Virginia Department of Health Professions
Board of Pharmacy

Virginia Board of Pharmacy

Pharmacy Inspection Report

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Pharmacy Permit Number:		Inspection Type:	
Legal Business Name:		Inspection Results:	
Address:		Inspection Date:	
		Inspector Name:	
City:		Pharmacist-in-Charge:	
State:		Pharmacist-in-Charge License Number:	
Zip Code:		Pharmacist-in-Charge Email:	
Telephone number:		Pharmacist on Duty:	
Toll free number:		Pharmacist on Duty License Number:	
Fax number:		Inspection Emailed To (person):	
FEIN:		Inspection Emailed To (email address):	
Pharmacy Email:			
Does the pharmacy have a PMP waiver?		If yes, does pharmacy dispense a covered substance?	

§ 54.1-2519 "Covered substance" means all controlled substances included in Schedules II, III, and IV; controlled substances included in Schedule V for which a prescription is required; naloxone; and all drugs of concern that are required to be reported to the Prescription Monitoring Program, pursuant to this chapter. "Covered substance" also includes cannabis products dispensed by a pharmaceutical processor in Virginia.

Pharmacy Hours of Operation	Is pharmacy open 24/7		
	Open		Closed
	Start Time: (24-hour format hh:mm)	End Time: (24-hour format hh:mm)	
Sunday			
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			
Saturday			

Pharmacy Personnel			
Total Pharmacists:		Total Registered Pharmacy Technicians:	
Total Registered Pharmacy Interns:		Number of Pharmacy Technician Trainees:	
Ratio Tech:Pharmacist present at time of inspection:		Number of Compounding Technicians	

Business Licensure Information for State of Residence and Federal (board of pharmacy, state controlled substance, DEA, FDA, etc.)			
License/Registration Agency	Business Name on License/Registration	License/Registration Type/Number	Expiration Date

TYPES OF PRACTICE - TYPE "X" FOR ALL THAT APPLY							
Chain-Community		Investigational Drugs, Clinical Trials/Research		Central Fill/ Shared Services		Central or Remote Processing	
Independent-Community		Hospital/Institutional		Specialty Pharmacy		Outsourcing Facility	
FQHC-Health Dept/Free Clinic/ CSB		Long-Term Care		Pilot Program		Nonsterile Compounding	
Home Health/Infusion		Narcotic Treatment Program (NTP)		Nuclear Pharmacy		Nonsterile Hazardous Drug Compounding	
Mail Order (only) - closed door		Internet Pharmacy (New Rx)		Manufacturer		Sterile Compounding	
Mail/Deliver (out-of-state list below)		Internet Pharmacy (Refill Rx)		Wholesale Distributor		Sterile Hazardous Drug Compounding	
Veterinary Pharmacy		Telepharmacy		Free Standing ED		Pharmacists initiating treatment	

Number of PECs	Check if pharmacy has no PECs		
Nonsterile Compounding powder hoods number:		Nonsterile HD Compounding BSC/CACI hoods number:	
Sterile Compounding Number LAFW hoods/areas:		Sterile HD Compounding Number of BSC hoods:	
Sterile Compounding Number BSC hoods:		Sterile HD Compounding Number of CACI hoods:	
Sterile Compounding Number CAI/CACI hoods:			

States to which the pharmacy mails/delivers compounded sterile drug products:

Comments

Virginia Board of Pharmacy
Pharmacy Routine Inspection Form

General Pharmacy Inspection

Deficiency Number			
	General Pharmacy & Staffing	**Result**	**Notes**
4	Pharmacist, Pharmacy Technician, or Pharmacy Intern license or registration current active. **[18VAC110-21-60] [18VAC110-21-110] [18VAC110-21-141] [18VAC110-21-170]**		
1	The pharmacist-in-charge (PIC) is in full and actual charge and fully engaged in the practice of pharmacy at this location. [**§54.1-3434]**		
1	PIC or the pharmacist on duty shall control all aspects of the practice of pharmacy. [**18VAC110-20-110]**		
5	Acts restricted to a pharmacist are performed only by a pharmacist or a directly monitored pharmacy intern. [**§54.1-3320]**		
102	Pharmacy exceeds scope of special or limited-use pharmacy permit. [**18VAC110-20-120]**		
2, 14	An application for a permit designating the new PIC shall be filed with the required fee within 14 days of the original date of resignation or termination of the PIC on a form provided by the board. It shall be unlawful for a pharmacy to operate without a new permit past the 14-day deadline unless the board receives a request for an extension prior to the deadline. The executive director for the board may grant an extension for up to an additional 14 days for good cause shown. [**§54.1-3434] [18VAC110-20-110] [18VAC110-20-240]**		
6	Consistent with patient safety, a pharmacist shall exercise sole authority in determining the maximum number of pharmacy technicians that he shall supervise; however, no pharmacist shall supervise more than four pharmacy technicians at one time. [**§54.1-3320]**		
3	No person shall perform the duties of a pharmacy technician without first being registered as a pharmacy technician or pharmacy technician trainee with the Board. [**§54.1-3321]**		
	Drug Receipt & Storage	**Result**	**Notes**
12a	Dispersion of Schedule II drugs. Schedule II drugs shall either be dispersed with other schedules of drugs or shall be maintained within a securely locked cabinet, drawer, or safe or maintained in a manner that combines the two methods for storage. The cabinet, drawer, or safe may remain unlocked during hours that the prescription department is open and a pharmacist is on duty. **[18VAC110-20-200]**		
35	Except for an emergency purchase from another pharmacy, a pharmacist may only purchase Schedule II through VI drugs from a wholesale distributor or warehouser licensed or registered by the board. [**18VAC110-20-395]**		
109	Any drug which has exceeded the expiration date, or is otherwise adulterated or misbranded, shall not be dispensed or sold; it shall be separated from the stock used for dispensing. **[18VAC110-20-200] [§54.1-3457]**		

Deficiency Number			
109	A pharmacy may return a dispensed drug to stock for redispensing that has never left the pharmacy premises or the control of the pharmacy delivery agent pursuant to § 54.1-3411.1 A 3 of the Code of Virginia under the following conditions: **[18VAC110-20-355]**		
	1. An expiration date shall be placed on the label prior to returning the drug to stock. In the absence of stability data to the contrary, the date on the label may not exceed the expiration date on the manufacturer's container or one year from the date the drug was originally dispensed and placed in the prescription vial, whichever date is earlier.		
	2. The restocked drug shall be used to fill the next prescription received for that product. In the event that the drug is not dispensed prior to the new assigned expiration date, it shall be removed from working stock as expired, and disposed of in accordance with 18VAC110-20-210.		
	3. If there is no lot number on the label of a drug returned to stock or on the prescription records that can be cross-referenced from the prescription label, the drug shall be removed from stock upon any recall of that drug product and returned to the manufacturer or otherwise disposed of in accordance with 18VAC110-20-210.		
111	Prescriptions awaiting delivery. Prescriptions prepared for delivery to the patient may be placed in a secured area outside of the prescription department, not accessible to the public, where access to the prescriptions is restricted to individuals designated by the pharmacist. With the permission of the pharmacist, the prepared prescriptions may be transferred to the patient at a time when the pharmacist is not on duty 1**8VAC110-20-200**		
	1. If a prescription is delivered at a time when the pharmacist is not on duty, written procedures shall be established and followed by the pharmacy that detail security of the dispensed prescriptions and a method of compliance with counseling requirements of § 54.1-3319 of the Code of Virginia.		
	2. Additionally, a log shall be made and maintained of all prescriptions delivered to a patient when a pharmacist is not present to include the patient's name, prescription number, date of delivery, and signature of the person receiving the prescription.		
	3. Such log shall be maintained for a period of one year.		
110	Controlled paraphernalia and Schedule VI medical devices shall not be placed in an area completely removed from the prescription department whereby patrons will have free access to such items or where the pharmacist cannot exercise reasonable supervision and control. **[18VAC110-20-200]**		
	Enclosure & Access	**Result**	**Notes**
12	All drugs are stored in the prescription department approved by the Board. **[18VAC110-20-190]**		
7	Drugs shall not be stocked in a remodeled location or moved to a new location until approval is granted by the inspector or board staff. [**18VAC110-20-140]**		

Deficiency Number			
11	The enclosure shall be constructed in such a manner that it protects the prescription drugs from unauthorized entry and from pilferage at all times whether or not a pharmacist is on duty. **[18VAC110-20-190]**		
9	The enclosure shall be locked and alarmed at all times when a pharmacist is not on duty. **[18VAC110-20-190]**		
11	The enclosure shall be capable of being locked in a secure manner at any time the pharmacist on duty is not present in the prescription department. **[18VAC110-20-190]**		
10	The keys or other means of entry into a locked prescription department and the alarm access code shall be restricted to pharmacists practicing at the pharmacy and authorized by the PIC. **[18VAC110-20-180] [18VAC110-20-190]**		
108	For emergency access, may place a key or other means of unlocking the prescription department and the alarm access code in a sealed envelope or other container with pharmacist's signature across the seal in a safe or vault or other secured place. [**18VAC110-20-190]**		
	Physical Standards, Sanitary Conditions, Equipment & Resources	**Result**	**Notes**
104	A sink with hot and cold running water shall be within the prescription department. A pharmacy issued a limited-use permit that does not stock prescription drugs as part of its operation is exempt from this requirement.**[18VAC110-20-150]**		
106	The entire area of any place bearing the name of a pharmacy shall be maintained in a clean and sanitary manner and in good repair and order. Adequate trash disposal facilities and receptacles shall be available. **[18VAC110-20-160]**		
8, 105	Adequate refrigeration facilities equipped with a monitoring thermometer for the storage of drugs requiring cold storage temperature shall be maintained within the prescription department, if the pharmacy stocks such drugs. A refrigerator is a cold place in which temperature is maintained thermostatically between 2° and 8°C (36° and 46°F). A freezer is a cold place in which the temperature is controlled between -25° and -10°C (-13° and 14°F). In those instances in which articles may have a recommended storage condition below -20°C (-4°F), the temperature of the storage location should be controlled to plus or minus 10 degrees. **[18VAC110-20-150]** *Enter temps of refrigerators and/or freezers*		
105	A pharmacy stocking drugs requiring cold storage temperature shall record the temperature daily and adjust the thermostat as necessary to ensure an appropriate temperature range. The record shall be maintained manually or electronically for a period of two years.		
107	A current dispensing information reference source consistent with the scope of pharmacy practice at the location of the permitted pharmacy. **[18VAC110-20-170]**		

Deficiency Number			
	Security	**Result**	**Notes**
	18VAC110-20-180 (B) ***Exceptions to provisions in this section:*** ***1. Alarm systems approved prior to November 4, 1993, will be deemed to meet the requirements of subdivisions A 1, A 2, and A 3 of this section, provided that no structural changes are made in the prescription department, that no changes are made in the security system, that the prescription department is not closed while the rest of the business remains open, and that a breaking and loss of drugs does not occur. If a breaking with a loss of drugs occurs, the pharmacy shall upgrade the alarm to meet the current standards and shall file an application with the board in accordance with 18VAC110-20-140 A within 14 days of the breaking.*** ***2. If the prescription department was located in a business with extended hours prior to November 4, 1993, and had met the special security requirements by having a floor to ceiling enclosure, a separately activated alarm system shall not be required.*** ***3. This section shall not apply to pharmacies which that are open and staffed by pharmacists 24 hours a day. If the pharmacy changes its hours or if it must be closed for any reason, the PIC or owner must immediately notify the board, file an application in accordance with 18VAC110-20-140 A, and have installed prior to closing, a security system that meets the requirements of subdivisions A 1 through A 4 of this section.***		
9, 9a	A device for the detection of breaking shall be installed in each prescription department of each pharmacy. The installation and the device shall be based on accepted alarm industry standards, and shall be subject to the following conditions: **[18VAC110-20-180]**		
	1. Device shall be a sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device.		
	2. Device shall have at least one hard-wired communication method.		
	3. Monitored in accordance with accepted industry standards, maintained in operating order, have an auxiliary source of power.		
	4. Capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational.		
	5. Fully protect the prescription department and shall be capable of detecting breaking by any means when activated.		
9	The alarm system shall be activated whenever the prescription department is closed for business or a pharmacist is not on duty. **[18VAC110-20-180] 18VAC110-20-190]**		
10	Access to the alarm system for the prescription department area of the pharmacy shall be restricted to the pharmacists working at the pharmacy. **[18VAC110-20-180] [18VAC110-20-190]**		
9a	The alarm system shall include a feature by which any breach in the alarm shall be communicated by the monitoring entity to the PIC or a pharmacist working at the pharmacy. [**18VAC110-20-180]**		
	Counseling & Prospective Review	**Result**	**Notes**
121	A pharmacist shall conduct a prospective drug review before each new prescription is dispensed or delivered to a patient or a person acting on behalf of the patient. Such review shall include: **[§54.1-3319]**		
	1. Screening for potential drug therapy problems due to therapeutic duplication		
	2. Drug-disease contraindications		
	3. Drug-drug interactions, including serious interactions with nonprescription or over-the-counter drugs		
	4. Incorrect drug dosage or duration of drug treatment		
	5. Drug-allergy interactions		
	6. Clinical use or abuse		

Deficiency Number			
120	A pharmacist shall offer to counsel any person who presents a new prescription for filling. The offer to counsel may be made in any manner the pharmacist deems appropriate in his professional judgment. **[§54.1-3319]**		
	Special Packaging	**Result**	**Notes**
126	Each drug dispensed to a person in a household shall be dispensed in special packaging except when otherwise directed in a prescription by a practitioner, when otherwise requested by the purchaser, or when such drug is exempted. **[18VAC110-20-350]**		
	If nonspecial packaging is requested, a notation shall be made on the dispensing record or other retrievable record. **[18VAC110-20-350]**		
	Inventories		
	18VAC110-20-240: Inventories of drugs in Schedules I and II shall be performed by physically counting the drugs. Inventories of drugs in Schedules III, IV, and V may be performed by estimating the count of drugs in Schedules III, IV, and V unless the container contains greater than 1,000 tablets or capsules or there has been a theft or any other unusual loss of drug and the exact kind and quantity of the drug loss is unknown.		
`	***18VAC110-20-140 (C): Although a closing inventory is not required, a complete and accurate inventory shall be taken of all Schedules II through V controlled substances on hand in accordance with § 54.1-3404 of the Code of Virginia on the date the pharmacist first engages in business under the new ownership. Inventories associated with any change in PIC shall also be performed in accordance with 18VAC110-20-110.***		
	Biennial Inventory	**Result**	**Notes**
13, 112	Biennial inventory taken at least every two years of all stocks on hand of Schedules I through V drugs. The biennial inventory shall be taken on any date which is within two years of the previous biennial inventory. **[§54.1-3404]** *Enter date of last inventory*		
13	No biennial inventory or inventory taken over 30 days late or substantially incomplete.		
112	Inventory available but taken late within 30 days of date due		
113	Inventories and records of all drugs listed in Schedules I and II shall be maintained separately from all other records of the pharmacy. **[18VAC110-20-240]**		
	Biennial inventory shall include the following information:		
	1. Drugs listed in Schedules I and II shall be maintained separately from all other records **[18VAC110-20-240]**		
	2. Indicate whether the inventory was taken prior to the opening of business or after close of business **[§54.1-3404]**		
	3. A 24-hour pharmacy with no opening or closing of business shall clearly document whether the receipt or distribution of drugs on the inventory date occurred before or after the inventory was taken. **[18VAC110-20-240]**		
	4. Signed and dated by the person taking the inventory [**18VAC110-20-240]**		
	Maintained completely and accurately for two years from the date of the transaction recorded **[§54.1-3404]**		
	Change of Pharmacist-in-Charge	**Result**	**Notes**
14	PIC CHANGE: The succeeding pharmacist-in-charge shall cause an inventory to be made of all Schedule I, II, III, IV and V drugs on hand. Inventory shall be completed as of the date he becomes pharmacist-in-charge and prior to opening for business on that date. **[§54.1-3434]** *Enter date of last inventory*		

Deficiency Number			
113	Inventories and records of all drugs listed in Schedules I and II shall be maintained separately from all other records of the pharmacy. **[18VAC110-20-240]**		
	Inventory shall include the following information:		
	1. Drugs listed in Schedules I and II shall be maintained separately from all other records **[18VAC110-20-240]**		
	2. Maintained completely and accurately for two years from the date of the transaction recorded **[18VAC110-20-240]**		
	3. A 24-hour pharmacy with no opening or closing of business shall clearly document whether the receipt or distribution of drugs on the inventory date occurred before or after the inventory was taken. **[18VAC110-20-240]**		
14	All records required by this section shall be filed chronologically and maintained for a period of not less than two years from the date of transaction. **[18VAC110-20-240]**		
	Prescription Order & Dispensing Standards	**Result**	**Notes**
	18VAC110-20-270: In addition to the requirements in § 54.1-3408.01 of the Code of Virginia for an oral prescription or written prescription, including those transmitted via facsimile or electronically, a prescription shall include a quantity or duration of the order by which the pharmacist can calculate the authorized quantity using directions for use. Except for prescriptions transmitted electronically in compliance with 18VAC110-20-285, written prescriptions shall also include the prescriber's manual signature. In cases of failed electronic prescriptions, Schedule VI prescriptions transmitted electronically may be routed to the pharmacy's facsimile machine and may bear an electronic signature.		
19	After the prescription has been prepared and prior to the delivery of the order, a pharmacist shall inspect the prescription product to verify its accuracy in all respects and place his initials on the record of dispensing as a certification of the accuracy of and the responsibility for the entire transaction. **[18VAC110-20-270]**		
	If more than one pharmacist is involved in verifying the accuracy of the prescription product, a record shall be maintained identifying the date of dispensing, each pharmacist involved in the process, and the individual task for which each pharmacist is responsible for verifying the accuracy. **[18VAC110-20-270]**		
19	Such record showing verification of accuracy shall be maintained on a pharmacy record and, if necessary, an alternate record consistent with 18VAC110-20-255 for the required time period of two years unless otherwise specified in regulation. If the dispensing involves central or remote processing, records of pharmacist verification shall be maintained in a manner consistent with 18VAC110-20-276 and 18VAC110-20-515. **[18VAC110-20-270]**		
	Perpetual Inventory	**Result**	**Notes**
15	Each pharmacy shall maintain a perpetual inventory of all Schedule II drugs received and dispensed that accurately indicates the physical count of each Schedule II drug "on-hand" at the time of performing the inventory. The perpetual inventory shall include a reconciliation of each Schedule II drug at least monthly with a written explanation for any difference between the physical count and the theoretical count. Electronic monitoring at the pharmacy or by another entity that provides alerts for discrepancies between drugs received and drugs dispensed is acceptable provided such alerts are reviewed at least monthly. **[18VAC110-20-240]**		
	All records required by this section shall be filed chronologically and maintained for a period of not less than two years from the date of transaction. **[18VAC110-20-240]**		

Deficiency Number			
	Drug Loss or Theft	**Result**	**Notes**
16	Whenever any registrant or licensee discovers a theft or any other unusual loss of any Schedule II, III, IV or V controlled substance, he shall immediately report such theft or loss to the Board. **[§54.1-3404]**		
16	Within 30 days after the discovery of a loss of any Schedule II, III, IV or V drugs, the registrant or licensee shall furnish the Board with a listing of the kind, quantity and strength of such drugs lost. **[§54.1-3404]**		
148	All records required pursuant to this section shall be maintained completely and accurately for two years from the date of the transaction recorded. **[§54.1-3404]**		
	Prescriptions	**Result**	**Notes**
17	A hard copy prescription shall be placed on file for every initial prescription dispensed and be maintained for two years from the date of last refill. NOTE: See 18VAC110-20-250 Electronic Image **[18VAC110-20-240]**		
17	All prescriptions shall be filed chronologically by date of initial dispensing or by date of initial entry into the automated data processing system in compliance with 18VAC110-20-250 if such a system is employed by the pharmacy. **[18VAC110-20-240]**		
17	Prescriptions for Schedule II drugs shall be maintained in a separate prescription file. **[18VAC110-20-240]**		
17	Prescriptions for Schedules III, IV, and V drugs shall be maintained either in a separate prescription file for drugs listed in Schedules III, IV, and V only or in such form that they are readily retrievable from the other prescriptions of the pharmacy. **[18VAC110-20-240]**		
17	**NOTE: . A chart order may serve as the hard-copy prescription for those patients in a hospital or long-term care facility, a patient receiving home infusion services, or a hospice patient pursuant to §54.1-3408.01 A of the Code of Virginia. When a chart order is intended for out-patient dispensing, it shall comply with requirements for a prescription in 18VAC110-20-286. [18VAC110-20-240]**		
	A chart order written for a patient in a hospital or long-term care facility, a patient receiving home infusion services, or a hospice patient pursuant to §54.1-3408.01 A of the Code of Virginia shall be exempt from having to contain all required information of a written prescription provided:		
	a. This information is contained in other readily retrievable records of the pharmacy; and		
	b. The pharmacy maintains and complies with a current policy and procedure manual that sets out where this information is maintained and how to retrieve it and the minimum requirements for chart orders consistent with state and federal law and accepted standard of care.		
	Requirements for filing of chart orders.		
	a. Chart orders shall be filed chronologically by date of initial dispensing with the following exception: If dispensing data can be produced showing a complete audit trail for any requested drug for a specified time period and each chart order is readily retrievable upon request, chart orders may be filed using another method. Such alternate method shall be clearly documented in a current policy and procedure manual.		
	b. If a single chart order contains both an order for a Schedule II drug and one or more orders for a drug in another schedule, where the Schedule II drug is not floor stocked, but is dispensed from the pharmacy pursuant to this order for the specific patient, the original order must be filed with records of dispensing of Schedule II drugs and a copy of the order placed in the file for other schedules.		

Deficiency Number			
	Automated Data Processing System	**Result**	**Notes**
18	An automated data processing system may be used for the storage and retrieval of original and refill dispensing information for prescriptions instead of manual record keeping requirements, subject to the following conditions: **[18VAC110-20-250]**		
	A prescription shall be placed on file as set forth in 18VAC110-20-240 B with the following provisions:		
	a. In lieu of a hard copy file for Schedule VI prescriptions, an electronic image of a prescription may be maintained in an electronic database provided it preserves and provides an exact image of the prescription that is clearly legible and made available within 48 hours of a request by a person authorized by law to have access to prescription information. Storing electronic images of prescriptions for Schedule II through V controlled substances instead of the hard copy shall only be authorized if such storage is allowed by federal law.		
	b. If the pharmacy system's automated data processing system fields are automatically populated by an electronic prescription, the automated record shall constitute the prescription and a hard copy or electronic image is not required.		
	c. For Schedule II through V controlled substances, electronic prescriptions shall be maintained in accordance with federal law and regulation.		
	Any computerized system shall provide retrieval (via computer monitor display or printout) of original prescription information for those prescriptions which are currently authorized for dispensing.		
	Any computerized system shall also provide retrieval via computer monitor display or printout of the dispensing history for prescriptions dispensed during the past two years.		
	Printout of dispensing data requirements. Any computerized system shall have the capability of producing a printout of any dispensing data which the user pharmacy is responsible for maintaining under the Drug Control Act § 54.1-3400 et seq. of the Code of Virginia) and any data entry of on-hold prescriptions. Such printout shall be provided within 48 hours of a request of an authorized agent.		
	Records of Receipt & Invoices	**Result**	**Notes**
114	Inventories and records of all drugs listed in Schedules I and II shall be maintained separately from all other records of the pharmacy. **[18VAC110-20-240]**		
	Inventories and records of drugs listed in Schedules III, IV, and V may be maintained separately or with records of Schedule VI drugs but shall not be maintained with other records of the pharmacy.		
	All executed order forms, prescriptions, and inventories of Schedules II through V drugs shall be maintained at the same address as the stock of drugs to which the records pertain. If authorized by DEA, other records pertaining to Schedules II through V drugs, such as invoices, may be maintained in an off-site database or in secured storage. All records in off-site storage shall be retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.		

Deficiency Number			
114	Invoices or other records showing receipts of Schedule VI drugs shall be maintained but may be stored in an electronic database or record as an electronic image that provides an exact, clearly legible image of the document or in secured storage either on site or off site. All records in off-site storage or database shall be retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.		
	All records shall be filed chronologically and maintained for a period of not less than two years from the date of transaction.		
	Records - Partial Dispensing	**Result**	**Notes**
119	The pharmacist dispensing any prescription shall record the date of dispensing and his initials on the prescription in (i) an automated data processing system used for the storage and retrieval of dispensing information for prescriptions or (ii) on another record that is accurate from which dispensing information is retrievable and in which the original prescription and any information maintained in such data processing system concerning such prescription can be found. **[§54.1-3412]**		
119	The partial filling of a prescription for a drug listed in Schedule II is permissible if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription, and he makes a notation of the quantity supplied on the face of the written prescription. The remaining portion of the prescription may be dispensed within 72 hours of the first partial dispensing; however, if the remaining portion is not or cannot be dispensed within the 72-hour period, the pharmacist shall so notify the prescribing practitioner. No further quantity may be supplied beyond 72 hours without a new prescription. **[18VAC110-20-310]**		
119	Prescriptions for Schedule II drugs written for patients in long-term care facilities may be dispensed in partial quantities, to include individual dosage units. For each partial dispensing, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained and readily retrievable) the date of the partial dispensing, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. The total quantity of Schedule II drugs in all partial dispensing shall not exceed the total quantity prescribed. Schedule II prescriptions shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of the drug. **[18VAC110-20-310]**		
119	Information pertaining to current Schedule II prescriptions for patients in a long-term care facility may be maintained in a computerized system if this system has the capability to permit: **[18VCA110-20-310]**		
	1. Output (display or printout) of the original prescription number, date of issue, identification of prescribing practitioner, identification of patient, identification of the long-term care facility, identification of drug authorized (to include dosage form, strength, and quantity), listing of partial dispensing under each prescription, and the information required in subsection B of this section.		
	2. Immediate (real time) updating of the prescription record each time a partial dispensing of the prescription is conducted.		

Deficiency Number			
119	A prescription for a Schedule II drug may be filled in partial quantities to include individual dosage units for a patient with a medical diagnosis documenting a terminal illness under the following conditions: **[18VAC110-20-310]**		
	1. The practitioner shall classify the patient as terminally ill, and the pharmacist shall verify and record such notation on the prescription.		
	2. On each partial filling, the pharmacist shall record the date, quantity dispensed, remaining quantity authorized to be dispensed, and the identity of the dispensing pharmacist.		
	3. Prior to the subsequent partial filling, the pharmacist shall determine that it is necessary. The total quantity of Schedule II drugs dispensed in all partial fillings shall not exceed the total quantity prescribed.		
	4. Schedule II prescriptions for terminally ill patients may be partially filled for a period not to exceed 60 days from the issue date unless terminated sooner.		
	5. Information pertaining to partial filling may be maintained in a computerized system under the conditions set forth in 18VAC110-20-320 subsection C.		
	A prescription for a Schedule II drug may be filled in partial quantities if the partial fill is requested by the patient or by the practitioner who wrote the prescription provided:		
	1. The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed;		
	2. The prescription is written and filled in accordance with state and federal law; and		
	3. The remaining portions are filled not later than 30 days after the date on which the prescription is written.		
119	A prescription for a drug listed in Schedule III, IV, or V shall not be dispensed or refilled more than six months after the date on which such prescription was issued, and no such prescription authorized to be filled may be refilled more than five times. **[18VAC110-20-320]**		
	1. Each refilling of a prescription shall be entered on the back of the prescription or on another record in accordance with §54.1-3414 of the code of Virginia, and 18VAC110-20-255, initialed, and dated by the pharmacist as of the date of dispensing. If the pharmacist merely initials and dates the prescription, it shall be presumed that the entire quantity ordered was dispensed.		
	2. The partial dispensing of a prescription for a drug listed in Schedule III, IV, or V is permissible, provided that:		
	a. Each partial dispensing is recorded in the same manner as a refilling;		
	b. The total quantity of drug dispensed in all partial dispensing does not exceed the total quantity prescribed; and		
	c. No dispensing occurs after six months after the date on which the prescription order was issued.		
119	Any other record used to record the date of dispensing or the identity of the pharmacist dispensing shall be maintained for a period of two years on premises. **[18VAC11-20-255]**		

Deficiency Number			
119	A pharmacy using such an alternative record shall maintain a current policy and procedure manual documenting **[18VAC110-20-255]**		
119	1. Procedures for using the record		
	2. How the record is integrated into the total dispensing record system		
	3. How the data included in the record shall be interpreted		
	Prescription Labeling	**Result**	**Notes**
124	Whenever a pharmacist dispenses any drug listed within Schedule II through VI on a prescription issued by a prescriber, he shall affix to the container in which such drug is dispensed, a label showing **[§54.1-3410]**		
	1. Prescription serial number or name of the drug		
	2. Date of initial filling		
	3. His name and address, or the name and address of the pharmacy		
	4. Name of the patient or, if the patient is an animal, the name of the owner of the animal and the species of the animal		
	5. Name of the prescriber by whom the prescription was written, except for those drugs dispensed to a patient in a hospital pursuant to a char order		
	6. Directions as may be stated on the prescription		
	7. Drug name and strength, when strength is applicable		
	8. Number of dosage units or, if liquid, the number of milliliters dispensed		
	For any drug product possessing a single active ingredient, the generic name of the drug shall be included on the label. **[18VAC110-20-330]**		
124	**NOTE: Does not apply to drugs dispensed to patients of a hospital or long term care facility where all drugs are administered by persons licensed to administer.**		
	If a generic drug is dispensed when a prescription is written for a brand name drug, the label shall contain the generic name followed by the words "generic for" followed by the brand name of the drug prescribed, and the label shall also contain the generic's brand name or the manufacturer or distributor of the drug dispensed. **[18VAC110-20-330]**		
124	**NOTE: Does not apply to drugs dispensed to patients of a hospital or long term care facility where all drugs are administered by persons licensed to administer.**		
	Prescription Order	**Result**	**Notes**
116	A drug listed in Schedule II shall be dispensed only upon receipt of a written prescription. NOTE: See 18VAC110-20-285 for faxing of prescription orders for Schedule II drugs. **[§54.1-3410]**		
116	A drug controlled by Schedules III through VI or a device controlled by Schedule VI shall be dispensed upon receipt of a written or oral prescription. **[§54.1-3410]**		
116	The agent of the prescriber on his behalf may orally transmit a prescription. The written record of the prescription specifies the full name of the agent of the prescriber. [**§54.1-3410]**		

Deficiency Number			
116	A written prescription shall be written with ink or individually typed or printed and shall contain: **[§54.1-3408.01]**		
	1. Name, address, and telephone number of the prescriber. 2. First and last name of the patient for whom the drug is prescribed. 3. Address of the patient shall either be placed upon the written prescription by the prescriber or his agent, or by the dispenser of the prescription. NOTE: If not otherwise prohibited by law, the dispenser may record the address of the patient in an electronic prescription dispensing record for that patient in lieu of recording it on the prescription. 4. Dated and signed by the prescriber on, the day when issued 5. A prescription for a controlled substance other than one controlled in Schedule VI shall also contain the federal controlled substances registration number assigned to the prescriber		
	Electronic Transmitted Prescription	**Result**	**Notes**
	Effective July 1, 2020 - Consistent with federal law and in accordance with regulations promulgated by the Board, prescriptions may be transmitted to a pharmacy as an electronic prescription or by facsimile machine and shall be treated as valid original prescriptions. Any prescription for a controlled substance that contains an opiate shall be issued as an electronic prescription. §54.1-3408.02		
116	Unless otherwise prohibited by law, an electronic prescription may be transmitted from the prescriber or an authorized agent as defined in § 54.1-3408.01 C of the Code of Virginia directly to the dispensing pharmacy. Electronic prescriptions of Schedule II-V controlled substances shall comply with any security or other requirements of federal law. All electronic prescriptions shall also comply with all security requirements of state law related to privacy of protected health information. **[18VAC110-20-285]**		
	A pharmacy receiving an electronic prescription shall maintain such prescription record in accordance with 18VAC110-20-250 A.		
	Faxed Prescription	**Result**	**Notes**
116	Unless otherwise prohibited by federal law, prescription orders for Schedules III through VI drugs may be transmitted to pharmacies by facsimile (fax) device upon the following conditions: **[18VAC110-20-280]**		
	1. The prescription shall be faxed only to the pharmacy of the patient's choice		
	2. A valid faxed prescription shall contain all required information for a prescription. A written prescription shall include the prescriber's signature.		
	3. An authorized agent may transmit an oral prescription by facsimile and shall record on the faxed prescription the agent's full name and wording that clearly indicates that the prescription being transmitted is an oral prescription		

Deficiency Number			
116	A faxed prescription shall be valid only if faxed from the prescriber's practice location, except in the following situations: **[18VAC110-20-280]**		
	1. Forwarding a faxed chart order from a long-term care facility or from a hospice, including a home hospice		
	2. Faxing an oral prescription by authorized agent under the conditions set forth in subdivision 3 of this subsection; or		
	3. Forwarding a written prescription by an authorized agent from a long-term care facility, provided		
	a. The provider pharmacy maintains written procedures for such transactions		
	b. The original prescription is obtained by the provider pharmacy within seven days of dispensing		
	c. The original prescription shall be attached to the faxed copy		
116	The following additional information shall be recorded on the faxed prescription: **[18VAC110-20-280]**		
	1. Date that the prescription was faxed		
	2. Printed name, address, phone number, and fax number of the authorized prescriber		
	3. The institution, if applicable, from which the prescription was faxed, including address, phone number and fax number		
116	Prescription orders for Schedule II drugs may only be faxed for information purposes and may not serve as the original written prescription authorizing dispensing, except for: **[18VAC110-20-280]**		
	1. Orders to be administered to long-term care facility and home infusion patients		
	2. Prescriptions written for a Schedule II narcotic substance for patients residing in a hospice certified by Medicare under Title XVIII or licensed by the state which may include home hospice		
	3. The prescriber shall note on the prescription if the patient is a hospice patient, and the prescription shall meet all requirements for a written prescription, including the prescriber's manual signature		
116	If the faxed prescription is of such quality that the print will fade and not remain legible for the required retention period the receiving pharmacist shall copy or transcribe the faxed prescription on paper of permanent quality. **[18VAC110-20-280]**		
116	Authorizations for refills may be faxed by the prescriber to the pharmacy provided the authorization includes: **[18VAC110-20-280]**		
	1. Patient's name & address		
	2. Drug name and strength, quantity		
	3. Directions for use,		
	4. Prescriber's name, prescriber's manual signature or agent's name		
	5. Date of authorization		

Deficiency Number			
	Emergency Prescription	**Result**	**Notes**
118	In case of an emergency situation, a pharmacist may dispense a drug listed in Schedule II upon receiving oral authorization of a prescribing practitioner, provided that: **[§54.1-3410] [18VAC110-20-290]**		
	1. The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period.		
	2. The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required in §54.1-3410 of the Drug Control Act, except for the signature of the prescribing practitioner.		
	3. If the pharmacist does not know the practitioner, he the pharmacist shall make a reasonable effort to determine that the oral authorization came from a practitioner using his the practitioner's phone number as listed in the telephone directory or other good-faith efforts to ensure his the practitioner's identity		
	4. Within seven days after authorizing an emergency oral prescription, the prescribing practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist.		
	5. The prescription shall have written on its face "Authorization for Emergency Dispensing" and the date of the oral order.		
118	6. The dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced to writing.		
	7. The pharmacist shall notify the nearest office of the Drug Enforcement Administration and the board if the prescribing practitioner fails to deliver a written prescription to the pharmacist.		
	Repackaging	**Result**	**Notes**
127	Control records of reconstitution of injectable, bulk compounding or the repackaging or prepackaging of drugs maintained for a period of one year or until the expiration, whichever is greater. **[18VAC110-20-355]**		
127	Control record includes the following information: **[18VAC110-20-355]**		
	1. Date repackaged		
	2. Name of the drug(s) used & strength of drug, if any		
	3. Quantity prepared		
	4. Assigned lot or control number		
	5. Manufacturer's or distributor's name and lot or control number		
	6. Expiration date		
20	7. Initials of the pharmacist verifying the process **[18VAC110-20-355]**		
127	The following information shall appear on any subsequently repackaged or reconstituted units: **[18VAC110-20-355]**		
	1. Drug name & strength of drug, if any		
	2. Assigned lot or control number or the manufacturer's or distributor's name and lot or control number		
	3. Appropriate expiration determined by the pharmacist in accordance with USP guidelines		
	Repackaging of drugs shall be performed in compliance with USP-NF standards.		

Deficiency Number			
127	Pharmacies using automated counting devices or dispensers in which drugs are removed from manufacturer's original packaging and placed in bulk bins shall comply with the following requirements:		
	A bin filling record shall be maintained, manually or in a computerized record for a period of one year from the date of filling from which information can be readily retrieved, for each bin including: **[18VAC110-20-355]**		
	1. Drug name and strength, if any		
	2. Name of the manufacturer or distributor		
	3. Manufacturer's control or lot numbers and expiration date for all lots placed into the bin at the time of filling		
	4. Any assigned lot number		
	5. An expiration date determined according to USP guidelines for repackaging		
	6. Date of filling		
20	7. Pharmacist's initials verifying the accuracy of the process **[18VAC110-20-355]**		
127	If more than one lot is added to a bin at the same time, the lot that expires first shall be used to determine the expiration date if shorter than a calculated date based on USP guidelines. **[18VAC110-20-355]**		
	Each bin shall be labeled in such a manner as to cross-reference the information on the filling record with the correct expiration date.		
	If only one lot is added to a bin at one time, but a subsequent lot may be added before the first has cleared, the automated device shall be constructed to reasonably dispense the first lot before the second lot is dispensed and the expiration date on the bin's label shall reflect the expiration date assigned to the earlier lot.		
	In the event of a drug recall involving one of multiple lots placed in a bin of an automated counting device in the last three months or if a recalled drug is known to remain in the bin, all drugs shall be removed from the bin and not used for patient care. The removal of drugs from the bin is not required if:		
	a. The technology of the automated counting device can ensure drugs in a particular lot have been cleared; or		
	b. The bin has been "run dry," with a record made of the "run dry" date, since the addition of the recalled lot number in which all drugs were completely removed prior to filling with a subsequent lot number.		
	An automated counting device shall be cleaned and maintained in accordance with recommended manufacturer guidelines and specifications.		

Deficiency Number			
	Continuous Quality Improvement	**Result**	**Notes**
	§ 54.1-3434.03. Continuous quality improvement program - Each pharmacy shall implement a program for continuous quality improvement, according to regulations of the Board. Such program shall provide for a systematic, ongoing process of analysis of dispensing errors that uses findings to formulate an appropriate response and to develop or improve pharmacy systems and workflow processes designed to prevent or reduce future errors. Any pharmacy that actively reports to a patient safety organization that has as its primary mission continuous quality improvement under the Patient Safety and Quality Improvement Act of 2005 (P.L. 109-41), shall be deemed in compliance with this section.		
142	Pharmacy Actively Reports to Patient Safety Organization **[18VAC110-20-418]**		
	A record indicating the date a report was submitted to a patient safety organization shall be maintained for 12 months from the date of reporting.		
	Pharmacies not actively reporting to patient safety organizations, consistent with §54.1-3434.03 and 18VAC110-20-10, shall implement a program for continuous quality improvement.		
142	Pharmacy does not actively report to a patient safety organization **[18VAC110-20-418]**		
	A separate record shall be maintained and available for inspection to ensure compliance with this section for 12 months from the date of the analysis of dispensing errors and shall include 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.		

Virginia Board of Pharmacy
Pharmacy Routine Inspection Form

Hazardous Drug Compounding Inspection for USP <800>

Deficiency Number	General Requirements	Result	Notes
	Pharmacy has identified if it stocks any hazardous drugs (HDs) on the NIOSH list.		
	Assessment of risk has been performed.		
	Pharmacy has identified a 'designated person' who is responsible for continuing to evaluate the fundamental practices and precautions for handling HDs.		
	If the pharmacy performs non-sterile HD compounding, the engineering controls comply with USP Chapter <800>.		
24, 133	1. Containment Primary Engineering Control (C-PEC)		
	a. Externally vented (preferred) or redundant–HEPA filtered in series Examples: CVE, Class I or II BSC, CACI		
	2. Containment Secondary Engineering Control (C-SEC)		
	a. Externally vented		
	b. 12 air changes per hour (ACPH)		
	c. Negative pressure between 0.01 and 0.03 inches of water column relative to adjacent areas		
	d. Fixed walls		
	If the pharmacy performs sterile HD compounding, the engineering controls comply with USP Chapter <800>.		
	ISO Class 7 buffer room with an ISO Class 7 ante-room		
22, 24	1. Containment Primary Engineering Control (C-PEC)		
	a. Externally vented. • Examples: Class II BSC or CACI		
23, 24	2. Containment Secondary Engineering Control (C-SEC)		
	a. Externally vented		
	b. 30 Air Changes Per Hour (ACPH)		
	c. Negative pressure between 0.01 and 0.03 inches of water column relative to adjacent areas.		
33, 33a	3. Maximum BUD as described in USP<797>		
	Unclassified C-SCA		
22, 24	1. Containment Primary Engineering Control (C-PEC)		
	a. Externally vented. • Examples: Class II BSC or CACI		
23, 24	2. Containment Secondary Engineering Control (C-SEC)		
	a. Externally vented		
	b. 12 Air Changes Per Hour (ACPH)		
	c. Negative pressure between 0.01 and 0.03 inches of water column relative to adjacent areas.		
33, 33a	3. Maximum BUD as described in USP<797> for CSPs prepared in a segregated compounding area.		

Virginia Board of Pharmacy

Pharmacy Routine Inspection Form

Nonsterile Compounding Inspection for USP <795>

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

Deficiency Number	General Operations and Information	Result	Notes
	The pharmacy has standard operating procedures (SOPs) on all aspects of the compounding operation that cover the minimum topic requirements in USP <795> standards.		
	The pharmacy has a designated person(s) who meets the requirements in USP <795> standards. ***Inspector note: Per USP, "The compounding facility must designate one or more individuals to be responsible and accountable for the performance and operation of the facility and personnel in the preparation of CNSPs."***		
	The pharmacy created and implemented a training program that is in compliance with USP <795> standards. ***Inspector note: Per USP, "Training and competency of personnel must be documented."***		
133	The compounding area meets the facility requirements in compliance with USP <795> standards.		
133	The pharmacy's storage area (for CNSPs, components, equipment, and containers) meets the requirements in compliance with USP <795> standards.		
29	In accordance with the conditions set forth in §54.1-3410.2 subsections A and B, pharmacists shall not distribute compounded drug products for subsequent distribution or sale to other persons or to commercial entities, including distribution to pharmacies or other entities under common ownership or control with the facility in which such compounding takes place; however, a pharmacist may distribute to a veterinarian in accordance with federal law. **[§54.1-3410.2]**		
29	Compounded products for companion animals, as defined in regulations promulgated by the Board of Veterinary Medicine, and distributed by a pharmacy to a veterinarian for further distribution or sale to his own patients shall be limited to drugs necessary to treat an emergent condition when timely access to a compounding pharmacy is not available as determined by the prescribing veterinarian. **[§54.1-3410.2]**		
29	A pharmacist may provide a reasonable amount of compounded products to practitioners of medicine, osteopathy, podiatry, or dentistry to administer to their patients, either personally or under their direct and immediate supervision, if there is a critical need to treat an emergency condition, or as allowed by federal law or regulations. A pharmacist may also provide compounded products to practitioners of veterinary medicine for office-based administration to their patients. **[§54.1-3410.2]**		

Deficiency Number			
27	Pharmacists may use bulk drug substances in compounding when such bulk drug substances: **[§54.1-3410.2]**		
	1. Comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if such monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding; or are drug substances that are components of drugs approved by the FDA for use in the United States; or are otherwise approved by the FDA; or are manufactured by an establishment that is registered by the FDA		
	2. Are distributed by a licensed wholesale distributor or registered nonresident wholesale distributor, or are distributed by a supplier otherwise approved by the Board and the FDA to distribute bulk drug substances if the pharmacist can establish purity and safety by reasonable means, such as lot analysis, manufacturer reputation, or reliability of the source.		
27	Pharmacists shall not engage in the following: **[§54.1-3410.2]**		
	1. The compounding for human use of a drug product that has been withdrawn or removed from the market by the FDA because such drug product or a component of such drug product has been found to be unsafe. However, this prohibition shall be limited to the scope of the FDA withdrawal		
28	2. The regular compounding or the compounding of inordinate amounts of any drug products that are essentially copies of commercially available drug products. However, this prohibition shall not include (i) the compounding of any commercially available product when there is a change in the product ordered by the prescriber for an individual patient, (ii) the compounding of a commercially manufactured drug only during times when the product is not available from the manufacturer or supplier, (iii) the compounding of a commercially manufactured drug whose manufacturer has notified the FDA that the drug is unavailable due to a current drug shortage, (iv) the compounding of a commercially manufactured drug when the prescriber has indicated in the oral or written prescription for an individual patient that there is an emergent need for a drug that is not readily available within the time medically necessary, or (v) the mixing of two or more commercially available products regardless of whether the end product is a commercially available product		
130a	Pharmacists who provide compounded products for office-based administration for treatment of an emergency condition or as allowed by federal law or regulations shall label all compounded products distributed to practitioners other than veterinarians for administration to their patients with: **[§54.1-3410.2]**		
	1. the statement "For Administering in Prescriber Practice Location Only"		
	2. the name and strength of the compounded medication or list of the active ingredients and strengths		
	3. the facility's control number		
	4. an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding		
	5. the name and address of the pharmacy		
	6. the quantity		

Deficiency Number			
130a	Pharmacists shall label all compounded products for companion animals, as defined in regulations promulgated by the Board of Veterinary Medicine, and distributed to a veterinarian for either further distribution or sale to his own patient or administration to his own patient with: **[54.1-3410.2]**		
	1. the statement "For Administering in Prescriber Practice Location Only"		
	2. the name and strength of the compounded medication or list of the active ingredients and strengths		
	3. the facility's control number		
	4. an appropriate beyond-use date as determined by the pharmacist in compliance with		
	5. the name and address of the pharmacy		
	6. the quantity		
20a	Pharmacists shall personally perform or personally supervise the compounding process, which shall include a final check for accuracy and conformity to the formula of the product being prepared, correct ingredients and calculations, accurate and precise measurements, appropriate conditions and procedures, and appearance of the final product. **[54.1-3410.2]**		
130	Pharmacists shall maintain records of all compounded drug products as part of the prescription, formula record, formula book, or other log or record. Records may be maintained electronically, manually, in a combination of both, or by any other readily retrievable method. **[54.1-3410.2]**		
130	In addition to other requirements for prescription records, records for products compounded pursuant to a prescription order for a single patient where only manufacturers' finished products are used as components shall include the: **[§54.1-3410.2]**		
	1. name and quantity of all components		
	2. the date of compounding and dispensing		
	3. the prescription number or other identifier of the prescription order		
	4. total quantity of finished product		
	5. signature or initials of the pharmacist or pharmacy technician performing the compounding		
	6. signature or initials of the pharmacist responsible for supervising the pharmacy technician and verifying the accuracy and integrity of compounded products.		
130	In addition to the requirements of §54.1-3410.2 subdivision I 1, records for products compounded in bulk or batch in advance of dispensing or when bulk drug substances are used shall include: **§54.1-3410.2]**		
	1. the generic name and the name of the manufacturer of each component or the brand name of each component		
	2. the manufacturer's lot number and expiration date for each component or when the original manufacturer's lot number and expiration date are unknown		
	3. the source of acquisition of the component		
	4. the assigned lot number if subdivided		
	5. the unit or package size and the number of units or packages prepared		
	6. the beyond-use date. The criteria for establishing the beyond-use date shall be available for inspection by the Board.		

Deficiency Number			
130	A complete compounding formula listing all procedures, necessary equipment, necessary environmental considerations, and other factors in detail shall be maintained where such instructions are necessary to replicate a compounded product or where the compounding is difficult or complex and must be done by a certain process in order to ensure the integrity of the finished product. **[§54.1-3410.2]**		
130a	Pharmacists shall label all compounded drug products that are dispensed pursuant to a prescription in accordance with this chapter and the Board's regulations, and shall include on the labeling an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding. **[§54.1-3410.2]**		
130a	A pharmacist may also engage in compounding of drug products in anticipation of receipt of prescriptions based on a routine, regularly observed prescribing pattern. Pharmacists shall label all products compounded prior to dispensing with: **§54.1-3410.2]**		
	1. the name and strength of the compounded medication or a list of the active ingredients and strengths		
	2. the pharmacy's assigned control number that corresponds with the compounding record		
	3. an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding		
	4. the quantity.		

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

Sterile Compounding Inspection for USP <797>

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

NABP Number	Deficiency Number		Result	Notes
		General Operations Information		
	21	The pharmacy engages in the compounding of sterile drug products and has a clean room that is compliant with USP-NF standards. **[§54.1-3410.2] [18VAC110-20-321]**		
	21a	The pharmacy is performing sterile compounding outside of a clean room. There is a compliant clean room present that is not utilized for preparation of compounded sterile drug products. **[§54.1-3410.2]**		
	29	In accordance with the conditions set forth in §54.1-3410.2 subsections A and B, pharmacists shall not distribute compounded drug products for subsequent distribution or sale to other persons or to commercial entities, including distribution to pharmacies or other entities under common ownership or control with the facility in which such compounding takes place; however, a pharmacist may distribute to a veterinarian in accordance with federal law. **[§54.1-3410.2]**		
	29	Compounded products for companion animals, as defined in regulations promulgated by the Board of Veterinary Medicine, and distributed by a pharmacy to a veterinarian for further distribution or sale to his own patients shall be limited to drugs necessary to treat an emergent condition when timely access to a compounding pharmacy is not available as determined by the prescribing veterinarian. **[§54.1-3410.2]**		
	29	A pharmacist may provide a reasonable amount of compounded products to practitioners of medicine, osteopathy, podiatry, or dentistry to administer to their patients, either personally or under their direct and immediate supervision, if there is a critical need to treat an emergency condition, or as allowed by federal law or regulations. A pharmacist may also provide compounded products to practitioners of veterinary medicine for office-based administration to their patients. **[§54.1-3410.2]**		
	27	Pharmacists may use bulk drug substances in compounding when such bulk drug substances: **[§54.1-3410.2]**		
		1. Comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if such monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding; or are drug substances that are components of drugs approved by the FDA for use in the United States; or are otherwise approved by the FDA; or are manufactured by an establishment that is registered by the FDA		
		2. Are distributed by a licensed wholesale distributor or registered nonresident wholesale distributor, or are distributed by a supplier otherwise approved by the Board and the FDA to distribute bulk drug substances if the pharmacist can establish purity and safety by reasonable means, such as lot analysis, manufacturer reputation, or reliability of the source.		
	27	Pharmacists shall not engage in the following: **[§54.1-3410.2]**		
	27	1. The compounding for human use of a drug product that has been withdrawn or removed from the market by the FDA because such drug product or a component of such drug product has been found to be unsafe. However, this prohibition shall be limited to the scope of the FDA withdrawal		

NABP Number	Deficiency Number		Result	Notes
	28	2. The regular compounding or the compounding of inordinate amounts of any drug products that are essentially copies of commercially available drug products. However, this prohibition shall not include (i) the compounding of any commercially available product when there is a change in the product ordered by the prescriber for an individual patient, (ii) the compounding of a commercially manufactured drug only during times when the product is not available from the manufacturer or supplier, (iii) the compounding of a commercially manufactured drug whose manufacturer has notified the FDA that the drug is unavailable due to a current drug shortage, (iv) the compounding of a commercially manufactured drug when the prescriber has indicated in the oral or written prescription for an individual patient that there is an emergent need for a drug that is not readily available within the time medically necessary, or (v) the mixing of two or more commercially available products regardless of whether the end product is a commercially available product		
	130a	Pharmacists who provide compounded products for office-based administration for treatment of an emergency condition or as allowed by federal law or regulations shall label all compounded products distributed to practitioners other than veterinarians for administration to their patients with: **[§54.1-3410.2]**		
		1. the statement "For Administering in Prescriber Practice Location Only"		
		2. the name and strength of the compounded medication or list of the active ingredients and strengths		
		3. the facility's control number		
		4. an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding		
		5. the name and address of the pharmacy		
		6. the quantity		
	130a	Pharmacists shall label all compounded products for companion animals, as defined in regulations promulgated by the Board of Veterinary Medicine, and distributed to a veterinarian for either further distribution or sale to his own patient or administration to his own patient with: **[54.1-3410.2]**		
		1. the statement "For Administering in Prescriber Practice Location Only"		
		2. the name and strength of the compounded medication or list of the active ingredients and strengths		
		3. the facility's control number		
		4. an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding		
		5. the name and address of the pharmacy		
		6. the quantity		
	20b	Pharmacists shall personally perform or personally supervise the compounding process, which shall include a final check for accuracy and conformity to the formula of the product being prepared, correct ingredients and calculations, accurate and precise measurements, appropriate conditions and procedures, and appearance of the final product. **[54.1-3410.2]**		
	130	Pharmacists shall maintain records of all compounded drug products as part of the prescription, formula record, formula book, or other log or record. Records may be maintained electronically, manually, in a combination of both, or by any other readily retrievable method. **[54.1-3410.2]**		

NABP Number	Deficiency Number		Result	Notes
	130	In addition to other requirements for prescription records, records for products compounded pursuant to a prescription order for a single patient where only manufacturers' finished products are used as components shall include the: **[§54.1-3410.2]**		
		1. name and quantity of all components		
		2. the date of compounding and dispensing		
		3. the prescription number or other identifier of the prescription order		
		4. total quantity of finished product		
		5. signature or initials of the pharmacist or pharmacy technician performing the compounding		
	20b	6. signature or initials of the pharmacist responsible for supervising the pharmacy technician and verifying the accuracy and integrity of compounded products.		
	130	In addition to the requirements of §54.1-3410.2 subdivision I 1, records for products compounded in bulk or batch in advance of dispensing or when bulk drug substances are used shall include: [**§54.1-3410.2]**		
		1. the generic name and the name of the manufacturer of each component or the brand name of each component		
		2. the manufacturer's lot number and expiration date for each component or when the original manufacturer's lot number and expiration date are unknown		
		3. the source of acquisition of the component		
		4. the assigned lot number if subdivided		
		5. the unit or package size and the number of units or packages prepared		
		6. the beyond-use date. The criteria for establishing the beyond-use date shall be available for inspection by the Board.		
	130	A complete compounding formula listing all procedures, necessary equipment, necessary environmental considerations, and other factors in detail shall be maintained where such instructions are necessary to replicate a compounded product or where the compounding is difficult or complex and must be done by a certain process in order to ensure the integrity of the finished product. **[§54.1-3410.2]**		
	130a	Pharmacists shall label all compounded drug products that are dispensed pursuant to a prescription in accordance with this chapter and the Board's regulations, and shall include on the labeling an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding. **[§54.1-3410.2]**		
	130a	A pharmacist may also engage in compounding of drug products in anticipation of receipt of prescriptions based on a routine, regularly observed prescribing pattern. Pharmacists shall label all products compounded prior to dispensing with: [**§54.1-3410.2]**		
		1. the name and strength of the compounded medication or a list of the active ingredients and strengths		
		2. the pharmacy's assigned control number that corresponds with the compounding record		
		3. an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding		
		4. the quantity.		

NABP Number	Deficiency Number		Result	Notes
		National Association of Boards of Pharmacy® Universal Inspection Form		
		Standard Operating Procedures (SOPs) for Compounded Sterile Preparations (CSPs)		
1.0		Does the pharmacy have a designated person(s) who meets the requirements in compliance with USP <797> standards? ***Inspector note: Per USP, "The compounding facility must designate one or more individuals (ie, the designated person(s)) to be responsible and accountable for the performance and operation of the facility and personnel in the preparation of CSPs and for performing other functions."*** ***If no, go to compliance statements.***		
1.1		The designated person(s) (for the QA program) has the training, experience, responsibility, and authority to perform the duties required of them.		
1.2		The designated person(s) is responsible and accountable for the performance and operation of the facility. ***Per USP, "The designated person(s) is responsible for ensuring that each area related to CSP preparation meets the classified air quality standard appropriate for the activities conducted in that area. The designated person(s) must also ensure that the ISO Class 5 areas are located, operated, maintained, monitored, and certified to have appropriate air quality."***		
1.3		The designated person(s) is responsible for personnel performing sterile compounding or other related functions (eg, quality checks and prescription dispensing of compounded preparations).		
1.4		The designated person(s) reviews facility SOPs at least every 12 months to ensure that they reflect current practice and such review is documented.		
1.5		The designated person(s) ensures that SOP revisions are implemented.		
1.6		The designated person(s) communicates all SOP revisions to all impacted personnel. ***Inspector note: USP <797> recommends that personnel should also document acknowledgment and communication of SOP changes and revisions.***		
1.7		The designated person(s) ensures that personnel demonstrate competency in performing every procedure that relates to their job function.		
1.8		The designated person(s) ensures that corrective actions are taken if problems, deviations, out-of-range results, failures, or errors are identified. ***Inspector note: Per USP, "Data collected in response to corrective actions must be reviewed to confirm that the actions taken have been effective."***		
2.0		Has the pharmacy developed and implemented SOPs that describe sterile compounding processes and other support activities in compliance with USP <797> standards? ***Inspector note: In order for this to be answered yes, all topics must be addressed if applicable to their business practices.*** ***If no, go to compliance statements.***		
2.1		**Scope of Practice:** Types of CSPs that are prepared (eg, immediate use, allergenic extracts, Category 1, Category 2, Category 3). Roles and responsibilities of the designated person(s).		
2.2		**Personnel Training and Evaluation:** Description of initial and ongoing training and competency for the designated person(s), compounding personnel, personnel with direct oversight of compounding personnel, and personnel who only perform restocking or cleaning, and disinfecting duties outside of the primary engineering control (PEC). Description of media-fill testing procedures, hand hygiene and garbing competency, and aseptic manipulation competency. Training and competency assessment of personnel on all sterilization methods and equipment used by the facility. Frequency of training is defined.		

NABP Number	Deficiency Number		Result	Notes
2.3		**Personal Hygiene and Garbing:** Description of the required garb, manner of storage, and order of garbing, including disinfection procedures for reusing goggles, respirators, and other reusable equipment. ***Inspector note: Per USP, the RABS (or pharmaceutical isolator) sleeve and glove changes should (not required) be changed per the manufacturer's recommendations and defined in the facility's SOPs.***		
2.4		**Facility Design and Engineering Controls:** Description of design requirements to maintain air quality standards and procedures for evaluating, maintaining, and certifying the areas used for compounding.		
2.5		**Certification and Recertification:** Description of sampling sites and procedures.		
2.6		**Microbiological Air and Surface Monitoring:** Description of the pharmacy's microbiological air and surface monitoring program which includes a diagram of the sampling locations, procedures for collecting samples, frequency of sampling, size of samples (eg, surface area, volume of air), time of day of sampling in relation to activities in the compounding area, and action levels that will trigger corrective actions and documentation requirements.		
2.7		**Cleaning, Disinfection, and Application of Sporicidal Disinfectants and Sterile 70% IPA:** Description of procedures for cleaning, disinfecting, and applying sporicidal disinfectants and include the frequency, methods, locations of cleaning, and documentation requirements.		
2.8		**Equipment:** Description of procedures for the calibration, maintenance, cleaning, use of the equipment, and documentation requirements.		
2.9		**Components:** Description of procedures that address the selection, receipt, evaluation, handling, storage, and documentation of all CSP components, including all ingredients and container closures.		
2.10		**Master Formulation and Compounding Records:** Description of procedures for developing and maintaining MFRs and required information, documentation, and record-keeping requirements for MFRs and CRs.		
2.11		**Release Inspections and Testing:** Description of release testing procedures (eg, visual inspections and/or sterility and endotoxin testing), out-of-specification procedures, corrective action procedures, and documentation requirements.		
2.12		**Labeling:** Procedures for labeling and label verification (confirming against the prescription or medication order, the MFR, and the CR) in order to prevent errors, CSP mix-ups, and required displayed information.		
2.13		**CSP handling, storage, packaging, shipping, and transport:** Processes and techniques for handling, storing, packaging, and transporting CSPs that include temperature monitoring, excursions, shipping containers, packaging requirements, and selected transportation modes.		
2.14		**Documentation:** Record keeping requirements and procedures for documentation maintenance and storage. ***Inspector note: USP requires readily retrievable records for two years; however, it is acknowledged that state or accreditation organizations may require records for a longer period of time.***		
2.15		**Sterilization and Depyrogenation:** Description of methods used for establishing and verifying the effectiveness of the terminal sterilization and depyrogenation methods selected, as well as the methods for maintaining and cleaning the sterilizing and depyrogenation equipment. ***If not applicable to their business practices, inspector should answer statement as N/A.***		
2.16		**Immediate Use CSPs:** Description of processes followed to meet all conditions of exemption from the requirements for Category 1, Category 2, and Category 3 CSPs. ***If not applicable to their business practices, inspector should answer statement as N/A.***		

NABP Number	Deficiency Number		Result	Notes
2.17		**Blood/Biological Handling:** Description of processes used to avoid cross-contamination and meet applicable regulatory requirements. ***If not applicable to their business practices, inspector should answer statement as N/A.***		
2.18		**Allergenic Extracts:** Description of procedures for training, competency assessments, personnel hygiene and garbing, facility requirements, cleaning and disinfecting, beyond use dates (BUDs), labeling, storage, shipping and transporting, and documentation. ***If applicable to their business practices, please complete the Allergenic Extracts module.*** ***If not applicable to their business practices, inspector should answer statement as N/A.***		
		CSPs - Immediate Use, Proprietary Vial/Bag Systems, and Blood-Derived		
3.0		Does the pharmacy prepare and dispense compounded sterile preparations for direct and immediate use?		
4.0		Does the pharmacy meet all conditions specified in USP <797> for CSPs compounded for direct and immediate use? ***Inspector note: Per USP <797>, all conditions must be met to qualify for exemptions of the requirements for Category 1, Category 2, and Category 3 CSPs.*** ***If no, go to compliance statements.***		
4.1		Aseptic techniques, processes, and procedures are followed. ***Inspector note: Per USP <797>, facility SOPs must describe procedures followed "to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other conventionally manufactured products or CSPs."***		
4.2		Personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and the facility's SOPs. ***Review personnel records to verify.***		
4.3		Preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs. ***Inspector note: Examples of this include approved labeling and/or published or unpublished stability and compatibility studies.***		
4.4		Preparation involves not more than three (3) different sterile products (eg, ingredients and/or components in a single container).		
4.5		Unused components from a single-use container are discarded after the preparation for one individual patient is complete (ie, single-dose containers are not used for more than one patient).		
4.6		Administration begins within four hours of the start of the preparation, and if not, the preparation is discarded. ***If administration is not performed within the same facility/campus of the pharmacy and/or is outside the pharmacy's control, inspector should answer statement as N/A.***		
4.7	130a	Unless the person preparing the preparation is administering or witnessing administration, the preparation is labeled with names and amounts of all active ingredients, name or initials of preparer, and exact four-hour time period in which administration must begin. ***If administration is not performed within the same facility/campus of the pharmacy and/or is outside the pharmacy's control, inspector should answer statement as N/A.***		

NABP Number	Deficiency Number		Result	Notes
5.0		Does the pharmacy prepare proprietary bag and vial systems (ex. addEASE, ADD-Vantage, Mini Bag Plus, Vial2Bag) in compliance with USP <797> standards? ***Inspector note: Docking and activation of proprietary bag and vial systems for immediate administration to an individual patient is out of scope of USP <797> and may be performed outside of an ISO Class 5 environment.*** ***If no, go to the compliance statements.*** ***If the pharmacy does not stock, prepare, and/or dispense any proprietary vial and bag systems, inspector should answer statement as N/A.***		
5.1		Docking for *future activation* and administration is performed in an ISO Class 5 environment and in accordance with requirements of USP <797>, with the exception of BUD assignment.		
5.2		BUD assignment is not longer than specified in the manufacturer's labeling.		
6.0		Does the pharmacy meet the conditions specified in USP <797> for CSPs to be prepared per approved labeling? ***Inspector note: Preparing a conventionally manufactured sterile product in accordance with the directions in the manufacturer's approved labeling is considered outside the scope of the USP chapter.*** ***If no, go to compliance statements.*** ***If the pharmacy only <u>compounds</u> sterile preparations (eg, does <u>not</u> prepare sterile preparations that strictly adheres to the conventionally manufactured approved labeling for preparation), inspector should answer statement as N/A.***		
6.1		The product is prepared as a single dose for an individual patient.		
6.2		The approved labeling includes information for the diluent, the resultant strength, the container closure system, and the storage time.		
7.0		Does the pharmacy perform compounding activities that require the manipulation of a patient's blood-derived or other biological material (eg, autologous serum)?		
8.0		For compounding activities that require the manipulation of a patient's blood-derived or other biological material, does the pharmacy perform manipulations that are clearly separated from other compounding activities and equipment used in CSP preparation activities and are controlled by specific SOPs to avoid any cross-contamination? ***Inspector note: Per USP, a separate cart could be used for blood-derived or other biological materials (a separate area is not required by the chapter). Pharmacy should change garb. Pharmacy to have cleaning processes as part of SOPs to avoid cross-contamination.*** ***If the pharmacy does not compound with blood products or other biological materials, inspector should answer statement as N/A. If the inspector answers the compliance question as "no", please describe your observations.***		

NABP Number	Deficiency Number		Result	Notes
		Facility Design and Engineering Controls		
9.0		**Segregated Compounding Area (SCA):** Does the pharmacy use an SCA as an SEC in compliance with USP <797> standards for facility design and environmental control? ***Inspector note: Per USP, only Category 1 CSPs may be compounded in a SCA.*** ***If no, go to compliance statements.*** ***If pharmacy only uses a cleanroom suite for sterile compounding preparations, inspector should answer question as N/A.***		
9.1		The facility is designed to afford a well-lighted and comfortable working environment.		
9.2		Only Category 1 CSPS are prepared in a SCA. ***If pharmacy is compounding Category 2 or Category 3 CSPs in a SCA, inspector should answer this statement as no and collect photographs and copies of the MFR, CR, and provide a description of their observations in the Inspector Notes.***		
9.3		The SCA is located away from unsealed windows, doors that connect to outdoors, and traffic flow. ***Inspector note: Per USP, "strong air currents from opened doors, personnel traffic, or air streams from the HVAC system can disrupt the unidirectional airflow of an open-faced PEC."***		
9.4		The SCA is located away from environmental control challenges and separate from areas not related to compounding (ie, restrooms, warehouses, food preparation areas).		
9.5		A visible perimeter establishes the boundaries of the SCA. ***Inspector note: Per USP, the SCA is defined as "a designated space, area, or room that is not required to be classified and is defined with a visible perimeter. The SCA must contain a PEC and is suitable for preparation of Category 1 CSPs only." USP further defines a perimeter as "a visible demarcation (such as a door, walls, or visible marking on the floor) that defines the SCA or AECA." The perimeter will be defined in the pharmacy's SOPs. Tape or an alternative method may be used to define this visible perimeter, since this is not a classified space.***		
9.6		Access to the SCA is restricted to authorized personnel. ***Inspector note: Per USP, authorized personnel includes personnel involved in compounding processes, maintenance, and cleaning.***		
9.7		Free-standing humidifiers/dehumidifiers and air conditioners are not located within the perimeter of the SCA.		
9.8		Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in the compounding area. ***Inspector note: Per USP, these items should be low-shedding, easily cleaned, and disinfected. This applies to items within the perimeter around the Primary Engineering Control (PEC).***		
9.9		Shipping cartons or other corrugated or uncoated cardboard are not allowed in the SCA.		
9.10		The SCA and all surfaces (walls, floors, counters, equipment) are clean, uncluttered, and dedicated to compounding.		
9.11		The sink is located inside the SCA or in close proximity and is located at least one meter away from the PEC.		
9.12		The area within one meter of the PEC is dedicated only for sterile compounding (eg, not storage, hand hygiene, donning and doffing garb, or other highly particle-generating activities, such as patient care).		
9.13		If overhangs or ledges are present in the SCA, are they easily cleanable? ***If no, describe observations in Inspector Notes.***		

NABP Number	Deficiency Number		Result	Notes
10.0		Are surfaces smooth, impervious, free from cracks and crevices, and non-shedding so they can be cleaned and disinfected? ***Inspector note: this is a recommendation by USP.*** ***If no, describe in comments Inspector Notes (eg, peeling of Formica countertops)*** .		
11.0		Are surfaces resistant to damage from cleaning, sanitizing, and sporicidal agents used? ***Inspector note: this is a recommendation by USP.*** ***If no, describe in comments inspector observations (ie observed rust on preparation cart or flaking of particle board on shelving).***		
12.0		**Cleanroom Suite:** Does the pharmacy use a Cleanroom Suite (ISO-classified anteroom and buffer room) as a SEC in compliance with USP <797> standards for facility design and environmental control? ***Inspector note: Per USP <797>, a cleanroom suite is required if compounding any Category 2 and Category 3 CSPs.*** ***If no, go to compliance statements.*** ***If pharmacy only uses an SCA for Category 1 CSPs, inspector should answer question as N/A.***		
12.1		Access to the cleanroom suite is restricted to authorized personnel. ***Inspector note: Per USP, authorized personnel includes personnel involved in compounding processes, maintenance, and cleaning. Some examples pharmacies may use to demonstrate compliance with this statement (but are not specifically required by the chapter) include posting a sign or creating a badge access point for authorized personnel to enter the cleanroom suite.***		
12.2	32	The facility is designed to afford a well-lit environment.		
12.3	32	The facility provides a comfortable working environment (eg, temperature and humidity settings so appropriate garb can be donned).		
12.4	32	The anteroom and buffer room are separated from surrounding unclassified areas by fixed walls and doors.		
12.5	32	Controls are in place to minimize the flow of lower-quality air into the more-controlled areas. ***Inspector note: Per USP, "strong air currents from opened doors, personnel traffic, or air streams from the HVAC system can disrupt the unidirectional airflow of an open-faced PEC."***		
12.6	23	Anterooms providing access to only positive pressure buffer rooms meet at least ISO Class 8 specifications. ***If the pharmacy has a negative pressure room, inspector should answer statement as N/A.***		
12.7	23	The anteroom provides access to a negative pressure room and meets at least ISO Class 7 specifications. ***If the pharmacy does not compound hazardous drugs, inspector should answer statement as N/A.***		
12.8	23	The buffer room, where the PEC is placed, meets ISO Class 7 or better air quality specifications. ***Inspector note: If the PEC is a pharmaceutical isolator, the buffer room must be at least ISO Class 8 air quality or better and an anteroom is not required.*** ***Per USP <797>, a pharmaceutical isolator is defined as an enclosure that provides HEPA-filtered ISO Class 5 unidirectional air operated at a continuously higher pressure than its surrounding environment and is decontaminated using an automated system. It uses only decontaminated interfaces or rapid transfer ports for materials transfer. A CAI or CACI is not a pharmaceutical isolator.***		
12.9	32	Air supply to the anteroom and buffer room is introduced through HEPA filters in the ceiling.		

NABP Number	Deficiency Number		Result	Notes
12.10	32	Air returns are located low on the wall. ***If the pharmacy has a visual smoke study (as described in the USP chapter and compliance statement below), inspector should answer statement as N/A.***		
12.11	32	A visual smoke study demonstrates an absence of stagnant air where particles can accumulate and is repeated if any equipment/placement changes when air returns are not located low on the wall. ***Inspector note: Per USP, "the smoke study, along with environmental monitoring, must be repeated whenever a change is made to the placement of equipment within the room or any other alteration is performed within the cleanroom suite that affects the quality of the air (eg, HVAC alterations, chapter of HEPA filter units)."*** ***If air returns are low on the wall, inspector should answer statement as N/A.***		
12.12	32	The anteroom has a line of demarcation to separate the dirty side from the clean side or has two separate anterooms, a dirty anteroom and a clean anteroom. ***Describe observations for the type of line of demarcation in the Inspector Notes.***		
12.13	32	Personnel enter the dirty side/room first from the unclassified area and the clean side/room is located closest to the buffer room.		
12.14	32	All surfaces (ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets) are smooth, impervious, free from cracks and crevices, and non-shedding.		
12.15	32	Junctures between ceilings and walls and between the walls and floors are sealed.		
12.16	32	If the ceiling consists of inlaid panels, the panels are caulked to seal them to the support frame. ***If the ceiling does not consist of inlaid panels, inspector should answer statement as N/A.***		
12.17	32	Walls are constructed of, or covered with, a durable material (eg, epoxy paint, heavy gauge polymer) and integrity of surface maintained.		
12.18	32	Walls, if paneled, are joined together and sealed to the support structure. ***If walls are not paneled, inspector should answer statement as N/A.***		
12.19	32	Floors include coving to the sidewall or the juncture between floor and wall is caulked.		
12.20	32	If overhangs or ledges are present, they are easily cleanable. ***If there are no overhangs, ledges, utility pipes, windowsills, etc, inspector should answer statement as N/A.***		
12.21	32	Exterior lens surfaces of the ceiling light fixtures are smooth, mounted flush, and sealed.		
12.22	32	All other penetrations through the ceiling or walls (eg, camera domes) are sealed.		
12.23	32	The buffer room does not contain plumbed water sources (eg, sinks, eyewashes, showers, or floor drains).		
12.24	32	The anteroom does not contain floor drains.		
13.0		Are **PECs** used to prepare CSPs located in the appropriate space (eg, buffer room or SCA) for category types prepared in compliance with USP <797> standards? ***Inspector to review certification reports and observe compounding area(s) to evaluate. If no, go to compliance statements.***		
13.1		All compounded sterile preparations (that are not for immediate use) are compounded in a PEC.		
13.2	22, 147	PEC is certified to maintain ISO 5 classification or better conditions during dynamic operating conditions. ***The inspector should only answer yes if the PEC has been certified within the past six months.***		

NABP Number	Deficiency Number		Result	Notes
13.3	22	The PEC is located out of traffic patterns and away from room air currents that could disrupt the intended airflow patterns inside the PEC. ***Review certification report.***		
13.4		Placement of the PEC allows for cleaning around the PEC.		
13.5	21	**Category 2 and Category 3**: PEC(s) are located in a cleanroom suite. ***If pharmacy only compounds Category 1 CSPs, inspector should answer this statement as N/A.***		
14.0		Does the pharmacy have any CAIs/CACIs used for sterile compounded preparations? ***If the pharmacy does not use any CAI/CACIs for compounding CSPs, inspector should answer question as N/A.***		
15.0		Are **CAIs/CACIs** (RABS) used for compounding sterile preparations operated in compliance with manufacturer specifications **and** USP <797> standards? ***If no, go to compliance statements.*** ***If the pharmacy does not use any CAI/CACIs for compounding CSPs, inspector should answer question as N/A.***		
15.1		The documented recovery time is followed after opening the CAI/CACI transfer chamber to maintain ISO Class 5 air quality. ***Inspector note: The recovery time should come from the manufacturer of the CAI/CACI.***		
15.2		Staff ensures that adequate recovery time is allowed after closing the CAI/CACI during compounding operations. ***Inspector note: The recovery time should come from the manufacturer of the CAI/CACI.***		
15.3	132	Sterile gloves are worn over the gloves attached to the CAI/CACI sleeve. ***Inspector note: Per USP, if using a RABS (ie, a CAI or CACI), disposable gloves should be (not required) worn inside the gloves attached to the RABS sleeves.***		
16.0		Are there controls in place to minimize the influx of contaminants from materials (supplies and equipment) and personnel as they move from areas of lower quality to those of higher quality in compliance with USP <797> standards? ***Inspector note: An example of material movement from lower quality air to higher quality air includes movement from a non-classified area to an ISO Class 8 anteroom, ISO Class 8 anteroom to an ISO Class 7 buffer room, or from an ISO Class 7 buffer room to an ISO Class 5 PEC.*** ***If no, go to compliance statements.***		
16.1		Before any item is introduced into the SEC, placed into the pass-through chamber, or brought into the SCA (providing that packaging integrity will not be compromised), it is wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% isopropyl alcohol (IPA) using low-lint wipers by personnel wearing gloves.		
16.2		Before any item is introduced into the PEC, it is wiped with sterile 70% IPA using sterile low-lint wipers and allowed to dry before use.		
17.0		Does the pharmacy have the appropriate facility design and controls (including the fixtures, types of equipment, materials, and supplies that are stored) in the classified areas in compliance with USP <797> standards? ***If no, go to compliance statements.***		

NABP Number	Deficiency Number		Result	Notes
17.1	32	The sink used for hand hygiene, located outside of the anteroom, is placed in an appropriate area and clean space to minimize the risk of bringing contaminants into the anteroom. ***Inspector note: Inspector should evaluate the sink location in relation to the activities that occur where the sink is located as well as the distance between the sink and the entrance to the compounding suite/SCA. Examples that may not be considered appropriate include but are not limited to: sink is located in the bathroom, an adjacent suite or property, or in an employee breakroom where food is prepared.*** ***If the sink is located in the anteroom, inspector should answer statement as N/A.***		
17.2	32	The sink used for hand hygiene, located inside of the anteroom, is placed in an appropriate area to minimize the risk of bringing contaminants into the buffer room. ***Inspector note: Inspector should evaluate the sink location in relation to the doors and compounding activities. For example, the sink is where compounders perform hand hygiene close to where garb is stored (where it can easily get wet/splashed).*** ***If the sink is located outside the anteroom, inspector should answer statement as N/A.***		
17.3		The doors into the anteroom from the general pharmacy area and from the anteroom into the clean/buffer room are prevented from both being open at the same time (eg, by interlocking, training of personnel, or signage).		
17.4		The inside and outside doors of a pass-through are prevented from both being open at the same time (eg, by interlocking, training of personnel, or signage).		
17.5		Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in a classified area or SCA. ***Inspector note: Per USP, items necessary for performing compounding activities are low-shedding and can be easily cleaned and disinfected.*** ***If no, describe the types of items that are observed. If appropriate, submit a photograph with inspection report.***		
17.6	32	Tacky mats are not used in the classified areas. ***Inspector note: Per USP <797>, "Tacky mats must not be placed within ISO-classified areas."***		
17.7		Shipping cartons or other corrugated or uncoated cardboard are not permitted in the classified areas.		
17.8	32	Carts used to transport components or equipment into classified areas are constructed from nonporous materials with cleanable casters and wheels.		
17.9		Carts (including casters) are cleaned and disinfected prior to moving from the dirty side to the clean side of the anteroom.		
18.0		Does the pharmacy's facility design for maintaining (eg, recording, monitoring, and controlling) temperature and humidity (eg, HVAC) comply with USP <797> standards? ***Inspector note: Compounded preparations that are finished and stored will be addressed in the general pharmacy module. Inspector should be aware that USP cleanroom temperature recommendations may not be harmonized with USP, FDA, or manufacturer/supplier temperature requirements for drug storage.*** ***If no, go to compliance statements.***		
18.1		The compounding area temperature and humidity is maintained by a heating, ventilation, and air conditioning (HVAC) system. ***If inspector finds a free-standing air conditioner, humidifier, or dehumidifier within the classified area or the SCA, the inspector should answer statement as "No."*** ***Additionally, inspector should describe what they observed, where the equipment was located, and collect/submit photographs.***		

NABP Number	Deficiency Number		Result	Notes
18.2		The pharmacy records the temperature of the cleanroom suite on days when sterile compounding occurs. ***If pharmacy does not use a continuous recording system, describe the frequency of temperature recording in the notes.***		
18.3		The pharmacy records the humidity of the cleanroom suite on days when sterile compounding occurs. ***If pharmacy does not use a continuous recording system, describe the frequency of humidity recording in the notes.***		
18.4		The pharmacy maintains records of temperature and humidity that are specific to the cleanroom suite. ***Temperature and humidity for drug storage areas will be documented in the general pharmacy module.*** ***If the pharmacy only uses an SCA, inspector should answer statement as N/A.***		
18.5		The pharmacy can readily retrieve temperature and humidity records. ***If the electronic monitoring system is only capable of providing text message alerts for excursions alone (eg, a report cannot be generated for ongoing temperature conditions), inspector should answer statement as "No."***		
18.6		The pharmacy controls temperature and humidity to maintain appropriate working conditions if no overnight drug storage occurs and/or is following the most restrictive drug label. ***Inspector note: Per USP <797>, the cleanroom suite should be maintained at a temperature of 20°C or cooler and a relative humidity of 60% or below to minimize the risk of microbial proliferation and to provide comfortable conditions for compounding personnel attired in the required garb.*** ***CRT is defined as 20°C-25°C per USP <659>.***		
18.7		The placement of the HVAC unit does not cause cross contamination or interfere with the functioning of the classified area. ***Inspector note: Air streams from the HVAC system(s) can disrupt the unidirectional airflow of an open faced PEC such as a laminar airflow workbench (LAFW).***		
18.8		Temperature monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. ***Inspector note: Monitoring devices are typically calibrated or replaced.***		
18.9		Humidity monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. ***Inspector note: Monitoring devices are typically calibrated or replaced.***		
19.0		Does the pharmacy store drugs in the cleanroom suite overnight and/or for long periods of time? ***Inspector note: Long periods of time is not defined as pre-compounding preparation right before compounding activities are commenced.***		
20.0		If the pharmacy is storing drugs inside the cleanroom suite overnight and/or long periods of time, are any of the drugs stored unable to tolerate temperature excursions?		
21.0		What is the current temperature of the cleanroom suite/SCA? ***Record in the Inspector Notes.***		
22.0		What is the current relative humidity percentage of the cleanroom suite/SCA? ***Record in the Inspector Notes.***		
23.0		Is the humidity maintained at less than 60% relative humidity (RH) in the compounding area to minimize risk of microbial proliferation?		

NABP Number	Deficiency Number		Result	Notes
24.0		Is differential positive pressure maintained in compliance with USP <797> standards? ***Inspector note: Per USP <797>, no pressure differential is required between the SCA and the surrounding area.*** ***If no, go to compliance statements.*** ***Inspector should view logs and current status (while observing compounding) to verify.*** ***If the pharmacy uses an SCA for sterile compounding environment, inspector should answer statement as N/A.***		
24.1		The facility design creates room separation to allow positive pressure differentials between spaces (rooms) for movement of air from higher quality air to lower quality air. ***Inspector should review a graphic of the airflow contained in the certification report.***		
24.2		The facility has a system in place to continuously monitor pressure differentials (eg, magnehelic gauge). ***Per USP, pressure differentials need to be monitored continuously, but personnel are not specifically required to visually monitor pressure during compounding activities.***		
24.3		The facility has a record system to record pressure differentials on days when compounding occurs. ***Inspector note: Per USP, the quantitative results from the pressure monitoring device must be reviewed and documented at least daily on the days when compounding is occurs.***		
24.4		The differential positive pressure between unclassified and the first space in the compounding suite is at least 0.020 inch water column. ***Inspector note: Per USP, certifiers should confirm (this is a USP recommendation) positive pressure around doorways, pass-throughs and any opening in the cleanroom suite with smoke testing (to confirm positive pressure is maintained) with initial certification of the cleanroom suite.*** ***If no, record the observed pressure differential between the two identified spaces (eg, ISO Class 8 anteroom and the general pharmacy area).***		
24.5		The differential positive pressure between adjacent classified areas is at least 0.020 inch water column. ***If no, record the observed pressure differential between the two identified spaces (eg, ISO Class 8 anteroom and the ISO Class 7 buffer room).***		
24.6		Pressure differential monitoring and quantitative results are reviewed and documented at least daily on days when compounding occurs.		
25.0		Does the pharmacy have a policy in place to cease compounding when the pharmacy is unable to maintain positive pressure differentials (outside of anticipated variations due to opening and closing of doors)?		
26.0		Are pressure differential monitoring procedures in place that include an alarm or alert when there is an excursion? ***Inspector note: USP <797> does not require there to be an alarm or an alert.***		
27.0		Does the facility perform both sterile and nonsterile compounding?		
28.0		If the pharmacy performs nonsterile compounding and sterile compounding, are the designated areas separate and distinct from each other?		
29.0		If PECs are placed into the same room that are used for both sterile and nonsterile compounding, is the pharmacy in compliance with USP <797> standards? ***Inspector note: Per USP <797>, PECs used for both sterile and nonsterile compounding may be placed in the same room only if the PECs are sufficiently effective that the room can continuously maintain ISO Class 7 classification.*** ***If no, go to compliance statements.*** ***If the pharmacy does not perform nonsterile compounding in the same room as sterile compounding, inspector should answer this question as N/A.***		

NABP Number	Deficiency Number		Result	Notes
29.1		PECs used for nonsterile compounding are placed at least one meter away from PECs used for sterile compounding.		
29.2		Particle-generating activity must not be performed while sterile compounding is in process.		
29.3		PECs are sufficiently effective that the room can continuously maintain ISO Class 7 classification air quality during nonsterile compounding.		
30.0		Does the pharmacy prepare Category 2 and Category 3 CSPs from nonsterile components? ***Inspector note: Category 1 CSPs can be made from nonsterile components.*** ***If the pharmacy does not compound using nonsterile components, the inspector should answer question as N/A.***		
31.0		Does the pharmacy's presterilization procedures comply with USP <797> standards? ***If no, go to compliance statements.***		
31.1	21b	Presterilization procedures, such as weighing and mixing, are completed in an ISO Class 8 or better environment (eg, anteroom or buffer room). ***Inspector note: This statement only applies for Category 2 and Category 3.***		
31.2	21b	Presterilization procedures, such as weighing and mixing, are performed in a single-use containment glove bag, CVE, BSC, or CACI to minimize the risk of airborne contamination. ***Inspector note: This statement only applies for Category 2 and Category 3. CVEs, BSCs, or CACIs used for presterilization procedures must be certified at least every six months.***		
		Certification and Environmental Monitoring Inspector to review past two (2) Certification reports for the SEC and all PECs.		
32.0		Does the pharmacy ensure that each area related to CSP preparation is certified to meet the classified air quality standard appropriate for the activities conducted in that area in compliance with USP <797> standards? ***If no, go to compliance statements.*** ***Inspector is to review current certification reports.***		
32.1		The most recent PEC and SEC certification reports are available for review.		
32.2	22, 23	Certification of all classified areas, including PECs, is performed at least every six months.		
32.3	22, 23	Certification of all classified areas, including PECs, is performed whenever a device is relocated or a major service to the facility is performed. ***Inspector note: Classified areas must be recertified if there are changes to the area such as redesign, construction, replacement or relocation of any PEC, or alteration in the configuration of the room that could affect airflow or air quality.***		
32.4		Certification reports are reviewed by the designated person(s). ***Inspector note: If the designated person(s) review is not documented, describe how it is ensured that the review occurred.***		
32.5	22	All ISO Class 5 PECs (laminar airflow workbenches or areas, BSCs, CAIs, CACIs, pharmaceutical isolators, IVLFZ, and robotic enclosures) have been certified within the last six months. ***If no, record the date of the last certification and include a copy of the certification report with the inspection report.***		
32.6	22	All PECs meet ISO Class 5 air quality requirements with (total, nonviable) particle counts documented within the report. ***Inspector note: Per ISO definition, ISO Class 5 areas are certified as having less than 3,520 particles per cubic meter of air under dynamic operating conditions.*** ***If no, describe what occurred and the pharmacy's response to total airborne particle sampling results, data evaluation, and action level (eg, pharmacy took PEC out of service, pharmacy ordered new HEPA filter, PEC was repaired and re-certified).***		

NABP Number	Deficiency Number		Result	Notes
32.7	23, 147	All ISO Class 7 and 8 SECs (clean/buffer rooms and anterooms) have been certified within the last six months. ***Inspector note: Per ISO definition, ISO Class 7 areas are certified as having less than 352,000 particles per cubic meter of air under dynamic operating conditions and ISO Class 8 areas are certified as having less than 3,520,000 particles per cubic meter of air under dynamic operating conditions.*** ***If no, record the date of the last certification and include a copy of the certification report with the inspection report.***		
32.8		All SECs meet ISO Class 7 air quality requirements and ISO Class 8 air quality requirements where permitted, with particle counts documented within the report. ***If no, describe what occurred and the pharmacy's response (eg, pharmacy reduced BUD, pharmacy used an alternative facility, pharmacy followed mitigation strategies, and/or disaster planning processes).***		
33.0		Does the certification report received by the pharmacy have all required elements documented for the pharmacy's designated person(s) to make an informed decision related to functionality of PEC and SEC environments in compliance with USP <797> standards? ***Inspector note: It is recommended that the designated person review the certification report in its entirety.*** ***If no, go to compliance statements.***		
33.1		The certification report includes information about the equipment used for performing each test including last calibration date (or date when next calibration is due). ***Inspector note: Per USP, "total particle count testing must be performed under dynamic operating conditions using calibrated electronic equipment" and "all impaction air samplers must be serviced and calibrated as recommended by the manufacturer."***		
33.2		The certification report includes the name of the certifier. ***Inspector note: Per USP <797>, a qualified certifier may have received training and education from professional organizations such as the American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) and Controlled Environment Testing Association (CETA). Both organizations provide certification (Registered Certification Professional – Sterile Compounding Facilities), education, and resources.***		
33.3	147	The certification report describes the "dynamic conditions" including the number of personnel in the cleanroom suite. ***Inspector note: Compounders can perform mock compounding activities and/or performing media-fill while the certifier is conducting testing. Number of personnel present in the SEC must be documented.***		
33.4	23	**SEC: Airflow testing** is performed and documented on the certification report to determine acceptability of the **air volume and room air exchange rate (ACPH)**. ***Inspector note: Per USP <797>, unclassified SCAs have no ACPH requirement.*** ***If pharmacy only compounds in an SCA, inspector should answer statement as N/A.***		
33.5	23	**SEC:** All of the following ACPH required elements were documented on the certification report: the ACPH from HVAC, the ACPH contributed from the PEC, and the total ACPH. ***If pharmacy only compounds in an SCA, inspector should answer statement as N/A.***		
33.6	23	**The ISO Class 8 anteroom** is certified and documented as having a minimum of 20 ACPH with at least 15 ACPH of the total air change rate coming from HVAC through HEPA filters located in the ceiling. ***If the pharmacy has an ISO Class 7 anteroom, inspector should mark as N/A.***		

NABP Number	Deficiency Number		Result	Notes
33.7	23	**The ISO Class 7 buffer room and ISO Class 7 anteroom (if required)** is certified and documented as having a minimum of 30 ACPH with at least 15 ACPH of the total air change rate in a room coming from the HVAC through HEPA filters located in the ceiling. ***Inspector note: If the PEC is used to meet the minimum total ACPH requirements, the PEC must not be turned off, except for maintenance.***		
33.8	23	**SEC: Airflow testing** is performed and documented on the certification report to determine acceptability of the **room pressure differential** in doorways between adjacent rooms.		
33.9	23	**SEC:** The differential pressure measured was at least 0.020 inch water column positive from the cleanroom to the anteroom and between the anteroom and all adjacent spaces with the doors closed. ***Inspector note: No pressure differential is required between the SCA and the surrounding area.***		
33.10	23	**SEC:** All SEC HEPA filters were leak tested (to confirm **HEPA filter integrity**).		
33.11	23	**SEC:** All SEC HEPA filters with leaks were repaired. ***If leaks were not repaired, describe what actions pharmacy took (eg, pharmacy implemented mitigation strategies such as reduced BUD or used alternative pharmacy location).*** ***If no repairs were needed, inspector should answer statement as N/A.***		
33.12	23, 147	**PEC:** (**Dynamic airflow**) **Smoke pattern tests** are performed for each PEC during dynamic operating conditions to demonstrate unidirectional airflow and sweeping action over and away from the CSPs. ***Inspector note: Per USP, "HEPA-filtered air must be supplied by the PEC at a velocity sufficient to sweep particles away from critical sites and maintain unidirectional airflow during operations. Proper design, control, and use minimizes turbulence and creation of eddies or stagnant air in the PEC."*** ***Describe if smoke pattern testing of PEC was documented thoroughly in the report or through video.***		
33.13	23, 147	**PEC: Dynamic airflow smoke pattern** confirms equipment and supplies necessary for performing compounding activities in the PEC do not disrupt unidirectional airflow. ***Inspector note: Per USP, "Proper placement of equipment in a PEC must be initially verified by a dynamic airflow smoke pattern test to demonstrate minimal disruption in airflow. The dynamic airflow smoke pattern test must be repeated if equipment is placed in a different location."***		
33.14	23, 147	**PEC: Total (nonviable) particle count** testing was performed under dynamic operating conditions using calibrated electronic equipment. ***Inspector note: Per USP, "Measurements of total airborne particles must be taken in each PEC at locations where there is greatest risk to the exposed CSPs, containers, and closures...Measurements of total airborne particles in other classified areas, including the buffer room(s) and anteroom(s), should be taken at representative locations that reflect the quality of air in the room(s)."***		
33.15	23	**PEC:** All PEC HEPA filters were leak tested (to confirm **HEPA filter integrity**). ***Inspector note: The certification report for each PEC should show air velocities within the PEC.***		
33.16	23	**PEC:** All PEC HEPA filters with leaks identified were repaired. ***If leaks were not repaired, describe what actions pharmacy took (example: PEC taken out of service until HEPA filter could be replaced).*** ***If no repairs were needed, inspector should answer statement as N/A.***		

NABP Number	Deficiency Number		Result	Notes
33.17	23	**PEC-IVLFZ**: Pharmacy's integrated vertical laminar flow zone (IVLFZ) meets design, functional requirements, and certification requirements under USP <797>. ***Inspector note: Per USP <797>, "Strategic location of air returns in addition to full coverage of HEPA-filters above the work surface is required. Both static and dynamic smoke studies of air returns in addition to full coverage of HEPA-filtered air void of turbulence, dead air zones, and refluxing from the HEPA filters to and across the entire work area and to the air returns must be documented (eg, with video)."*** ***If pharmacy does not use an IVLFZ, inspector should answer statement as N/A.***		
33.18	147	If a **robotic enclosure is used as the PEC**, or placed within the PEC, a dynamic airflow smoke pattern test must be performed initially and at least every 6 months thereafter to ensure that: 1) it is properly integrated into the facility, 2) there is no turbulence or refluxing at any critical site(s), 3) room air does not enter the PEC where sterile products and/or preparations may be exposed, and 4) all processes can be performed without introducing contamination to the direct compounding area(s). ***If pharmacy does not use a robotic enclosure, inspector should answer statement as N/A.***		
34.0		Was smoke testing performed in SEC to confirm all particle generating equipment (eg, computers, printers, refrigerators, PECs) do not disrupt airflow? ***Inspector note: This question will be N/A <u>unless</u> the pharmacy is new, has recently completed construction, or equipment has been moved within SEC since last certification.***		
35.0		Does the pharmacy have an established environmental monitoring (eg, microbiological air and surface monitoring) program in compliance with USP <797> standards? ***Inspector note: Per USP, "The goals of a microbiological air and surface monitoring program are to determine whether contamination is present at unacceptable levels and to assess whether proper personnel practices are being followed, cleaning and disinfecting agents are effective, and environmental quality is maintained."*** ***If no, go to compliance statements.***		
35.1	149	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed initially in the selected sampling sites to establish a baseline level of environmental quality for each classified area, ie, each ISO Class 5 PEC, each ISO Class 7, and ISO Class 8 room.		
35.2	149	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed in conjunction with the certification of new facilities and equipment.		
35.3	149	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed after any servicing of facilities or equipment.		
35.4	149	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed in response to identified problems (eg, positive growth in sterility tests of sterile compounded preparation).		
35.5	25d, 149	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed in response to identified trends (eg, repeated positive gloved fingertip and thumb sampling results, failed media fill testing, or repeated observations of air or surface contamination).		

NABP Number	Deficiency Number		Result	Notes
35.6		Results from the environmental monitoring program (eg, viable air and/or surface monitoring) are reviewed in response to changes that could impact the sterile compounding environment (eg, change in cleaning agents) and in conjunction with personnel data (ie, training records, visual observations, competency assessments) to assess the state of control and to identify potential risks of contamination. ***Inspector note: Per USP, the program is reviewed to "assess risks for contamination, potential routes of contamination, and the adequacy of cleaning and disinfecting agents and procedures. Regular review of the sampling data must be performed to detect trends and the results of the review must be documented."***		
35.7		The pharmacy ensures that viable air and surface sampling is performed by a trained and competent individual who is familiar with the methods and procedures for air sampling and surface testing. ***If sampling is conducted by internal personnel, inspector should verify that documented training and competencies are located in the employee file.***		
35.8		Environmental monitoring program (eg, viable air and/or surface monitoring) describes/identifies corrective actions to minimize the risk of CSP contamination and that these corrective actions are documented.		
36.0		Is surface sampling performed at the end of a compounding activity or shift but before the area has been cleaned and disinfected (to obtain a sample that is representative of the typical compounding conditions at the pharmacy)? ***Inspector note: this is a USP recommendation.***		
37.0		Does the pharmacy send out all air quality for viable airborne samples to an external lab (third party) for incubation and processing? ***If pharmacy exclusively does internal incubation and results processing, inspector should answer statement as N/A.***		
38.0		Does the pharmacy send out all surfaces for viable particle samples to an external lab (third party) for incubation and processing? ***If pharmacy exclusively does internal incubation and results processing, inspector should answer statement as N/A.***		
39.0		For any samples that are sent to an external lab (third party), does the pharmacy receive a report from the third party confirming incubation parameters meet USP <797> requirements (eg, the correct temperature and the correct length of incubation time are documented in the report)? ***Inspector note: Incubation parameters are the same as seen in statements 40.6-40.7 and 41.4-41.5.*** ***This question applies for any air or surface sample sent to an external lab.*** ***If no, describe observations.***		
40.0		Are processes for sampling and monitoring **air quality for viable airborne** particles in compliance with USP <797> standards? ***Inspector note: Per USP <797>, facilities performing any Category 3 compounding must adhere to the increased environmental monitoring requirements for all classified areas where Category 3 CSPs are compounded and increased environmental monitoring requirements apply at all times regardless of whether Category 3 CSPs are being compounded on a given day.*** ***Review six months of air sampling data to verify. If no, go to the compliance statements.***		
40.1		All classified areas are sampled using a volumetric active air sampling device (impaction air sampler). ***Inspector note: This sampling must be performed during dynamic operating conditions (to obtain a sample that is representative of the typical compounding conditions at the pharmacy).***		

NABP Number	Deficiency Number		Result	Notes
40.2		All classified areas are sampled at the **frequencies** specified by USP for volumetric active air sampling. ***Inspector note: Per USP <797>, Category 1 and Category 2 compounding frequency is every six months and Category 3 compounding frequency is monthly.*** ***For facilities compounding any Category 3 CSPs, this must be completed within 30 days prior to the commencement of any Category 3 compounding and at least monthly thereafter regardless of the frequency of compounding Category 3 CSPs.***		
40.3		At least one cubic meter (1000 L) of air is tested using the volumetric active air sampling device from each sample location.		
40.4		All impaction air samplers are serviced and calibrated as recommended by the manufacturer.		
40.5		The pharmacy uses an appropriate microbiological growth media for sampling. ***Inspector note: An appropriate microbiological growth media means a media that supports the growth of bacteria and fungi (eg, TSA), accompanied by a COA that verifies that the media meets expected growth promotion, pH, and sterilization requirements.***		
40.6		The pharmacy incubates all air samples for time and temperature in compliance with USP <797> following the one media device method. ***Inspector notes: Per USP <797> (Box 5), when using the one media device method, sampling media is to be covered, inverted, and incubated at 30°C–35°C for no less than 48 hours. Then, after examination and recording of results, further incubated at 20°C–25°C for no less than five additional days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***		
40.7		The pharmacy incubates all air samples for time and temperature in compliance with USP <797> following the alternative two media device method. ***Inspector note: Per USP <797> (Box 5), two samples may be collected for each sample location and incubated concurrently to shorten the overall incubation period. Both samples are TSA, or one sample is TSA and the other fungal media (eg, malt extract agar [MEA] or sabouraud dextrose agar [SDA]). Each sample is incubated in a separate incubator, one sample at 30°C-35°C for no less than 48 hours the other sample at 20°C-25°C for no less than five days. If fungal media is used, incubate at 20°C-25°C for no less than five days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***		
40.8		Results for all plates are recorded for each sample and did not exceed USP <797> Table 7 action levels (or internal action levels if more restrictive). **ISO Class 5: >1 cfu/m^3/device** **ISO Class 7: >10 cfu/m^3/device** **ISO Class 8: > 100 cfu/m^3/device** ***Inspector note: Per USP <797>, if two sampling media devices are collected at a single location, all recovered growth on each must be documented and action levels applied to each sampling media separately.***		
40.9		For any air sample locations exceeding action levels, pharmacy works with the assistance of a microbiologist to identify any microorganisms recovered to the genus level. ***Inspector note: Per USP <797>, an attempt must be made (meaning the lab attempted to identify the microorganisms and was unsuccessful).***		
40.10		For any areas that exceed action levels, an investigation is conducted to attempt to determine cause and a corrective action plan is implemented.		

NABP Number	Deficiency Number		Result	Notes
41.0		Are processes for sampling and monitoring **surfaces for viable particles** in compliance with USP <797> standards? ***Review six months of surface sampling data to verify. If no, go to the compliance statements.***		
41.1	149	**Surfaces** and pass-through chambers in the cleanroom suite and SCA are sampled for microbial contamination for each classified area. ***Inspector note: Sampling locations must include work surfaces in each classified room, the interior of each ISO Class 5 PEC, and all pass-through chambers connecting to classified areas. USP recommends samples be taken from: equipment contained within the PEC, staging or working area near the PEC, and frequently touched surfaces.***		
41.2	149	**Surfaces** within the cleanroom suite and SCA are sampled at the **frequencies** specified by USP for viable particle surface sampling. ***Inspector note: Category 1 and Category 2 CSP surface sampling frequency is monthly and Category 3 compounding is weekly, regardless of the frequency of compounding Category 3 CSPs.*** ***Additionally, surface sampling is to be performed within the PEC used to prepare Category 3 CSPs, at the end of each batch, before cleaning and disinfection occurs unless a self-enclosed robot is used. If a self-enclosed robot is used, frequency is at least once daily at the end of compounding operations.*** ***For facilities compounding any Category 3 CSPs, a surface sampling must be completed prior to assigning BUDs longer than the limits established in Table 13.***		
41.3		The pharmacy uses an appropriate microbiological growth media for sampling. ***Inspector note: An appropriate microbiological growth media means a surface sampling device with a raised convex surface for sampling flat surfaces is used that contain general microbial growth media that supports the growth of bacteria and fungi (eg, TSA supplemented with additives that neutralize effects of any disinfecting agent, eg, lecithin and polysorbate 80), accompanied by a COA that verifies that the media meets expected growth promotion, pH, and sterilization requirements. Per USP, "sterile swabs wetted with sterile water or a sterile neutralizing buffer may be used when sampling irregular surfaces and difficult-to-reach locations such as crevices, corners, and spaces between surfaces."***		
41.4		The pharmacy incubates all surface samples in compliance with USP <797> following the one media device method. ***Inspector notes: Per USP <797>, when using the one media device method, sampling media is to be covered, inverted, and incubated at 30°C-35°C for no less than 48 hours. Then, after examination and recording of results, further incubated at 20°C-25°C for no less than five additional days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***		
41.5		The pharmacy incubates all surface samples in compliance with USP <797> following the alternative two media device method. ***Inspector note: Per USP <797>, two samples may be collected for each sample location and incubated concurrently to shorten the overall incubation period. Both samples are TSA, or one sample is TSA and the other fungal media (eg, MEA or SDA). Media must be supplemented with neutralizing additives (eg, lecithin and polysorbate 80). Each sample is incubated in a separate incubator, one sample at 30°C-35°C for no less than 48 hours the other sample at 20°C-25°C for no less than five days. If fungal media is used, incubate at 20°C-25°C for no less than five days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***		

NABP Number	Deficiency Number		Result	Notes
41.6		Results for all plates are recorded for each sample and did not exceed USP <797> Table 8 action levels (or internal action levels if more restrictive). **ISO Class 5: >3 cfu/media device** **ISO Class 7: >5 cfu/media device** **ISO Class 8: > 50 cfu/media device** ***Inspector note: Per USP <797>, if two sampling media devices are collected at a single location, all recovered growth on each must be documented and action levels applied to each sampling media device separately.***		
41.7		For any surface sample locations exceeding action levels, pharmacy works with the assistance of a microbiologist to identify any microorganisms recovered to the genus level. ***Inspector note: Per USP <797>, an attempt must be made (meaning the lab attempted to identify the microorganisms and was unsuccessful).***		
41.8		For any areas that exceed action levels, an investigation is conducted to determine cause, and a corrective action plan is implemented.		
		Compounding Personal Hygiene and Garbing		
42.0		Does the pharmacy have a process to ensure all personnel entering the compounding area adhere to restrictions intended to minimize the risk of contamination in compliance with USP <797> standards? ***If no, go to compliance statements.***		
42.1	132	Compounding personnel are required to report conditions that may contaminate the sterile preparation and environment to the designated person(s). ***Inspector note: Per USP <797>, examples of conditions that have a higher risk of contaminating the CSP and sterile environment includes: rashes, recent tattoos, oozing sores, conjunctivitis, or active respiratory infections.***		
42.2	25d	The designated person(s) is responsible for evaluating whether compounding personnel should be excluded from working in compounding areas before their conditions have been resolved. ***Inspector note: Per USP <797>, the designated person(s) may permit accommodations as long as the quality of the CSP and environment will not be affected.***		
42.3	132	Any accommodations permitted by the designated person(s) are documented.		
42.4	132	Food (including mints, gum, etc) and drinks are not permitted in anterooms, buffer rooms, or segregated compounding areas.		
43.0		Does the pharmacy stock the necessary garb to ensure minimum garbing requirements are continuously met in compliance with USP <797> standards? ***If no, go to compliance statements.***		
43.1		The pharmacy stocks gowns and/or coveralls that are low-lint with sleeves that fit snugly around the wrists and an enclosed neck.		
43.2		The pharmacy stocks shoe covers that are low lint.		
43.3		The pharmacy stocks head covers that are low lint and cover the hair and ears.		
43.4		The pharmacy stocks facial hair covers (not masks) that are low-lint. ***If the pharmacy does not have personnel with beards, inspector should answer this statement as N/A.***		
43.5		The pharmacy stocks masks that are low lint.		
43.6		The pharmacy stocks sterile, powder-free gloves.		
43.7		**Category 1 and Category 2:** All non-disposable garb used to prepare Category 1 and Category 2 CSPs is laundered before reuse. ***If only disposable items are used, inspector should mark as N/A.***		

NABP Number	Deficiency Number		Result	Notes
43.8		**Category 3 only:** The pharmacy stocks low lint face and neck coverings that ensure no skin is exposed. ***Inspector note: This is an additional garbing requirement for facilities preparing any Category 3 CSPs.*** ***If the pharmacy does not prepare Category 3 CSPs, inspector should answer statement as N/A.***		
43.9		**Category 3 only:** The pharmacy stocks sterile, low lint outer garb (including sterile sleeves over gauntlet sleeves when a RABS is used). ***Inspector note: This is an additional garbing requirement for facilities preparing any Category 3 CSPs.*** ***If the pharmacy does not prepare Category 3 CSPs, inspector should answer statement as N/A.***		
43.10		**Category 3 only:** All non-disposable garb used to prepare Category 3 CSPs is **laundered and resterilized** with a validated cycle before each use. ***Document whether laundering and sterilization is performed in-house or by an outside vendor.*** ***If only disposable items are used, inspector should answer statement as N/A.***		
		Media-Fill		
44.0		Is the media-fill testing simulation performed by the pharmacy in compliance with USP <797> standards? ***Inspector note: Per USP, "When performing a media-fill test, simulate the most difficult and challenging aseptic compounding procedures encountered by the person replacing all the components used in the CSPs with soybean-casein digest media. The simulation must capture elements that could potentially affect the sterility of the CSP."*** ***If no, go to compliance statements.***		
44.1	25a, 26	The simulation captures factors associated with the length of the process that can pose contamination risk (eg, operator fatigue, quality of equipment).		
44.2	25a, 26	The simulation captures number of aseptic additions or transfers.		
44.3	25a, 26	The simulation captures number, type, and complexity of manipulations.		
44.4	25a, 26	The simulation captures number of personnel in the buffer room or SCA.		
44.5		Does the facility define "the most difficult and challenging procedures" and the rationale for how they are the most challenging? ***Inspector note: Best practice is for this to be documented in an SOP. Inspectors may also find this information documented on a training/competency assessment checklist. For complex/variety of compounding practices, inspectors may find additional media fills are completed (more than what is required by the USP chapters).***		
45.0		Are the pharmacy's media-fill storage, review, and preparation processes in compliance with USP <797> standards? ***If no, go to compliance statements.***		
45.1		If pharmacy uses commercial sterile microbial growth media, a COA was obtained. ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***		
45.2		The COA for the commercial sterile microbial growth media includes statements from the supplier that the lot of the growth media will support the growth of microorganisms. ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***		
45.3		Storage of commercial sterile microbial growth media is in accordance with manufacturer instructions. ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***		

NABP Number	Deficiency Number		Result	Notes
45.4		Commercial sterile microbial growth media is stored and used before its expiration date. ***Inspector note: Media is to be inoculated by the expiration date, meaning that the test needs to be started (not that incubation needs to be completed before the expiration date).*** ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***		
45.5		Sterile-to-sterile media-fill testing microbial growth media (non-commercial) was prepared and growth promotion capability was demonstrated prior to use, following USP <71>. ***If pharmacy only uses commercial sterile microbial growth media, inspector should answer statement as N/A.***		
45.6		Nonsterile starting components (commercially available nonsterile soybean-casein digest powder) are dissolved to make a 3% nonsterile solution, manipulated in a manner that simulates nonsterile-to-sterile compounding activities, with a minimum of one positive control container. ***If pharmacy does not perform sterile compounding using nonsterile ingredients, inspector should answer statement as N/A.***		
		Cleaning and Disinfection		
46.0		Is the pharmacy equipped with the necessary cleaning and disinfecting equipment and supplies that comply with USP <797> standards? ***If no, go to compliance statements.***		
46.1		All cleaning and disinfecting supplies (eg, wipers, sponges, pads, and mop heads), with the exception of tool handles and holders, are low lint.		
46.2		Reusable cleaning tools are made of cleanable materials (no wood handles or any other porous material).		
46.3		Reusable cleaning tools are dedicated for use in the classified areas or SCA and are not removed from these areas except for disposal.		
46.4		The pharmacy has the appropriate cleaners **EPA-registered disinfecting agent(s)** to adequately perform cleaning and disinfection. ***Inspector note: Examples of EPA-registered disinfectants include, but are not limited to: phenolics; oxidizers, such as peroxyacetic acid and sodium hypochlorite; quaternary ammonium; and hydrogen peroxide. If the agent is EPA-registered, a registration number will be on the label. Compounding personnel should have access to SDS and information/knowledge on dwell times. Per USP, Box 7, the pharmacy is to ensure the contact time specified by the manufacturer is achieved.*** ***Per USP, Inspector should check to see if agent is effective against Clostridium difficile.***		
46.5		The pharmacy has the appropriate **EPA-registered sporicidal agent(s)** to adequately perform sporicidal disinfection. ***Inspector notes: Examples of EPA-registered agents include but are not limited to: oxidizers such as peroxyacetic acid, sodium hypochlorite, and hydrogen peroxide. Compounding personnel should have access to SDS and information/knowledge on dwell times. Per USP, Box 8, the pharmacy is to ensure the contact time specified by the manufacturer is achieved.***		
46.6		All cleaning and disinfectant agents are appropriately labeled including expiration dates. ***Inspector should verify that no expired agents are present.***		
46.7		When used in the PEC, any cleaning and disinfecting agents that are not "ready-to-use" formulations are diluted using sterile water. ***If only ready-to-use formulations are used, inspector should answer statement as N/A.***		

NABP Number	Deficiency Number		Result	Notes
47.0		Does the pharmacy's documented **cleaning and disinfection** activities for surfaces in the classified areas and/or SCA comply with the **frequencies** specified in USP <797> Table 10? ***Review cleaning logs to verify. If no, go to compliance statements.***		
47.1		All interior surfaces of the PEC are cleaned and disinfected on days when compounding occurs.		
47.2		All interior surfaces of the PEC are cleaned and disinfected when surface contamination is known or suspected.		
47.3		The removable work tray inside the PEC is cleaned and disinfected on days when compounding occurs. ***If the PEC is not equipped with a removeable work tray, inspector should answer statement as N/A.***		
47.4		All equipment inside the PEC is cleaned and disinfected on days when compounding occurs.		
47.5		All work surfaces outside of the PEC (eg, counters, work tables) are cleaned and disinfected on days when compounding occurs.		
47.6		All pass-through chambers are cleaned and disinfected on days when compounding occurs. ***If the pharmacy is not equipped with a pass-through chamber, inspector should answer statement as N/A.***		
47.7		Floors in the buffer room, anteroom, and/or SCA are cleaned and disinfected on days when compounding occurs.		
47.8		Sinks used for hand hygiene are cleaned and disinfected on each day of use.		
47.9		Walls, doors, and door frames are cleaned and disinfected monthly.		
47.10		Storage and shelving bins are cleaned and disinfected monthly.		
47.11		All equipment outside the PEC are cleaned and disinfected monthly. ***Inspector note: Equipment in the SEC/SCA may include, but is not limited to: carts, refrigerators, computers, barcode readers, and label printers.***		
47.12		Ceilings in the buffer room and anteroom are cleaned and disinfected monthly. ***If the pharmacy performs compounding only in a SCA, inspector should answer statement as N/A.***		
47.13		Ceilings in the SCA are required to be cleaned and disinfected only when visibly soiled and when surface contamination is suspected. ***If the pharmacy performs compounding only in a cleanroom suite, inspector should answer statement as N/A.***		
47.14		The surface of the removable work tray and the area underneath the removable work tray of the PEC is cleaned and disinfected monthly. ***If the PEC is not equipped with a removable work tray, inspector should answer statement as N/A.***		
48.0		Does the pharmacy's documented application of **sporicidal disinfectant** on surfaces comply with the **frequencies** specified for each CSP category in USP <797> Table 10? ***Inspector note: Per USP <797>, if the pharmacy prepares any Category 3 CSPs, the cleaning requirements for Category 3 must be followed at all times regardless of whether a Category 3 CSPs is prepared on any given day.*** ***Review cleaning logs to verify. If no, go to compliance statements.***		
48.1		**Sporicidal disinfectant** is applied to all interior surfaces of the **PEC** at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.***		

NABP Number	Deficiency Number		Result	Notes
48.2		Sporicidal disinfectant is applied to equipment inside the PEC at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.***		
48.3		Sporicidal disinfectant is applied to work surfaces outside the PEC (eg, counters, work tables) at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, application frequency is monthly. For any Category 3 compounding, application frequency is weekly.***		
48.4		Sporicidal disinfectant is applied to surfaces in the pass-through chambers at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.*** ***If the facility is not equipped with a pass-through chamber, inspector should answer statement as N/A.***		
48.5		Sporicidal disinfectant is applied to the floors in the buffer room, anteroom, and SCA at least monthly. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.***		
48.6		Sporicidal disinfectant is applied to walls, doors, and door frames at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***		
48.7		Sporicidal disinfectant is applied to storage shelving and bins at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***		
48.8		Sporicidal disinfectant is applied to equipment stored outside the PEC at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***		
48.9		Sporicidal disinfectant is applied to ceilings in the buffer room, anteroom, and SCA at least monthly. ***Inspector note: Per USP <797>, Table 10, the application frequency is monthly for all category types. Per USP, ceilings of the SCA are required to be cleaned, disinfected, and applied with sporicidal disinfectant only when visibly soiled and when surface contamination is suspected. The SCA may not have an accessible ceiling.***		
48.10		Sporicidal disinfectant is applied to sinks used for hand hygiene at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***		
48.11		Sporicidal disinfectant is applied to the work surface of the removable tray in the PEC and area underneath the removable work tray at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.*** ***If the PEC is not equipped with a removable work tray, inspector should answer statement as N/A.***		

NABP Number	Deficiency Number		Result	Notes
		Components		
49.0		Does the pharmacy compound CSPs using active pharmaceutical ingredients (APIs) and non-API components? ***Inspector note: Per USP <797>, non-API components may include pharmaceutical excipients, sterile containers, and container closure systems.*** ***If the pharmacy does not compound using API or non-API components, inspector should answer this question as N/A.***		
50.0		Is the pharmacy's selection of active API and non-API components in compliance with USP <797> standards? ***Verify by selecting products from the shelf of different suppliers and ask to see the COAs for those products. If no, go to compliance statements.***		
50.1		**APIs**: APIs used are compliant with the criteria in the USP–NF monograph, if one exists. ***If pharmacy does not compound CSPs that have a USP monograph, inspector should answer this statement as N/A.***		
50.2		**APIs:** All APIs used have a COA that includes the specifications (eg, compendial requirements for quality) and that test results for the component show that the API meets expected quality.		
50.3		**APIs:** All APIs used are manufactured by an FDA-registered facility. ***Inspector note: This is a Federal Food, Drug, and Cosmetic Act, Section 503A, requirement as well. If the API comes from a repackager, the pharmacy must be able to confirm the manufacturer of the API was registered as an Establishment with FDA.***		
50.4		All **non-API components** comply with the criteria in the USP–NF monograph, if one exists.		
50.5		All **non-API components** are accompanied by documentation (eg, COA, labeling) that include the specifications and test results and shows that the component meets the specifications.		
50.6		All **non-API components** used are manufactured by an FDA-registered facility. ***Inspector note: Per USP <797>, "If a component cannot be obtained from an FDA-registered facility, the designated person(s) must select an acceptable and reliable source (see USP <1197> Good Distribution Practices for Bulk Pharmaceutical Excipients). The compounding facility must establish the identity, strength, purity, and quality of the ingredients obtained from that supplier by reasonable means. Reasonable means may include but are not limited to visual inspections, evaluation of a COA supplied by the manufacturer, and/or verification by analytically testing a sample to determine conformance with the COA or other specifications."***		
51.0		Does the pharmacy have processes in place to evaluate API and non-API components upon receipt and before use in compliance with USP <797> standards? ***Inspector note: Non-API components may be defined as excipients, containers, and container closure systems.*** ***If no, go to compliance statements.*** ***If the pharmacy does not compound with API or other non-API components, inspector should answer question as N/A.***		
51.1		APIs or other components have been evaluated for use in sterile drug preparation. ***Inspector note: Per USP <797>, "Components labeled with 'not for pharmaceutical use,' 'not for injectable use,' 'not for human use' or an equivalent statement must not be used to compound for these purposes."*** ***If no, photograph and describe in the notes column. Request copies of the invoices for products with these types of labels.***		

NABP Number	Deficiency Number		Result	Notes
51.2		Upon receipt of each lot of a component, personnel verify the labeling and condition of each component and examine the external packaging for evidence of deterioration and other aspects of unacceptable quality (eg, outer packaging is damaged, temperature-sensing indicators show that the component has been exposed to excessive temperatures).		
51.3		Each lot of commercially available sterile, depyrogenated containers and container-closure systems are accompanied by a COA or other documentation showing conformance with established specifications for sterility and depyrogenation requirements.		
51.4		The date of receipt by the pharmacy is clearly marked on each API or component package that lacks a vendor expiration date and are assigned and labeled with an expiration date not to exceed one year after receipt by the pharmacy.		
51.5		All components are reinspected before use. ***Inspector note: Per USP <797>, all packages must be inspected to detect container breaks, looseness of the cap or closure, and deviation from the expected appearance, aroma, and/or texture of the contents that might have occurred during storage. Sterile container closures are visually reinspected to ensure that they are free from defects that could compromise sterility and that they are otherwise suitable for their intended use.***		
51.6		Any component found to be of unacceptable quality upon receipt or reinspection prior to use is promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.		
51.7		Any other lots of that component from that vendor are examined to determine whether other lots have the same defect.		
		Equipment and Supplies		
52.0		Is the pharmacy equipped with the appropriate supplies and equipment used for compounding in compliance with USP <797> standards? ***If no, go to compliance statements.***		
52.1		Supplies (eg, beakers, utensils, needles, syringes, filters, and tubing sets) that contact components are not reactive, additive, sorptive, and do not alter the quality of sterile compounded preparation. ***Inspector note: The appropriate supplies are available as applicable to the type of CSPs prepared (eg, non-PVC, silicone-free, able to withstand high heat, able to be sterilized).***		
52.2		Any supplies that are in direct contact with CSPs are sterile and/or depyrogenated.		
52.3		The equipment must be able to be cleaned using the required agents and tools without damaging the equipment and/or contaminating the compounded preparation. ***Inspector note: Equipment used in compounding are of suitable composition and the surfaces that contact components are not reactive or sorptive.***		
52.4		When nonsterile ingredients, products, components, or devices (eg, non-sterile APIs and nonsterile vials and closures) are used for compounding, the pharmacy has the appropriate equipment to sterilize the finished product. Per USP, "Injectable compounded preparations that contain nonsterile components or that come into contact with nonsterile devices (eg, containers, tubing) during any phase of the compounding procedure must be sterilized within 6 hours after completing the preparation to minimize the generation of bacterial endotoxins in CSPs." ***If the pharmacy does not perform compounding that requires sterilization, inspector should answer statement as N/A.***		
53.0		Does the pharmacy operate and maintain records for all equipment used for compounding in accordance with manufacturer specifications and USP <797> standards? ***If no, go to compliance statements.***		

NABP Number	Deficiency Number		Result	Notes
53.1		Automated, mechanical, or electronic equipment (monitoring equipment, autoclaves, ovens, etc) are periodically inspected and calibrated yearly or in accordance with the equipment manufacturer guidelines.		
53.2		Automated compounding devices (ACDs) and other similar equipment (single channel or multi-channel) are assessed for accuracy and calibrated daily, prior to initial use, and a daily record is maintained. ***Inspector note: Per USP, "The precision of the equipment can be monitored based on an assessment of day-to-day variations in its accuracy measures. Compounding personnel must maintain a daily record of the accuracy measurements on the days the equipment is in use. Corrective actions must be implemented if accuracy measurements are outside the manufacturer's specification."***		
53.3		Incubators used for environmental and personnel monitoring are placed in a location outside of the sterile compounding area and calibrated in accordance with manufacturer's instructions. ***If the pharmacy does not incubate samples and or/media-fills in-house, inspector should answer statement as N/A.***		
53.4		Incubators used for environmental and personnel monitoring are monitored for temperature during incubation periods either manually or by use of a continuous recording device. ***Inspector note: Incubators store media at 20˚C-25˚C and 30˚C-35˚C. If the pharmacy has more than one incubator, review records for both incubators.*** ***View incubator temperature records to verify. Evaluate the size of the incubator and volume of media it can store. If the pharmacy does not incubate samples and/or media-fills in-house, inspector should answer statement as N/A.***		
Compounding Personnel Observation - Inspector ***must*** observe personnel performing compounding and related activities. This section will require the inspector to observe the staff while performing compounding and related activities. If the inspector is unable to view activities from a window or other observation area, it is expected they will gown/garb into compounding area. It is acceptable for pharmacy staff to perform mock compounding activities (with sterile saline or other drug) as long as all observations can be viewed.				
54.0		**Personnel Preparation Observation:** Before entering the compounding area, do compounding personnel remove any items that are not easily cleanable or are not necessary for compounding in compliance with USP <797> standards? ***If no, go to compliance statements.***		
54.1	132	All outer garments such as hats, scarves, sweaters, bandanas, vests, coats, and jackets are removed.		
54.2	132	Makeup and/or cosmetics are removed.		
54.3	132	All hand, wrist, and other exposed jewelry, including piercings such as earrings, lip or eyebrow piercings, etc, are removed and any jewelry that cannot be removed is covered.		
54.4	132	Earbuds or headphones are removed.		
54.5	132	Electronic devices that are not necessary for compounding or other required tasks are prohibited from entering the compounding areas.		
54.6	132	Nails are kept clean and neatly trimmed.		
54.7	132	Any nail polish, artificial nails, or extenders are removed.		
54.8	132	If worn, eyeglasses are wiped. ***If none of the pharmacy staff wear glasses, inspector should answer statement as N/A.***		
54.9	132	Any accommodations permitted by the designated person(s) have been documented. ***Inspector note: Per USP <797>, accommodations may be permitted as long as the quality of the CSP and environment will not be affected.***		
55.0		**Hand Hygiene Observation:** Were compounding personnel entering the compounding area observed performing the appropriate hand washing procedures in compliance with USP <797> standards? ***If no, go to compliance statements.***		

NABP Number	Deficiency Number		Result	Notes
55.1	132	All personnel entering the compounding area performed hand hygiene.		
55.2	132	The order of hand washing was performed in the appropriate sequence in relation to the placement of the sink. ***Inspector note: If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb.***		
55.3	132	Fingernails are cleaned under warm running water using a disposable nail cleaner (eg, nail pick). ***Inspector note: During observations, inspect whether nail picks are available for use when performing hand hygiene.***		
55.4	132	Brushes are not used for hand hygiene.		
55.5	132	Hands and forearms are washed up to the elbows with soap and warm water for at least 30 seconds. ***Inspector note: Compounding personnel describe method for ensuring they have washed for 30 seconds (example: clock or timer is available near the sink).***		
55.6	132	Soap containers are not refilled or topped off.		
55.7	132	Hands and forearms are completely dried up to the elbows with low-lint disposable towels or wipers.		
55.8	132	Hand dryers are not used for hand hygiene.		
56.0		**Garbing Observation:** Were compounding personnel observed following the appropriate garbing procedures in compliance with USP <797> standards? ***If no, go to compliance statements.***		
56.1	132	All personnel entering the compounding area are fully garbed (with the required garb as determined by the facility SOPs).		
56.2	132	Compounding personnel entering the cleanroom suite and/or SCA adhere to the minimum garbing requirements in USP <797>. ***Inspector note: Per USP <797>, additional garbing requirements must be continuously met in the buffer room where Category 3 CSPs are prepared, regardless of whether Category 3 CSPs are compounded on a given day.***		
56.3	132	Donning procedures are performed in an order that reduces the risk of contamination. ***Inspector note: USP recommends (not requires) the donning procedure to be performed in the anteroom.*** ***If no, inspector must describe in the notes column why a risk of contamination is a concern.***		
56.4	132	Doffing procedures are performed in an order that reduces the risk of contamination.		
56.5	132	The order of garbing was performed in the appropriate sequence in relation to the placement of the sink. ***Inspector note: If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb.***		
56.6	132	Sterile gloves are donned in a classified room or SCA.		
56.7	132	Skin is not exposed inside the ISO Class 5 PEC.		
56.8	132	Garb is replaced immediately if it becomes visibly soiled or if its integrity is compromised.		
56.9	132	**Category 1 and Category 2 only:** Upon exit of the compounding area, all garb (except for gowns) is discarded or laundered prior to reuse. ***Inspector note: Gowns (disposable and non-disposable) may be reused within the same shift by the same person only if stored appropriately.*** ***If the facility prepares any Category 3 CSPs, additional garbing requirements must be followed and gowns must not be reused, inspector should answer statement as N/A.***		

NABP Number	Deficiency Number		Result	Notes
56.10	132	**Category 1 and Category 2 only:** Gowns reused within the same shift and by the same person are maintained in a manner that prevents contamination. ***Inspector note: Per USP <797>, gowns stored for reuse must be maintained in a classified area or adjacent to or within the SCA in a manner that prevents contamination (eg, away from sinks to avoid splashing).*** ***If the facility prepares any Category 3 CSPs, additional garbing requirements must be followed and gowns must not be reused; inspector should answer statement as N/A.***		
57.0		List the name(s) of the CSPs observed by the inspector as part of live compounding demonstration.		
58.0		**Compounding Observation:** Are compounding personnel observed using the appropriate aseptic technique that ensures the quality of the CSP and the environment is maintained in compliance with USP <797> standards? ***If no, go to compliance statements.***		
58.1	21, 21a, 22	All sterile compounding is performed in a PEC with ISO Class 5 conditions or better. ***If the pharmacy only performs immediate use compounding, inspector should answer this statement as N/A.***		
58.2	21, 21a	**Category 2 and Category 3 only:** All PECs are placed in a cleanroom suite. ***Inspector note: Per USP, "If compounding only Category 1 CSPs, the PEC may be placed in an unclassified SCA."*** ***If the pharmacy only prepares Category 1 CSPs, inspector should answer this statement as N/A.***		
58.3		Compounding personnel ascertain before use that components are of the correct identity, appropriate quality, within the expiration date, and have been stored under the proper conditions.		
58.4		All items are wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% IPA prior to being introduced into the clean side of the anteroom, placed into a pass-through chamber, and/or brought into the SCA. ***Inspector note: The wiping procedure or agents used should not compromise the packaging integrity or render the product label unreadable. Disinfectant dwell time minimums, as specified by the manufacturer, are to be followed.***		
58.5		Before any item is introduced into the PEC, it is wiped with sterile 70% IPA using sterile low-lint wipers and allowed to dry before use. ***Inspector note: Per USP, "When sterile items are received in sealed containers designed to keep them sterile until opening, the sterile items may be removed from the covering as the supplies are introduced into the ISO Class 5 PEC without the need to wipe the individual sterile supply items with sterile 70% IPA. The wiping procedure must not render the product label unreadable."***		
58.6		Aseptic processes and manipulations are performed in a manner intended to minimize the risk of contamination. ***Inspector note: Observe the compounder's technique to ensure proper aseptic technique is utilized such as: preparation occurs in the direct compounding area (DCA); the compounder does not interrupt first air during the compounding process; proper set up of equipment, supplies, and components that ensure first air is not interrupted; the compounder handles the syringe in a manner that does not introduce contaminates (touch contamination on the plunger rod); proper entry and exit of materials in ISO Class 5 PEC; and frequent sanitization of gloves.***		
58.7		All critical sites (eg, vial stoppers, ampule necks, and IV bag septums) are wiped with sterile 70% IPA in the PEC and allowed to dry before puncturing.		
58.8		Gloves are disinfected with sterile 70% IPA immediately before compounding and regularly throughout the compounding process. ***Inspector note: Per USP, best practice is to re-sanitize each time hands re-enter the PEC. This may not occur when compounder is staging the next batch.***		

NABP Number	Deficiency Number		Result	Notes
58.9		Gloves are regularly inspected for holes, punctures, or tears, and are replaced immediately if such defects are detected.		
59.0		Do compounding personnel adhere to the USP established time limits for components after initial puncture or entry in compliance with USP <797> standards? ***Look at punctured, stored containers and confirm if puncture time or BUD is noted on the container and stored within time limits. If no, go to compliance statements.***		
59.1		Single dose containers (entered or punctured only in an ISO Class 5 air or cleaner air) are not used beyond 12 hours after initial puncture or entry or assigned BUD, whichever is shorter. ***Inspector note: This applies to conventionally manufactured single-dose vials, compounded single-dose CSPs used as components, and CSP stock solutions. The labeled storage requirements during that 12-hour period must be maintained. Additionally, per USP, "This time limit for entering or puncturing (a single-dose CSP or CSP stock solution) is not intended to restrict the BUD of the final CSP."***		
59.2		Multiple-use containers are not used for more than 28 days after initial puncture or entry, manufacturer specifications, or assigned BUD, whichever is shorter. ***Inspector note: This applies to conventionally manufactured multiple-dose vials and compounded multiple-dose CSPs used as components. Multiple-dose CSPs are required to meet the criteria for antimicrobial effectiveness testing (USP <51>) and must be stored under the conditions upon which its BUD is based (eg, refrigerator or controlled room temperature).***		
59.3		The remaining contents of opened single-dose ampules (or vials where container closure system has been removed) are discarded immediately. ***Inspector note: Ampules or vials where the container closure system has been removed must not be stored for any time period.***		
59.4		Pharmacy bulk package containers of sterile drugs for parenteral use are only entered or punctured in an ISO Class 5 PEC. ***Inspector note: Per USP, the pharmacy bulk package system must be used according to the manufacturer's labeling.***		
60.0		**Inspect several different finished compounded sterile preparations.** Are all the finished compounded sterile preparations free from any evidence of particulates, filaments, floaters, or signs of contamination? ***Inspector note: Additionally, list the name(s) of the compounded preparation(s) observed; description of type of contamination suspected (eg, filament or floater); number of preparations affected (eg, two of the five vials on the shelf); lot or batch information; BUD assigned; and collect photographs, copy of MFR, and CR.***		
61.0		Are there procedures for in-process checks performed by a pharmacist? ***Inspector note: In-process checks are safety steps for complex, multi-step compounding processes or high risk drugs or high risk populations (eg, neonates). 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. Some checks may be done retrospectively and with the assistance of technology.***		

NABP Number	Deficiency Number		Result	Notes
62.0		**Cleaning and Disinfection Observation:** Does the pharmacy perform cleaning and disinfection activities in compliance with USP <797> standards? ***If inspector is unable to observe cleaning activities (due to timing of compounding activities observed), inspector should interview compounder(s) to have them walk through their normal process. If this occurs, inspector should record in notes column "process only."*** ***If no, go to compliance statements.***		
62.1		All cleaning and disinfection activities are performed by appropriately garbed personnel.		
62.2		Cleaning and disinfection are performed on all surfaces in the classified area and SCA.		
62.3		Cleaning is performed in the direction of clean to dirty areas.		
62.4		Reusable cleaning tools are disinfected prior to and after each use.		
62.5		Only sterile cleaning, disinfecting, and sporicidal agents are permitted for use in the PEC. ***Inspector note: If pharmacy utilizes non-ready to use (RTU) agents, they must be diluted with sterile water. Per USP, "Once opened, sterile cleaning and disinfecting agents and supplies (eg, closed containers of sterile wipers) and sterile 70% IPA may be reused for a time period specified as by the manufacturer and/or described in the facility written SOPs."***		
62.6		Only sterile supplies and equipment are permitted for use in the PEC. ***Inspector notes: Non-disposable cleaning tools or handles must be properly disinfected prior to entering the PEC and prior to use.***		
62.7		Compounding personnel are using the appropriate sterile cleaning, disinfecting, and sporicidal agents within the PEC.		
62.8		Compounding personnel are using the appropriate cleaning and disinfecting procedures and techniques within the PEC. ***Inspector note: Per USP, "All cleaning, disinfecting, and application of sporicidal disinfectants must be documented according to the facility's SOPs"; "Cleaning must be performed in the direction of clean to dirty areas"; and when 70% sterile IPA is used, it is used last and allowed to dry. There are differing opinions on the best order of cleaning.*** ***Procedure includes using a sterile low-lint wiper to all surfaces. Allow surfaces to dry completely before beginning compounding.***		
62.9		The manufacturer's directions or published data for the minimum contact time is followed for each of the cleaning, disinfecting, and sporicidal disinfectant used. ***Per USP, contact times should be included in the SOP based on the agent used.***		
62.10		Sterile 70% IPA is applied to all surfaces in the ISO Class 5 PEC at the frequencies specified by USP during active compounding. ***Inspector note: Per USP <797>, sterile 70% IPA must be applied: immediately before initiating compounding procedures, to the work surface of the PEC at least every 30 minutes (if the compounding process takes 30 minutes or less), to the work surface of the PEC immediately after compounding (when the compounding process takes more than 30 minutes), after each batch or lot is completed, and after cleaning and disinfecting.***		
		Sterilization and Depyrogenation		
63.0		Does the pharmacy compound preparations with any nonsterile starting components?		

NABP Number	Deficiency Number		Result	Notes
64.0		Are injectable compounded preparations that contain nonsterile components or that come into contact with nonsterile devices (eg, containers, tubing) during any phase of the compounding procedure, sterilized within six hours after completing the preparation? ***If no, describe observations and collect a copy of the master formulation record, a copy of the compounding record, and a copy of the process for sterilization.*** ***If the pharmacy does not compound with nonsterile components or devices, or they only compound sterile ophthalmic and/or sterile drugs administered by inhalation, inspector should answer question as N/A.***		
65.0		**Filter Sterilization:** Does the pharmacy use the appropriate type of sterilization method, equipment, documentation, and testing in compliance with USP <797> standards? ***View compounding records for CSPs sterilized by filtration to verify.*** ***Inspector note: The sterilization method used must sterilize the CSP without degrading its physical and chemical stability (eg, affecting its strength, purity, or quality) or the packaging integrity.*** ***If no, go to compliance statements.*** ***If the pharmacy does not use this sterilization method, inspector should answer question as N/A.***		
65.1		Sterilization by filtration is performed in an ISO 5 environment.		
65.2		Filters used have enough capacity to filter the required volumes. ***Inspector note: Per USP, "The filter dimensions and the CSP to be sterilized by filtration should permit the sterilization process to be completed without the need for replacement of the filter during the process."***		
65.3		The 0.2 micron sterile micro-porous membrane filter used to sterilize CSP solutions is chemically and physically compatible with the CSP. ***Inspector note: Per USP <797>, sterilizing filters must be appropriate for pharmaceutical use. Sterilizing filters labeled "for laboratory use" or equivalent must not be used. "Sterilizing filters must be certified by the manufacturer to retain at least 10^7 microorganisms of a strain of Brevundimonas diminuta per square centimeter of upstream filter surface area under conditions similar to those in which the CSPs will be filtered (ie, pressure, flow rate, and volume filtered)."***		
65.4		Confirmation of filter integrity (bubble testing) is performed and documented for each filter used with each batch sterilized by filtration. ***Inspector note: If multiple filters are required for the compounding process, each of the filters must be tested.*** ***If no, collect a copy of the master formulation record and compounding record.***		
65.5		A prefiltration step is performed for any CSPs that are known to contain excessive particulate matter. ***Inspector note: The prefiltration step consists of using a filter with a larger nominal pore size (eg, 1.2 micron) or a separate filter of larger nominal pore size should be placed upstream of (ie, prior to) the sterilizing filter to remove gross particulate contaminants before the CSP is passed through the sterilizing-grade filter.***		
65.6		CSPs that are prepared using a filter that failed integrity tests are either discarded or, after investigating the cause of the failure and selection of an appropriate filter, refiltered for sterilization not more than one additional time. ***If no, collect a copy of the master formulation record and compounding record.***		
65.7		Single-use filters are only used once.		

NABP Number	Deficiency Number		Result	Notes
66.0		**Steam Sterilization:** Does the pharmacy use the appropriate type of sterilization method, equipment (autoclave), documentation, and testing in compliance with USP <797> standards? ***Inspector note: The sterilization method used must sterilize the CSP without degrading its physical and chemical stability (eg, affecting its strength, purity, or quality) or the packaging integrity.*** ***View documentation on compounding records for CSPs sterilized by steam to confirm. If no, go to compliance statements.*** ***If the pharmacy does not use this sterilization method, inspector should answer question as N/A.***		
66.1		The pharmacy has evaluated if steam sterilization would cause degradation of the drug. ***Inspector note: Per USP, compounded preparations that are degraded by moisture, pressure, or temperatures used may not be sterilized by steam heat.***		
66.2		Steam supplied is free of contaminants and generated using water per manufacturer's specifications.		
66.3		Solutions are passed through a 1.2 micron or smaller filter into the final containers to remove particulates before sterilization.		
66.4		Items are placed in the autoclave in a manner that allows steam to reach them without entrapment of air. ***Inspector note: The pharmacy should have the autoclave cycle validated for the size of the batch, sterilization temperature, and sterilization time to ensure the load will be sterile.***		
66.5		Sealed containers used are able to generate steam internally (eg, small amount of water in empty crimped vials).		
66.6		The appropriate biological indicators (USP <1229>) are used to verify the effectiveness of each sterilization run or load and documented in the compounding record. ***Inspector note: Per USP <797>, "The effectiveness of steam sterilization must be verified and documented with each sterilization run or load by using appropriate biological indicators, such as spores of Geobacillus stearothermophilus (ATCC 12980, ATCC 7953, or equivalent; see Biological Indicators for Sterilization USP <1229.5>), and other confirmation methods such as physicochemical indicators (see Physicochemical Integrators and Indicators for Sterilization USP <1229.9>). The date, run, and load numbers of the steam sterilizer used to sterilize a CSP is documented in the compounding record."***		
66.7		All items are directly exposed to steam under adequate pressure for the length of time necessary as determined by use of appropriate biological indicators to render the items sterile. ***Inspector note: Per USP <797>, the duration of the exposure period must include sufficient time for the entire contents of the CSP and other items to reach the sterilizing temperature. The CSP and other items must remain at the sterilizing temperature for the duration of the sterilization period (an example provided in the chapter is 20-60 minutes at 121°C saturated steam under a pressure of 15 psi, depending on the volume or size of the CSP being sterilized).*** ***Any parameters for the autoclave must be set through validation.***		
66.8		A calibrated data recorder or chart is used to monitor each cycle and to examine for cycle irregularities (eg, deviations in temperature or pressure) and results documented on the CR.		

NABP Number	Deficiency Number		Result	Notes
67.0		**Dry Heat Sterilization:** Does the pharmacy use the appropriate type of sterilization method, equipment, documentation, and testing in compliance with USP <797> standards? ***Inspector note: The sterilization method used must sterilize the CSP without degrading its physical and chemical stability (eg, affecting its strength, purity, or quality) or the packaging integrity. USP <1229.8> also applies.*** ***View documentation on compounding records for CSPs sterilized by dry heat to confirm. If no, go to compliance statements.*** ***If the pharmacy does not use this sterilization method, inspector should answer question as N/A.***		
67.1		The pharmacy has the appropriate dry heat sterilization equipment. ***Inspector note: Dry heat sterilization is usually performed in an oven designed for sterilization at 160°C or higher. The dry heat oven should be able to get to the appropriate temperature and pressure, for example, not be a toaster oven.***		
67.2		Solutions are passed through a 1.2 micron or smaller filter into the final containers to remove particulates before sterilization.		
67.3		During sterilization, sufficient space is left between materials to allow for circulation of hot air.		
67.4		CSPs and other items are exposed to dry heat for the length of time necessary for all items to reach sterilizing temperature of 160°C or higher. ***Inspector note: Per USP <797>, if lower temperatures are used, they are validated by biological indicators (see USP <1229.8>, Validation of Dry Heat Sterilization, Biological Indicators). The calibrated oven must be equipped with temperature controls and a timer.***		
67.5		The appropriate biological indicators are used to verify the effectiveness each sterilization run or load and documented in the compounding record. ***Inspector note: Per USP <797>, "The effectiveness of dry heat sterilization must be verified and documented with each sterilization run or load by using appropriate biological indicators, such as spores of Bacillus atrophaeus (ATCC 9372; see Biological Indicators for Sterilization USP <1229.5>) and other confirmation methods (e.g., temperature-sensing devices). The date, run, and load numbers of the dry heat oven used to sterilize a CSP must be documented in the CR."***		
67.6		A calibrated data recorder or chart is used to monitor each cycle and the data is reviewed to identify cycle irregularities (eg, deviations in temperature or exposure time) and results documented on the CR.		
68.0		**Dry Heat Depyrogenation:** Is the appropriate depyrogenation method used and documented in compliance with USP <797> standards? ***View documentation records of items depyrogenated to confirm.*** ***If the pharmacy does not use this method, inspector should answer question as N/A.***		
68.1		Glassware, metal, and other thermostable containers are exposed to dry heat for the length of time necessary for all items to be rendered pyrogen free.		
68.2	25	The effectiveness of the dry heat depyrogenation cycle is established and documented. ***Inspector note: Per USP <797>, this must be done initially, re-established any time there are changes made to the cycle (eg, load conditions, duration, temperature), and verified at least annually by using endotoxin challenge vials (ECVs) to demonstrate that the cycle is capable of achieving a ≥ 3-log reduction in endotoxins (see Bacterial Endotoxins Test USP <85>). The verification must be documented.***		

NABP Number	Deficiency Number		Result	Notes
68.3		Items that are not thermostable are depyrogenated by multiple rinses with sterile, nonpyrogenic water (eg, sterile water for injection or sterile water for irrigation) and then thoroughly drained or dried immediately before use in compounding. ***Inspector note: USP <1228.4> Depyrogenation by Rinsing also applies.***		
		Master Formulation and Compounding Records **Inspector should review a minimum of five (5) master formulation records and five (5) compounding records.**		
69.0		Are **Master Formulation Records (MFRs)** created and maintained in compliance with USP <797> standards? ***If no, go to A14compliance statements.***		
69.1	130	The pharmacy creates and maintains MFRs for CSPs that are prepared for more than one patient.		
69.2	130	MFR changes and alterations are approved and documented according to the pharmacy's SOPs.		
69.3	130	The pharmacy creates and maintains MFRs for CSPs that are prepared from nonsterile ingredients.		
69.4	130	The MFR includes the name, strength or activity, and dosage form of the sterile compounded preparation.		
69.5	130	The MFR includes the identities and amounts of all ingredients.		
69.6	130	The MFR includes the type and size of container closure.		
69.7	130	The MFR includes complete instructions for preparing the sterile compounded preparation, including equipment, supplies, a description of the compounding steps, and any special precautions.		
69.8	130	The MFR includes a physical description of the final CSP.		
69.9	130	The MFR includes the BUD and storage requirements.		
69.10	130	The MFR includes the reference source to support the stability of the CSP.		
69.11	130	The MFR includes quality control procedures (eg, pH testing, filter integrity testing).		
69.12	130	The MFR includes other information as needed to describe the compounding process and ensure repeatability (eg, adjusting pH and tonicity, sterilization method).		
69.13	130	The MFR includes all required release tests, and if applicable, sterility test methods, process, number and endotoxin test and limits.		
70.0		Are **Compounding Records (CR)** created and maintained in compliance with USP <797> standards? ***Inspector note: Per USP, a prescription or medication order or label may serve as the CR. Also, a copy of the MFR can be made that contains spaces for recording the information needed to complete the CR (eg, both the MFR and CR are on the same document/form). A CR may be kept electronically, if readily retrievable, as long as it contains all required information.*** ***If no, go to compliance statements.***		
70.1	130	The pharmacy creates and maintains CRs for all for immediate-use CSPs prepared for more than one patient. ***Inspector note: if pharmacy does not prepare any CSPs for immediate-use, inspector should answer compliance statement as N/A.***		
70.2	130	The pharmacy creates and maintains CRs for all Category 1, Category 2, and Category 3 CSPs.		
70.3	130	The CR includes the name, strength or activity, dosage form of the CSP, and (if applicable) the MFR reference.		
70.4	130	The CR includes the date and time of preparation.		
70.5	130	The CR includes an assigned internal identification number (eg, prescription, order, or lot number).		

NABP Number	Deficiency Number		Result	Notes
70.6	130	The CR includes the identity of the individual(s) involved in the compounding process.		
70.7	130	The CR includes identity of the individual(s) verifying the final CSP.		
70.8	130	The CR includes the name of each component.		
70.9	130	The CR includes the vendor/manufacturer, lot number, and expiration date for each component. ***Inspector note: this is required for CSPs prepared for more than one patient and for CSPs prepared from nonsterile ingredient(s).***		
70.10	130	The CR includes the weight or volume of each component.		
70.11	130	The CR includes the strength or activity of each component.		
70.12	130	The CR includes the total quantity compounded.		
70.13	130	The CR includes the final yield (eg, quantity, containers, number of units).		
70.14	130	The CR includes the assigned BUD and storage requirements.		
70.15	130	The CR includes results of quality-control procedures (eg, visual inspection, filter integrity testing, pH testing).		
70.16	130	The CR includes calculations made to determine and verify quantities and/or concentrations of components. ***Inspector note: Per USP, "If applicable, the CR must also include…Calculations."***		
70.17	20b	The CR is verified by the pharmacist for appropriateness and accuracy with in-process and final checks. ***Inspector note: "Documentation must comply with all laws and regulations of the applicable regulatory jurisdiction."***		
71.0		Are the pharmacy's labels for CSPs in compliance with USP <797> standards and display all required information? ***If no, go to compliance statements.***		
71.1	130a	Information on the label is prominently and legibly displayed. ***Inspector note: Definition of labeling includes other accompanying materials with the CSP, which includes, "written, printed, or graphic matter on the immediate container or on or inside any package or wrapper in which it is enclosed." The shipping container is not included in the definition of the "label."***		
71.2	130a	Labeling meets any state or federal regulatory requirements.		
71.3	130a	Labeling on the immediate container includes an assigned internal identification number (eg, barcode, prescription, order, or lot number).		
71.4	130a	Labeling on the immediate container includes the active ingredients and their amounts, activity, or concentration.		
71.5	130a	Labeling on the immediate container includes the storage conditions, if other than controlled room temperature.		
71.6	130a	Labeling on the immediate container includes the BUD. Per USP, "Each CSP label must state the date, or the hour and date, beyond which the preparation must not be used and must be discarded (ie, the BUD)."		
71.7	130a	The compounded CSP label does not use the term "expiration date" or equivalent.		
71.8	130a	Labeling on the immediate container includes the dosage form.		
71.9	130a	Labeling on the immediate container includes the total amount or volume when not obvious from the container.		
71.10	130a	Labeling on the immediate container states that the CSP is a single-dose container (when space permits).		
71.11	130a	Labeling on the immediate container states that the CSP is a multiple-dose container.		
71.12	130a	Labeling includes the route of administration, as applicable.		

NABP Number	Deficiency Number		Result	Notes
71.13	130a	Labeling includes any special handling instructions and/or warning statements, as applicable.		
71.14		Labeling includes the compounding facility name and contact information if the CSP is to be sent outside of the facility or health care system in which it was compounded.		
72.0		Does the label contain information identifying the CSP is a compounded preparation? ***Inspector note: Per USP, this is a recommendation/should.***		
		Establishing BUDs		
73.0		**Category 1 and Category 2 CSPs:** Does the pharmacy assign BUDs for Category 1 and Category 2 CSPs in compliance with USP <797> standards? ***If no, go to compliance statements.***		
73.1	33	The assigned BUD does not exceed the shortest expiration date of any of the individual commercially available starting components.		
73.2	33	When assigning BUDs, the pharmacy ensures that the CSP formulation remains chemically and physically stable and that its packaging maintains its integrity for the duration of the assigned BUD.		
73.3	33	**Category 1 CSPs:** BUDs for **Category 1 CSPs** prepared in an SCA do not exceed the limits established in Table 12. ***Inspector note: Per USP <797> Table 12, BUD maximum limits for Category 1 CSPs are defined as 12 hours at controlled room temperature (CRT 20°C-25°C) or 24 hours refrigerated (2°C-8°C).*** ***If no Category 1 CSPs are prepared, inspector should answer statement as N/A.***		
73.4	33	**Category 2 CSPs:** BUDs for **aseptically processed (by filtration) Category 2 CSPs** that **do not** undergo sterility testing do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for aseptically processed Category 2 CSPs using one or more nonsterile starting components are defined as: one day CRT; four days refrigerator; and 45 days freezer. Aseptically processed Category 2 CSPs using only sterile starting components are defined as: four days CRT; 10 days refrigerator; and 45 days freezer.*** ***If no aseptically processed Category 2 CSPs are prepared, inspector should answer statement as N/A.***		
73.5	33	**Category 2 CSPs:** BUDs for **aseptically processed (by filtration) Category 2 CSPs** where **sterility testing and endotoxin testing (if applicable) are performed** and passed do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for aseptically processed Category 2 CSPs, that were sterility tested and passed, regardless of starting components being sterile or nonsterile, are defined as: 30 days CRT; 45 days refrigerator; and 60 days freezer.*** ***If no aseptically processed Category 2 CSPs are prepared, inspector should answer statement as N/A.***		
73.6	33	**Category 2 CSPs:** BUDs for **terminally sterilized Category 2 CSPs** that **do not** undergo sterility testing do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for terminally sterilized to probability of nonsterile unit (PNSU) of 10^{-6} (eg, dry heat, steam, irradiation) Category 2 CSPs are defined as: 14 days CRT; 28 days refrigerator; and 45 days freezer.*** ***If no terminally sterilized Category 2 CSPs are prepared, inspector should answer statement as N/A.***		

NABP Number	Deficiency Number		Result	Notes
73.7	33	**Category 2 CSPs:** BUDs for **terminally sterilized Category 2 CSPs** where **sterility testing and endotoxin testing (if applicable) are performed** and passed do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for terminally sterilized to PNSU of 10^{-6} (eg, dry heat, steam, irradiation) Category 2 CSPs are defined as: 45 days CRT; 60 days refrigerator; and 90 days freezer. Endotoxin testing is required for Category 2 injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility testing.*** ***USP <797> recommends that all injectable Category 2 CSPs made from one or more nonsterile components are also endotoxin tested.*** ***If no terminally sterilized Category 2 CSPs are prepared, inspector should answer statement as N/A.***		
74.0		Does the pharmacy ensure the assigned BUD does not exceed the shortest beyond use date of any individual compounded components? ***Inspector note: Per USP, "the BUD should generally not exceed the shortest BUD of any of the individual compounded components. However, there may be acceptable instances when the BUD of the final CSP exceeds the BUD assigned to compounded components (eg, pH-altering solutions). If the assigned BUD of the final CSP exceeds the BUD of the compounded components, the physical, chemical, and microbiological quality of the final CSP must not be negatively impacted." Other examples where this may occur: formula within a formula, preservative-free compounded component used in a preserved final CSP, "in-use" times for pharmacy bulk packages, and cyclosporine ophthalmic stock solution.*** ***If no, inspector should describe the observations, including the name of the component whose BUD was shorter than the assigned BUD of the final CSP.***		
75.0		Are BUDs for **Category 3 CSPs** assigned in compliance with all conditions outlined in USP <797> standards and do not exceed the maximum limits established in Table 14? ***Inspector note: If all of the conditions described for Category 3 CSPs are not met, the applicable BUD must not exceed the established maximum limits in Table 13 for Category 2 CSPs.*** ***If no, go to compliance statements.*** ***If the pharmacy does not prepare Category 3 CSPs, inspector should answer question as N/A.***		
75.1	33a	The assigned BUD does not exceed the shortest expiration date of any of the individual starting components.		
75.2	33a	When assigning BUDs, the pharmacy ensures that the CSP formulation remains chemically and physically stable and its packaging maintains its integrity for the duration of the assigned BUD.		
75.3	33a	BUDs for **Category 3 CSPs** do not exceed the maximum limits for aseptically processed (eg, filtered) established in Table 14. ***Inspector note: Per USP <797> Table 14, BUD maximum limits for aseptically processed Category 3 CSPs where sterility testing (and endotoxin testing, if applicable) had been performed and passed are defined as: 60 days CRT; 90 days refrigerator; and 120 days frozen.***		
75.4	33a	BUDs for **Category 3 CSPs** do not exceed the maximum limits for terminally sterilized established in Table 14. ***Inspector note: Per USP <797> Table 14, BUD maximum limits terminally sterilized Category 3 CSPs where sterility testing (and endotoxin testing, if applicable) had been performed and passed are defined as: 90 days CRT; 120 days refrigerator; and 180 days frozen.***		

NABP Number	Deficiency Number		Result	Notes
75.5	33a	**Category 3 CSPs** are supported by stability data obtained using methods described in USP <1225> or a validated noninferior stability-indicating analytical method. ***Inspector note: Per USP <797>, Category 3 CSPs must prepared according to the EXACT formulation (API and other ingredients of identical grade and procedures) from which the stability data is derived. Category 3 CSPs must be packaged and stored in container closure of the same materials of composition as used in study and the facility must have documentation of the stability study.*** ***View records to verify the preparation exactly matches the preparation cited in the documentation including concentration of all active ingredients, excipients, etc.***		
75.6	33a	**Category 3 CSPs** undergo sterility testing. ***Inspector note: Sterility testing is performed on all Category 3 CSPs.***		
75.7	25	**Category 3 CSPs** undergo bacterial endotoxin testing. ***If all compounds prepared are ophthalmics and/or drug administered by inhalation, bacterial endotoxin is not required, inspector should answer statement as N/A.***		
75.8	33a	**Category 3 CSPs** undergo particulate matter testing. ***Inspector note: If the Category 3 CSP is an injection or an ophthalmic solution, particulate matter testing is also conducted once per formulation with acceptable results (See USP <788> Particulate Matter in Injections and USP <789> Particulate Matter in Ophthalmic Solutions).***		
75.9	33a	**Category 3 CSPs** undergo an evaluation for the container closure system. ***Inspector note: The container closure system used is evaluated for and conforms to container closure integrity to the end of the BUD (see USP <1207> Package Integrity Evaluation— Sterile Products). Evaluation must be done once for each formulation and for each container closure system in which it will be packaged.***		
76.0		Are **multiple-dose CSPs prepared** in compliance with USP <797> standards? ***If no, go to compliance statements.*** ***If the pharmacy does not prepare multiple-dose CSPs, inspector should answer question as N/A.***		
76.1		Multiple-dose CSPs are prepared as a Category 2 or Category 3 CSP only.		
76.2		When preservatives are used, they are appropriate for the CSP formulation and the route of administration. Inspector note: Per USP <797>, "The preservative must not be inactivated by any ingredients in the CSP, and some preservatives are not always appropriate for the patient (eg, neonates) or route of administration (eg, intrathecal or ophthalmic injection)."		

NABP Number	Deficiency Number		Result	Notes
76.3		Aqueous multiple-dose CSPs pass antimicrobial effectiveness testing in accordance with USP <51>. ***Inspector note: Per USP <797>, a test can be one test done for each formulation in the particular container-closure system in which it will be packaged, or test results provided by an FDA-registered facility or in appropriate peer-reviewed literature,, provided the sterile compounded preparation formulation and container-closure system used are exactly the same as those tested, unless a bracketing study is performed. The concentration of all other ingredients (including preservatives) must be the same throughout the bracketing study.*** ***Additionally, multiple-dose, nonpreserved, aqueous topical, and topical ophthalmic CSPs prepared as a Category 2 or Category 3 CSP are not required to pass antimicrobial effectiveness testing if the preparation is: For use by a single patient, labeled (in the label or labeling) to indicate that, once opened, it must be discarded after 24 hours when stored at controlled room temperature and/or that, once opened, it must be discarded after 72 hours when stored under refrigeration.***		
76.4		Multiple-dose CSPs are labeled to indicate the beyond use date of the CSP once it is opened or punctured. ***Inspector note: Labeling on the CSP should indicate that once the CSP container is entered or punctured, it must not be used for longer than the assigned BUD or 28 days (if supported by antimicrobial effectiveness testing results), whichever is shorter.*** ***Inspector should review the CR or final compounded preparation to verify the label contains this information.***		
76.5		Container-closure systems used are evaluated for maintaining integrity (USP <1207>) for each formulation and fill volume. ***Inspector note: Per USP <797>, the container closure integrity test needs to be conducted only once on each formulation and on fill volume in the particular container closure system in which the multiple-dose CSP will be packaged.***		
		Finished Preparation Release Checks and Tests		
77.0		Are all CSPs visually inspected for quality prior to release or dispensing in compliance with USP <797> standards? ***If no, go to compliance statements.***		
77.1		The CSP label is visually inspected to confirm that the CSP and its labeling match the prescription or medication order.		
77.2		CSPs are visually inspected for quality characteristics such as discoloration, visible particulates, or cloudiness.		
77.3		CSPs are visually inspected to verify container closure integrity (eg, checking for leakage, cracks in the container, or improper seals).		
77.4		A visual inspection is also repeated prior to release or dispense for CSPs that have been stored in the pharmacy and not released or dispensed on the day of preparation.		
77.5		Any CSPs found to be of unacceptable quality (eg, observed defects) are promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.		
78.0		For any CSPs assigned beyond use dates that require sterility testing, does the pharmacy ensure that all testing is performed, evaluated, and documented in accordance with USP <71> or a validated alternative method that is noninferior to USP <71> testing and USP <797> standards? ***Inspector note: Alternative testing methods may not be accepted in all regulatory jurisdictions that the pharmacy conducts business.*** ***If no, go to compliance statements.*** ***If the pharmacy does not prepare any CSPs that require sterility testing, inspector should mark as N/A.***		

NABP Number	Deficiency Number		Result	Notes
78.1		The required number of sterile compounded preparation units, as described in USP <71> and USP <797>, are tested. ***Inspector note: Per USP <71> Table 3, the minimum number of items to be tested for each medium is:*** ***Parenterals*** ***Not more than 100 containers = 10% or four containers, whichever is greater*** ***More than 100, but not more than 250 containers = 10 containers*** ***Large volume parenterals*** ***2% or 10 containers, whichever is less*** ***Non-parenterals (eye drops, inhalation, pellets, etc.)*** ***Not more than 200 containers = 5% or two containers, whichever is greater*** ***More than 200, but not more than 250 containers = 10 containers*** ***Per USP <797>, if the number of CSPs compounded in a single batch is less than what is needed for testing as specified in USP <71> Table 3, additional units must be compounded to be able to perform testing as follows:*** ****If 1-39 CSPs are compounded in a single batch, the sterility testing must be performed on a number of units equal to 10% of the number of CSPs prepared, rounded up to the next whole number.*** ****If more than 40 CSPs are prepared in a single batch, the sample sizes specified in USP <71> Table 3 must be used.***		
78.2		Batch sizes of sterile CSPs do not exceed 250. ***Inspector Note: Per USP <797>, the maximum batch size for all sterile compounded preparation requiring sterility testing is limited to 250 final yield units.***		
78.3		Pharmacy is utilizing an alternative method for sterility assurance testing (other than USP <71>). ***Inspector note: Per USP, "If an alternative method is used for sterility testing, the method must be validated (see USP <1223>) and demonstrated to be suitable for that CSP formulation."*** ***If an alternative method is used, describe the method used and how the pharmacy ensures they are compliant with state-specific regulations.***		
78.4		When sterility testing identifies a failure, the pharmacy has processes to investigate and identify any contributing factors. ***Inspector note: Per USP, "Sterility tests resulting in failures must prompt an investigation into the possible causes and must include identification of the microorganism, as well as an evaluation of the sterility testing procedure, compounding facility, process, and/or personnel that may have contributed to the failure. The source(s) of the contamination, if identified, must be corrected, and the facility must determine whether the conditions causing the sterility failure affect other CSPs. The investigation and resulting corrective actions must be documented."*** ***Additionally, some rapid sterility test methods do not allow for the identification of the recovered microorganisms. If one of these methods is used, the pharmacy is not in compliance with the chapter, as the investigation must include identification of the recovered microorganism.***		

NABP Number	Deficiency Number		Result	Notes
79.0		For any CSPs assigned BUDs that require **bacterial endotoxin testing**, does the pharmacy ensure that all testing is performed and documented in compliance with USP <85> and USP <797> standards? ***Inspector note: Endotoxin limits reflect limits in an official monograph, or calculated as described in USP Chapter <85> for the route of administration for humans, and for animals based on weight.*** ***Although USP <797> refers to USP <85> Bacterial Endotoxins Test for calculating endotoxin limits for the appropriate route of administration, it does not address products administered epidurally or administered directly into the central nervous system. CSPs administered epidurally should have the same endotoxin limit as that of intrathecally administered CSPs.*** ***If no, go to compliance statements.*** ***If the pharmacy does not prepare CSPs that require bacterial endotoxin testing, inspector should answer question as N/A.***		
79.1		The pharmacy has an appropriate procedure for calculating/determining endotoxin limits. ***Per USP, there are endotoxin limits listed in USP product and compounded preparation monographs. The laboratory may be performing the calculation rather than the pharmacy; however, if done in house, this should be included in the pharmacy SOPs.*** ***If the dosage form does not require, inspector should answer statement as N/A.***		
79.2		The pharmacy collects patient weight to make bacterial endotoxin calculation for an animal patient. ***If the dosage form does not require or the pharmacy does not compound sterile preparations for animals, inspector should answer statement as N/A.***		
79.3	25	Bacterial endotoxins testing (USP <85>) is performed on all **injectable Category 2 CSPs** compounded from one or more nonsterile components that are assigned a BUD requiring sterility testing per Table 13. ***Inspector note: USP <797> recommends that all injectable Category 2 CSPs made from one or more nonsterile components is also endotoxin tested.***		
79.4	25	Bacterial endotoxins testing (USP <85>) is performed on all **injectable Category 3 CSPs** compounded from one or more nonsterile components.		
79.5		Any CSPs with failed endotoxin testing are quarantined, not further released, and action is taken for any product released prior to receipt of failed test results. ***View testing records and note any products with failed results and actions taken.***		
		CSP Packaging, Shipping and Transport		
80.0		Are processes and techniques for packaging and transporting CSPs in compliance with USP <797> standards? ***If no, go to compliance statements.***		
80.1		The pharmacy uses the appropriate shipping containers and packaging materials (eg, coolers and light-resistant packaging) based on the product specifications.		
80.2		CSPs are appropriately packaged to protect against damage, leakage, contamination, degradation, and adsorption during storage and transport. ***Inspector should look at packaging materials used to ensure cushioning to prevent breakage of glass vials and ensure that container is generally clean without non-microbial growth that would come in direct contact with CSPs.***		
80.3		Specific handling instructions when applicable, are included on the exterior of the container.		
80.4		The pharmacy selects transport modes that ensure CSPs are delivered properly in undamaged, sterile, and stable conditions (eg, no undue exposure to heat, cold, or light). ***Inspector note: Transport modes include pneumatic tube transport systems and should not be used if the CSP is sensitive to shaking.***		

NABP Number	Deficiency Number		Result	Notes
		Quality Assurance and Quality Control		
81.0		**Quality Assurance and Quality Control (QA/QC):** Does the pharmacy's SOP on quality assurance and quality control meet the requirements in compliance with USP <797> standards? ***If no, go to compliance statements.***		
81.1		Description of procedures for complaint handling, adverse events, and recalls that include corrective action, investigation, reporting, and documentation requirements.		
81.2		**QA/QC Out-Of-Specification (OOS) SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to determine the severity of the problem and the urgency for implementation and completion of the recall.		
81.3		**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to determine the distribution of any affected CSP, including the date and quantity of distribution.		
81.4		**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to identify patients who have received the CSP.		
81.5		**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process for the disposal and documentation of the recalled CSP.		
81.6		**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to investigate and document the reason for failure.		
82.0		Does the pharmacy ensure that QA and QC programs are conducted in compliance with USP <797> standards? ***If no, go to compliance statements.***		
82.1		The pharmacy has a formal QA/QC program with documented activities. ***Inspector note: Per USP, "Designated person(s) must ensure that the facility has formal, written QA and QC programs that establish a system of: adherence to procedures; prevention and detection of errors and other quality problems; evaluation of complaints and adverse events; and appropriate investigations and corrective actions."***		
82.2		The pharmacy's QA/QC program is reviewed at least once every 12 months by the designated person(s) and the results of the review are documented.		
82.3		The designated person(s) reviews all complaints to determine whether the complaint indicates a potential quality problem with the CSP.		
82.4		All complaints and adverse events are thoroughly investigated. ***Inspector note: Per USP <797>, the timeframe is specified in the facility SOP. Additionally, USP states, "The investigation must consider whether the quality problem extends to other CSPs."*** ***If facility SOP permits a long investigation period, include in the inspector notes the SOP's expected time frame to complete an investigation. State may have a more aggressive time frame to complete an investigation and report quality events to the state.***		

NABP Number	Deficiency Number		Result	Notes
82.5		The record of each complaint is maintained by the pharmacy regardless of the source of the complaint (eg, email, telephone, or mail) and includes the minimum required information. ***Inspector note: Per USP <797>, the complaint record must contain the following information:*** ***-Name of the complainant or other unique identifier;*** ***-Date the complaint was received;*** ***-Nature of the complaint;*** ***-The response to the complaint; and*** ***-Results of any investigation and any follow-up.*** ***In addition, to the extent that the information is known, the following should be recorded:*** ***-The name and strength of the CSP and the assigned internal identification number (eg, prescription, order, or lot number).*** ***If no, inspector should document what is missing in the notes column.***		
82.6		The pharmacy's QA/QC program includes documentation of steps necessary for completing a recall, including reporting the recall to appropriate regulatory agencies. ***Inspector note: Per USP, "The recall must be reported to appropriate regulatory bodies as required by laws and regulations of the applicable regulatory jurisdiction."***		
83.0		If a CSP is dispensed or administered **before the results of release testing are known**, does the pharmacy ensure procedures for recalls and out-of-specification notifications are conducted and documented in compliance with USP <797> standards? ***Inspector note: Per USP <797>, if a CSP is dispensed or administered before the results of release testing are known, the facility must have procedures in place to notify, recall, and investigate.*** ***If no, go to compliance statements.***		
83.1		The pharmacy has a process in place to immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (eg, sterility, strength, purity, bacterial endotoxin, or other quality attributes).		
83.2		The pharmacy has a process in place to recall any unused dispensed CSPs and quarantine any stock remaining in the pharmacy.		
83.3		The pharmacy has a process in place to investigate if other lots are affected and recall if necessary.		
		Personnel Training and Evaluation - **Verify records of all compounding personnel (up to 10).**		
84.0		Is the pharmacy's documented hand hygiene and garbing competency evaluations compliant with USP <797> standards? ***Inspector note: Only "No" or "Missing" documents would cause this question to be answered no.*** ***If no, refer to the records review worksheet (columns G-J) for details.***		
85.0		Is the pharmacy's documented aseptic manipulation competency evaluation compliant with USP <797> standards? ***Inspector note: Only "No" or "Missing" documents would cause this question to be answered no.*** ***If no, refer to the records review worksheet (columns K-O) for details.***		
86.0		Is the pharmacy's documented training program and ongoing competency evaluation compliant with USP <797> standards? ***Inspector note: Only "No" or "Missing" documents would cause this question to be answered no.*** ***If no, refer to the records review worksheet (columns P-S) for details.***		

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

Virginia Board of Pharmacy
Pharmacy Routine Inspection Form

Nuclear Pharmacy Inspection for USP <825>			
The information and comments obtained in the Nuclear Pharmacy Inspection is based on USP Chapter <825>. Nuclear/Radiopharmaceuticals Preparation, Compounding, Dispensing and Repackaging			
Deficiency Number	**USP chapter references for each section in parenthesis**		
		Result	**Notes**
	Nonsterile Radiopharmaceuticals: (1.1)		
	Does the pharmacy compound nonsterile radiopharmaceuticals? *If so, list which of the following do they compound (eg Oral Capsules, oral solutions, other (if other, list those products in the notes)).*		
	Sterile Radiopharmaceuticals: (1.2)		
	Does the pharmacy compound sterile radiopharmaceuticals? *If so, list which of the following do they compound in the notes. (eg, intravenous, intrathecal, intraperitoneal, subcutaneous, intradermal, inhalations, ophthalmics, intra-organ instillations)*		
	Does the pharmacy compound sterile preparations involving one or more nonsterile components?		
25	If the pharmacy compounds sterile preparations requiring a sterilization procedure, is testing (eg filtration with bubble point testing) performed prior to dispensing?		
25	If the pharmacy compounds injectable sterile preparations involving one or more components that are not certified to be pyrogen-free, is pyrogen testing performed prior to dispensing?		
	Immediate Use of Sterile Radiopharmaceuticals: (3)		
	Does the pharmacy prepare and dispense sterile radiopharmaceuticals in a patient care setting as immediate use?		
21a	Does the pharmacy prepare immediate use sterile radiopharmaceuticals in an ambient environment without primary or secondary engineering controls?		
21a	Does handling for immediate use sterile radiopharmaceuticals in an ambient environment lacking primary and secondary engineering controls when intended for a single patient meet the following requirements? as applicable:		
	Are preparations (including minor deviations) and/or dispensing limited to use for a single patient?		
	Are preparation (including preparations with minor deviations) components sterile, conventionally manufactured drug products (e.g., NDA, ANDA)?		
	Are dispensing of drug products produced under an approved IND or RDRC protocol?		
	Are manipulations for any unit doses (e.g., decreasing the dosage, needle changes) or dispensing for one patient (e.g., withdrawing a dose) ?		
	Are preparations labeled for administration within 1 hour of the first container puncture or exposure of any critical site involved (e.g., syringe tip, needle hub or needle) to ambient air, whichever is first?		
	Are all components involved (e.g., Tc-99m sodium pertechnetate syringe or vial, final prepared radiopharmaceutical kit vial, diluent vial) discarded within 1 hour of being punctured or after use for a single patient administration, whichever is first?		

Deficiency Number	USP chapter references for each section in parenthesis	Result	Notes
	Does the pharmacy indicate that dose pooling (combining doses from two or more syringes to meet one patient's need) is performed as immediate use? Is any residual activity that remains is immediately discarded and not utilized for any other patient?		
	Does pharmacy staff follow proper hand hygiene and garbing?		
124	Does the pharmacy follow 10.4 Preparation of Radiolabeled Red Blood Cells for Immediate Use for red blood cell labeling?		
124	Does the pharmacy follow 12.2 Labeling for labeling?		
	Is area for sterile preparation and/or dispensing functionally separate from nonsterile compounding area (e.g., radiolabeling food) during the time of use?		
	Does the pharmacy require a segregated radiopharmaceutical processing area (SRPA), classified area, or PEC?		
	Are the number of steps or punctures limited?		
	Does the pharmacy require personnel to complete the aseptic qualifications as detailed in 4.1 Aseptic Qualifications (e.g., aseptic technique training with documented assessment, media fill challenge, gloved fingertip testing)?		
	Is adding non-radioactive, sterile and commercially manufactured pharmaceutical(s) only applicable if performing immediate use. *While adding a non-radioactive, sterile and commercially manufactured pharmaceutical (e.g., lidocaine) to a unit dose is otherwise considered compounding, it is allowed for immediate use purposes as long as all of the above are adhered to.*		
	Is dose splitting (splitting a unit dose for administration to more than one patient) performed as immediate use?		
21a	If performed, is dose splitting done in an ISO class 5 PEC in either an SRPA or in an ISO class 8 or better buffer area? *Note where this is performed.*		
	Personnel Qualifications, Training, and Hygiene: (4)		
	Are personnel trained in blood-borne pathogens (as appropriate)?		
132	Are individuals entering a handling area properly garbed and maintain proper personal hygiene to minimize the risk of contamination to the environment and/or radiopharmaceuticals?		
	Are individuals who have a condition that may pose a higher potential of contaminating the radiopharmaceutical and the environment with microorganisms (e.g., rashes, sunburn, recent tattoos, oozing sores, conjunctivitis, or active respiratory infection) reported to their supervisor?		
	Is the designated person responsible for evaluating whether these individuals should be excluded from working in sterile processing areas before their conditions are resolved?		
	Aseptic Qualification: (4.1)		
132	Do personnel prove competency under the observation of a designated person, as applicable to their jobs, prior to performing radiopharmaceutical aseptic tasks (that are beyond immediate use). *Note– these can be completed at a different site if all SOPs are identical for the applicable job function.*		

Deficiency Number	USP chapter references for each section in parenthesis		
		Result	Notes
	Do the minimum qualifications include the following?		
130	Aseptic technique with a documented assessment (written or electronic)		
132	Garbing and hand hygiene, as defined by policies and SOPs		
132	PEC cleaning and disinfecting		
130	Gloved fingertip and thumb sampling		
130	Media-fill testing (not required for non-compounding personnel)		
	Gloved fingertip and thumb sampling: (4.1)		
130	Is gloved fingertip and thumb sampling required for all personnel who enter and perform tasks in an ISO Class 5 PEC (e.g., aseptic manipulations, cleaning the PEC)?		
130	Is gloved fingertip and thumb sampling performed initially on both hands, immediately following hand hygiene and garbing?		
130	Is successful completion of initial gloved fingertip and thumb sampling defined as zero colony-forming units (cfu)?		
130	Is subsequent gloved fingertip and thumb sampling after media-fill testing defined as ≤3 cfu (total for both hands)?		
130	Is the gloved fingertip and thumb sampling performed with touch plates or other devices (e.g., plates, paddles, or slides) that contain a general microbial growth agar [e.g., trypticase soy agar (TSA) soybean–casein digest media] supplemented with neutralizing additives (e.g., lecithin and polysorbate 80) which support both bacterial and fungal growth?		
130	Per P&P review, gloves are not disinfected immediately before touching the sampling device.		
130	Is a gloved fingertip and thumb sample from both hands collected by rolling finger pads and thumb pad over the agar surface, using a separate sampling device for each hand?		
	Are the plates incubated in an incubator at 30°–35° C for no less than 48 h, and then at 20°–25° C for no less than 5 additional days?		
	Media-Fill Testing: (4.1)		
130	Is media-fill testing done for all personnel who prepare, compound, dispense, and repackage sterile radiopharmaceuticals?		
	Is testing reflective of the actual manipulations to be carried out by the individual and simulate the most challenging and stressful conditions to be encountered in the worker's duties?		
130	Are media-fill tests documented as defined by the facility's policies and SOPs?		
130	Are media-fill tests documented as defined by the facility's policies and SOPs?		
130	Does the certificate of analysis (CoA) include documentation of growth promotion testing for each lot of media used?		
25d	In the event of failure, are results of the evaluation and corrective actions documented and the documentation maintained to provide a record and long-term assessment of personnel competency?		
130	Do media and components used include the following?		
	manufacturer		
	expiration date		
	lot number		

Deficiency Number	USP chapter references for each section in parenthesis		
		Result	Notes
130	Does the documentation include at a minimum the following?		
	starting temperature for each interval of incubation		
	dates of incubation		
	results		
	name of the person evaluated		
	evaluation date		
	evaluation time		
	Reevaluation, Retraining, and Requalification: (4.2)		
25d	Do personnel who fail visual observation of hand hygiene, garbing, and aseptic technique, gloved fingertip and thumb sampling, or media-fill testing successfully pass reevaluations in the deficient area(s) before they can resume processing of sterile radiopharmaceuticals?		
130	Are all failures, retraining, and re-evaluations documented?		
132	Do personnel successfully complete requalification in the core competencies via demonstrated through observation, written testing, and hands-on demonstration of skills?		
	Timing of Reevaluation and Requalification: (4.2)		
	Visual observation: Are personnel visually observed while performing hand hygiene, garbing SOPs, and aseptic technique procedures both initially, and then at least once every 12 months?		
25d	**Gloved fingertip and thumb sampling:** Do personnel perform fingertip and thumb sampling 3 times initially, and then every 12 months (in conjunction with media-fill testing).		
25d	**Media-fill testing:** After initial qualification, is a media-fill test of all personnel engaged in sterile radiopharmaceutical processing performed at least every 12 months (in conjunction with gloved fingertip and thumb sampling)?		
	Cleaning and disinfecting: Does the pharmacy retrain and requalify personnel in the cleaning and disinfecting of sterile processing areas every 12 months or in conjunction with any change(s) in cleaning and disinfecting SOPs, whichever is sooner?		
	After a pause in sterile radiopharmaceutical processing: Are personnel that have not performed radiopharmaceutical processing in more than 6 months requalified in all core competencies before resuming duties?		
130	**Sterile compounding using a nonsterile drug substance or components:** Are personnel who perform sterile compounding using a nonsterile drug substance or components requalified in all core competencies every 6 months?		
	Hand Hygiene and Garbing for Immediate Use: (4.4)		
132	Hand hygiene: Do personnel wash hands and arms to the wrists with soap and water or use a suitable alcohol-based hand rub with a time based on institution policies to reduce bioburden on the hands?		
132	Garbing: Immediately after hand hygiene, do personnel don a clean coat/gown that has not been exposed to a patient or patient care area, and either don sterile gloves or don nonsterile disposable gloves and then disinfect the gloves with sterile 70% IPA?		
132	Is a different lab coat worn to care for a patient than the coat/gown used for radiopharmaceutical preparation?		

Deficiency Number	USP chapter references for each section in parenthesis		
		Result	Notes
	Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Area: (4.5)		
132	Before entering the SRPA or buffer area, do personnel remove all the following (as applicable)? (Radiation dosimetry devices are allowed, as required by the RAM license).		
	Outer garments (e.g., bandanas, coats, hats, jackets, sweaters, vests)		
	All cosmetics		
	All hand, wrist, and other exposed jewelry including piercings that could interfere with the effectiveness of the garbing		
	Nail products (e.g., artificial nails, polish, extenders). {Natural nails kept neat and trimmed.}		
	Ear buds		
	Headphones		
132	Are electronic devices that are not necessary for compounding or other required tasks banned from the SRPA?		
132	Do personnel don shoe covers, head/hair/facial hair cover(s) and face masks? Note – these items are donned in an order that eliminates the greatest risk of contamination, as defined in facility SOPs.		
132	Does the process before entering the buffer area or SRPA include the following?		
	Remove visible debris from underneath fingernails under warm running water using a disposable nail cleaner		
	Wash hands and arms up the elbows with soap and water for at least 30 seconds and then dry using low-lint towels		
	Electronic hand dryers are not permitted		
	Hand antisepsis cleansing is performed using a suitable alcohol-based hand rub		
	Don a low-lint gown with sleeves that fit snugly around the wrist and enclosed at the neck. Note: Disposable gowns are preferred.		
	If reusable gowns are used, a clean gown is donned daily.		
	Aseptically don sterile, powder-free gloves. Gloves completely and snugly cover the ends of the gown cuffs so that skin on the wrists and upper hands is completely enveloped.		
132	Do personnel periodically apply sterile 70% IPA to gloves while balancing the risk of radioactivity contamination; due to touching or handling potentially nonsterile materials?		
132	Do personnel inspect the gloves they are wearing for holes, punctures, radioactivity contamination, or tears?		
132	If a defect, radioactivity contamination, or malfunction is detected, do personnel immediately do the following?		
	Remove the gloves		
	Repeat antiseptic hand cleansing using an alcohol-based hand rub		
	Don new sterile gloves		
	Personnel avoid touch contamination of container septa, needles, syringe and needle hubs, and other critical sites		

Deficiency Number	USP chapter references for each section in parenthesis		
		Result	Notes
132	Do exiting processes for buffer area or SRPA include the following?		
	Shoe covers, head/hair/facial hair cover(s), face masks and gloves are properly disposed of		
	New PPE is used for each re-entry		
	Gowns may be re-used within the same shift if maintained to minimize contamination (eg away from sinks)		
	Gowns are in a classified area or,		
	Gown are kept in (or immediately outside of) the SRPA		
	Facility Design and Environmental Controls: (5.1)		
	Is the facility is designed to minimize airborne contamination (for sterile radiopharmaceutical facilities)?		
105	Are the temperatures in classified areas and SRPA continuously maintained at 25 degrees C or cooler?		
105	Are the temperatures monitored in the classified areas and SRPA each day that they are used, either manually or by a continuous recording device?		
130	Are the temperature readings of the classified areas and SRPA documented at least once daily or stored in a continuous recording device and retrievable?		
130	Are temperature monitoring devices calibrated and verified for accuracy at least every 12 months or as required by the manufacturer?		
	Recommendation: The humidity in classified areas and SRPA are continuously maintained at a relative humidity (RH) below 60%.		
130	Are the humidity readings of the classified areas and SRPA documented at least once daily or stored in a continuous recording device and retrievable?		
130	Are humidity monitoring devices calibrated and verified for accuracy at least every 12 months or as required by the manufacturer?		
	Types of Secondary Engineering Controls and Design: (5.1)		
	Were placement of doors, door surfaces, and movement of the door, all of which can affect airflow, considered when designing doors for a sterile radiopharmaceutical processing facility?		
	Are tacky surfaces not used in ISO-classified areas?		
	Are the PEC located in a SEC?		
32	When the PEC is located in an SEC which is an ISO-classified buffer room with an ante room, does all of the following apply?		
	Is the ISO-classified ante-room and buffer area separated from the surrounding unclassified areas of the facility with fixed walls and doors?		
	Are facility design and controls in place to minimize the flow of lower-quality air into the more controlled areas?		
	Is the air supplied to the classified areas introduced through HEPA filters that are located in the ceiling?		
32, 147	Are returns low on the wall unless a visual smoke study demonstrates an absence of stagnant airflow where particulate will accumulate?		
32,147	Is a smoke study of the PEC repeated whenever a change to the placement of the PEC within the area is made?		

Deficiency Number	USP chapter references for each section in parenthesis	Result	Notes
	Is the classified areas equipped with a pressure-differential monitoring system?		
	Does the ante-room have a line of demarcation to separate the clean side from the less clean side?		
	Is the ante-room entered through the less clean side, and the clean side is the area closest to the buffer area?		
132	Is required garb worn prior to crossing the line of demarcation?		
	When the PEC is located in an SEC, which is an unclassified area, without an ante room or buffer area (aka SRPA), the following apply:		
	Only sterile radiopharmaceutical preparation, preparation with minor deviations, dispensing, and repackaging may be performed in an SRPA		
	The SRPA is located away from unsealed windows, doors that connect to the outdoors, and traffic flow which may adversely affect the air quality in the PEC.		
	A visible perimeter establishes the boundaries of the SRPA.		
	Access to the SRPA is restricted to authorized personnel and required materials.		
	An SRPA is not located adjacent to environmental control challenges		
	If the SRPA meets ISO Class 8 total airborne particle count specifications, it can also be used for storage and elution of non-direct infusion radionuclide generators (e.g., Tc-99m)		
	If a pass-through is used to prevent influx of contaminants, both doors are never opened at the same time.		
	The Radiopharmaceutical Processing Environment: (5.1)		
22, 147	Is the PEC certified to meet ISO Class 5 or better conditions (3520 particle count (with limit ≥0.5 µm) per cubic meter) under dynamic operating conditions?		
	Is the airflow in the PEC unidirectional (laminar flow)?		
	Is "first air" at the face of the filter free from airborne particulate contamination?		
	Is the HEPA-filtered air supplied in the direct processing area (DPA) at a velocity sufficient to sweep particles away from aseptic processing areas and maintain unidirectional airflow as much as possible during operations, given the limitations added from the radiation shielding in the DPA?		
147	Are in situ air pattern analyses via smoke studies conducted at the critical area to demonstrate unidirectional airflow and sweeping action under dynamic conditions?		
	Types of PECs and Placement: (5.1)		
	Does the placement of the PEC allow for cleaning around the PEC?		
	Laminar airflow workbench (LAFW): Does a LAFW used for preparing radiopharmaceuticals provide vertical unidirectional HEPA-filtered airflow?		
	In cases where the LAFW is located within the segregated containment area of a hot-cell, it is acceptable for a horizontal unidirectional HEPA-filtered airflow pattern to be utilized.		
22	**Placement of PEC**: Is the PEC located out of traffic patterns and away from area air currents that could disrupt the intended airflow patterns inside the PEC?		
	If used only to prepare, prepare with minor deviations, dispense, or repackage sterile radiopharmaceuticals the ISO Class 5 PEC may be placed in an unclassified SRPA.		
	If used to compound sterile radiopharmaceuticals, the PEC is located within an ISO Class 7 or better buffer area with an ISO Class 8 or better anteroom.		

Deficiency Number	USP chapter references for each section in parenthesis		
		Result	Notes
147	Is a dynamic airflow smoke pattern test performed initially and at least every 6 months to ensure that the PEC is properly placed into the facility and that workers understand how to utilize the unidirectional airflow to maintain first air as much as possible given the limitations added from the radiation shielding in the DPA?		
	Air-Exchange Requirements		***Note to Inspector:*** *Airflow is measured in terms of the number of HEPA-filtered air changes per hour (ACPH). SRPA do not have an ACPH requirement.*
23	For ISO-classified rooms, does the total ACPH maintain the ISO class under dynamic operating conditions?		
23	Are at least 15 ACPH of the total air change rate in a room come from the HVAC through HEPA filters located in the ceiling?		
23	Is there a minimum of 30 total HEPA-filtered ACPH supplied to ISO Class 7 areas?		
	Does HEPA-filtered air from the PEC, added to the HVAC-supplied HEPA-filtered air, increase the total HEPA-filtered ACPH to at least 30 ACPH?		
	If the PEC is used to meet the minimum total ACPH requirements, is the PEC not turned off except for maintenance?		
	Are both the ACPH from HVAC contributed from the PEC, and the total ACPH documented on certification reports?		
23	Is a minimum of 20 ACPH of HEPA-filtered air supplied to ISO Class 8 areas?		
	Are ante-rooms where activity levels are high, required more HEPA-filtered ACPH to maintain ISO Class 8 under dynamic operating conditions?		
	Are the total ACPH documented on certification reports?		
	Creating Areas to Achieve Easily Cleanable Conditions		
	Classified Areas: (5.2)		
32	Are the surfaces of ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets in the classified area smooth, impervious, free from cracks and crevices, and non-shedding, so they can be cleaned and disinfected, and to minimize spaces in which microorganisms and other contaminants can accumulate?		
32	Are junctures between the ceiling and the walls and between the wall and the floor sealed to eliminate cracks and crevices where dirt can accumulate?		
32	If ceilings consist of inlaid panels, are each panel caulked or otherwise sealed and secured to seal them to the support frame?		
32	Are walls constructed of or covered with a durable material (e.g., epoxy-painted walls or heavy-gauge polymer) and the integrity of the surface maintained?		
32	Are panels joined together and sealed to each other and the support structure?		
32	Do floors include coving to the sidewall or the juncture between the floor and wall are caulked?		
32	If overhangs or ledges are present, are they easily cleanable?		
32	Is the exterior lens surface of ceiling light fixtures smooth, mounted flush, and sealed?		
32	Are any other penetrations through the ceiling or walls sealed?		

Deficiency Number	USP chapter references for each section in parenthesis	Result	Notes
	SRPA: (5.2)		
32	Is the SRPA and all surfaces (e.g., walls, floors, counters, equipment) within the SRPA clean, uncluttered, and dedicated to sterile radiopharmaceutical processing activities?		
	Recommendation: Surfaces in the SRPA are smooth, impervious, free from cracks and crevices, and non-shedding, so they can be easily cleaned and disinfected, and to minimize spaces in which microorganisms and other contaminants can accumulate.		
	Recommendation: Surfaces are be resistant to damage by cleaning agents, disinfectants, and tools used to clean.		
	Recommendation: Dust-collecting overhangs such as utility pipes, ledges, and windowsills are minimized.		
	If overhangs or ledges are present, are they easily cleanable?		
	Establishing and Maintaining Pressure Differentials: (5.7)		
	Any time a pressure differential is required, is there a pressure monitoring device?		
	In a classified area, is a pressure differential monitoring system used to continuously monitor the pressure differential between the ante-room(s) and buffer area(s) and between the ante-room and the general environment outside the classified area(s) or area(s)?		
130	Are the results from the pressure monitoring system reviewed and documented at least daily on days the area is used?		
130	All pressure monitoring devices are tested for accuracy and required performance at least every 6 months.		
	Certification of PEC and Environment in which the PEC is located: (5.7)		
22	Certification of the classified areas, including the PEC, is performed initially.		
22	Recertification is performed at least every 6 months.		
	Procedures outlined in the current CETA certification guide for Sterile Compounding Facilities, or an equivalent guideline, are followed.		
147	Airflow testing is performed to determine acceptability of the air velocity, the air exchange rate, and area pressure cascade to ensure that air consistently flows from most to least clean areas, and that the appropriate quality of air is maintained under dynamic operating conditions.		
	HEPA filter integrity testing is performed (HEPA filters are leak tested after installation and as part of recertification).		
147	Total Particle Counts testing is performed and conducted under dynamic operating conditions using calibrated electronic equipment.		
147	Smoke Visualization Studies are performed under either simulated or dynamic operating conditions to demonstrate unidirectional airflow and sweeping action over and away from the preparation(s).		
	Are other equivalents for certifying the PEC performed and documented per facility SOPs, in cases where technologies exist for hot-cell and PEC configurations that are not consistent for certification by the current CETA standards?		
	In this case, the PEC maintains the environmental equivalent for total particle counts and the protection of the ISO Class 5 area from intrusions of lesser controlled air.		

Deficiency Number	USP chapter references for each section in parenthesis	Result	Notes
	Daily Monitoring of Environment: (5.7)		
130	The temperature and humidity is monitored in the SRPA or area containing a hot-cell, and if in a classified area the pressure is monitored, each day that radiopharmaceutical handling occurs, either manually or by a continuous recording device.		
130	Does Monitoring include the following?		
	Recommendation: Relative humidity is kept at 60% or lower		
	Are temperature continuous readings confirmed daily to have remained within the acceptable range?		
	Are relative humidity continuous readings confirmed daily to have remained within the acceptable range?		
	Are excursion documented and, if applicable, appropriate corrective actions taken?		
	Are temperature monitoring devices verified for accuracy every 12 months or as required by the manufacturer?		
	Are monitoring of pressure differentials performed?		
	Microbial Air and Surface Monitoring: (6)		
149	Has the pharmacy developed and implemented written air and surface monitoring procedures for all sterile radiopharmaceutical classified areas?		
149	Are air and surface monitoring results and the corrective actions documented, and records readily retrievable as required by jurisdictional laws and regulations?		
	General Monitoring Requirements: (6.1)		
149	Is the air and surface monitoring program clearly described in the established SOPs of the facility and include a diagram of the sampling locations, SOPs for collecting samples, frequency of sampling, size of samples (e.g., surface area, volume of air), time of day of sampling in relation to activities in the classified areas, and action levels that will trigger corrective action?		
	Are samples obtained from locations that pose the highest possible contamination risk to the sterile radiopharmaceuticals involved with the operation's processes and are likely to be representative of the conditions throughout the area?		
130	Are all air sampling devices serviced and calibrated as recommended by the manufacturer?		
147	Are air and surface sampling conducted during actual or simulated dynamic operating conditions to confirm that the required environmental quality in classified areas is maintained?		
	Is sampling carried out at the conclusion of sterile radiopharmaceutical processing but prior to cleaning and disinfecting the surface area?		
	Is sampling performed in all of the following circumstances?		
	In conjunction with the certification of new facilities and equipment?		
	After any modification of facilities or equipment		
	In response to identified problems (e.g., positive growth in sterility tests of compounded radiopharmaceuticals)?		
	In response to identified trends (e.g., repeated positive gloved fingertip sampling results or failed media-fill testing involving more than one operator where a review of the operator technique shows no reasonable flaws in process; repeated observations of air or surface contamination)?		

Deficiency Number	USP chapter references for each section in parenthesis		
		Result	Notes
	In response to changes that could impact the controlled area environments (e.g., significant change in cleaning process or the agents involved)?		
	Is Prompt corrective action in response to any adverse findings taken to maintain the necessary environmental quality for handling sterile radiopharmaceutical?		
	Is data also reviewed following corrective actions to confirm that the actions taken have been effective in achieving the required air and surface quality levels?		
	Monitoring Air Quality for Viable Airborne Particles		
	Viable Air Sampling: Timing and Locations: (6.2)		
22, 23, 147	Volumetric active air sampling of all classified areas (e.g., ISO Class 5 PEC and ISO Class 7 and 8 areas) using an impaction device are conducted during dynamic operating or simulated operating conditions at least every 6 months.		
	Are the results of the sampling recorded on an environmental sampling form based on sample type (i.e., viable air) and include the sample location, and sample date?		
	Are general microbiological growth medium that supports the growth of bacteria and fungi used (e.g., TSA medium)?		
	Do CoA(s) from the manufacturer verify that the medium meets the expected growth promotion, pH, and sterilization requirements?		
	Are samples incubated in a temperature monitored incubator with a calibrated measuring device?		
130	Is the incubator temperature monitored during incubation, either manually or by a continuous recording device, and the results reviewed and documented?		
	Are the incubators used for microbiological testing placed in a location outside of any classified area or SRPA and kept away from areas where compounding or sterile processing activities are carried out?		
	Data Evaluation and Action Levels: (6.2)		
149	Air Sampling Action Levels (cfu/cubic meter (1000L) of air per plate) are within the appropriate range: ISO Class 5 - >1 ISO Class 7 - >10 ISO Class 8 - >100		
149	Are cfu counts evaluated against the action levels and in relation to previous data to identify adverse results and/or trends?		
	If two pieces of media were collected at a single location, are all recovered growth documented and action levels are applied individually to each plate/device (i.e., results from each cubic meter of air sampled are compared to the action level for that area)?		
149	If levels measured during the viable air monitoring program exceed the action levels for the ISO classification levels of the area sampled, is the cause investigated, and corrective action is taken?		
	Is the corrective action plan dependent on the cfu count and the microorganism recovered?		
	If levels measured during viable air sampling exceed the levels, is an attempt made to identify any microorganism recovered to the genus level with the assistance of a qualified individual?		
130	Is the corrective action plan documented?		

Deficiency Number	USP chapter references for each section in parenthesis		
		Result	Notes
	Surface Sampling: Timing and Locations (6.3)		
149	Is surface sampling of all classified areas and all PECs conducted at least monthly for the detection of microbial contamination?		
149	Is each classified area sampled?		
149	Is the DPA of the PEC, and any equipment permanently contained in the PEC, sampled?		
149	Are work surfaces in classified areas near the PEC, frequently touched surfaces in classified areas, and pass-through enclosure(s) for all classified areas evaluated to determine the locations that pose the greatest risk of harboring microbial contamination?		
149	Is surface sampling performed at the end of the radiopharmaceutical aseptic activities or shift, but before the area has been cleaned and disinfected?		
149	Do radiopharmaceutical personnel consider the appropriate exposure and contamination prevention measures prior to and while collecting samples?		
149	If the worker assesses that the risk for exposure is not in conformance with ALARA safety standards, are measures taken to eliminate the risk (e.g., implementation of appropriate shielding, performing the sampling at a later time or alternate day)?		
	Sampling Procedures: (6.3)		
149	Are surface sampling devices (e.g., plates, paddles, or slides) containing microbial growth media used for sampling flat surfaces?		
149	Are CoAs from the manufacturer verified that the media meet the expected growth promotion, pH, and sterilization requirements?		
149	Do surface sampling devices contain general microbial growth media (e.g., TSA) supplemented with neutralizing additives (e.g., lecithin and polysorbate 80) to neutralize the effects of any residual disinfecting agents?		
	After sampling, is the sampled area thoroughly cleaned and disinfected?		
149	Does the facility use two samples for each sampling location?		
	Are both TSA?		
	Is one TSA and one Fungal?		
	Is each sample incubated in a separate incubator?		
	Is one sample media incubated at 30°–35° C for no less than 48 hours?		
	If fungal media are used as one of the samples, is it fungal media sample incubated the at 20°–25° C or no less than 5 days?		
	Are the total number of discrete colonies of microorganisms on each sample counted as cfu per sample?		
149, 130	Are the results of the sampling recorded?		
	Data Evaluation and Action Levels: (6.3)		
149	Surface Sampling Action Levels (cfu/device or swab) are within the appropriate range: ISO Class 5 - >3 ISO Class 7 - >5 ISO Class 8 - >50		
149	Are cfu counts evaluated against the action levels and in relation to previous data to identify adverse results and/or trends?		

Deficiency Number	USP chapter references for each section in parenthesis		
		Result	Notes
	If two pieces of media were collected at a single location, is all recovered growth on each documented and action levels are applied to each piece of media individually (i.e., results from each sampling device are compared to the action level for that area)?		
149	If levels measured during the viable air monitoring program exceed the action levels for the ISO classification levels of the area sampled, is the cause investigated, and corrective action is taken?		
	Is data collected in response to corrective actions reviewed to confirm that the actions taken have been effective?		
	Is the corrective action plan dependent on the cfu count and the microorganism recovered?		
	If levels measured during surface sampling exceed the levels, is an attempt made to identify any microorganism recovered to the genus level with the assistance of a qualified individual?		
130	Is the corrective action plan documented?		
	Cleaning and Disinfecting: (7)		
	Are all cleaning and disinfecting activities performed by trained and appropriately garbed personnel using facility approved agents and procedures described in written SOPs?		
	Is cleaning performed in the direction of most to least clean areas?		
	Are the frequency, method(s), and location(s) of cleaning, disinfecting, and sporicidal agent use established in written SOPs, in accordance with the manufacturer's instructions when available, or based on sound microbiological cleaning techniques when unavailable, and followed by all cleaning personnel?		
	Is the manufacturer's direction or published data for the minimum contact time followed for the cleaning, disinfecting, and sporicidal agents used?		
	When sterile 70% IPA is used, is it allowed to dry?		
	Are all cleaning, disinfecting, and application of sporicidal agents documented according to facility SOPs?		
	Are surfaces cleaned prior to being disinfected unless an Environmental Protection Agency (EPA)-registered (or equivalent) one-step disinfectant cleaner is used to accomplish both the cleaning and disinfection in one step?		
	After cleaning and disinfecting or the application of a one-step disinfectant cleaner in a PEC, is sterile 70% IPA applied to remove any residue?		
	Does cleaning and disinfecting surfaces occur at the minimum frequencies in Table 5 or if activities are not performed daily, cleaning and disinfecting completed before initiating activities?		
	Is the act of reducing or removing radioactivity (radioactive decontamination) from an object or surface balanced with the risk of spreading radioactive contamination?		
	Is this balance specified in SOPs (e.g., trigger levels for safe cleaning)?		

Deficiency Number	USP chapter references for each section in parenthesis		
		Result	Notes
	Minimum Frequency for Cleaning and Disinfecting Surfaces in Classified Areas and within the Perimeter of the SRPA: (7)		
	Does Cleaning of the PEC(s) and equipment inside the PEC(s) and/or PEC and the equipment inside the PEC(s) located in a hot-cell occurs in the following situations?		
	Prior to performing sterile processing of radiopharmaceuticals on each day that activities are carried out, are the walls, bars, torso shield and any exposed surface of equipment inside the PEC cleaned to the extent possible as specified by the equipment manufacturer or the assessment of a qualified individual (e.g., microbiologist or industrial hygienist)?		
	Is radioactive contamination shielded with appropriate temporary material, providing the material is covered with low-lint absorbent pads or has equivalent low shedding properties?		
	Does disinfecting of the PEC(s) and equipment inside the PEC(s) and/or PEC and the equipment inside the PEC(s) located in a hot-cell occur in the following situations?		
	Following cleaning on each day that activities are carried out, are exposed surfaces of the equipment disinfected to the extent possible as specified by the equipment manufacturer or the assessment of a qualified individual (e.g., microbiologist or industrial hygienist)?		
	When used, are low-lint absorbent pads removed and the PEC surveyed for radioactive contamination prior to disinfecting?		
	Are new pads replaced after disinfecting or as required after spills?		
	Does Cleaning and Disinfecting occurs DAILY for the following?		
	PEC(s) and equipment inside the PEC(s)		
	Surface of sink(s)		
	PEC and equipment inside the PEC(s) located in a hot cell.		
	Hot-cells (all interior surfaces, dependent on design, equipment, and shielding present)		
	Work surface(s) outside the PEC		
	Floor(s)		
	Does Cleaning and Disinfecting occurs MONTHLY for the following?		
	Ceiling(s)		
	Wall(s), door(s), door frame(s), and other fixtures		
	Storage shelving and storage bins		
	Does Sporicidal application occurs MONTHLY for the following?		
	PEC(s) and equipment inside the PEC(s)		
	Surface of sink(s)		
	Hot-cells (all interior surfaces, dependent on design, equipment, and shielding present)		
	PEC and the equipment inside the PEC(s) located in a hot-cell		
	Work surface(s) outside the PEC		
	Ceiling(s)		
	Wall(s), door(s), door frame(s), and other fixtures		
	Floor(s)		
	Storage shelving and storage bins		

Deficiency Number	USP chapter references for each section in parenthesis		
		Result	Notes
	Cleaning, Disinfecting and Sporicidal Agents: (7.1)		***Note to Inspector*** *: Some EPA-registered (or equivalent) one-step disinfectant cleaners may have sporicidal properties.*
	Are cleaning and disinfecting agents selected and used with careful consideration of compatibilities, effectiveness, and user safety?		
	Are considerations when selecting and using disinfectants include their anti-microbial activity, inactivation by organic matter, residue, shelf life, preparation requirements of the agent, and suitability for surfaces being disinfected?		
	After the disinfectant is applied on the surface to be disinfected, is the disinfectant allowed to dwell for the minimum contact time specified by the manufacturer, during which time the surface cannot be disturbed?		
	Is only sterile 70% IPA used in the ISO Class 5 PEC?		
	Are sporicidal agents used at least monthly on all surfaces in classified areas and SRPAs?		
	Cleaning Supplies: (7.2)		
	Are all cleaning supplies (e.g., wipers and mop heads), with the exception of tool handles and holders, low-lint?		
	If disposable cleaning supplies are used, are they discarded after each cleaning activity?		
	Are reusable cleaning tools made of cleanable materials (e.g., no wooden handles) and are cleaned and disinfected before and after each use?		
	Are reusable cleaning tools dedicated for use in the classified areas or SRPAs and are not removed from these areas except for disposal?		
	Are reusable cleaning tools discarded after an appropriate amount of time, to be determined based on the condition of the tools?		
	Are cleaning supplies used in the classified areas and SRPAs disposed in a manner that minimizes the potential for dispersing particulates into the air (e.g., with minimal agitation, away from work surfaces)?		
	Cleaning and Disinfecting the PEC: (7.3)		
	Is the PEC cleaned and disinfected at the minimum frequencies specified in Table 5?		
	If the PEC contains a removable work tray, are all sides of the work tray and the area underneath the work tray cleaned and disinfected at least monthly?		
	If necessary are all surfaces of the PEC surveyed for radioactive contamination and follow facility SOPs to decontaminate?		
	If necessary, any particles, debris, or residue removed with an appropriate solution (e.g., Sterile Water for Injection or Sterile Water for Irrigation) using sterile, low-lint wipers?		
	Is a cleaning agent applied followed by a disinfecting agent or an EPA-registered (or equivalent) one-step disinfectant cleaner and ensure that the contact time specified per manufacturer instructions is achieved?		
	Is sterile 70% IPA applied?		
	Are the surfaces allowed to dry completely before beginning activities?		
	Is the PEC wiped with a sporicidal agent at least monthly?		

Deficiency Number	USP chapter references for each section in parenthesis		
		Result	Notes
	Disinfecting Supplies for Classified Areas and SRPAs: (7.4)		
	Are shipping carton(s) or other corrugated or uncoated cardboard prohibited in the classified area (e.g., clean side of ante-room) or within the perimeter of the SRPA?		
	Before items are introduced into a classified area or SRPA, are they wiped with a sporicidal agent, EPA-registered (or equivalent) one-step disinfectant cleaner, or sterile 70% IPA using low-lint wipers?		
	After the sporicidal or sterile disinfectant is applied onto the surface, is the agent allowed to dwell on the surface for the minimum contact time specified by the manufacturer?		
	Is the agent used for disinfecting the packaging compatible with the packaging and not render the product label unreadable?		
	Are any items to be transferred into the PEC from the classified area or SRPA disinfected with a sterile disinfectant (e.g., sterile 70% IPA)?		
	If radiopharmaceuticals are being processed by remote means in a hot-cell, the opening of sterile packages (e.g., syringes, luer lock caps) may not be possible by remote means within the ISO Class 5 area.		
130a	In this case, are the syringes opened and appropriately labeled outside of the ISO Class 5 environment and placed in disinfected shielding, immediately prior to the forthcoming dispensing cycle?		
	Disinfecting Critical Sites: (7.5)		
	Are critical sites (e.g., vial stoppers) wiped with sterile 70% IPA? Note: If the vial shield top is then closed, the septum is disinfected again with sterile 70% IPA prior to another needle puncture.		
	Is the critical site wiped ensuring that both chemical and mechanical actions are used to remove contaminants?		
	Is the sterile 70% IPA allowed to dry before piercing critical sites?		
	Is the septum wiped with sterile 70% IPA frequently whenever multiple punctures are occurring (e.g., removing several individual doses from a multiple-dose container)?		
	Documentation: (9)		
130	Are applicable records (hard-copy or electronic), including policies and SOPs, maintained for all activities involved in repackaging, preparing, preparing with minor deviations, compounding, and dispensing radiopharmaceuticals?		

Deficiency Number	USP chapter references for each section in parenthesis	Result	Notes
130	Do such records include all but are not limited to the following?		
	Personnel training and testing including visual assessment of aseptic technique competency		
	Validation		
	Garbing		
	Hand hygiene		
	Equipment/environment cleaning and disinfecting		
	Gloved fingertip and thumb sampling		
	Media fill evaluation initially		
	Media fill follow up testing at specified intervals		
	Equipment maintenance and cleaning/disinfecting		
	End product radiochemical purity and other testing, as applicable, results of preparations, preparations with minor deviations, and compounded preparations		
	Master Formulation Record (MFR) for preparation with minor deviation(s) and compounding		
	Validation of stability testing to support the assigned BUD from SOPs by the compounder or derived from accepted literature		
	Investigations and corrective actions and tracking of events to closure.		
130	Do Testing and Monitoring of environmental controls include the following?		
	ISO classification		
	ACPH		
	Pressure differentials		
	Temperature		
	Recommendation: Humidity		
	Viable air		
	Viable surface		
	Total particle test results		
	Records for Preparation with Minor Deviations/Compounding: (9.2)		
130	Does the record for preparation with minor deviation or compounding includes at a minimum, as applicable, the following?		
	Name of the radiopharmaceutical		
	Physical form (eg capsule or solution)		
	Name and quantity of ingredients including calibration time for radioactive ingredients (e.g., 100 mCi Tc 99m sodium pertechnetate @ 1300)		
	Total volume		
	Reference to the MFR		
	Any deviation from the MFR, if applicable		
	Name of vendor or manufacturer, lot numbers, and expiration dates of all ingredients and components		
	Name of the person who prepared and name of the supervising personnel (e.g., ANP)		
	Date and time of preparation		

Deficiency Number	USP chapter references for each section in parenthesis		
		Result	Notes
130	Assigned internal identification number (e.g., lot number)		
	Unique reference [e.g., prescription, order number(s)]		
	Assigned BUD and storage requirements		
	Documentation of QC results		
	Preparation of Radiolabeled Blood Components (10.3)		***Note to Inspector:*** *Handling blood and radiolabeling of blood components requires special attention to biological risks and need to be handled with standard precautions using aseptic technique to prevent the introduction of new microorganisms into the preparation that will be administered.*
	The preparation BUD does not exceed 6 hours after the blood sample is obtained from the patient or blood bank.		
	Equipment and supplies are never shared with other activities unless they are first thoroughly cleaned and disinfected.		
	Do special precautions when radiolabeling of blood components for non-immediate use include the following?		
	There is complete physical separation (either fixed or non-fixed wall) of areas where blood products are handled from areas where non-blood products are handled. An ISO Class 5 BSC located in an ISO Class 7 buffer area is required for blood-labeling processes. If more than one ISO Class 5 PEC is located within the ISO Class 7 buffer area, policies and SOPs are in place to include certification that the SEC meets conditions of air quality at maximum occupancy under dynamic operating conditions.		
	One radiolabeling procedure per PEC at a time. Blood products from more than one patient are never manipulated at the same workstation at the same time. Each area has dedicated supplies, equipment, and waste disposal to eliminate sharing of these items or overlap in pathways.		
	Thorough cleaning and disinfection of the ISO Class 5 BSC and all reusable equipment within, occurs prior to starting another blood component radiolabeling procedure.		
	If a dedicated dose calibrator is not available, then a means of preventing the blood container(s) from contaminating the dose calibrator is used or the dose calibrator dipper and liner is cleaned and disinfected following the radioassay.		
	Centrifuge is located within the ISO Class 7 buffer area that is dedicated for blood component radiolabeling processes.		
	Dedicated (per each radiolabeling procedure) consumable products (e.g., 0.9% sodium chloride injection, diluent, tubes, syringes, and other supplies) necessary for each individual patient radiolabeling procedure.		
	All tubes and syringes in contact with the patient's blood components are clearly labeled with the patient's name and at least one additional identifier (e.g., date of birth, medical record number, barcode).		
	Dedicated syringe shields and vial shields.		
	Any garb that enters the ISO Class 5 BSC is removed and replaced before handling anything else not related to performing this procedure.		
	Removal of all disposable items from the ISO Class 5 BSC is utilized in each radiolabeling procedure.		

Deficiency Number	USP chapter references for each section in parenthesis	Result	Notes
	Cleaning and disinfection of all reusable equipment and components (e.g., BSC, centrifuge, dose calibrator, syringe shields, vial shields, syringe transport shields and delivery cases) is done after each radiolabeling procedure prior to any further use. Policies and SOPs address cleaning and disinfection processes including the use of an EPA-registered (or equivalent) one-step disinfectant cleaner with activity against blood-borne pathogens followed by sterile 70% IPA. Sterile 70% IPA alone is not sufficient.		
	After the completion of blood radiolabeling procedures, 4.5 Hand Hygiene and Garbing requirements for Buffer Areas and segregated Radiopharmaceutical Processing Area are followed.		
	Preparation of Radiolabeled Blood Cells for Immediate Use (10.4)		
	Is In vitro red blood cell labeling prepared with the following conditions?		
	A dedicated space for blood handling is designated through the entirety of the blood radiolabeling process. This area is free from clutter and not used for any other radiopharmaceutical preparation or handling until the completion of cleaning and disinfection.		
	Only one radiolabeling procedure is performed at a time or there are documented processes that maintain the integrity of samples and environment.		
	Dedicated equipment is used for blood radiolabeling procedure (e.g., L-block, syringe shield, vial shield, forceps, needle recapper).		
	If a dedicated dose calibrator is not available, then a means of preventing the blood container(s) from contaminating the dose calibrator or a cleaning and disinfecting procedure with an appropriate product is used to decontaminate the dipper and liner of the dose calibrator following the radioassay		
	A cleaning and disinfecting procedure with an appropriate agent(s) is used to decontaminate the area and equipment prior to and after the radiolabeling is complete and all disposable components have been discarded		
	All requirements in 4.4 Hand Hygiene and Garbing for Immediate Use Preparations are followed.		
	The start time of the preparation begins with the initial container puncture or the exposure of a critical site (e.g., syringe tip, needle hub or needle) to ambient air, whichever is first.		
	The compounded product has a BUD of 1 hour		
	Compounding: (11)		***Note to Inspector:*** *The combining, mixing, pooling, or otherwise altering (excluding preparation with minor deviations) of a conventionally manufactured radiopharmaceutical or synthesizing/formulating a radiopharmaceutical from bulk drug substances and radionuclides.*
130	Each compounding activity is based on a pre-established written procedure and includes maintenance of compounding records.		
	The compounding record provides traceability for components and person(s) involved.		

Deficiency Number	USP chapter references for each section in parenthesis	Result	Notes
21a	All sterile compounding, using aseptic technique, is performed in an ISO 5 PEC. Compounding employees are using appropriate aseptic technique. May require inspector to garb and enter clean/buffer room. Pay attention to first air, entry and exit of materials in ISO Class 5 PEC, appropriate frequent sanitization of gloves, appropriate cleaning and cleanliness of the direct compounding area (DCA). When applicable, Compounding MUST be observed, if compounding is not being performed at the time of survey mark item as "Non-Compliant".		
27	Compounding is not be performed for any radiopharmaceutical(s) that has been withdrawn from the market because of safety or lack of effectiveness, unless part of an institutional review board approved investigational study.		
28	Radiopharmaceuticals that are essentially copies of marketed FDA-approved radiopharmaceuticals are not be compounded unless there is a change that produces a clinical difference for an identified individual patient, as determined by a prescriber.		
	Compounding Nonsterile Radiopharmaceuticals (11.1)		***Note to Inspector:*** *Compounding nonsterile radiopharmaceuticals is the combining, mixing, diluting, pooling, reconstituting or otherwise altering a drug or bulk drug substance other than as provided by the manufacturer's package insert to create a nonsterile radiopharmaceutical.*
133	Areas designated for nonsterile compounding are cleaned, uncluttered and separated from areas designated for sterile radiopharmaceuticals.		
133	The placement of equipment and materials are designed to prevent cross-contamination.		
	When feasible, disposable material is used to reduce the chance of cross-contamination.		
	Each compound has a unique MFR.		
130	The preparation information is documented on a compounding record.		
	The MFR details the selection of all components.		
	The ingredients obtained from sources in this preferential order: FDA-approved product; FDA-registered facility; and lastly, if the ingredients for the compound are not available from either of these two sources, the MFR details the selection of a material that is suitable for the intended use.		
	The MFR establishes the identity, strength, purity, and quality of the ingredients by validated means (e.g., CoA).		
	A BUD for the compounded radiopharmaceutical is validated, taking into account the stability of the ingredients, any intermediate containers, the final container, and the storage conditions.		
	A BUD cannot be extended past the labeled expiration date of any component in the compound.		
	If the compounded radiopharmaceutical(s) includes components from other preparations or preparations with minor deviations, the BUD of the final compounded radiopharmaceutical does not exceed the shortest remaining BUD of any of those components.		

Deficiency Number	USP chapter references for each section in parenthesis		
		Result	Notes
	Sterile Compounding: (11.2)		***Note to Inspector:*** *Kit-splitting (also referred to as "fractionation") may be used to meet patient need.*
	Do personnel responsible for compounding consider all possible interactions between the components, such as altered chemical stability, radiochemical stability, solubility, or other parameters (e.g., osmolality) related to changes in pH, excipients, or other factors, in determining an appropriate BUD?		
	Do the compounding activities involve the addition of a conventionally manufactured drug product (e.g., Ascorbic Acid Injection, Lidocaine Hydrochloride Injection, Sodium Bicarbonate Injection) approved by the appropriate regulatory agency to a radiopharmaceutical?		
	Does the pharmacy split conventionally marketed kits?		
	Do personnel responsible consider all possible interactions of kit components with these other containers (e.g., container walls, closures), as well as possible alterations in stability (e.g., physical stability, chemical stability) that may affect radiolabeling yields or performance parameters, when determining an appropriate BUD?		
	Systematic QC testing is performed to validate the appropriateness of a particular BUD.		
	Sterile Compounding Using Nonsterile Drug Substance or Components: (11.3)		
	Some sterile compounding activities involve the use of materials other than commercially marketed products, such as drug substances and/or radionuclides.		
25	If one or more materials or components are not certified to be sterile and pyrogen-free, a sterilization procedure (e.g., filtration with bubble point testing) and testing described in <85> is performed. Record calibration date of the bubble test pressure gauge, as applicable.		
	The designated person for compounding is responsible for ensuring that the final preparation complies with pre-established standards or acceptance criteria for identity, quality, and purity.		
	The designated person considers all possible interactions between the components, such as altered chemical stability, radiochemical stability, solubility, or other parameters (e.g., osmolality) related to changes in pH, excipients, or other factors, in determining an appropriate BUD.		
	Testing to validate the appropriateness of a particular BUD may be required.		
27	If compounding involves a bulk drug substance, the radiopharmaceutical complies with standards of an applicable USP or NF monograph, if one exists, or be a component of an approved drug product.		
	A bulk drug substance includes a radionuclide, a ligand, or other substance, such as a precursor that becomes an active ingredient in the final radiopharmaceutical.		
27	Each bulk drug substance is manufactured by drug establishments registered with FDA and be accompanied by a valid CoA or equivalent testing procedures.		
27	If compounding involves excipients or other inactive ingredients, the excipients or other inactive ingredients comply with standards of an applicable USP or NF monograph, if one exists.		
27	It is also acceptable that any excipients or other inactive ingredients be approved products, manufactured by a drug establishment registered with the FDA.		

Deficiency Number	USP chapter references for each section in parenthesis		
		Result	Notes
	Labeling: (12.2)		
130a	Is the inner container (e.g. syringe, vial) labeled with all of the following?		
	Standard radiation symbol		
	The words “Caution—Radioactive Material”		
	For all therapeutic and blood-products, the patient name/identifier		
	Radionuclide and chemical form (generic name)		
	Radioactivity at the date and time of calibration		
130a	Is the outer shielding (e.g., syringe or vial shielding) labeled with all the following?		
	Standard radiation symbol		
	The words “Caution—Radioactive Material”		
	For all therapeutic and blood-products, the patient name/identifier		
	The radionuclide and chemical form (generic name)		
	Radioactivity with units at time of calibration and the calibration time		
	Volume or number of units (e.g., 2 capsules), as applicable		
	Product expiration or BUD, as applicable, and any special storage and handling requirements for non-immediate use (e.g., refrigeration, resuspension)		
	Route of administration		
	Complaint Handling: (14.2)		
	Has the nuclear pharmacy developed and implemented SOPs for handling complaints? Note: Complaints may include concerns or reports on the quality and container labeling of, or possible adverse reactions to, a specific radiopharmaceutical.		
	Does the designated person review all complaints to determine if they indicate potential quality problems with the radiopharmaceutical?		
	If a complaint indicates potential quality issues with radiopharmaceuticals, is an investigation into the potential cause of the issue completed?		
	Does the investigation consider whether the quality problem could extend to other radiopharmaceuticals?		
	Is corrective action, if necessary, implemented for all potentially affected radiopharmaceuticals?		
	Does the investigation consider whether to initiate a recall of potentially affected radiopharmaceuticals and whether to cease sterile compounding until all underlying problems have been identified and corrected?		
130	Is a readily retrievable record (written or electronic) of each complaint kept by the facility, regardless of the source of the complaint (e.g., e-mail, telephone, mail)?		
130	Does the record contain all of the following?		
	The name of the complainant		
	The date the complaint was received		
	The nature of the complaint		
	The response to the complaint		
	If known, the name and strength of the radiopharmaceutical and the assigned internal identification number (e.g., prescription, order, or lot number).		

Deficiency Number	USP chapter references for each section in parenthesis		
		Result	Notes
130	Does the record also include the findings of any investigation and any follow-up?		
130	Are records of complaints easily retrievable for review and evaluation for possible trends?		
130	Are records retained in accordance with the record keeping requirements?		

The information and comments obtained in the Nuclear Pharmacy Inspection is based on USP Chapter <825>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Alternate Delivery			
Deficiency Number			
	Alternate Delivery	Result	Notes
	IN ADDITION TO DIRECT HAND DELIVERY TO A PATIENT OR PATIENT'S AGENT OR DELIVERY TO A PATIENT'S RESIDENCE, A PHARMACY MAY DELIVER TO 1) ANOTHER PHARMACY, 2) A PRACTITIONER OF THE HEALING ARTS LICENSED TO PRACTICE PHARMACY OR TO SELL CONTROLLED SUBSTANCES, 3) AN AUTHORIZED PERSON OR ENTITY HOLDING A CONTROLLED SUBSTANCES REGISTRATION ISSUED FOR THIS PURPOSE [18VAC110-20-275]		
122	**ROUTINE DELIVERY TO ANOTHER PHARMACY [18VAC110-20-275]**		
	One pharmacy may fill prescriptions and deliver the prescriptions to a second pharmacy for patient pickup or direct delivery to the patient provided:		
	1. The two pharmacies have the same owner, ***or***		
	2. Have a written contract or agreement specifying the services to be provided by each pharmacy, the responsibilities of each pharmacy, and the manner in which each pharmacy will comply with all applicable federal and state law		
	Each pharmacy using such a drug delivery system shall maintain and comply with all procedures in a current policy and procedure manual that includes the following information:		
	1. A description of how each pharmacy will comply with all applicable federal and state law		
	2. Procedure for maintaining required, retrievable dispensing records to include		
	a. Which pharmacy maintains the hard-copy prescription		
	b. Which pharmacy maintains the active prescription record for refilling purposes		
	c. How each pharmacy will access prescription information necessary to carry out its assigned responsibilities		
	d. Method of recordkeeping for identifying the pharmacist or pharmacists responsible for dispensing the prescription and counseling the patient		
	e. How and where this information can be accessed upon request by the board		
	3. Procedure for tracking the prescription during each stage of the filling, dispensing, and delivery process		
	4. Procedure for identifying on the prescription label all pharmacies involved in filling and dispensing the prescription		
	5. Policy and procedure for providing adequate security to protect the confidentiality and integrity of patient information		
	6. Policy and procedure for ensuring accuracy and accountability in the delivery process		
	7. Procedure and recordkeeping for returning to the initiating pharmacy any prescriptions that are not delivered to the patient		
	8. Procedure for informing the patient and obtaining consent for using such a dispensing and delivery process		
	Drugs waiting to be picked up at or delivered from the second pharmacy shall be stored in accordance with subsection A of 18VAC110-20-200		

Deficiency Number			
122	**ROUTINE DELIVERY TO A PRACTITIONER OF THE HEALING ARTS LICENSED BY THE BOARD TO PRACTICE PHARMACY OR TO SELL CONTROLLED SUBSTANCES OR OTHER AUTHORIZED PERSON OR ENTITY HOLDING A CONTROLLED SUBSTANCES REGISTRATION [18VAC110-20-275]**		
	A prescription may be delivered by a pharmacy to the office of such a practitioner or other authorized person provided:		
	1. There is a written contract or agreement between the two parties describing the procedures for such a delivery system and the responsibilities of each party		
	2. Each pharmacy using this delivery system shall maintain a policy and procedure manual that includes the following information:		
	a. Procedure for tracking and assuring security, accountability, integrity, and accuracy of delivery for the dispensed prescription from the time it leaves the pharmacy until it is handed to the patient or agent of the patient		
	b. Procedure for providing counseling		
	c. Procedure and recordkeeping for return of any prescription medications not delivered to the patient		
	d. Procedure for assuring confidentiality of patient information;		
	e. Procedure for informing the patient and obtaining consent for using such a delivery process		
	3. Prescriptions waiting to be picked up by a patient at the alternate site shall be stored in a lockable room or lockable cabinet, cart, or other device which cannot be easily moved and which shall be locked at all times when not in use		
	4. Access shall be restricted to the licensed practitioner of the healing arts or the responsible party listed on the application for the controlled substances registration, or either person's designee.		
	5. The contracts or agreements and the policy and procedure manuals required by this section for alternate delivery shall be maintained both at the originating pharmacy as well as the alternate delivery site		

Deficiency Number			
	NON-ROUTINE DELIVERIES TO A PHARMACY, PSD AND/OR CSR [18VAC110-20-275 (F)]		
122	A prescription may be delivered by a pharmacy to the office of such a practitioner or other authorized person provided:		
	1. Pharmacy shall notify the alternate delivery site of the anticipated arrival date of the shipment, the exact address to where the drug was shipped, the name of the patient for whom the drug was dispensed, and any special storage requirements.		
	2. The pharmacy shall provide counseling or ensure a process is in place for the patient to receive counseling.		
	3. Prescriptions delivered to the alternate delivery site shall be stored in a lockable room or lockable cabinet, cart, or other device that cannot be easily moved and that shall be locked at all times when not in use. Access shall be restricted to the licensed prescriber, pharmacist, or either person's designee.		
	4. The pharmacy shall provide a procedure for the return of any prescription drugs not delivered or subsequently administered to the patient		
	A pharmacy shall not deliver dispensed drugs to a patient's residence that are intended to be subsequently transported by the patient or patient's agent to a hospital, medical clinic, prescriber's office, or pharmacy for administration and that require special storage, reconstitution or compounding prior to administration. An exception to this requirement may be made for patients with inherited bleeding disorders who may require therapy to prevent or treat bleeding episodes.		

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Long Term Care			
Deficiency Number			
	Automated Dispensing Device [18VAC110-20-555]	**Result**	**Notes**
	Note: A nursing home without an in-house pharmacy shall obtain a controlled substances registration prior to using an automated dispensing system, unless the system is exclusively stocked with drugs that would be kept in a stat-drug box pursuant to 18VAC110-20-550 or an emergency drug kit pursuant to 18VAC110-20-540 and are solely administered for stat or emergency administration.		
	Does this pharmacy provide drugs to a nursing home that utilizes an automated dispensing system?		
	If **YES**: Is the system is exclusively stocked with drugs that would be kept in a stat-drug box pursuant to 18VAC110-20-550 or an emergency drug kit pursuant to 18VAC110-20-540 and are solely administered for stat or emergency administration.		
138	If **NO**: The Nursing home possess Controlled Substances Registration pursuant to 18VAC 110-20-555 (2)?		
	Floor Stock [18VAC110-20-560]	**Result**	**Notes**
140,141	Prescription drugs, as defined in the Drug Control Act, shall not be floor stocked by a long-term care facility, except those in the stat-drug box or emergency drug box or as provided for in 18VAC110-20-560.		
141	In addition to an emergency box or stat-drug box, a long-term care facility in which only those persons licensed to administer are administering drugs may maintain a stock of intravenous fluids, irrigation fluids, heparin flush kits, medicinal gases, sterile water and saline, and prescription devices. Such stock shall be limited to a listing to be determined by the provider pharmacist in consultation with the medical and nursing staff of the institution.		
	Emergency Drug Kit [18VAC110-20-540]	**Result**	**Notes**
	Drugs that would be stocked in an emergency kit, pursuant to this section, may be stocked in an automated drug dispensing system in a nursing home in accordance with 18VAC110-20-555.		
140	The contents of the emergency kit shall be of such a nature that the absence of the drugs would threaten the survival of the patients.		
	The contents of the kit or an automated drug dispensing system, as provided in subsection 18VAC110-20-555 (B), shall be determined by the provider pharmacist in consultation with the medical and nursing staff of the institutions and shall be limited to drugs for administration by injection or inhalation only, except that Nitroglycerin SL, diazepam rectal gel, and the intranasal spray formulation of naloxone may be included.		
	The contents of the kit shall be determined by the provider pharmacist in consultation with the medical and nursing staff of the institutions and shall be limited to drugs for administration by injection or inhalation only, except that Nitroglycerin SL and diazepam rectal gel may be included.		

Deficiency Number			
	a. The dispensing pharmacy must have a method of sealing such kits so that once the seal is broken, it cannot be reasonably resealed without the breach being detected.		
	b. If a seal is used, it shall have a unique numeric or alphanumeric identifier to preclude replication, resealing, or both. The pharmacy shall maintain a record of the seal identifiers when placed on a box or kit and maintain the record until such time as the seal is replaced.		
	c. In lieu of seals, a kit with a built-in mechanism preventing resealing or relocking once opened except by the provider pharmacy is also acceptable.		
	The kit shall have a form to be filled out upon opening the kit and removing contents to write the name of the person opening the kit, the date, time and name and quantity of items removed. The opened kit is maintained under secure conditions and returned to the pharmacy within 72 hours for replenishing.		
	Any drug used from the kit shall be covered by a prescription, signed by the prescriber, when legally required, within 72 hours.		
	Stat Drug Box [18VAC110-20-550]	**Result**	**Notes**
	The pharmacy may provide more than one stat-drug box to a long-term care facility. Contents of the multiple boxes are not required to be uniform. **Drugs that would be stocked in a stat-drug box, pursuant to this section, may be stocked in an automated drug dispensing system in a nursing home in accordance with 18VAC110-20-555.**		
	The quantity of drugs in Schedules II through V stocked in the automated drug dispensing system shall be determined by the provider pharmacist in consultation with the medical and nursing staff of the nursing home.		
140	An additional drug box called a stat-drug box may be prepared by a pharmacy to provide for initiating therapy prior to the receipt of ordered drugs from the pharmacy. Access to the stat-drug box is restricted to a licensed nurse, pharmacist, or prescriber and only these licensed individuals may administer a drug taken from the stat-drug box. Additionally, a valid prescription or lawful order of a prescriber must exist prior to the removal of any drug from the stat-drug box. A stat-drug box shall be subject to the following conditions:		
	1. The box is sealed in such a manner that will preclude the loss of drugs.		
	a. The dispensing pharmacy must have a method of sealing such boxes so that once the seal is broken; it cannot be reasonably resealed without the breach being detected.		
	b. If a seal is used, it shall have a unique numeric or alphanumeric identifier to preclude replication and/or resealing. The pharmacy shall maintain a record of the seal identifiers when placed on a box and maintain the record until such time as the seal is replaced.		
	c. In lieu of seals, a box with a built-in mechanism preventing resealing or relocking once opened except by the provider pharmacy is also acceptable.		
	2. The box shall have a form to be filled out upon opening the box and removing contents to write the name of the person opening the box, the date, the time and the name and quantity of items removed. When the stat-drug box has been opened, it is returned to the pharmacy.		

Deficiency Number			
	3. There shall be a listing of the contents of the box maintained in the pharmacy and also attached to the box in the facility. This same listing shall become a part of the policy and procedure manual of the facility served by the pharmacy.		
	4. The drug listing on the box shall bear an expiration date for the box. The expiration date shall be the day on which the first drug in the box will expire.		
	5. The contents of the box shall be limited to those drugs in which a delay in initiating therapy may result in harm to the patient.		
	a. The listing of drugs contained in the stat-drug box shall be determined by the provider pharmacist in consultation with the medical and nursing staff of the long-term care facility.		
	b. The stat-drug box shall contain no more than 20 solid dosage units per schedule of Schedule II through V drugs except that one unit of liquid, not to exceed 30 ml, may be substituted for a solid dosage unit in each drug schedule. If the unit of a liquid that may contain more than one dose is removed from the stat-box pursuant to a patient order, the remainder shall be stored with that patient's other drugs, may be used for subsequent doses administered to that patient, and shall not be administered to any other patient.		

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Hospital			
Deficiency Number			
	General	**Result**	**Notes**
7, 9, 9a, 10, 11, 12, 111, 144	Prior to the opening of a satellite pharmacy within the hospital, the PIC shall notify the board as required by 18VAC110-20-140 and shall ensure compliance with subsections B through G of 18VAC110-20-150, 18VAC110-20-160, 18VAC110-20-170, 18VAC110-20-180 and 18VAC110-20-190. No drugs shall be stocked in a satellite pharmacy until an inspection has been completed and approval given for opening. **[18VAC110-20-440]**		
136	Authorized nurse may have access to a supply of drugs maintained by the pharmacy at a location outside the pharmacy in order to obtain emergency medication during hours the pharmacy is closed. [**18VAC110-20-450]**		
	Drug is available in the manufacturer's original package or in units which have been prepared and labeled by a pharmacist.		
	A separate record shall be made and left at the location of the stock of drugs that includes the following information:		
	1. Date of withdrawal		
	2. Name of patient		
	3. Name of the drug, strength, dosage form and dose prescribed		
	4. Number of doses removed		
	5. Signature of the authorized nurse		
	Records are maintained within the pharmacy for a period of one year.		
30	If the after-hours supply is maintained in an area of the hospital that is not open and continuously staffed, an alarm that meets the requirements of 18VAC110-20-180 shall be installed and activated at all times. [**18VAC110-20-180]**		
	Emergency Medical Services	**Result**	**Notes**
139	The pharmacy may prepare a drug kit for a licensed emergency medical services agency provided: [**18VAC110-20-500]**		
	The PIC of the hospital pharmacy shall be responsible for all prescription drugs and Schedule VI controlled devices contained in this drug kit. Except as authorized in **18VAC110-20-505**, a pharmacist shall check each drug kit after filling the kit, and initial the filling record certifying the accuracy and integrity of the contents of the kit.		
	The drug kit is sealed, secured, and stored in such a manner that it will deter theft or loss of drugs and devices and aid in detection of such theft or loss.		
	a. The hospital pharmacy shall have a method of sealing the kits such that once the seal is broken, it cannot be reasonably resealed without the breach being detected.		
	b. If a seal is used, it shall have a unique numeric or alphanumeric identifier to preclude replication or resealing. The pharmacy shall maintain a record of the seal identifiers when placed on a kit and maintain the record for a period of one year.		
	c. In lieu of a seal, a kit with a built-in mechanism preventing resealing or relocking once opened except by the provider pharmacy may be used.		

Deficiency Number			
	Drugs and devices may be administered by an EMS provider upon an oral or written order or standing protocol of an authorized medical practitioner in accordance with § 54.1-3408 of the Code of Virginia. Oral orders shall be reduced to writing by the EMS provider and shall be signed by a medical practitioner. Written standing protocols shall be signed by the operational medical director for the EMS agency. A current copy of the signed standing protocol shall be maintained by the pharmacy participating in the kit exchange. The EMS provider shall make a record of all drugs and devices administered to a patient.		
	When the drug kit has been opened, the kit shall be returned to the pharmacy and exchanged for an unopened kit. The record of the drugs administered shall accompany the opened kit when exchanged. An accurate record shall be maintained by the pharmacy on the exchange of the drug kit for a period of one year. A pharmacist, pharmacy technician, or nurse shall reconcile the Schedule II, III, IV, or V drugs in the kit at the time the opened kit is returned. A record of the reconciliation, to include any noted discrepancies, shall be maintained by the pharmacy for a period of two years from the time of exchange. The theft or any other unusual loss of any Schedule II, III, IV, or V controlled substance shall be reported in accordance with § 54.1-3404 of the Code of Virginia.		
	Accurate records of the following shall be maintained by the pharmacy on the exchange of the drug kit for a period of one year:		
	a. The record of filling and verifying the kit to include the drug contents of the kit, the initials of the pharmacist verifying the contents, the date of verification, a record of an identifier if a seal is used, and the assigned expiration date for the kit, which shall be no later than the expiration date associated with the first drug or device scheduled to expire.		
	b. The record of the exchange of the kit to include the date of exchange and the name of EMS agency and EMS provider receiving the kit.		
	Destruction of partially used Schedules II, III, IV, and V drugs shall be accomplished by two persons, one of whom shall be the EMS provider and the other shall be a pharmacist, nurse, prescriber, pharmacy technician, or a second EMS provider. Documentation shall be maintained in the pharmacy for a period of two years from the date of destruction.		
	The record of the drugs and devices administered shall be maintained as a part of the pharmacy records pursuant to state and federal regulations for a period of not less than two years.		
	Intravenous and irrigation solutions provided by a hospital pharmacy to an emergency medical services agency may be stored separately outside the kit.		
	Any drug or device showing evidence of damage or tampering shall be immediately removed from the kit and replaced.		
	In lieu of exchange by the hospital pharmacy, the PIC of the hospital pharmacy may authorize the exchange of the kit by the emergency department. Exchange of the kit in the emergency department shall only be performed by a pharmacist, nurse, or prescriber if the kit contents include Schedule II, III, IV, or V drugs.		

Deficiency Number			
	A licensed EMS agency may obtain a controlled substances registration pursuant to § 54.1-3423 D of the Code of Virginia for the purpose of performing a one-to-one exchange of Schedule VI drugs or devices.		
	1. The controlled substances registration may be issued to a single agency or to multiple agencies within a single jurisdiction.		
	2. The controlled substances registration issued solely for this intended purpose does not authorize the storage of drugs within the agency facility.		
	3. Pursuant to § 54.1-3434.02 of the Code of Virginia, the EMS provider may directly obtain Schedule VI drugs and devices from an automated drug dispensing device.		
	4. If such drugs or devices are obtained from a nurse, pharmacist, or prescriber, it shall be in accordance with the procedures established by the pharmacist-in-charge, which shall include a requirement to record the date of exchange, name of licensed person providing drug or device, name of the EMS agency and provider receiving the drug or device, and assigned expiration date. Such record shall be maintained by the pharmacy for one year from the date of exchange.		
	5. If an EMS agency is performing a one-to-one exchange of Schedule VI drugs or devices, Schedule II, III, IV, or V drugs shall remain in a separate, sealed container and shall only be exchanged in accordance with provisions of subsection A of this section.		
	Floor Stock	**Result**	**Notes**
	A pharmacist shall check all Schedule II-VI drugs delivered to a hospital unit as floor-stock before the drugs leave the pharmacy and shall initial or sign manually or electronically the record of distribution verifying the accuracy of the distribution. [**18VAC110-20-460]**		
	A delivery receipt shall be obtained for Schedule II through V drugs supplied as floor stock that contains the following information:		
	1. Date		
	2. Drug name and strength		
	3. Quantity		
	4. Hospital unit receiving drug		
	5. Manual or electronic signatures of the dispensing pharmacist and the receiving nurse		
137	A record of disposition/administration shall be used to document administration of Schedule II through V drugs when a floor stock system is used for such drugs. The record shall be returned to the pharmacy within three months of its issue.		
	The PIC or his designee shall:		
	1. Match returned records with delivery receipts to verify that all records are returned		
	2. Periodically audit returned administration records for completeness as to patient's names, dose, date and time of administration, signature or initials of person administering the drug, and date the record is returned		
	3. Verify that all additions to inventory are recorded, that all additions to and deductions from inventory are correctly calculated, that sums carried from one record to the next are correctly recorded		
	4. Periodically verify that doses documented on administration records are reflected in the medical record		
	5. Initial the returned record		

Deficiency Number			
137	All records required by this section shall be filed chronologically by date of issue, and retained for two years from the date of return at the address of the pharmacy. Schedule VI records may be maintained in offsite storage or as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic storage is retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent. Schedule II-V records may only be stored offsite or electronically as described in this subsection if authorized by DEA or in federal law or regulation. The filing requirements of 18VAC110-20-240 A 1 for separation of Schedule II records shall be met for administration records if the Schedule II drugs are listed in a separate section on a page that contains other schedules of drugs.		
	Policies & Procedures	**Result**	**Notes**
134	Policies & procedures for and assuring maintenance of the proper storage, security, and dispensing of all drugs used throughout the hospital. [**18VAC110-20-440]**		
135	Policy and procedure for providing reviews of drug therapy. [**18VAC110-20-440]**		
	Use of Radio-Frequency Identification	**Result**	**Notes**
	A hospital pharmacy may use radio-frequency identification (RFID) to verify the accuracy of drugs placed into a kit for licensed emergency medical services pursuant to 18VAC110-20-500 or other kits used as floor stock throughout the hospital under the following conditions **[18VAC110-20-505]**:		
	A pharmacist shall be responsible for performing and verifying the accuracy of the following tasks:		
	a. The addition, modification, or deletion of drug information into the RFID database for assignment of a RFID tag to an individual drug; and		
	b. The development of the contents of the kit in the RFID database and the associated drug-specific RFID tags		
	A pharmacy technician may place the RFID tag on the drugs, and a pharmacist shall verify that all drugs have been accurately tagged prior to storing the drugs in the pharmacy's inventory.		
	A pharmacy technician may remove RFID-tagged drugs from the pharmacy's inventory whose RFID tags have been previously verified for accuracy by a pharmacist and place the drugs into the kit's container. A pharmacy technician may then place the container into the pharmacy's device that reads the RFID tags to verify if the correct drugs have been placed into the container as compared to the list of the kit's contents in the RFID database.		
	A pharmacist shall perform a daily random check for verification of the accuracy of 5.0% of all kits prepared that day utilizing the RFID technology. A manual or electronic record from which information can be readily retrieved, shall be maintained that includes:		
	a. The date of verification;		
	b. A description of all discrepancies identified, if any; and		
	c. The initials of pharmacist verifying the accuracy of the process.		
	Pharmacies engaged in RFID tagging of drugs shall be exempt from the requirements in subsection C of 18VAC110-20-490, subsection A of 18VAC110-20-460, and subsection A of 18VAC110-20-355.		
	All records required by this subsection shall be maintained for a period of one year from the date of verification by the pharmacist.		

Central or Remote Processing - Community, Retail & Mail Order			
Deficiency Number			
	Central or Remote Processing	**Result**	**Notes**
123	Centralized or remote processing of a prescription does not include the dispensing of a drug, but does include any of the following activities related to the dispensing process: **[18VAC110-20-276]**		
	1. Receiving, interpreting, analyzing, or clarifying prescriptions.		
	2. Entering prescription and patient data into a data processing system		
	3. Transferring prescription information.		
	4. Performing a prospective drug review as set forth in § 54.1-3319 of the Code of Virginia		
	5. Obtaining refill or substitution authorizations, or otherwise communicating with the prescriber concerning a patient's prescription		
	6. Interpreting clinical data for prior authorization for dispensing;		
	7. Performing therapeutic interventions		
	8. Providing drug information or counseling concerning a patient's prescription to the patient or patient's agent.		
	A pharmacy may outsource certain prescription processing functions as described in subsection A to another pharmacy in Virginia or a registered non-resident pharmacy under the following conditions:		
	1. The pharmacies shall either have the same owner or have a written contract describing the scope of services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with all federal and state laws and regulations related to the practice of pharmacy;		
	2. Any central or remote pharmacy shall comply with Virginia law and regulation with respect to requirements for supervision of pharmacy technicians and the duties which are restricted to pharmacists and pharmacy technicians. Pharmacy technicians at the remote pharmacy shall either be registered in Virginia or possess credentials substantially equivalent to those required for a technician registered in Virginia;		
	3. A pharmacist licensed in Virginia, whether at the remote pharmacy or the dispensing pharmacy, shall perform a check for accuracy on all processing done by the remote processor; and		
	4. The pharmacies shall share a common electronic file or have technology which allows sufficient information necessary to process a non-dispensing function.		

Deficiency Number			
123	Any pharmacy that outsources prescription processing to another pharmacy shall provide notification of such to patients. A one-time written notification or a sign posted in the pharmacy in a location that is readily visible to the public will satisfy this notification requirement. The notice shall state the name of any contract pharmacy providing central or remote prescription processing. If the pharmacy uses a network of pharmacies under common ownership, this fact shall be disclosed in the notice.		
	A policy and procedure manual that relates to remote processing shall be maintained at each pharmacy involved in the processing of a prescription and available for inspections. The manual shall include at a minimum:		
	1. The responsibilities of each pharmacy;		
	2. A list of the name, address, telephone numbers, and permit/registration numbers of all pharmacies involved in central or remote processing;		
	3. Procedures for protecting the confidentiality and integrity of patient information;		
	4. Procedures for ensuring that pharmacists performing prospective drug reviews have access to appropriate drug information resources;		
	5. Procedures for maintaining required records;		
	6. Procedures for complying with all applicable laws and regulations to include counseling;		
	7. Procedures for objectively and systematically monitoring and evaluating the quality of the program to resolve problems and improve services; and		
	8. Procedures for annually reviewing the written policies and procedures for needed modifications and documenting such review.		
	In addition to any other required records, pharmacies engaged in central or remote processing shall maintain retrievable records which show, for each prescription processed, each individual processing function and identity of the pharmacist or pharmacy technician who performs a processing function and the pharmacist who checked the processing function, if applicable.		
	1. The records may be maintained separately by each pharmacy, or in a common electronic file shared by both pharmacies provided the system can produce a record showing each processing task, the identity of the person performing each task, and the location where each task was performed.		
	2. The record shall be readily retrievable for at least the past two years through the primary dispensing pharmacy, and shall be available for inspection by the board.		

Remote Order Prescription Processing - Hospitals & Long Term Care

Deficiency Number	Remote Order Prescription Processing - Hospitals & Long Term Care	Result	Notes
123	Pharmacy does not dispense drugs, but does include any of the following activities related to the dispensing process: **[18VAC110-20-515]**		
	1. Receiving, interpreting, analyzing, or clarifying prescriptions.		
	2. Entering prescription and patient data into a data processing system		
	3. Transferring prescription information.		
	4. Performing a prospective drug review to include an evaluation of a prescription order and patient records for over- or under-utilization of medication, therapeutic duplication of medication, drug-disease contraindications, drug interactions, incorrect drug dosage or duration of drug treatment, or clinical abuse or misuse of medication		
	5. Obtaining substitution authorizations, or otherwise communicating with the prescriber concerning a patient's order.		
	6. Interpreting or acting on clinical data		
	7. Performing therapeutic interventions		
	8. Providing drug information to the medical or nursing staff of the hospital or long term care facility		
	9. Authorizing the administration of the drug to the patient by appropriate hospital or LTC facility staff		
	The primary pharmacy providing pharmacy services may outsource certain order processing functions to another pharmacy in Virginia or a registered non-resident pharmacy.		
	1. The pharmacies shall either have the same owner or have a written contract describing the scope of services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with all federal and state laws and regulations related to the practice of pharmacy;		
	2. Any central or remote pharmacy shall comply with Virginia law and regulation with respect to requirements for supervision of pharmacy technicians and the duties which are restricted to pharmacists and pharmacy technicians. Pharmacy technicians at the remote pharmacy shall either be registered in Virginia or possess credentials substantially equivalent to those required for a technician registered in Virginia;		
	3. Any pharmacist participating in remote prescription order processing shall be a Virginia licensed pharmacist; and		
	4. The pharmacies shall share a common electronic file or have technology which allows sufficient information necessary to process a prescription order.		

Deficiency Number			
123	A policy and procedure manual that relates to remote processing shall be maintained at each pharmacy involved in the processing of a prescription and available for inspections. The manual shall include at a minimum:		
	1. The responsibilities of each pharmacy		
	2. A list of the name, address, telephone numbers, and permit /registration numbers of all pharmacies involved in remote processing		
	3. Procedures for protecting the confidentiality and integrity of patient information.		
	4. Procedures for ensuring that pharmacists performing drug reviews have access to appropriate drug information resources		
	5. Procedures for maintaining required records.		
	6. Procedures for complying with all applicable laws and regulations.		
	7. Procedures for objectively and systematically monitoring and evaluating the quality of the program to resolve problems and improve services.		
	8. Procedure for annually reviewing the written policies/procedures for needed modifications and documenting such review.		
	A pharmacy involved in remote prescription order processing shall maintain a record that identifies each person who performed a processing function for every order.		
	1. The record shall be available by prescription order or by patient name.		
	2. The record may be maintained in a common electronic file if the record is maintained in such a manner that the data processing system can produce a printout which identifies every person who performed a task involved in processing a prescription order and the location where the task was processed.		
	3. The record shall be readily retrievable for at least the past two years through the primary dispensing pharmacy, and shall be available for inspection by the board.		

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Pharmacy Routine Inspection Form

Automated Drug Dispensing System - Hospital			
Deficiency Number			
	Automated Drug Dispensing System - Hospital	**Result**	**Notes**
138	Drugs are placed in the automated drug dispensing system in a hospital and are under the control of a pharmacy providing services to the hospital **[§54.1-3434.02]**		
	The pharmacist-in-charge of the pharmacy providing services to the hospital has established procedures for:		
	1. assuring the accurate stocking and proper storage of drugs in the automated drug dispensing system		
	2. ensuring accountability for and security of all drugs utilized in the automated drug dispensing system until the time such drugs are removed from the automated drug dispensing system for administration to the patients		
	3. periodically inspecting and auditing automated drug dispensing systems to assure the proper storage, security, and accountability for all drugs placed in and removed from automated drug dispensing systems		
	4. reviewing the operation and maintenance of automated drug dispensing systems.		
	Removal of drugs from any automated drug dispensing system for administration to patients can only be made pursuant to a valid prescription or lawful order of a prescriber		
	Adequate security for automated drug dispensing systems is provided, as evidenced by written policies and procedures, for		
	1. preventing unauthorized access,		
	2. complying with federal and state regulations on prescribing and dispensing controlled substances,		
	3. maintaining patient confidentiality,		
	4. assuring compliance with the requirements of §54.1-3434.02		
	Accountability for drugs dispensed from automated drug dispensing systems is vested in the pharmacist-in-charge of a pharmacy located within the hospital or the pharmacist-in-charge of any outside pharmacy providing pharmacy services to the hospital;		
	Filling and stocking of drugs into an automated drug dispensing system shall be performed by a pharmacist or a registered pharmacy technician, who shall be an employee of the provider pharmacy and shall be properly trained in accordance with established standards set forth in a policy and procedure manual maintained by the provider pharmacy.		
	Drugs placed into and removed from automated drug dispensing systems for administration to patients shall be in the manufacturer's or distributor's sealed original packaging or in unit-dose containers packaged by the pharmacy.		

Deficiency Number			
A hospital may use automated devices for the dispensing and administration of drugs pursuant to §54.1-3301 of the Code of Virginia and §§54.3401 and 54.1-3434.02 of the Drug Control Act and in accordance with 18VAC110-20-270, 18VAC110-20-420 or 18VAC110-20-460 as applicable. The following conditions shall apply: [18VAC110-20-490]			
	Policy & Procedures & Access Codes	**Result**	**Notes**
138	Proper use of the automated dispensing devices and means of compliance with requirements shall be set forth in the pharmacy's policy and procedure manual, which shall include provisions for granting and terminating user access.		
	Personnel allowed access to an automated dispensing device shall have a specific access code which records the identity of the person accessing the device. The device may verify access codes using biometric identification or other coded identification after the initial log-on in order to eliminate sharing or theft of access codes.		
	Distribution of Drugs from the Pharmacy	**Result**	**Notes**
138	Prior to removal of drugs from the pharmacy, a delivery record shall be generated for all drugs to be placed in an automated dispensing device. The delivery record shall include the date; drug name, dosage form, and strength; quantity; hospital unit and a unique identifier for the specific device receiving the drug; initials of the person loading the automated dispensing device; and initials of the pharmacist checking the drugs to be removed from the pharmacy and the delivery record for accuracy.		
	At the time of loading any Schedules II through V drug, the person loading will verify that the count of that drug in the automated dispensing device is correct. Any discrepancy noted shall be recorded on the delivery record and immediately reported to the pharmacist in charge, who shall be responsible for ensuring reconciliation of the discrepancy or properly reporting of a loss.		
	Distribution of Drugs from the Device	**Result**	**Notes**
138	Automated dispensing devices in hospitals shall be capable of producing a hard-copy record of distribution that shall show patient name, drug name and strength, dose withdrawn, date and time of withdrawal from the device, and identity of person withdrawing the drug. The record shall be filed in chronological order from date of issue or maintained electronically.		
	If an automated dispensing device is used to obtain drugs for dispensing from an emergency room, a separate dispensing record is not required provided the automated record distinguishes dispensing from administration and records the identity of the physician who is dispensing.		
	Discrepancy Reports	**Result**	**Notes**
138	A discrepancy report for all Schedules II through V drugs and any drugs of concern, as defined in § 54.1-3456.1 of the Code of Virginia, shall be generated for each discrepancy in the count of a drug on hand in the device. Each such report shall be initiated or resolved by the PIC or his designee within 72 hours of the time the discrepancy was discovered or, if determined to be a theft or an unusual loss of drugs, shall be immediately reported to the board in accordance with § 54.1-3404 E of the Drug Control Act.		

Deficiency Number			
	Reviews & Audits	**Result**	**Notes**
138	The PIC or his designee shall conduct at least a monthly review for compliance with written policy and procedures which are consistent with subsection A of § 54.1-3434.02 for security and use of the automated dispensing devices, to include procedures for timely termination of access codes, when applicable, and proper recordkeeping.		
138	The PIC or his designee shall conduct at least a monthly audit to review distribution of Schedules II through V drugs from each automated dispensing device as follows:		
	a. The audit shall reconcile records of all quantities of Schedules II through V drugs dispensed from the pharmacy with records of all quantities loaded into each device to detect whether any drug recorded as removed from the pharmacy was diverted rather than being placed in the proper device.		
	b. If a pharmacy has an ongoing method for perpetually monitoring drugs in Schedules II-V to ensure drugs dispensed from the pharmacy have been loaded into the device and not diverted, such as with the use of perpetual inventory management software, then the audit required in this subsection may be limited to the discrepancies or exceptions as identified by the method for perpetually monitoring the drugs.		
138	The PIC or his designee shall conduct at least a monthly audit to review the dispensing and administration records of Schedules II through V drugs from each automated dispensing device as follows:		
	a. The audit shall include a review of administration records for each device per month for possible diversion by fraudulent charting. The review shall include all Schedules II through V drugs administered for a time period of not less than 24 consecutive hours during the audit period.		
	b. The hard-copy distribution and administration records printed out and reviewed in the audit shall be initialed and dated by the person conducting the audit. If nonpharmacist personnel conduct the audit, a pharmacist shall review the record and shall initial and date the record.		
	c. The PIC or his designee shall be exempt from requirements of this audit if reconciliation software which provides a statistical analysis is used to generate reports at least monthly. The statistical analysis shall be based on:		
	(1) Peer-to-peer comparisons of use for that unit or department; and		
	(2) Monitoring of overrides and unresolved discrepancies.		
	d. The report shall be used to identify suspicious activity which includes usage beyond three standard deviations in peer-to-peer comparisons. A focused audit of the suspicious activity and individuals associated with the activity shall be performed whenever suspicious activity is identified from the reports.		
	The PIC or his designee shall maintain a record of compliance with the reviews and audits in accordance with subsection H of this section.		

Deficiency Number			
	Inspections	**Result**	**Notes**
138	Automated dispensing devices shall be inspected monthly by pharmacy personnel to verify proper storage, proper location of drugs within the device, expiration dates, the security of drugs and validity of access codes. The PIC or his designee shall maintain documentation of the inspection in accordance with subsection H of this section. With the exception of a monthly physical review of look-alike and sound-alike drugs stored within matrix drawers or open access areas within the device, such monthly inspection shall not require physical inspection of the device if the device is capable of and performs the following:		
138	a. At least daily monitoring of refrigerator or freezer storage with documented temperature ranges, variances, and resolutions;		
	b. Automatic identification and isolation of the location of each drug within the device using a machine readable product identifier, such as barcode technology, and generation of a report verifying the applicable settings;		
	c. Electronic tracking of drug expiration dates and generation of proactive reports allowing for the replacement of drugs prior to their expiration date; and		
	d. Electronic detection of the opening of the device, identification of the person accessing the device, automatic denial of access to the device during malfunctions and mechanical errors, and generation of reports of any malfunction and mechanical error.		
	Records	**Result**	**Notes**
138	All records required by this section shall be maintained for a period of not less than two years. Records shall be maintained at the address of the pharmacy providing services to the hospital except manual Schedule VI distribution records, reports auditing for indications of suspicious activity, and focused audits, all of which may be maintained in offsite storage or electronically as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic records are retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.		
	Distribution and delivery records and required initials may be generated or maintained electronically provided:		
	a. The system being used has the capability of recording an electronic signature that is a unique identifier and restricted to the individual required to initial or sign the record.		
	b. The records are maintained in a read-only format that cannot be altered after the information is recorded.		
	c. The system used is capable of producing a hard-copy printout of the records upon request.		
	Schedules II through V distribution and delivery records may also be stored off site or electronically in compliance with requirements of subdivision 1 of this subsection and if authorized by DEA or in federal law or regulation.		

Deficiency Number			
138	Hard-copy distribution and administration records that are printed and reviewed in conducting required audits may be maintained at an off-site location or electronically provided they can be readily retrieved upon request; provided they are maintained in a read-only format that does not allow alteration of the records; and provided a separate log is maintained for a period of two years showing dates of audit and review, the identity of the automated dispensing device being audited, the time period covered by the audit and review, and the initials of all reviewers.		

Automated Drug Dispensing System and Remote Dispensing System - Nursing Home, State Facilities and Crisis Stabilization Units			
Deficiency Number			
	ADD and RDU in Approved Facilities	**Result**	**Notes**
Nursing homes licensed pursuant to Title 32.1, state facilities as defined in 37.2-100 established pursuant to Title 37.2, facilities as defined in 37.2-100 that are licensed by Department of Behavioral Health and Developmental Services and provide site-based crisis stabilization services, or other facilities authorized by the Board may use automated drug dispensing systems, as defined in § 54.1-3401 of the Code of Virginia, upon meeting the following conditions: [18VAC110-20-555]			
138	Drugs placed in an automated drug dispensing system or remote dispensing system in a nursing home or facility shall be under the control of the pharmacy providing services to the nursing home or facility, the pharmacy shall have on-line communication with and control of the automated drug dispensing system, and access to any drug for a patient shall be controlled by the pharmacy.		
	A nursing home or facility without an in-house pharmacy shall obtain a controlled substances registration prior to using an automated dispensing system, unless the system is exclusively stocked with drugs that would be kept in a stat-drug box pursuant to 18VAC110-20-550 or an emergency drug kit pursuant to 18VAC110-20-540 and are solely administered for stat or emergency administration.		
138	Except when the automated drug dispensing system is used exclusively for administration of drugs for emergencies, a pharmacy located outside the hospital, nursing home or facility it services must obtain a controlled substance registration issued in the name of the provider pharmacy at the address of the facility where the system is located and a registration from the DEA, if required, prior to stocking controlled substances in Schedules II-VI.		
	For facilities not required to obtain a controlled substance registration, access to the automated dispensing device shall be restricted to a licensed nurse, pharmacist, or prescriber, or a registered pharmacy technician for the purpose of stocking or reloading.		
	Distribution of Drugs from the Pharmacy & Device	**Result**	**Notes**
138	Removal of drugs from any automated drug dispensing system or remote dispensing system for administration to patients can only be made pursuant to a valid prescription or lawful order of a prescriber under the following conditions:		
31	a. A drug, including a drug that would be stocked in a stat-drug box pursuant to subsection B of 18VAC110-20-550, may not be administered to a patient from an automated dispensing device until a pharmacist has reviewed the prescription order and electronically authorized the access of that drug for that particular patient in accordance with the order.		
138	b. The PIC of the provider pharmacy shall ensure that a pharmacist who has online access to the system is available at all times to review a prescription order as needed and authorize administering pursuant to the order reviewed.		
	c. Drugs that would be stocked in an emergency drug kit pursuant to 18VAC110-20-540 may be accessed prior to receiving electronic authorization from the pharmacist provided that the absence of the drugs would threaten the survival of the patients.		

Deficiency Number			
	d. Automated dispensing devices shall be capable of producing a hard-copy record of distribution that shall show patient name, drug name and strength, dose withdrawn, dose to be administered, date and time of withdrawal from the device, and identity of person withdrawing the drug.		
138	Drugs placed in automated dispensing devices shall be in the manufacturer's sealed original unit dose or unit-of-use packaging or in repackaged unit-dose containers in compliance with the requirements of 18VAC110-20-355 relating to repackaging, labeling, and records.		
138	Prior to removal of drugs from the pharmacy, a delivery record shall be generated for all drugs to be placed in an automated dispensing device which shall include the date; drug name, dosage form, and strength; quantity; nursing home; and a unique identifier for the specific device receiving drugs; and initials of pharmacist checking the order of drugs to be removed from the pharmacy and the records of distribution for accuracy.		
138	At the direction of the PIC, drugs may be loaded in the device by a pharmacist or a pharmacy technician adequately trained in the proper loading of the system.		
	At the time of loading, the delivery record for all Schedules II through VI drugs shall be signed by a nurse or other person authorized to administer drugs from that specific device, and the record returned to the pharmacy.		
	At the time of loading any Schedules II through V drug, the person loading will verify that the count of that drug in the automated dispensing device is correct. Any discrepancy noted shall be recorded on the delivery record and immediately reported to the PIC, who shall be responsible for reconciliation of the discrepancy or properly reporting of a loss.		
	Reviews & Audits	**Result**	**Notes**
138	The PIC of the provider pharmacy or his designee shall conduct at least a monthly audit to review distribution and administration of Schedules II through V drugs from each automated dispensing device as follows:		
	a. The audit shall reconcile records of all quantities of Schedules II through V drugs dispensed from the pharmacy with records of all quantities loaded into each device to detect whether any drugs recorded as removed from the pharmacy were diverted rather than being placed in the proper device.		
	b. A discrepancy report shall be generated for each discrepancy in the count of a drug on hand in the device. Each such report shall be resolved by the PIC or his designee within 72 hours of the time the discrepancy was discovered or, if determined to be a theft or an unusual loss of drugs, shall be immediately reported to the board in accordance with § 54.1-3404 E of the Drug Control Act.		
	c. The audit shall include a review of a sample of administration records from each device per month for possible diversion by fraudulent charting. A sample shall include all Schedule II through V drugs administered for a time period of not less than 24 consecutive hours during the audit period.		
	d. The audit shall include a check of medical records to ensure that a valid order exists for a random sample of doses recorded as administered.		
	e. The audit shall also check for compliance with written procedures for security and use of the automated dispensing devices, accuracy of distribution from the device, and proper recordkeeping.		

Deficiency Number			
138	f. The hard-copy distribution and administration records printed out and reviewed in the audit shall be initialed and dated by the person conducting the audit. If nonpharmacist personnel conduct the audit, a pharmacist shall review the record and shall initial and date the record.		
	Inspections	**Result**	**Notes**
138	Automated dispensing devices shall be inspected monthly by pharmacy personnel to verify proper storage, proper location of drugs within the device, expiration dates, the security of drugs and validity of access codes.		
	Personnel allowed access to an automated dispensing device shall have a specific access code which records the identity of the person accessing the device.		
	Policy & Procedures & Access Codes	**Result**	**Notes**
138	The PIC of the pharmacy providing services to the nursing home shall establish, maintain, and assure compliance with written policy and procedure for the accurate stocking and proper storage of drugs in the automated drug dispensing system, accountability for and security of all drugs maintained in the automated drug dispensing system, preventing unauthorized access to the system, tracking access to the system, complying with federal and state regulations related to the storage and dispensing of controlled substances, maintaining patient confidentiality, maintaining required records, and assuring compliance with the requirements of this chapter. The manual shall be capable of being accessed at both the pharmacy and the nursing home.		
	Records	**Result**	**Notes**
138	All records required by this section shall be filed in chronological order from date of issue and maintained for a period of not less than two years. Records shall be maintained at the address of the pharmacy providing services to the nursing home except:		
	a. Manual Schedule VI distribution records may be maintained in offsite storage or electronically as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic storage is retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.		
	b. Distribution and delivery records and required signatures may be generated or maintained electronically provided:		
	(1) The system being used has the capability of recording an electronic signature that is a unique identifier and restricted to the individual required to initial or sign the record.		
	(2) The records are maintained in a read-only format that cannot be altered after the information is recorded.		
	(3) The system used is capable of producing a hard-copy printout of the records upon request.		
	c. Schedules II-V distribution and delivery records may only be stored offsite or electronically as described in subdivisions 14 a and 14 b of this section if authorized by DEA or in federal law or regulation.		

Deficiency Number			
138	d. Hard-copy distribution and administration records that are printed and reviewed in conducting required audits may be maintained offsite or electronically provided they can be readily retrieved upon request; provided they are maintained in a read-only format that does not allow alteration of the records; and provided a separate log is maintained for a period of two years showing dates of audit and review, the identity of the automated dispensing device being audited, the time period covered by the audit and review, and the initials of all reviewers.		

Virginia Board of Pharmacy
Pharmacy Routine Inspection Form

Unit Dose Dispensing Systems

Deficiency Number	Unit Dose Dispensing Systems	Result	Notes
	A unit dose drug dispensing system may be utilized for the dispensing of drugs to patients in a hospital or long-term care facility. The following requirements shall apply regardless of whether licensed or unlicensed persons administer medications		
128	Any equipment outside the pharmacy used to house drugs to be administered in a unit dose system shall be fitted with a locking mechanism and locked at all times when unattended. [**18VAC110-20-420]**		
	A signed order by the prescribing practitioner shall accompany the requests for a Schedule II drug, except that a verbal order for a hospital patient for a Schedule II controlled substance may be transmitted to a licensed nurse or pharmacist at the hospital who shall promptly reduce the order to writing in the patient's chart. Such an order shall be signed by the prescriber within 72 hours.		
	Properly trained personnel may transcribe the prescriber's drug orders to a patient profile card, fill the medication carts, and perform other such duties related to a unit dose distribution system provided these are done under the personal supervision of a pharmacist.		
	All dosages and drugs shall be labeled with the drug name, strength, lot number and expiration date when indicated.		
	The patient's individual drug drawer or tray shall be labeled in a manner to identify the patient and his location without violating health privacy laws.		
	All unit dose drugs intended for internal use shall be maintained in the patient's individual drawer or tray unless special storage conditions are necessary.		
	A back-up dose of a drug of not more than one dose unit may be maintained in the patient's drawer, tray, or special storage area provided that the dose is maintained in the patient's drawer, tray, or special storage area with the other drugs for that patient.		
	A record shall be made and maintained within the pharmacy for a period of one year showing:		
	1. Date of filling of the drug cart		
	2. Location of the drug cart		
	3. Initials of the person who filled the drug cart		
19	4. The initials of the pharmacist checking and certifying the contents of the drug cart in accordance with the provisions in 18VAC110-20-270 C. **[18VAC110-20-420] [18VAC110-20-270]**		
128	A patient profile record or medication card will be accepted as the dispensing record of the pharmacy for unit dose dispensing systems only, subject to the following conditions:		

Deficiency Number			
	1. Record of dispensing must be entered on the patient profile record or medication card at the time the drug drawer or tray is filled.		
128	2. In the case of Schedule II through V drugs, after the patient profile record or medication card has been completed, the card must be maintained for two years.		
	3. In the case of the computer-based distribution system, a uniformly maintained "fill list" or other document containing substantially the same information may be accepted as the dispensing record for Schedule II through VI drugs. Records of disposition/administration for floor stock drugs as provided in 18VAC110-20-460 B will be accepted for drugs distributed as floor stock.		
	Hospitals or long-term care facilities where only those persons licensed to administer are administering drugs, the pharmacy shall not dispense more than a seven-day supply of a drug in a solid, oral dosage form at any one given time.		
	In addition to the requirements listed in subsection A of 18VAC110-20-420, the following requirements apply to those long-term care facilities in which unlicensed persons administer drugs:		
	1. The pharmacy providing medications to such facility shall dispense no more than a 72-hour supply of drugs in a solid, oral dosage form at any one given time.		
	2. The pharmacy shall provide to persons administering medications training specific to the particular unit dose system being used		
	3. The pharmacy shall provide a medication administration record to the facility listing each drug to be administered with full dosage directions to include no abbreviations		
	4. The drugs in a unit dose system shall be placed in slots within a drawer labeled or coded to indicate time of administration		

Virginia Board of Pharmacy
Pharmacy Routine Inspection Form

Robotic Pharmacy System			
Deficiency Number			
	Robotic Pharmacy Systems	**Result**	**Notes**
129	Consistent with 18VAC110-20-420, a pharmacy providing services to a hospital or a long-term care facility and operating a robotic pharmacy system that dispenses drugs in bar-coded unit dose or compliance packaging is exempted from 18VAC110-20-270 B, provided the accuracy of the final dispensed prescription product complies with a written quality assurance plan and requirements of this chapter. The following requirements for operation of a robotic pharmacy system shall apply: **[18VAC110-20-425]**		
	1. Pharmacists shall review for accuracy and appropriateness of therapy all data entry of prescription orders into the computer operating the system.		
	2. The packaging, repackaging, stocking and restocking of the robotic pharmacy system shall be performed by pharmacy technicians or pharmacists.		
	3. Pharmacists shall verify and check for the accuracy of all drugs packaged or repackaged for use by the robot by a visual check of both labeling and contents prior to stocking the drugs in the robotic pharmacy system.		
129	a. A repackaging record shall be maintained in accordance with 18VAC110-20-355 A. **[18VAC110-20-425] [18VAC110-20-355]**		
20	b. The verifying pharmacist shall initial the record. **[18VAC110-20-425]**		
129	c. Packaging and labeling, including the appropriate beyond-use date, shall conform to requirements of this chapter and current USP-NF standard.		
	A written policy and procedure must be maintained and complied with and shall include at a minimum, procedures for ensuring:		
	a. Accurate packaging and repackaging of all drugs for use in the robotic pharmacy system, to include properly labeled barcodes, and method for ensuring pharmacist verification of all packaged and repacked drugs compliant with this chapter and assigned barcodes;		
	b. Accurate stocking and restocking of the robotic pharmacy system;		
	c. Removing expired drugs;		
	d. Proper handling of drugs that may be dropped by the robotic pharmacy system;		
	e. Performing routine maintenance of robotic pharmacy system as indicated by manufacturer's schedules and recommendations;		
	f. Accurate dispensing of drugs via robotic pharmacy system for cart fills, first doses, and cart fill updates during normal operation and during any scheduled or unscheduled downtime;		
	g. Accurate recording of any scheduled or unanticipated downtime with an explanation of the problem to include the time span of the downtime and the resolution		
	h. Appropriately performing an analysis to investigate, dentify, and correct sources of discrepancies or errors associated with the robotic pharmacy system;		
	h. Maintaining quality assurance reports.		

Deficiency Number			
20	All manual picks shall be checked by pharmacists. **[18VAC110-20-425]**		
129	If it is identified that the robot selected an incorrect medication, the pharmacy shall identify and correct the source of discrepancy or error in compliance with the pharmacy's policies and procedures prior to resuming full operations of the robot. An investigation of the cause of the event shall be completed, and the outcome of the corrective action plan shall be summarized and documented in a readily retrievable format.		
	Quarterly quality assurance reports demonstrating the accuracy of the robot shall be maintained. At a minimum, these reports shall include a summary indicating the date and description of all discrepancies that include discrepancies involving the packaging, repackaging, and dispensing of drugs via the robotic pharmacy system found during that quarter plus a cumulative summary since initiation of the robotic pharmacy system.		
19	Intravenous admixture robotics may be utilized to compound drugs in compliance with § 54.1-3410.2 of the Code of Virginia and 18VAC110-20-321; however, a pharmacist shall verify the accuracy of all compounded drugs pursuant to 18VAVC110-20-270 B.		
	Medication carousels functioning with or without a robotic pharmacy system in a hospital may be utilized to store and guide the selection of drugs to be dispensed or removed from the pharmacy under the following conditions **[18VAC110-20-425 C]**:		
129	The entry of drug information into the barcode database for assignment of a barcode to an individual drug shall be performed by a pharmacist who shall verify the accuracy of the barcode assignment.		
	A pharmacist is not required to verify the accuracy of a patient-specific drug removed from a medication carousel if:		
20	a. The entry of the order for a patient-specific drug into the pharmacy's dispensing software is verified by a pharmacist for accuracy and is electronically transmitted to the medication carousel; and		
	b. The patient-specific drug removed from the medication carousel by a pharmacy technician is verified for accuracy by the pharmacy technician who shall scan each drug unit removed from the medication carousel prior to dispensing, and a nurse or other person authorized to administer the drug scans each drug unit using barcode technology to verify the accuracy of the drug prior to administration of the drug to the patient. The requirement for scanning by a nurse or other person authorized to administer is waived in an emergent event when a delay would cause imminent harm to the patient; or		
129	c. The patient-specific drug is checked by two pharmacy technicians if a hospital does not have the capability for the drug to be verified for accuracy by scanning each drug unit. The first pharmacy technician removing the patient-specific drug from the medication carousel shall perform a visual inspection of each drug unit for accuracy and then double check the accuracy by scanning an individual unit of each drug. A second, different pharmacy technician shall perform a separate visual inspection of each drug unit and scan an individual unit of each drug for final verification. A nurse or other person authorized to administer the drug shall scan each drug unit prior to administration, unless the drug is being administered to treat an emergent event when a delay would cause imminent harm to the patient.		

Deficiency Number			
	A pharmacist is not required to verify the accuracy of the drug removed from the medication carousel by a pharmacy technician if that drug is intended to be placed into an automated drug dispensing system as defined in § 54.1-3401 of the Code of Virginia or distributed to another entity legally authorized to possess the drug if:		
129	a. The list of drugs to be removed from the medication carousel for loading or replenishing an individual automated dispensing system is electronically transmitted to the medication carousel; and		
129	b. The drug removed from the medication carousel is verified for accuracy by the pharmacy technician by scanning each drug unit removed from the medication carousel prior to leaving the pharmacy and delivering the drug to the automated drug dispensing system or distributed to another entity, and a nurse or other person authorized to administer the drug scans each drug unit using barcode technology to verify the accuracy of the drug prior to administration of the drug to the patient. If the drug is placed into an automated drug dispensing system located within a hospital, or the entity receiving the distributed drug, wherein a nurse or other person authorized to administer the drug will not be able to scan each drug unit using barcode technology to verify the accuracy of the drug prior to patient administration, then a second verification for accuracy shall be performed by a pharmacy technician by scanning each drug unit at the time of placing the drugs into the automated dispensing system; or		
129	c. The drug intended for restocking an automated dispensing device is checked by two pharmacy technicians if the hospital does not have the capability for scanning each drug unit. The first pharmacy technician removing the drug for restocking from the medication carousel shall perform a visual inspection of each drug unit for accuracy and then double check the accuracy by scanning an individual unit of each drug of the automated dispensing device restock order prior to leaving the pharmacy. A second, different pharmacy technician shall perform a separate visual inspection of each drug unit and scan an individual unit for each drug of the restock order for final verification at the time of placing the drug into the automated dispensing device. A nurse or other person authorized to administer the drug shall scan each drug unit prior to administration, unless the drug is being administered to treat an emergent event where a delay would cause imminent harm to the patient.		
129	A pharmacist shall verify the accuracy of all drugs that are manually removed from the medication carousel by a pharmacy technician without the use of barcode scanning technology to verify the accuracy of the selection of the drug product prior to dispensing those drugs or those drugs leaving the pharmacy.		
20	A pharmacist shall perform a daily random check for verification of the accuracy of 5.0% of drugs prepared that day utilizing the medication carousel technology. A manual or electronic record, from which information can be readily retrieved, shall be maintained and shall include:		
129	a. The date of verification;		
	b. A description of all discrepancies identified, if any; and		

Deficiency Number			
19	c. The initials of the pharmacist verifying the accuracy of the process.		
129	All records required by this section shall be maintained at the address of the pharmacy for a minimum of two years. Records may be maintained in offsite storage or as an electronic image that provides an exact image of the document that is clearly legible, provided such offsite or electronic storage is retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent of the board **[18VAC110-20-425 D]**.		

The Virginia Board of Pharmacy
Pharmacy Inspection

Pharmacy Name		Permit Number		Date	

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Pharmacy Inspection

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