Inspection Details

Name	Test Pharmacy	**Case #**		**Permit**	14549
Address	123 Apple St Chapel Hill, NC 27516	**Person Providing Info**		**Inspection Date**	06/25/2024
		Person In Charge	Jack William Campbell, IV	**Inspection User**	Brashears, Krystal
# RPhs	2	**Rx Volume/Date**	200	**Inspection District**	DISTRICT3
# Techs	2	**Hours**			
Follow-Up CAP	No	**Office**	No		
CAP Requested	No	**Commercial Use**	No		
CAP Documentation Received	No	**Ship to Other States**	No		
Additional Documents	Yes	**States Shipped To**			
Office Use		**Commercial Use Documented**			
Office Use Comments		**Clinical Indication**			

Non-Sterile Compounding

Non-Sterile	No
Does the pharmacy engage in Occasional Basic Non-Sterile Compounding?	
Does facility engage in moderate or complex sterile compounding?	
Does facility engage in Hazardous Drug Compounding?	
Is there documented clinical indication for the approved medication?	

Sterile Compounding

Sterile Compounding	No
Does facility compound Immediate Use CSP?	
Does facility compound Category 1 Sterile Compounding?	
Does facility compound Category 2 Sterile Compounding?	
Does facility compound Category 3 Sterile Compounding?	
Does facility compound hazardous medications?	
Does facility compound Allergenic Extracts?	

Comments

None

General Pharmacy Inspection

	Answer	Question
1)	Unanswered	90-85.15A (a) - tech must register with the Board within 30 days after the date of completing the training program. 46.3301 (b) - Current registration of a pharmacy tech shall be readily available for inspection.
2)	Unanswered	90-85.15A (c) - 2:1 ratio, if ratio above provide waiver documentation. Any technician above the 2:1 ratio must be certified (document approval date).
3)	Unanswered	90-85.23- PM license, permit and current renewal shall be posted. Licenses and renewals of each RPh. are readily available for inspection.
4)	Unanswered	90-85.25 (b) - PM shall report within 10 days any disaster, accident, theft.
5)	Unanswered	90-85.26 (a) - prescriptions preserved for 3 years. (b) - Documentation of alleged medication errors.
6)	Unanswered	90-85.29 (1) - prescription label shall contain a discard date that is earlier of 1 yr. from date dispensed or manufacturer's exp. date, whichever is earlier. (2) - not manufacturer's obscure exp. date and storage statement when product dispensed in original container.
7)	Unanswered	90-85.32 (a) - prescriptions marked PRN not refilled more than 1 yr. after issue date.
8)	Unanswered	90-85.47 - Quality Assurance Program
9)	Unanswered	90-640 (b) - ID badge
10)	Unanswered	CFR 201.17- Misbranded drugs: Medications stored in pharmacy should be labeled with an expiration date and

General Pharmacy Inspection

	Answer	Question
		manufacturer lot number. Note: Return to stock prescription vial with the pharmacy's own label affixed will not be deemed misbranded.
11)	Unanswered	46.106-134.1 (4)(b)- label lacks any requirement listed in the subsection. (px name, name/add. of pharmacy, disp. rph's name, rx #, fill date of rx, prescriber name, dir. for use, name & strength of drug.)
12)	Unanswered	46.1601 (a)(2)- posted Pharmacy hours. (4)(A-E)- reference library, hard copy or electronic. (5)- lavatory facilities w/ hot and cold running water; clean, orderly and sanitary. (b)(1) records are readily retrievable. (b)(2)- toll free number on labels of dispensed medications. (e)- pharmacy permit is countersigned by rph-mgr. as represented in the application.
13)	Unanswered	46.1802 (a) - refills limited to prescriber's orders.
14)	Unanswered	46.1803 - All records pertaining to the filling and refilling of prescriptions shall be available to designated employees of the Board during normal business hours.
15)	Unanswered	46.1806 - proper documentation and handling of transferred rxs.
16)	Unanswered	46.1818 - label shall list generic name of drug, even if unavailable to dispense or generic is not authorized.
17)	Unanswered	46.2302 (a)(1-5) - records of dispensing shall be kept for 3 years.
18)	Unanswered	46.2303 - records of prescription filling and refilling shall be kept for 3 yrs.
19)	Unanswered	46.2304 (1) - produce sight-readable documents. (3) - RPh. responsible for completeness and accuracy of entries, provides documentation that prescription information entered is correct. (5) - pharmacy has an auxiliary recordkeeping system. (7) - current version of drug interactions software is utilized
20)	Unanswered	46.2305 - To maintain the confidentiality of patients' prescription orders, there must be adequate safeguards or security of the records.
21)	Unanswered	21. 46.2502 (a) - PM shall assure that rx meds & cs meds are safe/secure within the pharmacy. (b) - PM is present one-half the hrs. the pharmacy is open or 32 hrs. /wk., whichever is less. The temporary pharmacist in charge should not exceed ninety (90) days, must be present twenty (20) hours a week in the pharmacy. A pharmacy may not operate for a period of more than 30 days without a pharmacist employed or otherwise engaged as a permanent or temporary pharmacist-manager who has signed the permit for that pharmacy. (d) - system of inventory recordkeeping and control to detect any shortage or discrepancies of cs meds. (e) - control of all keys to pharmacy. (j) - written disaster plan. (k) - separate from the dispensing stock all drugs more than 6 months out of date.
22)	Unanswered	46.3001 (a) - policy/procedure for all outdated, improperly labeled, adulterated damaged, or unwanted drugs or drug containers are destroyed or disposed.

USP <825> Inspection Questions

	Answer	Question
		A: Personnel Qualifications, Training, and Hygiene
1)	Unanswered	Personnel must prove competency, as applicable to their job functions, prior to performing radiopharmaceutical aseptic tasks. Documentation that all applicable personnel passed initial and annual written exams include:
2)	Unanswered	a. Cleaning and disinfecting;
3)	Unanswered	b. Hand hygiene and garbing;
4)	Unanswered	c. Aseptic technique
5)	Unanswered	d. Gloved Fingertip and thumb sampling
6)	Unanswered	e. Media Fill testing
7)	Unanswered	Policy and Procedure for Personnel training and testing.
8)	Unanswered	Observed and appropriately documented cleaning and disinfection qualification, initially, with any change in SOPs, and annually. Includes ancillary, non-compounding personnel, if applicable.
9)	Unanswered	Observed and appropriately documented hand hygiene and garbing qualifications, initially and annually. Includes ancillary, non-compounding personnel, if applicable.
10)	Unanswered	Observed and appropriately documented aseptic technique qualification, initially and annually.
11)	Unanswered	Observed and appropriately documented three initial gloved fingertip and thumb samplings, performed immediately following hand hygiene and garbing, with zero growth. Includes ancillary, non-compounding personnel, if applicable.

USP <825> Inspection Questions		
	Answer	**Question**
12)	Unanswered	Observed and appropriately documented annual gloved fingertip and thumb samplings, performed after media fill, with equal to or less than 3 total CFUs.
13)	Unanswered	Observed and appropriately documented initial and annual media fill test simulating the most challenging and stressful work conditions.
14)	Unanswered	Documentation of retraining, reevaluation and retesting of personnel who fail any testing or qualifications.
15)	Unanswered	Personnel that have not performed sterile radiopharmaceutical processing for more than 6 months are requalified prior to resuming duties.
B: Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Areas		
1)	Unanswered	Policy and Procedure for Garbing and hand hygiene.
2)	Unanswered	Personnel remove outer garments, make-up, all hand, wrists, and other exposed jewelry including piercings that can interfere with the effectiveness of garbing. Radiation dosimetry devices are allowed.
3)	Unanswered	Personnel's nails are kept natural, neat, and trimmed keep nails natural and short.
4)	Unanswered	Personnel report conditions that may pose a higher potential of contaminating the environment with microorganisms (e.g. rashes, sunburn, recent tattoos, oozing sores, conjunctivitis, or active respiratory infection) and the designated person evaluates whether an individual may enter the buffer area or SRPA.
5)	Unanswered	Garb with shoe covers, head/hair/facial hair covers, and facemasks in order per facility SOPs and to minimize the risk of contamination.
6)	Unanswered	Performs hand hygiene appropriately up to the elbows for 30 seconds and effectively removes debris under nails by using a disposable nail pick.
7)	Unanswered	Use appropriate alcohol-based hand rub prior to donning Sterile Gloves.
8)	Unanswered	Don low lint gown with sleeves that fit snuggly around the wrist and enclose at the neck. Disposable gowns are preferred, if reusable gowns are used, a clean gown must be donned daily.
9)	Unanswered	Personnel must aseptically don sterile powder free gloves.
10)	Unanswered	70% Sterile alcohol must be periodically applied to sterile gloves when handling non-sterile materials while balancing the risk of radioactivity.
11)	Unanswered	Gloves are routinely inspected for holes, punctures, tears, or radioactivity contamination. Gloves must be disposed and hand cleansing repeated.
C: Facility and Engineering Controls		
1)	Unanswered	The floor is smooth, impervious, free from cracks and crevices, non-shedding, sealed, and coved where it meets the walls.
2)	Unanswered	Ceilings are smooth, impervious, free from cracks and crevices, non-shedding, and sealed where it meets the walls. Ceiling tiles are caulked or otherwise sealed to support the frame.
3)	Unanswered	Walls are constructed of or covered with a durable material (i.e. epoxy paint). smooth, impervious, free from cracks and crevices, non-shedding, and sealed.
4)	Unanswered	Accessories and furniture are easily cleanable, smooth, impervious, free from cracks and crevices, and non-shedding. Limited to necessary equipment in ante and buffer areas.
5)	Unanswered	Sink placed on the clean side of the anteroom. If located outside of anteroom it must be located in clean space to minimize the risk of bringing in contaminants.
6)	Unanswered	The buffer room has no sink, drain, or water source.
7)	Unanswered	Temperature recorded daily. Ante and buffer area temperature maintained at 25 C or cooler.
8)	Unanswered	Drugs stored at appropriate controlled storage temperatures: Room 68-77 F or 20-25 C.
9)	Unanswered	Drugs stored at appropriate controlled storage temperatures: Refrigerated 36-46 F or 2-8 C.
10)	Unanswered	Humidity recorded daily. Relative humidity maintained below 60%.
11)	Unanswered	Temperature and humidity monitoring devices are verified for accuracy every 12 months or as required by the manufacturer.
12)	Unanswered	Buffer room is positive pressure of at least 0.02-inch water column to anteroom and recorded daily.
13)	Unanswered	Anteroom is positive pressure of at least 0.02-inch water column to unclassified portions of the restricted area and recorded daily.
14)	Unanswered	Restricted areas are negative pressure compared to unrestricted areas, if applicable (volatile or airborne

USP <825> Inspection Questions		
	Answer	**Question**
		radiopharmaceuticals (i.e. I-131 sodium iodide and Xenon).
15)	Unanswered	No tacky surfaces or mats inside ISO classified areas.
16)	Unanswered	Food, drinks, and materials exposed in patient care and treatment areas do not enter ante or buffer areas.
D: Segregated Radiopharmaceutical Processing Area (SRPA)		
1)	Yes	Does the facility have an SRPA?
2)	Unanswered	All surfaces (e.g., walls, floors, counters, equipment) clean, uncluttered and dedicated to sterile processing activities.
3)	Unanswered	All surfaces (e.g., walls, floors, counters, equipment) smooth, impervious, free from cracks and crevices, and non-shedding.
4)	Unanswered	Accessories and furniture are easily cleanable, smooth, impervious, free from cracks and crevices, and non-shedding. Limited to necessary equipment in SRPA.
5)	Unanswered	Sink appropriately located at least one meter away from PEC and generators if present.
6)	Unanswered	Temperature recorded daily. SRPA temperature maintained at 25 C or cooler and recorded daily.
7)	Unanswered	Drugs stored at appropriate controlled storage temperatures: Room 68-77 F or 20-25 C and recorded daily.
8)	Unanswered	Drugs stored at appropriate controlled storage temperatures: Refrigerated 36-46 F or 2-8 C and recorded daily.
9)	Unanswered	Humidity recorded daily. Relative humidity maintained below 60%.
10)	Unanswered	Temperature and humidity monitoring devices verified for accuracy every 12 months or as required by manufacturer.
11)	Unanswered	Restricted area is negative pressure compared to unrestricted area, if applicable (volatile or airborne radiopharmaceuticals (i.e. I-131 sodium iodide and Xenon).
12)	Unanswered	Non-direct infusion radionuclide generators stored and eluted in area that meets ISO Class 8.
E: Environmental Controls and Certification		
1)	Unanswered	All ISO Class 5 PECs and ISO Class 7 and/or ISO Class 8 rooms have been certified as required.
2)	Unanswered	Certification performed to CETA standards or equivalent standards.
3)	Unanswered	Certifier’s equipment calibrated to manufacturer standards.
4)	Unanswered	Ante room has HEPA filtered air certified to ISO Class 8 or better.
5)	Unanswered	Ante room has appropriate ACPH: ISO Class 8 minimum 20 ACPH, ISO Class 7 minimum 30 ACPH.
6)	Unanswered	Buffer room has HEPA filtered air certified to ISO Class 7 or better.
7)	Unanswered	Buffer room has minimum 30 ACPH, 15 ACPH must be supplied by room HVAC.
8)	Unanswered	ISO Class 7 areas not more than 352,000 particles per cubic meter of air, taken under dynamic conditions.
9)	Unanswered	ISO Class 8 area not more than 3,520,000 particles per cubic meter of air, taken under dynamic conditions.
10)	Unanswered	Room HEPA filters leak tested and repaired if needed.
11)	Unanswered	PEC(s) certified to meet ISO Class 5 or better conditions.
12)	Unanswered	ISO Class 5 area not more than 3520 particles per cubic meter of air, taken under dynamic conditions.
13)	Unanswered	Smoke visualization study performed at least every 6 months in direct processing area to demonstrate unidirectional airflow under simulated or dynamic conditions.
14)	Unanswered	PEC airflow velocity measured.
F: Microbial air and surface Monitoring		
1)	Unanswered	Air and surface microbial sampling was performed in all classified areas and PEC under simulated or dynamic conditions.
2)	Unanswered	Air and surface monitoring program includes documentation of:
3)	Unanswered	a. Date and time of sampling;
4)	Unanswered	b. Sampling locations;
5)	Unanswered	c. Method of collection;
6)	Unanswered	d. Frequency of sampling;

USP <825> Inspection Questions		
	Answer	**Question**
7)	Unanswered	e. Size of samples (e.g., surface area, volume of air);
8)	Unanswered	f. Time of day in relation to processing activities; and
9)	Unanswered	g. Action levels.
10)	Unanswered	Viable air sampling of all classified areas and PECs performed at least every 6 months using an active impaction device during dynamic or simulated operating conditions with 1000 liters of air sampled.
11)	Unanswered	Viable air sampling was performed with appropriate growth media and proper incubation of media to support growth of bacteria and fungi.
12)	Unanswered	Viable air microbial action levels:
13)	Unanswered	a. ISO Class 5: greater than 1 CFU
14)	Unanswered	b. ISO Class 7: greater than 10 CFU
15)	Unanswered	c. ISO Class 8: greater than 100 CFU
16)	Unanswered	Surface sampling performed at least monthly in:
17)	Unanswered	a. All classified areas, including frequently touched surfaces;
18)	Unanswered	b. PEC;
19)	Unanswered	c. Direct processing area and any permanent equipment in PEC;
20)	Unanswered	d. Staging and work surfaces near the PEC; and
21)	Unanswered	e. Pass through.
22)	Unanswered	Surface sampling performed with appropriate microbial growth media supplemented with neutralizing additives (e.g., TSA with lecithin and polysorbate 80) and media properly incubated to support bacteria and fungi growth.
23)	Unanswered	Surface sampling microbial action levels:
24)	Unanswered	a. ISO Class 5: greater than 3 CFU
25)	Unanswered	b. ISO Class 7: greater than 5 CFU
26)	Unanswered	c. ISO Class 8: greater than 50 CFU
27)	Unanswered	Incubators located outside of any classified area or SRPA and temperature recorded daily during incubation with calibrated measuring device.
28)	Unanswered	If action levels for either air or surface sampling exceeded, CFU to be identified to the genus level.
29)	Unanswered	Documented investigation and corrective action plan when air or surface sampling action levels exceeded to include evaluation of personnel practices, effectiveness of cleaning and environmental quality.
G: Cleaning and Disinfecting		
1)	Unanswered	Policy and Procedure for monitoring for radioactive contamination and decontamination of those surfaces.
2)	Unanswered	No shipping cartons or other corrugated or uncoated cardboard allowed in classified areas or within SRPA.
3)	Unanswered	Disposable, absorbent pad clean and low-lint.
4)	Unanswered	All items are wiped with a sporicidal agent, EPA-registered one-step disinfectant cleaner, or sterile 70% IPA using low-lint wipers prior to introduction into anteroom or SRPA.
5)	Unanswered	Any item transferred into the ISO 5 PEC disinfected with sterile disinfectant (sterile 70% IPA).
6)	Unanswered	Critical sites are wiped with sterile 70% IPA that is allowed to dry prior to piercing.
7)	Unanswered	Personnel appropriately garbed when cleaning.
8)	Unanswered	Cleaning and Disinfecting agent (maybe one-step disinfectant cleaner) appropriate for bacteria, fungi, and viruses.
9)	Unanswered	Daily Cleaning and Disinfecting of Ante and Buffer area or SRPA including work surfaces, sink, and floors.
10)	Unanswered	Daily Cleaning and Disinfecting of hot-cell.
11)	Unanswered	Daily Cleaning and Disinfecting of ISO 5 PEC and all equipment within PEC.
12)	Unanswered	Cleaning and Disinfecting of ISO 5 PEC include the following:
13)	Unanswered	a. Survey for radioactive contamination
14)	Unanswered	b. Removal of any particles, debris, or residue with an appropriate solution (sterile water) and sterile, low-lint

USP <825> Inspection Questions		
	Answer	**Question**
		wipers.
15)	Unanswered	c. Cleaning and Disinfecting agent applied for specified contact time.
13)	Unanswered	d. Sterile 70% IPA applied.
17)	Unanswered	e. Surface allowed to dry completely before beginning activity.
18)	Unanswered	f. Sporicidal agent used at least monthly.
19)	Unanswered	Monthly cleaning of ceilings, walls, and storage shelving and storage bins within Ante and Buffer area or SRPA.
20)	Unanswered	Monthly use of appropriate sporicidal agent on all surfaces and PEC within Ante and Buffer area and SRPA.
21)	Unanswered	Cleaning, disinfecting and sporicidal agents allowed to dwell based on manufacturer specified minimum contact time.
22)	Unanswered	Radiation shielding and other equipment used in ante and buffer area, SRPA, or PEC exposed to patient care areas cleaned and disinfected before returning to processing areas.
H: Documentation		
1)	Unanswered	Preparations, preparations with minor deviations, and compounded radiopharmaceuticals undergo appropriate in-house quality control testing.
2)	Unanswered	Sterile radiopharmaceutical final doses appropriately radioassayed.
3)	Unanswered	Documented master formulation record and preparation record for all compounded preparations or preparations with minor deviations from manufacturer instructions.
4)	Unanswered	Sterile radiopharmaceutical final doses appropriately radioassayed.
5)	Unanswered	Master formulation record documents:
6)	Unanswered	a. Name of the radiopharmaceutical
7)	Unanswered	b. Name, identity, strength, purity, and quantity of ingredients
8)	Unanswered	c. Detailed procedure
9)	Unanswered	d. Range of radioactivity and range of volume
10)	Unanswered	e. Equipment to be used including PEC or SEC, if applicable
11)	Unanswered	f. Required quality control tests
12)	Unanswered	g. Trained personnel and required garbing if different from SOP
13)	Unanswered	h. Container
14)	Unanswered	i. Reference for BUD assignment and storage conditions
15)	Unanswered	Preparation record for preparations with minor deviations or compounded preparations documents:
16)	Unanswered	a. Name of the radiopharmaceutical
17)	Unanswered	b. Physical form or dosage form
18)	Unanswered	c. Name and quantity of ingredients including calibration time for radioactive ingredients
19)	Unanswered	d. Total volume
20)	Unanswered	e. Reference to MFR and any deviations from MFR
21)	Unanswered	f. Name of manufacturer/vendor, lot numbers and expiration dates of all ingredients and components
22)	Unanswered	g. Name of compounder and verifying/supervising pharmacist
23)	Unanswered	h. Date and time of preparation
24)	Unanswered	i. Assigned lot number and/or prescription/order number
25)	Unanswered	j. BUD and storage requirements
26)	Unanswered	k. Quality control results
27)	Unanswered	In the absence of sterility testing, radiopharmaceuticals assigned a maximum BUD based on preparation conditions.
28)	Unanswered	a. SRPA: 12 hours
29)	Unanswered	b. ISO Class 8 ante and buffer room: 24 hours

USP <825> Inspection Questions		
	Answer	**Question**
30)	Unanswered	c. ISO Class 7 or 8 ante and ISO Class 7 buffer room: 96 hours
31)	Unanswered	Inner container appropriately labeled with:
32)	Unanswered	a. Standard radiation symbol
33)	Unanswered	b. “Caution-Radioactive Material”
34)	Unanswered	c. Patient name/identifier for all therapeutic products
35)	Unanswered	d. Radionuclide and chemical form
36)	Unanswered	e. Radioactivity at the date and time of calibration
37)	Unanswered	Outer container/shielding appropriately labeled with:
38)	Unanswered	a. Standard radiation symbol
39)	Unanswered	b. “Caution-Radioactive Material”
40)	Unanswered	c. Patient name/identifier for all therapeutic products
41)	Unanswered	d. Radionuclide and chemical form
42)	Unanswered	e. Radioactivity at the date and time of calibration
43)	Unanswered	f. Volume or number of units dispensed
44)	Unanswered	g. Product expiration or BUD and any special storage and handling instructions
45)	Unanswered	h. Route of administration
46)	Unanswered	In the absence of sterility testing, radiopharmaceuticals assigned a maximum BUD based on preparation conditions.
47)	Unanswered	a. SRPA: 12 hours
48)	Unanswered	b. ISO Class 8 ante and buffer room: 24 hours
49)	Unanswered	c. ISO Class 7 or 8 ante and ISO Class 7 buffer room: 96 hours
I: Remote Aseptic Processing Involving a Hot-Cell		
1)	Yes	Does facility do I: Remote Aseptic Processing Involving a Hot-Cell?
2)	Unanswered	Personnel garb according to contamination risk.
3)	Unanswered	If sterile packages not opened remotely in hot cell – syringes may be opened and labeled outside of ISO 5 environment and placed in disinfected shielding.
4)	Unanswered	Personnel use correct aseptic technique.
5)	Unanswered	Critical sites wiped with sterile 70% IPA that is allowed to dry prior to piercing.
6)	Unanswered	Staging of supplies and materials in PEC does not allow influx of unclassified air into PEC.
7)	Unanswered	Maximum BUD of 12 hours.
J: Radiolabeling Blood Components		
1)	Yes	Does facility do Radiolabeling with Blood Components?
2)	Unanswered	Policy and Procedure for handling and manipulation of blood-derived or other biological material and biohazardous radioactive sharps to avoid contamination
3)	Unanswered	Physical separation with either fixed or non-fixed wall from areas where non-blood products are handled.
4)	Unanswered	Blood labeling was performed in ISO Class 5 BSC in an ISO Class 7 buffer area.
5)	Unanswered	One radiolabeling procedure per PEC at a time. Blood products from more than one patient must never be manipulated at the same workstation at the same time.
6)	Unanswered	Maximum of 6-hour BUD after blood sample obtained.
7)	Unanswered	BSC and all reusable equipment and components were cleaned and disinfected after each radiolabeling procedure.
8)	Unanswered	Dedicated supplies including consumable products and syringe shields and vial shields for each patient.
9)	Unanswered	All tubes and syringes in contact with patient’s blood components clearly labeled with patient name and additional identifier.
10)	Unanswered	Removal and replacement of any garb that enters BSC before handling of anything not related to a radiolabeling

USP <825> Inspection Questions		
	Answer	**Question**
		procedure.
11)	Unanswered	Complete hand hygiene and garbing procedures upon completion of blood radiolabeling procedures.
K: Non-sterile Radiopharmaceuticals		
1)	Yes	Does facility prepare non-sterile radiopharmaceuticals?
2)	Unanswered	Personnel trained per facility policy.
3)	Unanswered	Personnel garbed per facility policy.
4)	Unanswered	Nonsterile processing area has appropriate environmental controls, if applicable:
5)	Unanswered	a. Negative air pressure area
6)	Unanswered	b. Chemical fume hood
7)	Unanswered	c. Activated charcoal filters
8)	Unanswered	Nonsterile processing area is clean and uncluttered.
9)	Unanswered	Nonsterile processing area is separate from sterile processing area.
10)	Unanswered	Documented process for cleaning nonsterile processing area between preparation cycles of different nonsterile products.
11)	Unanswered	Documented master formulation record and preparation record for all compounded preparations or preparations with minor deviations from manufacturer instructions.
12)	Unanswered	Master formulation record documents:
13)	Unanswered	a. Name of the radiopharmaceutical
14)	Unanswered	b. Name, identity, strength, purity, and quantity of ingredients
15)	Unanswered	c. Detailed procedure
16)	Unanswered	d. Range of radioactivity and range of volume
17)	Unanswered	e. Equipment to be used including PEC or SEC, if applicable
18)	Unanswered	f. Required quality control tests
19)	Unanswered	g. Trained personnel and required garbing if different from SOP
20)	Unanswered	h. Container
21)	Unanswered	i. Reference for BUD assignment and storage conditions
22)	Unanswered	Preparation record for preparations with minor deviations or compounded preparations documents:
23)	Unanswered	a. Name of the radiopharmaceutical
24)	Unanswered	b. Physical form or dosage form
25)	Unanswered	c. Name and quantity of ingredients including calibration time for radioactive ingredients
26)	Unanswered	d. Total volume
27)	Unanswered	e. Reference to MFR and any deviations from MFR
28)	Unanswered	f. Name of manufacturer/vendor, lot numbers and expiration dates of all ingredients and components
29)	Unanswered	g. Name of compounder and verifying/supervising pharmacist
30)	Unanswered	h. Date and time of preparation
31)	Unanswered	i. Assigned lot number and/or prescription/order number
32)	Unanswered	j. BUD and storage requirements
33)	Unanswered	k. Quality control results
34)	Unanswered	Nonsterile radiopharmaceuticals appropriately radioassayed.
35)	Unanswered	Inner container appropriately labeled with:
36)	Unanswered	a. Standard radiation symbol
37)	Unanswered	b. “Caution-Radioactive Material”
38)	Unanswered	c. Patient name/identifier for all therapeutic products

USP <825> Inspection Questions		
	Answer	**Question**
39)	Unanswered	d. Radionuclide and chemical form
40)	Unanswered	e. Radioactivity at the date and time of calibration
41)	Unanswered	Outer container/shielding appropriately labeled with:
42)	Unanswered	a. Standard radiation symbol
43)	Unanswered	b. “Caution-Radioactive Material”
44)	Unanswered	c. Patient name/identifier for all therapeutic products
45)	Unanswered	d. Radionuclide and chemical form
46)	Unanswered	e. Radioactivity at the date and time of calibration
47)	Unanswered	f. Volume or number of units dispensed
48)	Unanswered	g. Product expiration or BUD and any special storage and handling instructions
49)	Unanswered	h. Route of administration
L: Quality Assurance and Quality Control		
1)	Unanswered	Formally established QA and QC programs overseen by a designated person.
2)	Unanswered	QA and QC programs include system of:
3)	Unanswered	a. Adherence to procedures;
4)	Unanswered	b. Prevention and detection of errors;
5)	Unanswered	c. Evaluation of complaints and adverse events; and
6)	Unanswered	d. Investigation and correct actions.
7)	Unanswered	Documented annual review of QA and QC programs.
8)	Unanswered	If radiopharmaceutical dispensed before results of release testing, prescriber notified of any specification failures with the potential to cause patient harm.
9)	Unanswered	Designated person reviews all complaints and investigates any complaints that indicate a potential quality problem with a radiopharmaceutical.
10)	Unanswered	Documented record of all complaints and investigation results.