general pharmacy area and from the anteroom into the clean room are prevented from both being open at the same time. *By interlocking, training of personnel, or signage.*					
53.00	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.*					
53.01		RECOMMENDED: Pass-throughs are located between outside areas and the anteroom, or between the anteroom and the buffer room (and NOT between the outside areas directly into the buffer room).				
54.00	RECOMMENDED: The immediate area around the doorway or pass-through into the ante room from the general areas is free of particle generating materials (such as corrugated cardboard, etc.) and is located in an area that limits particles (not next to an outside door or window, etc.) to limit potential contamination from being brought in through the entry.					

55.00	**BSC or LAFW that is NOT located in an ISO Class 7 clean/buffer room:** BSC or LAFW has been certified to maintain ISO Class 5 during compounding activities.		VA-21A VA-22				
55.01		Used only for low-risk compounded preparations with a 12-hour or less BUD assigned.	VA-21A VA-22				
55.02		All garbing requirements adhered to	VA-21A VA-22				
55.03		Located in an area that is maintained under sanitary conditions only be traveled by persons engaging in the compounding of sterile preparations	VA-21A VA-22				
55.04		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?	VA-21A VA-22				
55.05		Has the sink separated from the immediate area of the ISO Class 5 workbench (not adjacent) and an eyewash station	VA-21A VA-22				

56.00	**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. **Indicate Make & Model:**		**VA-21A VA-22**				
56.01		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.	**VA-21A VA-22**				
56.02		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.	**VA-21A VA-22**				
56.03		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	**VA-21A VA-22**				
56.04		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.	**VA-24**				
Notes (refer to question number above)							

Cleaning and Disinfection			Total Non-Compliant (includes Unknowns)	Non-Compliant		Compliant	
				N/A	Unknown		
57.00	Are all personnel performing cleaning appropriately garbed?	VA-32					
58.00	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).*	VA-32					
59.00	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?	VA-32					
60.00	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.	VA-32					
61.00	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?	VA-32					
62.00	Are cleaning and sanitizing agents appropriately labeled including expiration dates? *Verify no expired agents present*	VA-32					
63.00	Are appropriate cleaning agents used that are effective for bacteria, viruses, fungi, and spores?	VA-32					
64.00	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?	VA-32					
65.00	Does the cleaning of the ISO 5 PEC include cleaning with sterile water **and** sanitizing with sterile 70% IPA using a nonlinting wipe?	VA-32					

66.00	Does daily cleaning and sanitizing include counters and easily cleanable work surfaces?	VA-32				
67.00	Does daily cleaning include the floors starting from the clean room and working outwards? *Floor cleaning is not to occur during compounding.*	VA-32				
68.00	If fatigue mats are used, are they cleaned daily and let dry on both sides?	VA-32				
69.00	Is a tacky mat used and if so, is there a procedure in place regarding replacement?	VA-32				
70.00	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.	VA-32				
71.00	Is enough time allocated for cleaning activities?					
Notes (refer to question number above)						

Training:			**Total Non-Compliant (includes Unknowns)**	**Non-Compliant**	**Compliant**	**Unknown**	**N/A**
Total number of records reviewed:							
72.00	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.*						
72.01		All personnel performing compounding are not allowed to compound until training and initial testing is successfully completed.					

72.02		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.					
73.00	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.*						
74.00	There is documentation 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.						
75.00	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*						
76.00	If the pharmacy uses relief personnel from outside agencies to perform sterile compounding, training and certifications are verified. *View documentation.*						
77.00	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 in "Notes" below if testing more than annually.*						
78.00	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 in "Notes" below if testing more than annually.*						
79.00	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 in "Notes" below if testing more than annually.*		**VA-25C VA-26 VA-26A**				

80.00	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). Indicate frequency in "Notes" below if testing more than annually.*	**VA-26**				
81.00	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 in "Notes" below if testing more than annually.*	**VA-26**				
82.00	The media-fill testing procedures include:					
82.01	• Media selection (including obtaining COAs or growth promotion certificates from suppliers)					
82.02	• Fill volume					
82.03	• Incubation time and temperature (30-35°C for a minimum of 7 days then 20-25°C for 7 days)					
82.04	• Inspection of filled units					
82.05	• Documentation					
82.06	• Interpretation of results (including identifying microbes down to genus level)					
82.07	• Action levels set with the correction actions required					

83.00	**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/plate upon revalidation. Indicate frequency in "Notes" below if testing more than every 6 months.*		**VA-25C**				
84.00	**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 in "Notes" below if testing more than every 6 months.*		**VA-25C**				
85.00	**Failed testing:** Employees who have failed any testing are prohibited from compounding until training is performed/reviewed and subsequent testing is performed successfully.		**VA-26A**				
85.01		Gloved fingertip tests or media fill tests that 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.					
85.02		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.					
Notes (refer to question number above)							

Garbing			Total Non-Compliant (includes Unknowns)	Non-Compliant		Compliant	
				N/A	Unknown		
86.00	Personnel are prohibited from compounding, or entering the clean/buffer room or ante room if they have a rash, sunburn, weeping sores, conjunctivitis, or an active respiratory infection.	VA-132					
87.00	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.*	VA-132					
88.00	Personnel are required to remove all hand and wrist jewelry, and all visible jewelry or piercings such as earrings, lip or eyebrow piercings, etc. when entering clean/buffer room.	VA-132					
89.00	Personnel are prohibited from wearing artificial nails or extenders, and required to keep natural nails neat and trimmed.	VA-132					
90.00	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)	VA-132					
91.00	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.*	VA-132					
91.01	There is a mirror available to check that all hair is covered.	VA-132					
92.00	Hand cleaning is performed in the ante-room 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.*	VA-132					
93.00	The gown is nonshedding with sleeves that fit snugly around the wrists and enclosed at the neck.	VA-132					

94.00	All bare skin is covered on the arms and the legs (no bare ankles, wrists, etc.).		VA-132				
95.00	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.*		VA-132				
96.00	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.		VA-132				
97.00	Pharmacists or other personnel do NOT enter the ante-room 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.*		VA-132				
98.00	Pharmacists or other personnel do NOT enter the clean room without fully washing and garbing (wearing just a mask to check technician's work, for example)		VA-132				
Notes (refer to question number above)							

Environmental Monitoring			**Total Non-Compliant (includes Unknowns)**	**Non-Compliant**	**Compliant**	**Unknown**	**N/A**
99.00	The most recent PEC and room certification report is available.						
99.01		All ISO Class 7 and 8 SECs (cleanrooms and ante rooms) have been certified within the last 6 months. *If non-compliant, record the date of the last certification below.* **VA-23**	VA-23				

99.02		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 below.* **VA-22**	**VA-22**					
99.03		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. *Record date of last two certifications.* **VA-22** **VA-23**	**VA-23**					
			Date of LAST Certification:		Date of PREVIOUS Certification			
99.04		Certification is performed to the Controlled Environment Testing Association (CETA) standard (USP: CETA CAG-003-2006-11 Certification Guide for Sterile Compounding Facilities) and is noted on the report.						
99.05		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 standard.						
99.06		The PIC 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.	**VA-147**					
100.00	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)							
100.01		The equipment used had not exceeded its calibration date at the time of certification						
101.00	The HEPA filtered air changes per hour (ACPH) were measured for the compounding rooms							
101.01		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.*						

101.02		ISO class 7 ante-room is certified as having a minimum of 30 ACPH. *Ante room must be ISO class 7 if connected to a NIOSH hazardous compounding clean room.*					
101.03		ISO class 8 ante-room is certified as having the **recommended** minimum of 20 ACPH.					
101.04		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.*					
101.05		If a CACI is used in a non-HEPA filtered room, the room is certified to maintain a minimum of 12 ACPH.					
102.00	Air pattern analysis using smoke testing was performed under dynamic conditions (people working in the hoods and rooms). *The smoke flow is described in the report for the various tests such as turbulent, sluggish, smooth, etc.*		**VA-147**				
102.01		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).	**VA-147**				
102.02		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	**VA-147**				
102.03		Air pattern analysis conducted around particle generating equipment *while the equipment was in operation* to confirm air flow.	**VA-147**				
103.00	Differential air pressure between rooms was measured.		**VA-32**				
103.01		The differential pressure measured was at least 0.02" water column positive from the cleanroom to the ante-room and between the ante-room and all adjacent spaces with the doors closed.	**VA-32**				
103.02		The differential pressure measured was at least 0.01" water column negative from the hazardous clean room to the ante room with the doors closed.	**VA-32**				

104.00	Displacement airflow between rooms or areas was measured. *This is for a clean room without a door that closes to the ante room - may be an open space or may have plastic strips in doorways.*						
104.01		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 ante-room. *Note that it is very important to maintain this velocity across the entire opening and the report should indicate multiple points of measure across all openings.*					
105.00	Particle counts of particles 0.5um and larger were measured under dynamic conditions.		**VA-147 VA-23**				
105.01		ISO Class 5 areas and hoods are certified as having less than 3,520 particles per cubic meter of air.	**VA-147 VA-23**				
105.02		ISO Class 7 areas are certified as having less than 352,000 particles per cubic meter of air.	**VA-147 VA-23**				
105.03		ISO Class 8 areas are certified as having less than 3,520,000 particles per cubic meter of air.	**VA-147 VA-23**				

106.00	HEPA filter tests were performed.		VA-147 VA-23				
106.01		All room HEPA filters were leak tested and if leaks found, they were fixed	VA-147 VA-23				
106.02		All hood HEPA filters were leak tested and if leaks found, they were fixed	VA-147 VA-23				
107.00	Rooms or hoods with failed tests are not used for compounding until the conditions are corrected and verified by subsequent testing.		VA-22 VA-23				
108.00	Viable air and surface sampling tests have been conducted at least every 6 months. *If sampling is performed more often, document frequency below in "Notes".*		VA-131				
108.01		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.*	VA-131				
108.02		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>.*	VA-131				
108.03		Air samples were taken in each ISO Class 5 PEC, and in each sterile compounding room and ante room and the samples are at least 400 liters in volume? *Note: recommendation in ISO 5 PEC is 1000 liters.*	VA-131				

108.04		Surface samples performed on all direct compounding areas inside of each ISO 5 PEC, in each room, inside any pass-throughs, and on surfaces likely to be contaminated due to position relative to doorways, etc.	**VA-131**				
108.05		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*	**VA-131**				
108.06		CFUs detected by any means: (viable air or surface sampling, media fills, 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.*	**VA-131**				
108.07		If the number of CFUs detected exceeds action levels, compounding ceases, immediate remediation and investigation into the cause conducted, and compounding not resumed until subsequent tests are performed successfully.	**VA-131**				
108.08		If **any** mold, yeast, coagulase positive staphylococcus, or gram negative rods were detected (whether or not the number of CFUs exceeds action levels), compounding ceases, immediate remediation and investigation into the cause conducted, and compounding not resumed until subsequent tests are performed successfully.	**VA-131**				
108.09		The testing report indicates growth promotion testing or documentation and sterility quality control testing of the media plates was performed. *Positive and negative control tests important to validate results of viable testing.*	**VA-131**				
108.10		The testing results report includes media lot numbers and expiration dates and a signature of the laboratory analyst and/or reviewer.	**VA-131**				

109.00	Facilities performing routine air or surface sampling with internal qualified personnel routinely validate sampling procedures. *Indicate the outside vendor used to validate procedures and frequency of validation below in "Notes".*				
Notes (refer to question number above)					

Compounding Equipment			**Total Non-Compliant (includes Unknowns)**	**Non-Compliant**		**Compliant**	
				N/A	**Unknown**		
110.00	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.*						
111.00	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.		**VA-133**				
112.00	All temperature and humidity monitoring devices (thermometers, hygrometers, probes, etc.) are periodically inspected, and calibrated yearly or in accordance with the equipment manufacturer guidelines. Calibration is documented						
113.00	Scales, balances, or other equipment used for measurement are regularly calibrated, and validated at least annually. *If scales are NOT validated and sealed by a state or local weights and measures agency, describe procedure used below in notes.*						
114.00	RECOMMENDED: PEC (hood) <u>prefilters</u> are checked and replaced regularly. *View replacement log or documentation of filter check and replacement by certification company* .						
115.00	Automated Compounding Devices (ACDs) are used for sterile compounding (such as repeater pumps) and there is a P&P for the use and calibration.		**VA-133**				
115.01		There is documentation of the ACD tubing being changed or discarded every 24 hours					
115.02		The ACD is used when performing media fill testing.					

Notes (refer to question number above)				

	Compounding Procedures	Total Non-Compliant (includes Unknowns)	Non-Compliant		Compliant	
			N/A	Unknown		
116.00	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					
117.00	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)?					
118.00	Essential paper related products (syringe overwraps, work records contained in a protective plastic sleeve) are wiped down with sterile 70% IPA before bring brought into the buffer or clean area.					
119.00	Supplies required for the scheduled operations of the shift are prepared and decontaminated by wiping or spraying the outer surface with sterile 70% IPA (or removing the outer wrap as the item is introduced into the aseptic work area) and brought into the buffer or clean area in a bin or on a movable cart.					
120.00	Compounding employees are using appropriate aseptic technique. *May require inspector to garb and enter clean 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, 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 and mark "Non-Compliant".*					
121.00	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.					

122.00	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.					
123.00	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.*					
124.00	The remaining contents of opened single-dose ampules are discarded immediately. *May not be stored for any time period.*					
125.00	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.					
126.00	The compounding record is complete. *View several completed compounds.*					
126.01		1. Official or assigned name, strength and dosage of the preparation				
126.02		2. Names, lot numbers and expiration dates of all components				
126.03		3. Total quantity or number of units compounded				
126.04		4. Person compounding the preparation				
126.05		5. Person performing the quality control procedures				
126.06		6. Person who approved the preparation				
126.07		7. Date of compounding				
126.08		8. Assigned internal identification number or prescription number				
126.09		9. Assigned BUD and reference if extended beyond USP guidelines				
126.10		10. Duplicate label				
126.11		11. Sterilization method (if applicable)				

126.12		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				
127.00	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.*					
128.00	Labels on BATCH preparations include:					
1280.10		Name of all contents				
128.02		Quantity of all contents				
128.03		Date of preparation (or internal code providing information)				
128.04		Time of preparation (or internal code providing information)				
128.05		Identification of person compounding				
128.06		Identification of pharmacist verifying				
128.07		Stability (BUD)				
128.08		Auxillary labels indicated (for appropriate packaging and labeling of hazardous materials)				
128.09		RECOMMENDED: Labels on batch single-use containers are clearly marked as "Single Use Only"				
129.00	Labels on PATIENT-SPECIFIC containers, in addition to standard label requirements, also include:					
129.01		Identification of person preparing				
129.02		Identification of person verifying				
129.03		Stability (BUD)				
129.04		Flow rate, if applicable				
129.05		Appropriate packaging and labeling of hazardous materials				

129.06		RECOMMENDED: Labels on patient-specific single-use containers are clearly marked as "Single Use Only"					
130.00	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 THE BOARD IMMEDIATELY.**						
131.00	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	**VA-25** **VA-33**					
132.00	Extended BUDs are assigned and are supported with stability documentation. *View records, preparation must exactly match the preparation cited in the documentation including concentration of all active ingredients, excipients, etc.*	**VA-25** **VA-33**					
133.00	Extended BUDs are assigned and the facility has 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.*	**VA-25** **VA-33**					
134.00	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.	**VA-130A**					
135.00	**Filter sterilization** in an ISO 5 environment and documentation includes: *View documentation on compounding records of items sterilized by filtration to confirm.*						
135.01	1. 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", for example).						

135.02	2. That filtering is completed rapidly without filter replacement				
135.03	3. Confirmation of filter integrity (bubble testing) is performed for each filter used with each batch sterilized by filtration.				
136.00	**Steam sterilization** documentation includes: 1. The autoclave has been validated for the exposure time and mass of the items to be sterilized 2. Ensures live steam contacts all ingredients and surfaces to be sterilized, effectiveness verified with biological indicators and temperature sensing devices 3. Solutions are passed through a 1.2 micron or smaller filter into the final containers to remove particulates before sterilization 4. Heated filtered air is evenly distributed throughout the chamber with a blower 5. That the CSP will not be adversely affected by the steam and heat 6. The description of steam sterilization includes conditions and duration for specific CSPs				
136.01	1. The autoclave has been validated for the exposure time and mass of the items to be sterilized				
136.02	2. Ensures live steam contacts all ingredients and surfaces to be sterilized, effectiveness verified with biological indicators and temperature sensing devices				
136.03	3. Solutions are passed through a 1.2 micron or smaller filter into the final containers to remove particulates before sterilization				
136.04	4. Heated filtered air is evenly distributed throughout the chamber with a blower				
136.05	5. That the CSP will not be adversely affected by the steam and heat				
136.06	6. The description of steam sterilization includes conditions and duration for specific CSPs				

137.00	**Dry heat sterilization** documentation includes: 1. Dry heat is only used for those items that cannot be sterilized by steam or would be damaged by moisture 2. Sufficient space is left between materials to allow for air circulation 3. The description of dry heat sterilization includes conditions and duration for specific CSPs 4. That the effectiveness of steam sterilization is verified each time using appropriate biological indicators 5. The oven is equipped with a system for controlling and recording temperature and exposure period				
137.01	1. Dry heat is only used for those items that cannot be sterilized by steam or would be damaged by moisture				
137.02	2. Sufficient space is left between materials to allow for air circulation				
137.03	3. The description of dry heat sterilization includes conditions and duration for specific CSPs				
137.04	4. That the effectiveness of steam sterilization is verified each time using appropriate biological indicators				
137.05	5. The oven is equipped with a system for controlling and recording temperature and exposure period				
138.00	**Depyrogenation by dry heat** documentation includes: 1. Dry heat depyrogenation is used to render glassware and containers (such as vials) free from pyrogens as well as viable microbes 2. The description of the cycle and duration for specific load items 3. The effectiveness of the cycle is verified using endotoxin challenge vials (ECVs) 4. Bacterial endotoxin testing is performed on the ECVs to verify the cycle is capable of achieving a three log reduction in endotoxins				
138.01	1. Dry heat depyrogenation is used to render glassware and containers (such as vials) free from pyrogens as well as viable microbes				
138.02	2. The description of the cycle and duration for specific load items				
138.03	3. The effectiveness of the cycle is verified using endotoxin challenge vials (ECVs)				
138.04	4. Bacterial endotoxin testing is performed on the ECVs to verify the cycle is capable of achieving a three log reduction in endotoxins				

139.00	Other methods of sterilization are used with documented procedures and validation performed. *Indicate method in Notes below.*				
Notes (refer to question number above)					

Finished Preparation Release Checks and Tests			**Total Non-Compliant (includes Unknowns)**	**Non-Compliant**		**Compliant**	
				N/A	**Unknown**		
140.00	Are products checked for particulates or other foreign matter against both a light and a dark colored background?						
141.00	Are there checks for container and closure integrity?						
142.00	Is compounding accuracy documented by verification of steps?						
143.00	Is verification of ingredient identity and quantity verified? *Is there a reconciliation of components?*						
144.00	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.*						
145.00	**Sterility testing (USP <71>).** *If testing is performed to a higher standard than the minimums below, describe in "Notes" below.*						
145.01		Sterility testing includes both bacterial and fungal testing.					
145.02		Sterility testing is performed for all CSPs that have extended BUDS.					
145.03		Sterility testing is performed for CSPs prepared in batches of more than 25 identical containers					

145.04		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					
145.05		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.					
145.06		For products failing testing, product is quarantined, and an investigation is performed including microbial identification and action taken.					
145.07		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.					
146.00	**Endotoxin testing (USP <85>).** *If testing is performed to a higher standard than the minimums below, describe in "Notes" below.*		**VA-25**				
146.01		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)	**VA-25**				
146.02		High-risk CSPs prepared in multiple dose vials for administration to multiple patients,	**VA-25**				
146.03		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	**VA-25**				
146.04		For products failing testing, product is quarantined, and an investigation is performed and action taken.	**VA-25**				

147.00	RECOMMENDED: **Potency testing is performed.** *Describe for which products or circumstances potency testing is performed in "Notes: below*				
148.00	View testing records. Products that have failed sterility, endotoxin, purity or potency testing have been quarantined and destroyed, or recalled if dispensed or distributed, and appropriate investigation performed to determine cause and correction or training performed to prevent future occurrence.				
Notes (refer to question number above)					

Patient Counseling and Communication		**Total Non-Compliant (includes Unknowns)**	**Non-Compliant**	**Compliant**	**Unknown**	**N/A**
149.00	Do patient/caregiver training programs or materials contain information and precautions regarding the handling and disposal of hazardous products such as chemotherapy medications?	VA-131				
150.00	Compounding pharmacies: Are the above required printed drug information materials (drug information, PPI, MedGuides, etc.) provided for the compounded products?	VA-131				
151.00	Compounding pharmacies: 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?	VA-131				
152.00	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.	VA-131				

VIRGINIA - Other Documentation		Total Non-Compliant (includes Unknowns)	Non-Compliant		Compliant	
			N/A	Unknown		
VS1.00	Documentation of daily monitoring and documentation of temperature in drug storage refrigerators in patient care settings are maintained at required temperature.	VA-131				
VS2.00	Documentation of monthly inspection of drug storage areas by pharmacy personnel to confirm compliance with appropriate storage conditions, separation of drugs and food, proper use of multiple-dose containers, avoidance of using single-use containers as multiple-dose containers, and security from unauthorized personnel.	VA-131				
VS3.00	Specific handling and exposure instructions are included on the exteriors of containers packed with CSP.	VA-131				
VS4.00	Labels and accessory labeling includes clearly readable beyond-use dates and storage instructions.	VA-131				
VS5.00	High-risk compounded sterile preparations intended for use are improperly stored.	Va-25B				
VS6.00	Sterile compounding with no clean room.	VA-21				
Notes (refer to question number above)						

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.

The Virginia Board of Pharmacy
Pharmacy Inspection

Pharmacy Name		Pharmacy license number		Date	

The Virginia Board of Pharmacy
Pharmacy Inspection

Pharmacy Name		Pharmacy license number		Date	

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Email: pharmbd@dhp.virginia.gov

INSPECTION SUMMARY

Facility Name:
Permit Number:
Address:
Inspection Date:
Enforcement Guidance Document 76.21.1: Rev Date:
Board of Pharmacy Guidance Document 110-9: Rev Date:

☐ Does not Compound ☐ Nonsterile Compounding
☐ Sterile Compounding Risk Level: ☐ High ☐ Medium ☐ Low
☐ No Deficiencies Identified

Inspection Summary & ☐ Inspection IPHCO (Check if applicable) provided to:
(insert name and license number of pharmacist)

DEFICIENCIES

No.	LAW/REGULATION	DEFICIENCY
1	Delete unused rows	Text will automatically wrap. If all text is not visible, you will need to adjust the row height.
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DEFICIENCIES

No.	LAW/REGULATION	DEFICIENCY
1		
2		

No monetary penalty for less than 5 deficiencies
$250 monetary penalty for 5 deficiencies
$100 Monetary penalty for each additional deficiency

Virginia Board of Pharmacy
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233
Office: 804-367-4456
Fax: 804-527-4472
Email: pharmbd@dhp.virginia.gov

INSPECTION SUMMARY

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COMMENTS

No.	LAW/REGULATION	DEFICIENCY
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