National Association of Boards of Pharmacy® Universal Nuclear USP <825> Inspection Form	West Virginia Board of Pharmacy 1207 Quarrier Street, Fourth Floor Charleston, WV 25301 Phone: 304-558-0558 Fax: (304)-558-0573

Nuclear Pharmacy Inspection

Business e-Profile ID:			**Inspection Information**
Legal Business Name:		**Inspection Date:**	
Doing Business As (DBA):		**Start Time:** **24-hour format (13:00)**	
Address:		**End Time:** **24-hour format (13:00)**	
City:		**Onsite Inspection Date(s):**	
State:		**Start Time(s):** **24-hour format (13:00)**	
Zip Code:		**End Time(s):** **24-hour format (13:00)**	
Telephone number:		**Inspector Name:**	
Toll free number:		**Inspection Performed by** **(NABP, State, etc):**	
Fax number:		**Observer Name/Affiliation** **(if applicable):**	
Website:		**Observer Name/Affiliation** **(if applicable):**	

Focused Information

The facility is encouraged to read the inspection report in its entirety and carefully.
Specific Module(s) and/or Question(s) to which the facility may want to consider further response are:
WV Institutional Pharmacy Inspection Report -
NABP Nuclear Pharmacy Inspection-

Pharmacy Hours of Operation	Check if 24/7 ☐		
	Open		Closed
	Start Time: (24-hour format)	End Time: (24-hour format)	(X)
Sunday			☐
Monday			☐
Tuesday			☐
Wednesday			☐
Thursday			☐
Friday			☐
Saturday			☐

Key Pharmacy Personnel	Name	Contact (e-mail)	e-Profile ID
Designated Person			
Designated Person			
Pharmacist in Charge			
Radiation Safety Officer (RSO)			
HIPAA privacy officer			

Personnel Present at Time of Inspection	Name	Title	License or registration available and current
1			☐
2			☐
3			☐
4			☐
5			☐
6			☐
7			☐
8			☐
9			☐
10			☐

If more than 10, list the first 10 below, then list the title and number (eg: 2 designated persons, 4 pharmacists, 6 technicians, 2 technicians-in-training, 1 intern, 4 clerks, etc) for the additional personnel present.

Business Licensure Information for State of Residence and Federal
(Board of Pharmacy, State Controlled Substance, State Radiation Control Agency, Drug Enforcement Administration (DEA), Food and Drug Administration (FDA), Nuclear Regulatory Commission (NRC))

License/Registration Agency	Business Name on License/Registration	Registration/License Type	Registration/License Number & Expiration Date
West Virginia Board of Pharmacy			
Drug Enforcement Administration			
Nuclear Regulatory Commission			

Inspector Notes: List states in which Non-Resident licenses are held.

Documents collected as part of the inspection.
To obtain a copy of these documents please contact the facility directly. They are not included in the final report.

Document Name	Description

	Type(s) of practice Type "X" for all that apply and "N/A" when they do NOT		Type(s) of practice Type "X" for all that apply and "N/A" when they do NOT
Ship/Deliver (in state)	Choose an item.	Manufacturer	Choose an item.
Ship/Deliver (out-of-state, list below)	Choose an item.	Wholesale Distributor (WD)	Choose an item.
Central Fill/Processing/Shared Services	Choose an item.	Handles Positron Emission Tomography (PET) Preparations	Choose an item.
Institutional	Choose an item.	Handles Nonsterile Preparations	Choose an item.
Free Standing	Choose an item.	Handles Sterile Preparations (eg including minor deviations)	Choose an item.
Telepharmacy	Choose an item.	Handles Investigational New Drugs (IND)	Choose an item.
Provide radiopharmaceuticals for 'Office Use'	Choose an item.	Handles Blood Preparations	Choose an item.
Provide radiopharmaceuticals for 'Physician Use'	Choose an item.	Handles Volatile Isotopes (Xe-133 gas, liquid I-131 NaI)	Choose an item.
Outsourcing Facility	Choose an item.	Provide radiopharmaceuticals for Immediate Use	Choose an item.
Handles Sterile dispensing and repackaging	Choose an item.		

Facility Size (in Square Feet) and Number of PECs		Personnel	
Total Nuclear Pharmacy size:		Total Nuclear Pharmacists:	
Nonsterile Processing area size:		Total Nuclear Pharmacy Technicians:	
Sterile Processing Anteroom size:		Total Interns or Students:	
Sterile Processing Clean/Buffer Room size:		Total Other Personnel:	
Blood Preparations Processing Room size:		Total Nuclear Pharmacist Hours Per Week:	
Size of the decay storage area:		Total Nuclear Pharmacy Technician Hours Per Week:	
Sterile number of PECs:		Board Certified Nuclear Pharmacist (BCNP):	
Nonsterile number of PECs:			
Blood Preparations - number of PECs (eg BSC):			
Segregated Radiopharmaceutical processing area (SRPA) size:			
Number of Hot Cells:			

Volume Dispensed		Volume Distributed	
Total Prescriptions Dispensed/day:		Total Orders Distributed/day:	
% Veterinary		% Veterinary	
% Controlled Substances		% Controlled Substances	
% Nonsterile Compounded		% Nonsterile Compounded	
% Sterile Compounded		% Sterile Compounded	
% of Sterile preparations		% of Sterile preparations	
% of Nonsterile preparations		% of Nonsterile preparations	

Definitions: DISPENSE means to provide a prescription product or compound pursuant to a patient-specific prescription.
DISTRIBUTE means to provide a prescription product or compound to a prescriber or health care entity for office use or stock and is NOT patient specific - is not labeled with the patient name at the pharmacy. HD means drugs on the National Institute for Occupational Safety and Health (NIOSH) list of HD such as hormones, chemotherapy, etc.
There are currently no radiopharmaceuticals which are considered NIOSH HDs.

States to which the pharmacy ships/delivers prescription products and volume dispensed, and volume distributed per day (or week or month): Note: if not available, request information be sent to VPP and note that information was requested in grid.			
State	**Volume Dispensed**	**Volume DISTRIBUTED**	**/day, week, month**
Alabama (AL)			
Alaska (AK)			
Arizona (AZ)			
Arkansas (AR)			
California (CA)			
Colorado (CO)			
Connecticut (CT)			
Delaware (DE)			
District of Columbia (DC)			
Florida (FL)			
Georgia (GA)			
Hawaii (HI)			
Idaho (ID)			
Illinois (IL)			
Indiana (IN)			
Iowa (IA)			
Kansas (KS)			
Kentucky (KY)			
Louisiana (LA)			
Maine (ME)			
Maryland (MD)			
Massachusetts (MA)			
Michigan (MI)			
Minnesota (MN)			
Mississippi (MS)			
Missouri (MO)			
Montana (MT)			

States to which the pharmacy ships/delivers prescription products and volume dispensed, and volume distributed per day (or week or month): Note: if not available, request information be sent to VPP and note that information was requested in grid.			
State	**Volume Dispensed**	**Volume DISTRIBUTED**	**/day, week, month**
Nebraska (NE)			
Nevada (NV)			
New Hampshire (NH)			
New Jersey (NJ)			
New Mexico (NM)			
New York (NY)			
North Carolina (NC)			
North Dakota (ND)			
Ohio (OH)			
Oklahoma (OK)			
Oregon (OR)			
Pennsylvania (PA)			
Rhode Island (RI)			
South Carolina (SC)			
South Dakota (SD)			
Tennessee (TN)			
Texas (TX)			
Utah (UT)			
Vermont (VT)			
Virginia (VA)			
Washington (WA)			
West Virginia (WV)			
Wisconsin (WI)			
Wyoming (WY)			
Other:			

National Association of Boards of Pharmacy®
Universal Inspection Form

Nuclear Pharmacy Inspection

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Nuclear/Radiopharmaceuticals Preparation, Compounding, Dispensing and Repackaging

Facility Name:
e-Profile ID:
Inspection Date:

		Finding	Notes	USP Reference(s)
	Nonsterile Radiopharmaceuticals			1.1
1.00	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)).*	Choose an item.		1.1
2.00	Does the pharmacy obtain conventionally manufactured nonsterile drug products for dispensing? *If so, list those products in the notes.*	Choose an item.		1.1
3.00	Does the pharmacy obtain compounded nonsterile preparations from 503B-registered outsourcing facilities for dispensing? *If so, list those products/outsourcers in the notes.*	Choose an item.		1.1
	Sterile Radiopharmaceuticals			1.2
4.00	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)*	Choose an item.		1.2
5.00	Does the pharmacy obtain conventionally manufactured sterile drug products for dispensing? *If so, list those products in the notes.*	Choose an item.		1.2
6.00	Does the pharmacy obtain compounded sterile preparations from 503B-registered outsourcing facilities for dispensing? *If so, list those products/outsourcers in the notes.*	Choose an item.		1.2
7.00	Does the pharmacy compound sterile preparations involving one or more nonsterile components?	Choose an item.		1.2
8.00	If the pharmacy compounds sterile preparations requiring a sterilization procedure, is testing (eg filtration with bubble point testing) performed prior to dispensing?	Choose an item.		1.2
9.00	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?	Choose an item.		1.2
	Immediate Use of Sterile Radiopharmaceuticals			3
10.00	Does the pharmacy prepare and dispense sterile radiopharmaceuticals in a patient care setting as immediate use?	Choose an item.		3
11.00	Does the pharmacy prepare immediate use sterile radiopharmaceuticals in an ambient environment without primary or secondary engineering controls?	Choose an item.		3
12.00	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:	Choose an item.		3
12.01	Are preparations (including minor deviations) and/or dispensing limited to use for a single patient?	Choose an item.		3

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12.02	Are preparation (including preparations with minor deviations) components sterile, conventionally manufactured drug products (e.g., NDA, ANDA)?	Choose an item.		3
12.03	Are dispensing of drug products produced under an approved IND or RDRC protocol?	Choose an item.		3
12.04	Are manipulations for any unit doses (e.g., decreasing the dosage, needle changes) or dispensing for one patient (e.g., withdrawing a dose) ?	Choose an item.		3
12.05	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?	Choose an item.		3
12.06	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?	Choose an item.		3
12.07	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?	Choose an item.		3
12.08	Does pharmacy staff follow proper hand hygiene and garbing?	Choose an item.		3
12.09	Does the pharmacy follow 10.4 Preparation of Radiolabeled Red Blood Cells for Immediate Use for red blood cell labeling?	Choose an item.		10.4
12.10	Does the pharmacy follow 12.2 Labeling for labeling?	Choose an item.		12.2
12.11	Is area for sterile preparation and/or dispensing functionally separate from nonsterile compounding area (e.g., radiolabeling food) during the time of use?	Choose an item.		
12.12	Does the pharmacy require a segregated radiopharmaceutical processing area (SRPA), classified area, or PEC?	Choose an item.		
12.13	Are the number of steps or punctures limited?	Choose an item.		
12.14	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)?	Choose an item.		4.1
12.15	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.*	Choose an item.		
12.16	Is dose splitting (splitting a unit dose for administration to more than one patient) performed as immediate use?	Choose an item.		
12.17	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.*	Choose an item.		

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		Finding	Notes	USP Reference(s)
	Personnel Qualifications, Training, and Hygiene			4
13.00	Are personnel trained to work with radiopharmaceuticals per policies and standard operating procedures (SOPs) authorized by an ANP or AU (eg physician)?	Choose an item.		4
14.00	Do personnel follow these policies or SOPs of the ANP or AU (eg physician) and work under their supervision?	Choose an item.		4
14.01	Are personnel trained in blood-borne pathogens (as appropriate)?	Choose an item.		4
15.00	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?	Choose an item.		4
15.01	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?	Choose an item.		4
15.02	Is the designated person responsible for evaluating whether these individuals should be excluded from working in sterile processing areas before their conditions are resolved?	Choose an item.		4
16.00	Have all personnel of reproductive capability who handle, or compound radiopharmaceuticals/radioactive materials confirmed in writing they understand the risks of handling radiopharmaceuticals/radioactive materials?	Choose an item.		4
17.00	Is there documentation of training for other employees (including drivers, warehouse, receiving, administrative, clerks, etc.) who may have contact with radiopharmaceuticals/radioactive materials on handling the spills associated with these?	Choose an item.		4
18.00	Can personnel demonstrate knowledge and can verbalize the principles of the safe use of RAM – time (working quickly/efficiently), distance (not handling RAM directly, using tongs), and shielding (using lead containers and shields in work areas)?	Choose an item.		4
19.00	Can personnel demonstrate a knowledge of emergency procedures and are able to point out the locations of the eyewash station, emergency spill kit, and can verbalize how to handle contamination including reporting?	Choose an item.		4
	Aseptic Qualifications		***Note to Inspector:*** *Check two (2) employee personnel files for documentation (1 RPh and 1 Tech), as appropriate*	4.1
20.00	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.*	Choose an item.		4.1
21.00	Do the minimum qualifications include the following?	Choose an item.		4.1
21.01	Aseptic technique with a documented assessment (written or electronic)	Choose an item.		4.1

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21.02	Garbing and hand hygiene, as defined by policies and SOPs	Choose an item.		4.1
21.03	PEC cleaning and disinfecting	Choose an item.		4.1
21.04	Gloved fingertip and thumb sampling	Choose an item.		4.1
21.05	Media-fill testing (not required for non-compounding personnel)	Choose an item.		4.1
	Gloved Fingertip and Thumb Sampling			4.1
22.00	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)?	Choose an item.		4.1
23.00	Is gloved fingertip and thumb sampling performed initially on both hands, immediately following hand hygiene and garbing?	Choose an item.		4.1
23.01	Is successful completion of initial gloved fingertip and thumb sampling defined as zero colony- forming units (cfu)?	Choose an item.		4.1
24.00	Is subsequent gloved fingertip and thumb sampling after media-fill testing defined as ≤3 cfu (total for both hands)?	Choose an item.		4.1
25.00	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?	Choose an item.		4.1
26.00	Per P&P review, gloves are not disinfected immediately before touching the sampling device.	Choose an item.		4.1
27.00	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?	Choose an item.		4.1
28.00	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?	Choose an item.		4.1
	Media-Fill Testing			4.1
29.00	Is media-fill testing done for all personnel who prepare, compound, dispense, and repackage sterile radiopharmaceuticals?	Choose an item.		4.1
30.00	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?	Choose an item.		4.1
31.00	Are media-fill tests documented as defined by the facility's policies and SOPs?	Choose an item.		4.1
32.00	*Recommendation: Are media-fill tests be performed at the end of a work session in the PEC.*	Choose an item.		4.1
33.00	Are media-fill tests performed with a commercial source of soybean–casein digest medium?	Choose an item.		4.1

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34.00	Do those performing sterile-to-sterile processing activities start with sterile media?	Choose an item.		4.1
35.00	Do those performing nonsterile-to-sterile compounding use a nonsterile soybean–casein digest powder to make a solution?	Choose an item.		4.1
35.01	Is dissolved nonsterile commercially available soybean–casein digest medium in nonbacteriostatic water to make a 3% nonsterile solution?	Choose an item.		4.1
35.02	Is the final media manipulated in a manner that simulates nonsterile-to-sterile compounding activities?	Choose an item.		4.1
35.03	Is the final media prepared with at least 1 container as the positive control to demonstrate growth promotion, which is indicated by visible turbidity upon incubation?	Choose an item.		4.1
36.00	Does the certificate of analysis (CoA) include documentation of growth promotion testing for each lot of media used?	Choose an item.		4.1
37.00	Once the media-fill simulation is completed and the final containers are filled with the test medium, are the media filled containers incubated for 7 days at 20°–25° C followed by 7 days at 30°–35° C to detect a broad spectrum of microorganisms? Note: Failure is indicated by visible turbidity or other visual manifestations of growth in the medium in 1 or more container–closure unit(s) on or before 14 days.	Choose an item.		4.1
38.00	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?	Choose an item.		4.1
39.00	Do media and components used include the following?	Choose an item.		4.1
39.01	manufacturer	Choose an item.		4.1
39.02	expiration date	Choose an item.		4.1
39.03	lot number	Choose an item.		4.1
40.00	Does the documentation include at a minimum the following?	Choose an item.		4.1
40.01	starting temperature for each interval of incubation	Choose an item.		4.1
40.02	dates of incubation	Choose an item.		4.1
40.03	results	Choose an item.		4.1
40.04	name of the person evaluated	Choose an item.		4.1
40.05	evaluation date	Choose an item.		4.1
40.06	evaluation time	Choose an item.		4.1
	Reevaluation, Retraining, and Requalification			4.2
41.00	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?	Choose an item.		4.2

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42.00	Are all failures, retraining, and re-evaluations documented?	Choose an item.		4.2
43.00	Do personnel successfully complete requalification in the core competencies via demonstrated through observation, written testing, and hands-on demonstration of skills?	Choose an item.		4.2
	Timing of Reevaluation and Requalification			4.2
44.00	**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?	Choose an item.		4.2
45.00	**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).	Choose an item.		4.2
46.00	**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)?	Choose an item.		4.2
47.00	**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?	Choose an item.		4.2
48.00	**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?	Choose an item.		4.2
49.00	**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?	Choose an item.		4.2
	Ancillary Personnel			4.3
50.00	Are personnel who are authorized to be within the sterile processing area and do not handle sterile preparations required to complete all training and testing other than training on media-fill testing ?	Choose an item.		4.3
51.00	Do other personnel or visitors (e.g., auditors, regulators, student observers) comply with garbing and gloving SOPs without the need to prove competency?	Choose an item.		4.3
	Hand Hygiene and Garbing for Immediate Use Preparations			4.4
52.00	**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?	Choose an item.		4.4

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53.00	**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?	Choose an item.		4.4
54.00	Is a different lab coat worn to care for a patient than the coat/gown used for radiopharmaceutical preparation?	Choose an item.		4.4
	Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Area			4.5
55.00	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).*	Choose an item.		4.5
55.01	Outer garments (e.g., bandanas, coats, hats, jackets, sweaters, vests)	Choose an item.		4.5
55.02	All cosmetics	Choose an item.		4.5
55.03	All hand, wrist, and other exposed jewelry including piercings that could interfere with the effectiveness of the garbing	Choose an item.		4.5
55.04	Nail products (e.g., artificial nails, polish, extenders). {Natural nails kept neat and trimmed.}	Choose an item.		4.5
55.05	Ear buds	Choose an item.		4.5
55.06	Headphones	Choose an item.		4.5
56.00	Are electronic devices that are not necessary for compounding or other required tasks banned from the SRPA?	Choose an item.		4.5
57.00	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.	Choose an item.		4.5
58.00	Does the process before entering the buffer area or SRPA include the following?	Choose an item.		4.5
58.01	Remove visible debris from underneath fingernails under warm running water using a disposable nail cleaner	Choose an item.		4.5
58.02	Wash hands and arms up the elbows with soap and water for at least 30 seconds and then dry using low-lint towels	Choose an item.		4.5
58.03	Electronic hand dryers are not permitted	Choose an item.		4.5
58.04	Hand antisepsis cleansing is performed using a suitable alcohol-based hand rub	Choose an item.		4.5
58.05	Don a low-lint gown with sleeves that fit snugly around the wrist and enclosed at the neck. *Note: Disposable gowns are preferred.*	Choose an item.		4.5
58.06	If reusable gowns are used, a clean gown is donned daily.	Choose an item.		4.5

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58.07	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.	Choose an item.		4.5
59.00	Does the routine process include the following?	Choose an item.		4.5
59.01	Do personnel periodically apply sterile 70% IPA to gloves while balancing the risk of radioactivity contamination; due to touching or handling potentially nonsterile materials?	Choose an item.		4.5
59.02	Do personnel inspect the gloves they are wearing for holes, punctures, radioactivity contamination, or tears?	Choose an item.		4.5
59.03	If a defect, radioactivity contamination, or malfunction is detected, do personnel immediately do the following?	Choose an item.		4.5
59.04	Remove the gloves	Choose an item.		4.5
59.05	Repeat antiseptic hand cleansing using an alcohol-based hand rub	Choose an item.		4.5
59.06	Don new sterile gloves	Choose an item.		4.5
59.07	Personnel avoid touch contamination of container septa, needles, syringe and needle hubs, and other critical sites	Choose an item.		4.5
60.00	Do exiting processes for buffer area or SRPA include the following?	Choose an item.		4.5
60.01	Shoe covers, head/hair/facial hair cover(s), face masks and gloves are properly disposed of	Choose an item.		4.5
60.02	New PPE is used for each re-entry	Choose an item.		4.5
60.03	Gowns may be re-used within the same shift if maintained to minimize contamination (eg away from sinks)	Choose an item.		4.5
60.04	Gowns are in a classified area or,	Choose an item.		4.5
60.05	Gown are kept in (or immediately outside of) the SRPA	Choose an item.		4.5
	Facility Design and Environmental Controls			5.1
61.00	Is the facility is designed to minimize airborne contamination (for sterile radiopharmaceutical facilities)?	Choose an item.		5.1
62.00	Is the facility is well-lighted?	Choose an item.		5.1
63.00	Are the refrigerator and freezer restricted to drug products only (no food)?	Choose an item.		5.1
64.00	Are the temperatures in classified areas and SRPA continuously maintained at 25 degrees C or cooler?	Choose an item.		5.1
65.00	Are the temperatures monitored in the classified areas and SRPA each day that they are used, either manually or by a continuous recording device?	Choose an item.		5.1
66.00	Are the temperature readings of the classified areas and SRPA documented at least once daily or stored in a continuous recording device and retrievable?	Choose an item.		5.1
67.00	Are the temperature readings reviewed as described in the facility's SOPs?	Choose an item.		5.1

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		Finding	Notes	USP Reference(s)
68.00	Are free-standing air conditioners used within the classified area or SRPA?	Choose an item.		5.1
69.00	Are temperature monitoring devices calibrated and verified for accuracy at least every 12 months or as required by the manufacturer?	Choose an item.		5.1
70.00	*Recommendation: The humidity in classified areas and SRPA are continuously maintained at a relative humidity (RH) below 60%.*	Choose an item.		5.1
71.00	Is the humidity monitored in the classified areas and SRPA each day that it is used, either manually or by a continuous recording device?	Choose an item.		5.1
72.00	Are the humidity readings of the classified areas and SRPA documented at least once daily or stored in a continuous recording device and retrievable?	Choose an item.		5.1
73.00	Are the humidity readings reviewed as described in the facility's SOPs?	Choose an item.		5.1
74.00	Are free-standing humidifiers/dehumidifier used within the classified area or SRPA?	Choose an item.		5.1
75.00	Are humidity monitoring devices calibrated and verified for accuracy at least every 12 months or as required by the manufacturer?	Choose an item.		5.1
76.00	Is the designated person responsible to ensure the following?	Choose an item.		5.1
76.01	Does each area related to sterile radiopharmaceutical processes meet the classified air quality standard appropriate for the activities to be conducted in that area?	Choose an item.		5.1
76.02	Are ISO Class 5 PECs located, operated, maintained, monitored, and certified to have appropriate air quality?	Choose an item.		5.1
	Types of Secondary Engineering Controls and Design:			5.1
77.00	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?	Choose an item.		5.1
78.00	Are tacky surfaces not used in ISO-classified areas?	Choose an item.		5.1
79.00	Are the PEC located in a SEC?	Choose an item.		5.1
80.00	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?	Choose an item.		5.1
80.01	Is the ISO-classified ante-room and buffer area separated from the surrounding unclassified areas of the facility with fixed walls and doors?	Choose an item.		5.1
80.02	Are facility design and controls in place to minimize the flow of lower-quality air into the more controlled areas?	Choose an item.		5.1
80.03	Is the air supplied to the classified areas introduced through HEPA filters that are located in the ceiling?	Choose an item.		5.1
80.04	Are returns low on the wall unless a visual smoke study demonstrates an absence of stagnant airflow where particulate will accumulate?	Choose an item.		5.1
80.05	Is a smoke study of the PEC repeated whenever a change to the placement of the PEC within the area is made?	Choose an item.		5.1

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80.06	Is the classified areas equipped with a pressure-differential monitoring system?	Choose an item.		5.1
80.07	Does the ante-room have a line of demarcation to separate the clean side from the less clean side?	Choose an item.		5.1
80.08	Is the ante-room entered through the less clean side, and the clean side is the area closest to the buffer area?	Choose an item.		5.1
80.09	Is required garb worn prior to crossing the line of demarcation?	Choose an item.		5.1
81.00	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:	Choose an item.		5.1
81.01	Only sterile radiopharmaceutical preparation, preparation with minor deviations, dispensing, and repackaging may be performed in an SRPA	Choose an item.		5.1
81.02	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.	Choose an item.		5.1
81.03	A visible perimeter establishes the boundaries of the SRPA.	Choose an item.		5.1
81.04	Access to the SRPA is restricted to authorized personnel and required materials.	Choose an item.		5.1
81.05	An SRPA is not located adjacent to environmental control challenges	Choose an item.		5.1
81.06	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)	Choose an item.		5.1
82.00	If a pass-through is used to prevent influx of contaminants, both doors are never opened at the same time.	Choose an item.		5.1
83.00	*Recommendation: Interlocking mechanisms are used in the pass-through(s).*	Choose an item.		5.1
	The Radiopharmaceutical Processing Environment:			5.1
84.00	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?	Choose an item.		5.1
85.00	Is the airflow in the PEC unidirectional (laminar flow)?	Choose an item.		5.1
86.00	Is "first air" at the face of the filter free from airborne particulate contamination?	Choose an item.		5.1
87.00	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?	Choose an item.		5.1
88.00	Are in situ air pattern analyses via smoke studies conducted at the critical area to demonstrate unidirectional airflow and sweeping action under dynamic conditions?	Choose an item.		5.1
	Types of PECs and Placement:			5.1
89.00	Does the placement of the PEC allow for cleaning around the PEC?	Choose an item.		5.1
90.00	**Laminar airflow workbench (LAFW):** Does a LAFW used for preparing radiopharmaceuticals provide vertical unidirectional HEPA-filtered airflow?	Choose an item.		5.1

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91.00	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.	Choose an item.		5.1
92.00	**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?	Choose an item.		5.1
92.01	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.	Choose an item.		5.1
92.02	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.	Choose an item.		5.1
93.00	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?	Choose an item.		5.1
	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.*	
94.00	For ISO-classified rooms, does the total ACPH maintain the ISO class under dynamic operating conditions?	Choose an item.		
95.00	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?	Choose an item.		
96.00	Is there a minimum of 30 total HEPA-filtered ACPH supplied to ISO Class 7 areas?	Choose an item.		
96.01	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?	Choose an item.		
96.02	If the PEC is used to meet the minimum total ACPH requirements, is the PEC not turned off except for maintenance?	Choose an item.		
96.03	Are both the ACPH from HVAC contributed from the PEC, and the total ACPH documented on certification reports?	Choose an item.		
97.00	Is a minimum of 20 ACPH of HEPA-filtered air supplied to ISO Class 8 areas?	Choose an item.		
97.01	Are ante-rooms where activity levels are high, required more HEPA-filtered ACPH to maintain ISO Class 8 under dynamic operating conditions?	Choose an item.		
97.02	Are the total ACPH documented on certification reports?	Choose an item.		
	Creating Areas to Achieve Easily Cleanable Conditions			5.2
	Classified Areas:			5.2

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		Finding	Notes	USP Reference(s)
98.00	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?	Choose an item.		5.2
99.00	*Recommendation: Surfaces are resistant to damage by cleaning agents, disinfectants, and tools used toclean.*	Choose an item.		5.2
100.00	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?	Choose an item.		5.2
101.00	If ceilings consist of inlaid panels, are each panel caulked or otherwise sealed and secured to seal them to the support frame?	Choose an item.		5.2
102.00	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?	Choose an item.		5.2
103.00	Are panels joined together and sealed to each other and the support structure?	Choose an item.		5.2
104.00	Do floors include coving to the sidewall or the juncture between the floor and wall are caulked?	Choose an item.		5.2
105.00	*Recommendation: Classified areas minimize dust-collecting overhangs such as utility pipes, ledges, and windowsills.*	Choose an item.		5.2
106.00	If overhangs or ledges are present, are they easily cleanable?	Choose an item.		5.2
107.00	Is the exterior lens surface of ceiling light fixtures smooth, mounted flush, and sealed?	Choose an item.		5.2
108.00	Are any other penetrations through the ceiling or walls sealed?	Choose an item.		5.2
	SRPA:			5.2
109.00	Is the SRPA and all surfaces (e.g., walls, floors, counters, equipment) within the SRPA clean, uncluttered, and dedicated to sterile radiopharmaceutical processing activities?	Choose an item.		5.2
110.00	*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.*	Choose an item.		5.2
111.00	*Recommendation: Surfaces are be resistant to damage by cleaning agents, disinfectants, and tools used to clean.*	Choose an item.		5.2
112.00	*Recommendation: Dust-collecting overhangs such as utility pipes, ledges, and windowsills are minimized.*	Choose an item.		5.2
113.00	If overhangs or ledges are present, are they easily cleanable?	Choose an item.		5.2
	Water Sources:			5.3
114.00	*Recommendation: Sinks are hands-free use with a closed system of soap (i.e., non-refillable).*	Choose an item.		5.3

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115.00	In facilities with an ante room and buffer room, is the sink placed inside or outside of the ante room? *Note placement, inside or outside.*	Choose an item.		5.3
115.01	If the sink is located outside of the ante-room, it is located in a clean space to minimize the risk of bringing in contaminants into the anteroom.	Choose an item.		5.3
115.02	If the sink is located inside the ante-room, describe where it is located.	Choose an item.		5.3
115.03	The buffer area does not contain plumbed water sources [e.g., sink(s), eyewash(es), shower(s), or floor drain(s)].	Choose an item.		5.3
115.04	The ante room does not contain floor drain(s).	Choose an item.		5.3
116.00	*Recommendation: If installed, sprinkler systems in classified areas are recessed & covered and are easily cleanable.*	Choose an item.		5.3
117.00	In facilities with a SRPA design:			5.3
117.01	Is the sink accessible but located at least 1 m from the PEC and generators, if present?	Choose an item.		5.3
117.02	Is the sink not located inside the perimeter of the SRPA?	Choose an item.		5.3
	Placement and Movement of Materials:			5.4
118.00	Are only furniture, equipment, and other materials necessary permitted in the classified area or SRPA?	Choose an item.		5.4
118.01	*Recommendation: Are furniture, equipment and materials low-shedding and easily cleaned & disinfected.*	Choose an item.		5.4
118.02	Does the number, design, location, and manner of furniture, equipment and material installation not adversely impact environmental air quality and promote effective cleaning and disinfecting?	Choose an item.		5.4
119.00	Are shipping carton(s) or other corrugated or uncoated cardboard not allowed in the classified area or SRPA?	Choose an item.		5.4
120.00	Are carts used to transport components or equipment into classified areas constructed from nonporous materials with cleanable casters and wheels?	Choose an item.		5.4
121.00	In a classified area, are carts not moved from the dirty side to the clean side of the anteroom unless the entire cart, including casters, is cleaned and disinfected?	Choose an item.		5.4
122.00	Are all items wiped with low-lint wipers and an appropriate disinfectant by personnel wearing gloves before they are brought into the clean side of ante-room(s), pass-through(s), into an SRPA or into an ISO 5 PEC?	Choose an item.		5.4
	Classified Areas:			5.5

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123.00	Are activities and tasks carried out within the buffer area limited to only those necessary?	Choose an item.		5.5
124.00	Are food and drinks exposed in patient care and treatment areas not in the ante-rooms or buffer areas?	Choose an item.		5.5
125.00	When processing activities require the manipulation of blood-derived or other biological material (e.g., radiolabeling patient's or donor's blood cells) do the following occur?	Choose an item.		5.5
125.01	Are the manipulations clearly separated from routine material-handling procedures and equipment used in radiopharmaceutical preparation activities?	Choose an item.		5.5
125.02	Are manipulations controlled by specific SOPs to avoid any cross-contamination?	Choose an item.		5.5
	Remote Aseptic Processing Involving a Hot-Cell:		***Note to Inspector*** *: In settings where tasks are carried out within the hot-cell enclosure not within an ISO-classified space by remote means (i.e., no direct intervention by personnel into the ISO Class 5 space), it is not necessary for personnel to don the garbing described in this chapter for that environment to carry out these aseptic manipulations or to perform other routine tasks in the general area where the hot-cell is located.*	5.6
126.00	Does a hot-cell device provide an inherent physical segregation for the ISO Class 5 aseptic processing area?	Choose an item.		5.6
127.00	If the hot-cell is located in an ISO-classified space, do personnel garb according to requirements of <825> for that environment?	Choose an item.		5.6
128.00	If hand and arm incursions into the interior of the hot-cell occur causing personnel to stage the required materials and supplies, do personnel garb in relation to the contamination risk associated with the individual hot-cell/ISO Class 5 relationship?	Choose an item.		5.6
129.00	For situations where a PEC device is located within a hot-cell, all the following apply:	Choose an item.		5.6
129.01	Do dynamic airflow smoke pattern tests show that the staging of supplies and materials in the demarcated PEC area does not allow the influx of unclassified air into the PEC?	Choose an item.		5.6
129.02	For interventions that are outside of the PEC, do personnel garb in nonsterile gloves and a low-particulate lab coat?	Choose an item.		5.6
129.03	If the hot-cell has failed the airflow smoke pattern test, are personnel required to garb differently?	Choose an item.		5.6
130.00	For situations where the hot-cell is an integrated HEPA filtration system with a clear demarcated area that is a PEC, the following apply:	Choose an item.		5.6

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130.01	Do dynamic airflow smoke pattern tests show that the staging of supplies and materials into the demarcated PEC area does not allow the influx of less than ISO Class 5 quality air into the PEC?	Choose an item.		5.6
130.02	If a failure of the airflow smoke pattern test require personnel to garb in accordance with 4.5 Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Area for all incursions into the PEC.	Choose an item.		5.6
131.00	For other hot-cell/PEC configurations and technologies that may exist, the following apply:	Choose an item.		5.6
131.01	Does verification (either by airflow smoke pattern tests or other manufacturer specified methods) ensure, upon each certification, that the staging of materials and supplies does not allow for the intrusion of less than ISO Class 5 air into the designated ISO Class 5 space?	Choose an item.		5.6
131.02	Does failure of the airflow smoke pattern test require personnel to garb in accordance with 4.5 Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Area for all incursions into the hot-cell?	Choose an item.		5.6
	Environmental Controls:			5.7
132.00	Do all RAM users comply with the conditions specified in their approved RAM license application and regulations, and RAM license conditions may supersede the following requirements for environmental controls? Refer to the RAM license for pressure requirements, as applicable.	Choose an item.		5.7
133.00	Do positive pressure environments have a minimum differential positive pressure of 0.02-inch water column between each ISO-classified area (e.g., between the buffer area and ante-room)?	Choose an item.		5.7
134.00	Is the pressure differential between the ante-room and the unclassified area no less than a positive 0.02-inch water column?	Choose an item.		5.7
134.01	Is the buffer area, if present, positive pressure compared to the ante-room?	Choose an item.		5.7
134.02	Is the ante-room, if present, positive pressure compared to unclassified portions of the restricted area?	Choose an item.		5.7
135.00	Is the restricted area, in the presence of volatile or airborne radiopharmaceuticals, negative pressure compared to the unrestricted area?	Choose an item.		5.7
136.00	Is the SRPA negative pressure compared to unrestricted areas in the presence of volatile or airborne radiopharmaceuticals (e.g., I-131 sodium iodide and Xe-133 gas)?	Choose an item.		5.7
	Establishing and Maintaining Pressure Differentials:			5.7
137.00	Any time a pressure differential is required, is there a pressure monitoring device?	Choose an item.		5.7

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138.00	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)?	Choose an item.		5.7
139.00	Are the results from the pressure monitoring system reviewed and documented at least daily on days the area is used?	Choose an item.		5.7
140.00	All pressure monitoring devices are tested for accuracy and required performance at least every 6 months.	Choose an item.		5.7
	Ambient Atmosphere for Immediate Use Preparations:			5.7
141.00	All of the following requirements met in ambient atmosphere environments:	Choose an item.		5.7
141.01	Is non-patient care space, functionally separate (not necessarily a different area) from the patient care area, such as a radiopharmaceutical handling space, or hot lab, in a hospital, clinic, or mobile coach?	Choose an item.		5.7
141.02	Is there a designated area for medication preparation that is clean and free from clutter?	Choose an item.		5.7
141.03	Is it a low traffic area (i.e., limited number of people going in and out or moving around the area during times that radiopharmaceutical processing is being carried out)?	Choose an item.		5.7
	SRPA with Vertical Flow ISO Class 5 PEC(s) for Radiopharmaceutical Preparations:			5.7
142.00	Does the SRPA with Vertical Flow ISO Class 5 PEC(s) for Radiopharmaceutical Preparations meet the following requirements?	Choose an item.		5.7
142.01	Area surrounding the PEC may be ambient (unclassified) atmosphere.	Choose an item.		5.7
142.02	Area is clean, uncluttered, and dedicated to the processing of radiopharmaceuticals.	Choose an item.		5.7
142.03	Appropriate for preparation, preparation with minor deviations, repackaging, and dispensing of radiopharmaceuticals.	Choose an item.		5.7
142.04	An area that is used to store and elute non-direct infusion radionuclide generators (e.g., Tc-99m) must meet ISO Class 8 total airborne particle-count specifications.	Choose an item.		5.7
	An ISO Class 8 Buffer Area with Vertical Flow ISO Class 5 PEC(s) with an Adjacent ISO Class 8 Ante-Room:		***Note to Inspector**: Activities - preparation, preparation with minor deviations, repacking, and dispensing of radiopharmaceuticals; storage & elution of non-direct infusion radionuclide generators.*	5.7

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143.00	ISO Class 8 Buffer Area with Vertical Flow ISO Class 5 PEC(s) with an Adjacent ISO Class 8 Ante-Room environment is appropriate for all activities listed in SRPA with Vertical Flow ISO Class 5 PEC(s) for Radiopharmaceutical Preparations.	Choose an item.		5.7
	An ISO Class 7 Buffer Area with Vertical Flow ISO Class 5 PEC(s) with an Adjacent ISO Class 8 Ante-Room:		***Note to Inspector**: Activities - preparation, preparation with minor deviations, repacking, and dispensing of radiopharmaceuticals; storage & elution of non-direct infusion radionuclide generators.*	5.7
144.00	ISO Class 7 Buffer Area with Vertical Flow ISO Class 5 PEC(s) with an Adjacent ISO Class 8 Ante-Room environment is appropriate for all activities listed in An ISO Class 8 Buffer Area with Vertical Flow ISO Class 5 PEC(s) with an Adjacent ISO Class 8 Ante-Room and sterile compounding.	Choose an item.		5.7
	Hot-Cell:		***Note to Inspector**: Activities - preparation, preparation with minor deviations, repacking, and dispensing of radiopharmaceuticals; storage & elution of non-direct infusion radionuclide generators.*	5.7
145.00	Hot-Cell environment is appropriate for all activities listed in SRPA with Vertical Flow ISO Class 5 PEC(s) for Radiopharmaceutical Preparations.	Choose an item.		5.7
	Certification of PEC and Environment in which the PEC is located:			5.7
146.00	Certification of the classified areas, including the PEC, is performed initially.	Choose an item.		5.7
147.00	Recertification is performed at least every 6 months.	Choose an item.		5.7
148.00	Procedures outlined in the current CETA certification guide for Sterile Compounding Facilities, or an equivalent guideline, are followed.	Choose an item.		5.7
149.00	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.	Choose an item.		5.7
150.00	HEPA filter integrity testing is performed (HEPA filters are leak tested after installation and as part of recertification).	Choose an item.		5.7
151.00	Total Particle Counts testing is performed and conducted under dynamic operating conditions using calibrated electronic equipment.	Choose an item.		5.7
152.00	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).	Choose an item.		5.7

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153.00	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?	Choose an item.		5.7
154.00	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.	Choose an item.		5.7
	Daily Monitoring of Environment:			5.7
155.00	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.	Choose an item.		5.7
156.00	Does Monitoring include the following?	Choose an item.		5.7
156.01	*Recommendation: Relative humidity is kept at 60% or lower*	Choose an item.		5.7
156.02	Are temperature continuous readings confirmed daily to have remained within the acceptable range?	Choose an item.		5.7
156.03	Are relative humidity continuous readings confirmed daily to have remained within the acceptable range?	Choose an item.		5.7
156.04	Are excursion documented and, if applicable, appropriate corrective actions taken?	Choose an item.		5.7
156.05	Are temperature monitoring devices verified for accuracy every 12 months or as required by the manufacturer?	Choose an item.		5.7
156.06	Are monitoring of pressure differentials performed?	Choose an item.		5.7
	Microbial Air and Surface Monitoring:			6
157.00	Has the pharmacy developed and implemented written air and surface monitoring procedures for all sterile radiopharmaceutical classified areas?	Choose an item.		6
158.00	Are air and surface monitoring results and the corrective actions documented, and records readily retrievable as required by jurisdictional laws and regulations?	Choose an item.		6
	General Monitoring Requirements:			6.1
159.00	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?	Choose an item.		6.1
159.01	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?	Choose an item.		6.1
160.00	Are personnel who operate the equipment trained in the proper operation of the air and surface sampling equipment to ensure accurate and reproducible sampling?	Choose an item.		6.1

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161.00	Are all air sampling devices serviced and calibrated as recommended by the manufacturer?	Choose an item.		6.1
162.00	Does the microbiological air and surface monitoring program include viable impact volumetric airborne particulate sampling and surface sampling?	Choose an item.		6.1
163.00	Are air and surface sampling performed initially for PECs & classified areas in a facility to establish a baseline level of environmental quality?	Choose an item.		6.1
164.00	After initial sampling, are the PECs & classified area(s) monitored according to the minimum frequencies?	Choose an item.		6.1
165.00	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?	Choose an item.		6.1
166.00	Is sampling carried out at the conclusion of sterile radiopharmaceutical processing but prior to cleaning and disinfecting the surface area?	Choose an item.		6.1
167.00	Is sampling performed in all of the following circumstances?	Choose an item.		6.1
167.01	In conjunction with the certification of new facilities and equipment?	Choose an item.		6.1
167.02	After any modification of facilities or equipment	Choose an item.		6.1
167.03	In response to identified problems (e.g., positive growth in sterility tests of compounded radiopharmaceuticals)?	Choose an item.		6.1
167.04	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)?	Choose an item.		6.1
167.05	In response to changes that could impact the controlled area environments (e.g., significant change in cleaning process or the agents involved)?	Choose an item.		6.1
168.00	Is regular review of the sampling data performed to detect trends such as elevated levels of microbial bioburden, elevated levels of nonviable particulates, or other adverse changes within the environment?	Choose an item.		6.1
169.00	Are results reviewed in conjunction with personnel data (i.e., training records, visual observations, competency assessments) to assess the state of control and to identify potential risks of contamination?	Choose an item.		6.1
170.00	Is Prompt corrective action in response to any adverse findings taken to maintain the necessary environmental quality for handling sterile radiopharmaceutical?	Choose an item.		6.1
171.00	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?	Choose an item.		6.1
	Monitoring Air Quality for Viable Airborne Particles:			6.2
	Viable Air Sampling: Timing and Locations			6.2

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172.00	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.	Choose an item.		6.2
173.00	Does viable air sampling include the following?	Choose an item.		6.2
173.01	Following the manufacturer's instructions for operation of the air sampling device, including placement of media?	Choose an item.		6.2
173.02	Using the sampling device, test at least 1 cubic meter or 1000 liters of air from each location sampled?	Choose an item.		6.2
173.03	At the end of the sampling, retrieve the media plates/devices and cover?	Choose an item.		6.2
173.04	Inverting the media and incubate at 30°–35° C for no less than 48 hours. Examine for growth. Record the total number of discrete colonies of microorganisms on each plate as cfu/m3 of air on an environmental sampling form based on sample type (i.e., viable air). Include sample location and date?	Choose an item.		6.2
173.05	Incubates the inverted media at 20°–25° C for no less than 5 additional days? Examines the media plates for growth? Records the total number of discrete colonies of microorganisms on each plate as cfu/m3 of air on an environmental sampling form based on sample type (i.e., viable air)? Includes sample location and date?	Choose an item.		6.2
174.00	To shorten the overall incubation period, can two samples be collected for each sample location and incubated concurrently?	Choose an item.		6.2
175.00	Both samples could be TSA, or one sample could be TSA and the other fungal media [e.g., malt extract agar (MEA) or sabouraud dextrose agar (SDA)]. *Describe samples in notes.*	Choose an item.		6.2
176.00	Each sample is incubated in a separate incubator.	Choose an item.		6.2
177.00	One sample is incubated at 30°–35°C for no less than 48 hours and the other sample is incubated at 20°–25° C for no less than 5 days.	Choose an item.		6.2
178.00	Fungal media samples are incubated at 20°–25° C for no less than 5 days.	Choose an item.		6.2
179.00	The count of the total number of discrete colonies of microorganisms are done on each sample and these results are recorded as cfu per sample.	Choose an item.		6.2
180.00	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?	Choose an item.		6.2
181.00	Are general microbiological growth medium that supports the growth of bacteria and fungi used (e.g., TSA medium)?	Choose an item.		6.2
182.00	Do CoA(s) from the manufacturer verify that the medium meets the expected growth promotion, pH, and sterilization requirements?	Choose an item.		6.2
183.00	Are samples incubated in a temperature monitored incubator with a calibrated measuring device?	Choose an item.		6.2

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184.00	Is the incubator temperature monitored during incubation, either manually or by a continuous recording device, and the results reviewed and documented?	Choose an item.		6.2
185.00	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?	Choose an item.		6.2
	Data Evaluation and Action Levels:			6.2
186.00	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*	Choose an item.		6.2
187.00	Are cfu counts evaluated against the action levels and in relation to previous data to identify adverse results and/or trends?	Choose an item.		6.2
187.01	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)?	Choose an item.		6.2
188.00	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?	Choose an item.		6.2
188.01	Is the corrective action plan dependent on the cfu count and the microorganism recovered?	Choose an item.		6.2
188.02	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?	Choose an item.		6.2
188.03	Is the corrective action plan documented?	Choose an item.		6.2
188.04	*Recommendation: The extent of the investigation is consistent with the deviation and includes an evaluation of trends.*	Choose an item.		6.2
	Monitoring Surfaces for Viable Particles:			6.3
189.00	Are all sampling sites and procedures described in the facility's SOP?	Choose an item.		6.3
	Surface Sampling: Timing and Locations			6.3
190.00	Is surface sampling of all classified areas and all PECs conducted at least monthly for the detection of microbial contamination?	Choose an item.		6.3
191.00	Is each classified area sampled?	Choose an item.		6.3
192.00	Is the DPA of the PEC, and any equipment permanently contained in the PEC, sampled?	Choose an item.		6.3

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193.00	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?	Choose an item.		6.3
194.00	Is surface sampling performed at the end of the radiopharmaceutical aseptic activities or shift, but before the area has been cleaned and disinfected?	Choose an item.		6.3
195.00	Do radiopharmaceutical personnel consider the appropriate exposure and contamination prevention measures prior to and while collecting samples?	Choose an item.		6.3
196.00	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)?	Choose an item.		6.3
	Sampling Procedures:			6.3
197.00	Are surface sampling devices (e.g., plates, paddles, or slides) containing microbial growth media used for sampling flat surfaces?	Choose an item.		6.3
198.00	Are CoAs from the manufacturer verified that the media meet the expected growth promotion, pH, and sterilization requirements?	Choose an item.		6.3
199.00	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?	Choose an item.		6.3
200.00	If used, do contact plates have a raised convex surface?	Choose an item.		6.3
201.00	Are sterile swabs wetted with sterile water or a sterile neutralizing buffer used when sampling irregular surfaces and difficult-to-reach locations, such as crevices, corners, and spaces between surfaces?	Choose an item.		6.3
202.00	After sampling, is the sampled area thoroughly cleaned and disinfected?	Choose an item.		6.3
203.00	Are the following procedures for surface sampling on flat surfaces used?	Choose an item.		6.3
203.01	Remove the cover from the surface sampling device. Firmly press, using a rolling motion, if possible, the media surface onto the surface to be sampled. The surface sampling device will leave a residue of growth medium on the sample site. After sampling, use sterile 70% IPA to remove residue. Cover each surface sampling device.	Choose an item.		6.3
203.02	If using plates, invert the plates.	Choose an item.		6.3
203.03	Incubate the surface sampling devices at 30°–35° C for no less than 48 hours. Examine for growth. Record the total number of discrete colonies of microorganisms on each media device as cfu/sample on an environmental sampling form based on sample type (i.e., surface). Include sample location and date.	Choose an item.		6.3

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203.04	Incubate the sampling device at 20°–25° C for no less than 5 additional days. Examine the media plates for growth. Record the total number of discrete colonies of microorganisms (cfu/sample) on the environmental sampling record based on sample type (i.e., surface). Include sample location and date.	Choose an item.		6.3
204.00	Does the facility use two samples for each sampling location?	Choose an item.		6.3
204.01	Are both TSA?	Choose an item.		6.3
204.02	Is one TSA and one Fungal?	Choose an item.		6.3
204.03	Is each sample incubated in a separate incubator?	Choose an item.		6.3
204.04	Is one sample media incubated at 30°–35° C for no less than 48 hours?	Choose an item.		6.3
204.05	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?	Choose an item.		6.3
204.06	Are the total number of discrete colonies of microorganisms on each sample counted as cfu per sample?	Choose an item.		6.3
204.07	Are the results of the sampling recorded?	Choose an item.		6.3
	Data Evaluation and Action Levels:			6.3
205.00	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*	Choose an item.		6.3
206.00	Are cfu counts evaluated against the action levels and in relation to previous data to identify adverse results and/or trends?	Choose an item.		6.3
206.01	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)?	Choose an item.		6.3
207.00	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?	Choose an item.		6.3
207.01	Is data collected in response to corrective actions reviewed to confirm that the actions taken have been effective?	Choose an item.		6.3
207.02	Is the corrective action plan dependent on the cfu count and the microorganism recovered?	Choose an item.		6.3
207.03	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?	Choose an item.		6.3
207.04	Is the corrective action plan documented?	Choose an item.		6.3

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207.05	*Recommendation: The extent of the investigation is consistent with the deviation and includes an evaluation of trends.*	Choose an item.		6.3
	Cleaning and Disinfecting			7
208.00	Are all cleaning and disinfecting activities performed by trained and appropriately garbed personnel using facility approved agents and procedures described in written SOPs?	Choose an item.		7
209.00	Is cleaning performed in the direction of most to least clean areas?	Choose an item.		7
210.00	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?	Choose an item.		7
210.01	Is the manufacturer's direction or published data for the minimum contact time followed for the cleaning, disinfecting, and sporicidal agents used?	Choose an item.		7
210.02	When sterile 70% IPA is used, is it allowed to dry?	Choose an item.		7
211.00	Are all cleaning, disinfecting, and application of sporicidal agents documented according to facility SOPs?	Choose an item.		7
212.00	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?	Choose an item.		7
212.01	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?	Choose an item.		7
213.00	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?	Choose an item.		7
214.00	Is the act of reducing or removing radioactivity (radioactive decontamination) from an object or surface balanced with the risk of spreading radioactive contamination?	Choose an item.		7
214.01	*Recommendation: Areas shielded until radiation exposure levels lowered.*	Choose an item.		7
214.02	Is this balance specified in SOPs (e.g., trigger levels for safe cleaning)?	Choose an item.		7
214.03	*Recommendation: The PEC is checked for radioactive contamination prior to cleaning and disinfecting to prevent spreading radioactive contamination in the PEC.*	Choose an item.		7
	Minimum Frequency for Cleaning and Disinfecting Surfaces in Classified Areas and within the perimeter of the SRPA:			7
215.00	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?	Choose an item.		7

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215.01	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)?	Choose an item.		7
215.02	Is radioactive contamination shielded with appropriate temporary material, providing the material is covered with low-lint absorbent pads or has equivalent low shedding properties?	Choose an item.		7
216.00	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?	Choose an item.		7
216.01	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)?	Choose an item.		7
216.02	When used, are low-lint absorbent pads removed and the PEC surveyed for radioactive contamination prior to disinfecting?	Choose an item.		7
216.03	Are new pads replaced after disinfecting or as required after spills?	Choose an item.		7
217.00	Does Cleaning and Disinfecting occurs **DAILY** for the following?	Choose an item.		7
217.01	PEC(s) and equipment inside the PEC(s)	Choose an item.		7
217.02	Surface of sink(s)	Choose an item.		7
217.03	PEC and equipment inside the PEC(s) located in a hot cell.	Choose an item.		7
217.04	Hot-cells (all interior surfaces, dependent on design, equipment, and shielding present)	Choose an item.		7
217.05	Work surface(s) outside the PEC	Choose an item.		7
217.06	Floor(s)	Choose an item.		7
218.00	Does Cleaning and Disinfecting occurs **MONTHLY** for the following?	Choose an item.		7
218.01	Ceiling(s)	Choose an item.		7
218.02	Wall(s), door(s), door frame(s), and other fixtures	Choose an item.		7
218.03	Storage shelving and storage bins	Choose an item.		7
219.00	Does Sporicidal application occurs **MONTHLY** for the following?	Choose an item.		7
219.01	PEC(s) and equipment inside the PEC(s)	Choose an item.		7
219.02	Surface of sink(s)	Choose an item.		7
219.03	Hot-cells (all interior surfaces, dependent on design, equipment, and shielding present)	Choose an item.		7
219.04	PEC and the equipment inside the PEC(s) located in a hot-cell	Choose an item.		7

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219.05	Work surface(s) outside the PEC	Choose an item.		7
219.06	Ceiling(s)	Choose an item.		7
219.07	Wall(s), door(s), door frame(s), and other fixtures	Choose an item.		7
219.08	Floor(s)	Choose an item.		7
219.09	Storage shelving and storage bins	Choose an item.		7
	Cleaning, Disinfecting and Sporicidal Agents:		***Note to Inspector**: Some EPA-registered (or equivalent) one-step disinfectant cleaners may have sporicidal properties.*	7.1
220.00	Are cleaning and disinfecting agents selected and used with careful consideration of compatibilities, effectiveness, and user safety?	Choose an item.		7.1
221.00	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?	Choose an item.		7.1
221.01	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?	Choose an item.		7.1
222.00	Is only sterile 70% IPA used in the ISO Class 5 PEC?	Choose an item.		7.1
223.00	Are sporicidal agents used at least monthly on all surfaces in classified areas and SRPAs?	Choose an item.		7.1
	Cleaning Supplies:			7.2
224.00	Are all cleaning supplies (e.g., wipers and mop heads), with the exception of tool handles and holders, low-lint?	Choose an item.		7.2
225.00	*Recommendation: All cleaning supplies (e.g., wipers and mop heads), with the exception of tool handles and holders are disposable.*	Choose an item.		7.2
225.01	If disposable cleaning supplies are used, are they discarded after each cleaning activity?	Choose an item.		7.2
226.00	Are reusable cleaning tools made of cleanable materials (e.g., no wooden handles) and are cleaned and disinfected before and after each use?	Choose an item.		7.2
227.00	Are reusable cleaning tools dedicated for use in the classified areas or SRPAs and are not removed from these areas except for disposal?	Choose an item.		7.2
228.00	Are reusable cleaning tools discarded after an appropriate amount of time, to be determined based on the condition of the tools?	Choose an item.		7.2
229.00	*Recommendation: Cleaning supplies and solutions used in the classified areas and SRPAs are be monitored for radioactive contamination after use and prior to disposal, as per facility SOPs.*	Choose an item.		7.2
230.00	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)?	Choose an item.		7.2

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	Cleaning and Disinfecting the PEC:			7.3
231.00	Is the PEC cleaned and disinfected at the minimum frequencies specified in Table 5?	Choose an item.		7.3
232.00	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?	Choose an item.		7.3
233.00	If necessary are all surfaces of the PEC surveyed for radioactive contamination and follow facility SOPs to decontaminate?	Choose an item.		7.3
234.00	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?	Choose an item.		7.3
235.00	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?	Choose an item.		7.3
236.00	Is sterile 70% IPA applied?	Choose an item.		7.3
237.00	Are the surfaces allowed to dry completely before beginning activities?	Choose an item.		7.3
238.00	Is the PEC wiped with a sporicidal agent at least monthly?	Choose an item.		7.3
	Disinfecting Supplies for Classified Areas and SRPAs:			7.4
239.00	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?	Choose an item.		7.4
240.00	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?	Choose an item.		7.4
241.00	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?	Choose an item.		7.4
241.01	Is the agent used for disinfecting the packaging compatible with the packaging and not render the product label unreadable?	Choose an item.		7.4
242.00	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)?	Choose an item.		7.4
243.00	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.			7.4
243.01	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?	Choose an item.		7.4
	Disinfecting Critical Sites:			7.5

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244.00	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.*	Choose an item.		7.5
245.00	Is the critical site wiped ensuring that both chemical and mechanical actions are used to remove contaminants?	Choose an item.		7.5
246.00	Is the sterile 70% IPA allowed to dry before piercing critical sites?	Choose an item.		7.5
247.00	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)?	Choose an item.		7.5
	Cleaning and Disinfecting Items from Patient Care Area:			7.6
248.00	Is radiation shielding and equipment used in the classified area/SRPA or PEC that is exposed to patient care areas during the process of administration cleaned and disinfected before returning to any classified area (e.g., buffer or ante-room) or SRPA in accordance with the Centers for Disease Control and Prevention Guidelines 1 classified as noncritical equipment requiring low-risk disinfection?	Choose an item.		7.6
249.00	Are syringes that have been used in a patient care area not brought back into the classified area (e.g., buffer or ante-room) or SRPA for re-assaying or disposal unless the syringe is sealed inside an impervious container (e.g., sealed plastic bag) that is disinfected prior to entry into the classified area or SRPA?	Choose an item.		7.6
250.00	Is equipment that has been exposed to needles and syringes contaminated with blood-borne pathogens and RAMs considered mixed waste (e.g., syringe shields and syringe carrying containers)?	Choose an item.		7.6
250.01	Is this equipment cleaned and disinfected through actions regulated by the facility's SOPs?	Choose an item.		7.6
250.02	Is equipment that contained or was in contact with mixed waste cleaned and disinfected with an appropriate agent(s) for blood?	Choose an item.		7.6
	Assigning BUDs:			8
251.00	Does the pharmacy have policies and SOPs appropriate to the assignment of BUD and maintain documentation of applicable study results and calculations?	Choose an item.		8
252.00	*Recommendation: Studies of radiolabeling efficiency and radiochemical stability employ quality control (QC) testing methods described in the manufacturer's package insert, USP monographs and general chapters, or other equivalent testing methods and are sufficiently rigorous to allow statistical confidence in the results.*	Choose an item.		8
253.00	Does the pharmacy have SOPs to collect and evaluate complaints associated with the use of radiopharmaceuticals having assigned BUDs?	Choose an item.		8
254.00	*Recommendation: Policies and SOPs are also in place to reevaluate the assigned BUD based on complaints, which may include repeating studies and/or performing additional studies on radiolabeling efficiency and/or radiochemical stability.*	Choose an item.		8

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255.00	Does the individual responsible for the manipulation assign the BUD based on established testing data, either performed in-house or obtained from peer reviewed literature?	Choose an item.		8
256.00	Preparation Conditions for Sterile Radiopharmaceuticals: *Describe condition used at the pharmacy in notes section (Table 7).*			8
257.00	For compounded preparations (sterile and nonsterile) plus preparations with minor deviations, is BUD dependent on maintenance of quality and purity including radiochemical purity, radionuclidic purity and other applicable parameters as specified in individual monographs or as clinically appropriate?	Choose an item.		8
258.00	Assignment of BUD for a radiopharmaceutical considers several factors, as appropriate. Issues of concern include all but are not limited to the following:	Choose an item.		8
259.00	*Recommendation: The assigned BUD does not exceed the sterility-related times listed in Table 7 unless a longer time is justified by Sterility tests per <71>.*	Choose an item.		8
260.00	Radiochemical Purity - Is the assigned BUD based on stability studies in which these variables are controlled and are representative of the conditions of actual use?	Choose an item.		8
261.00	*Recommendation: For factors that allow a range of values (e.g., storage temperature, quantity of radioactivity, radioactivity concentration), studies are conducted at the extreme of the ranges.*	Choose an item.		8
262.00	Radionuclidic purity - USP monographs for Tc-99m radiopharmaceuticals require that the radionuclidic impurity Mo-99 not exceed 0.15 µCi Mo-99 per mCi Tc-99m at the time of administration.	Choose an item.		8
263.00	Are calculations of radionuclidic purity at future times necessary to ensure compliance throughout the assigned BUD?	Choose an item.		8
264.00	Age of the generator eluate - Extension of the BUD for Tc-99m pertechnetate intended for radiolabeling of kits take into account the build-up of Tc-99 and peroxides over time.	Choose an item.		8
265.00	Number of particles - For radiolabeled particulates, the number of particles per unit radioactivity increases over time as the radionuclide decays. Calculation of the number of MAA particles in the patient dose is conducted to ensure compliance with the prescribed particle range throughout the assigned BUD.	Choose an item.		8
266.00	Specific Activity - For some receptor-based radiopharmaceuticals, the mass quantity may influence uptake. In such situations, the assigned BUD ensures that the patient dose contains no more than the specified mass.	Choose an item.		8
267.00	Container Type – The assigned BUD is determined in the proper storage container.	Choose an item.		8
268.00	*Cell Viability – Recommendation: The assigned BUD is as short as circumstances reasonably allow so as to maximize cell viability.*	Choose an item.		8

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269.00	In the case of manufactured radiopharmaceuticals that are distributed to nuclear pharmacies or other healthcare facilities for terminal distribution/dispensing, the assigned BUD of the dispensed dose cannot exceed the expiration date/time of the manufactured radiopharmaceutical(s).	Choose an item.		8
270.00	In the case of radiopharmaceuticals prepared from kits, the BUD of a dispensed dose cannot exceed the assigned BUD of the finished kit preparation.	Choose an item.		8
271.00	A radiopharmaceutical may not exceed the shortest BUD of any of its components.	Choose an item.		8
	Documentation:			9
272.00	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?	Choose an item.		9
273.00	Do such records include all but are not limited to the following?	Choose an item.		9
273.01	Personnel training and testing including visual assessment of aseptic technique competency	Choose an item.		9
273.02	Validation	Choose an item.		9
273.03	Garbing	Choose an item.		9
273.04	Hand hygiene	Choose an item.		9
273.05	Equipment/environment cleaning and disinfecting	Choose an item.		9
273.06	Gloved fingertip and thumb sampling	Choose an item.		9
273.07	Media fill evaluation initially	Choose an item.		9
273.08	Media fill follow up testing at specified intervals	Choose an item.		9
273.09	Equipment maintenance and cleaning/disinfecting	Choose an item.		9
273.10	End product radiochemical purity and other testing, as applicable, results of preparations, preparations with minor deviations, and compounded preparations	Choose an item.		9
273.11	Master Formulation Record (MFR) for preparation with minor deviation(s) and compounding	Choose an item.		9
273.12	Validation of stability testing to support the assigned BUD from SOPs by the compounder or derived from accepted literature	Choose an item.		9
273.13	Investigations and corrective actions and tracking of events to closure.	Choose an item.		9
274.00	Do Testing and Monitoring of environmental controls include the following?	Choose an item.		9
274.01	ISO classification	Choose an item.		9
274.02	ACPH	Choose an item.		9
274.03	Pressure differentials	Choose an item.		9
274.04	Temperature	Choose an item.		9
274.05	*Recommendation: Humidity*	Choose an item.		9

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		Finding	Notes	USP Reference(s)
274.06	Viable air	Choose an item.		9
274.07	Viable surface	Choose an item.		9
274.08	Total particle test results	Choose an item.		9
	Master Formulation Record:			9.1
275.00	Preparations with minor deviations or compounding have a MFR. *Note: A MFR is not required for a preparation following the manufacturer's instructions.*	Choose an item.		9.1
276.00	Do the elements of the MFR include at a minimum the following?	Choose an item.		9.1
276.01	Name of the radiopharmaceutical	Choose an item.		9.1
276.02	Name or ID number, pharmacy, strength, purity, quality, and quantity of ingredients with validated documentation (e.g., CoA)	Choose an item.		9.1
276.03	Detailed procedure (e.g., heating, components, incubation time)	Choose an item.		9.1
276.04	Range of radioactivity	Choose an item.		9.1
276.05	Range of volume	Choose an item.		9.1
276.06	Equipment to be used	Choose an item.		9.1
276.07	PEC and SEC to be used, if applicable	Choose an item.		9.1
276.08	Quality control tests to be performed for final release of the radiopharmaceutical (e.g., radiochemical purity, pH)	Choose an item.		9.1
276.09	Procedures for depyrogenation and sterility procedures and validations, as applicable, including limits	Choose an item.		9.1
276.10	Trained Personnel	Choose an item.		9.1
276.11	Garbing procedure, if different than standard procedure	Choose an item.		9.1
276.12	Container(s)	Choose an item.		9.1
276.13	Reference source of the BUD assignment and storage conditions	Choose an item.		9.1
	Records for Preparation with Minor Deviations/Compounding:			9.2
277.00	Does the record for preparation with minor deviation or compounding includes at a minimum, as applicable, the following?	Choose an item.		9.2
277.01	Name of the radiopharmaceutical	Choose an item.		9.2
277.02	Physical form (eg capsule or solution)	Choose an item.		9.2
277.03	Name and quantity of ingredients including calibration time for radioactive ingredients (e.g., 100 mCi Tc 99m sodium pertechnetate @ 1300)	Choose an item.		9.2
277.04	Total volume	Choose an item.		9.2
277.05	Reference to the MFR	Choose an item.		9.2
277.06	Any deviation from the MFR, if applicable	Choose an item.		9.2

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		Finding	Notes	USP Reference(s)
277.07	Name of vendor or manufacturer, lot numbers, and expiration dates of all ingredients and components	Choose an item.		9.2
277.08	Name of the person who prepared and name of the supervising personnel (e.g., ANP)	Choose an item.		9.2
277.09	Date and time of preparation	Choose an item.		9.2
277.10	Assigned internal identification number (e.g., lot number)	Choose an item.		9.2
277.11	Unique reference [e.g., prescription, order number(s)]	Choose an item.		9.2
277.12	Assigned BUD and storage requirements	Choose an item.		9.2
277.13	Documentation of QC results	Choose an item.		9.2
	Preparation			10
278.00	The individual responsible for preparing the radiopharmaceutical(s) ensures that the final preparation complies with quality and purity specifications throughout the assigned BUD.	Choose an item.		10
279.00	Do the quality and purity specifications include, as appropriate for the preparation, the following?	Choose an item.		10
279.01	Radionuclidic purity	Choose an item.		10
279.02	Radiochemical purity	Choose an item.		10
279.03	Chemical purity	Choose an item.		10
279.04	Physical and chemical properties	Choose an item.		10
	Preparation Following Manufacturer Instructions			10.1
	Nonsterile Preparations			10.1
280.00	For nonsterile preparations, manufacturer preparation instructions are followed (e.g., I-131 NaI capsules or solution), taking into account appropriate radiation safety considerations and environmental controls, if applicable (e.g., negative air pressure area, chemical fume hood, activated charcoal filters when handling a potentially volatile radionuclide).	Choose an item.		10.1
281.00	*Recommendation: The area is cleaned and uncluttered to ensure the overall integrity and quality of the prepared radiopharmaceutical(s).*	Choose an item.		10.1
282.00	*Recommendation: There is a documented process for activities (e.g., cleaning) between the preparation cycles of different nonsterile products, to decrease the likelihood of contamination from other prepared products.*	Choose an item.		10.1
	Sterile Preparations			10.1

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283.00	For sterile preparations (including intravascular devices), manufacturer preparation instructions are followed, taking into account appropriate radiation safety considerations, appropriate environmental controls, and aseptic handling practices to maintain sterility.	Choose an item.		10.1
284.00	The minimum environmental standard for the preparation of sterile radiopharmaceuticals beyond immediate-use is within an ISO Classified area or device.	Choose an item.		10.1
	Preparation with Minor Deviations			10.2
285.00	In some cases, radiopharmaceuticals are prepared with minor deviations from manufacturer instructions that are necessary to accommodate circumstances not contemplated in the FDA approved labeling.	Choose an item.		10.2
285.01	Deviations from manufacturer preparation instructions for radiopharmaceuticals maintain the same ingredients but may differ in their proportions.	Choose an item.		10.2
286.00	The minor deviations utilized require appropriate in-house QC testing, designed to validate the radiochemical purity of the product for the entirety of the BUD or are supported by appropriate peer-reviewed publications.	Choose an item.		10.2
287.00	Do the pharmacy radiopharmaceutical preparations with minor deviations include all of the following when applicable?	Choose an item.		10.2
287.01	Altering the quantity of radioactivity or volume added to the vial	Choose an item.		10.2
287.02	Changes in step-by-step operations (e.g., dilute Tc-99m sodium pertechnetate after rather than before addition to the vial)	Choose an item.		10.2
287.03	Using alternative devices or equipment (e.g., a heating block rather than a hot water bath, using a different sized needle, different shielding materials)	Choose an item.		10.2
287.04	Using QC test methods other than those described in the product labeling (e.g., radiochemical purity)	Choose an item.		10.2
287.05	Filtering Tc-99m sulfur colloid	Choose an item.		10.2
287.06	Other, (if so, describe in the notes)	Choose an item.		10.2
	Preparation of Radiolabeled Blood Components		***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.*	10.3
288.00	The preparation BUD does not exceed 6 hours after the blood sample is obtained from the patient or blood bank.	Choose an item.		10.3
289.00	Equipment and supplies are never shared with other activities unless they are first thoroughly cleaned and disinfected.	Choose an item.		10.3

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290.00	Do special precautions when radiolabeling of blood components for non-immediate use include the following?	Choose an item.		10.3
290.01	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.	Choose an item.		10.3
290.02	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.	Choose an item.		10.3
290.03	Thorough cleaning and disinfection of the ISO Class 5 BSC and all reusable equipment within, occurs prior to starting another blood component radiolabeling procedure.	Choose an item.		10.3
290.04	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.	Choose an item.		10.3
290.05	Centrifuge is located within the ISO Class 7 buffer area that is dedicated for blood component radiolabeling processes.	Choose an item.		10.3
290.06	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.	Choose an item.		10.3
290.07	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).	Choose an item.		10.3
290.08	Dedicated syringe shields and vial shields.	Choose an item.		10.3
290.09	Any garb that enters the ISO Class 5 BSC is removed and replaced before handling anything else not related to performing this procedure.	Choose an item.		10.3
290.10	Removal of all disposable items from the ISO Class 5 BSC is utilized in each radiolabeling procedure.	Choose an item.		10.3

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290.11	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.	Choose an item.		10.3
290.12	After the completion of blood radiolabeling procedures, 4.5 Hand Hygiene and Garbing requirements for Buffer Areas and segregated Radiopharmaceutical Processing Area are followed.	Choose an item.		10.3
	Preparation of Radiolabeled Red Blood Cells for Immediate Use			10.4
291.00	Is In vitro red blood cell labeling prepared with the following conditions?	Choose an item.		10.4
291.01	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.	Choose an item.		10.4
291.02	Only one radiolabeling procedure is performed at a time or there are documented processes that maintain the integrity of samples and environment.	Choose an item.		10.4
291.03	Dedicated equipment is used for blood radiolabeling procedure (e.g., L-block, syringe shield, vial shield, forceps, needle recapper).	Choose an item.		10.4
291.04	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	Choose an item.		10.4
291.05	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	Choose an item.		10.4
291.06	All requirements in 4.4 Hand Hygiene and Garbing for Immediate Use Preparations are followed.	Choose an item.		10.4
291.07	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.	Choose an item.		10.4
291.08	The compounded product has a BUD of 1 hour	Choose an item.		10.4

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	Compounding		***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.*	**11**
292.00	Each compounding activity is based on a pre-established written procedure and includes maintenance of compounding records.	Choose an item.		**11**
292.01	The compounding record provides traceability for components and person(s) involved.	Choose an item.		**11**
293.00	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".*	Choose an item.		**11**
293.01	If compounding is not being performed at the time of survey, ask that a compounding pharmacist or technician prepare a compound for you to observe the compounding process. *If the pharmacy staff refuses or is unable to perform compounding for you to observe, document on the "**Denial of Authorization**" form. List individual who signs the Denial of Authorization.*			**11**
294.00	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.	Choose an item.		**11**
295.00	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.	Choose an item.		**11**
	Compounding Nonsterile Radiopharmaceuticals		***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.*	**11.1**
296.00	Areas designated for nonsterile compounding are cleaned, uncluttered and separated from areas designated for sterile radiopharmaceuticals.	Choose an item.		**11.1**
297.00	*Recommendation: Compounding takes into account RAM licensing requirements for appropriate radiation safety considerations and utilize appropriate environmental controls, if applicable.*	Choose an item.		**11.1**

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298.00	The placement of equipment and materials are designed to prevent cross-contamination.	Choose an item.		11.1
299.00	When feasible, disposable material is used to reduce the chance of cross-contamination.	Choose an item.		11.1
300.00	Each compound has a unique MFR.	Choose an item.		11.1
301.00	The preparation information is documented on a compounding record.	Choose an item.		11.1
302.00	The MFR details the selection of all components.	Choose an item.		11.1
303.00	**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.	Choose an item.		11.1
304.00	The MFR establishes the identity, strength, purity, and quality of the ingredients by validated means (e.g., CoA).	Choose an item.		11.1
305.00	Requirements for nonsterile oral meal components are limited to common food grade description and are not required to establish identity by validated means.	Choose an item.		11.1
306.00	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.	Choose an item.		11.1
306.01	A BUD cannot be extended past the labeled expiration date of any component in the compound.	Choose an item.		11.1
306.02	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.	Choose an item.		11.1
	Sterile Compounding		***Note to Inspector**: Kit-splitting (also referred to as "fractionation") may be used to meet patient need.*	11.2
307.00	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?	Choose an item.		11.2
308.00	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?	Choose an item.		11.2
309.00	Does the pharmacy split conventionally marketed kits?	Choose an item.		11.2

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310.00	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?	Choose an item.		11.2
310.01	Systematic QC testing is performed to validate the appropriateness of a particular BUD.	Choose an item.		11.2
	Sterile Compounding Using Nonsterile Drug Substance or Components			11.3
311.00	Some sterile compounding activities involve the use of materials other than commercially marketed products, such as drug substances and/or radionuclides.	Choose an item.		11.3
311.01	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.*	Choose an item.		11.3
312.00	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.	Choose an item.		11.3
313.00	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.	Choose an item.		11.3
313.01	Testing to validate the appropriateness of a particular BUD may be required.	Choose an item.		11.3
314.00	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.	Choose an item.		11.3
314.01	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.	Choose an item.		11.3
315.00	Each bulk drug substance is manufactured by drug establishments registered with FDA and be accompanied by a valid CoA or equivalent testing procedures.	Choose an item.		11.3
316.00	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.	Choose an item.		11.3
317.00	It is also acceptable that any excipients or other inactive ingredients be approved products, manufactured by a drug establishment registered with the FDA.	Choose an item.		11.3
	Dispensing and Radioassay		***Note to Inspector:*** *Dispensing refers to the manipulations necessary to transfer the prescribed or ordered amount of radiopharmaceutical into the final container (e.g., syringe or vial).*	12.1

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		Finding	Notes	USP Reference(s)
318.00	Labeling of the final patient-ready dose or ordered amount of a radiopharmaceutical is also a component of the dispensing process.	Choose an item.		12.1
319.00	Except for an unopened manufacturer container, the final dose or ordered amount is radioassayed (i.e., in a dose calibrator).	Choose an item.		12.1
320.00	*Recommendation: The measured activity is mathematically corrected for radioactive decay to the time of scheduled administration (calibration time).*	Choose an item.		12.1
321.00	The activity at calibration time is always be within federal, state, and local variance limits.	Choose an item.		12.1
	Labeling			12.2
322.00	*Recommendation: All personnel distributing and/or dispensing radiopharmaceuticals verify that any labeling is in compliance with regulatory agencies.*	Choose an item.		12.2
323.00	Is the inner container (e.g. syringe, vial) labeled with all of the following?	Choose an item.		12.2
323.01	Standard radiation symbol	Choose an item.		12.2
323.02	The words "Caution—Radioactive Material"	Choose an item.		12.2
323.03	For all therapeutic and blood-products, the patient name/identifier	Choose an item.		12.2
323.04	Radionuclide and chemical form (generic name)	Choose an item.		12.2
323.05	Radioactivity at the date and time of calibration	Choose an item.		12.2
324.00	Is the outer shielding (e.g., syringe or vial shielding) labeled with all the following?	Choose an item.		12.2
324.01	Standard radiation symbol	Choose an item.		12.2
324.02	The words "Caution—Radioactive Material"	Choose an item.		12.2
324.03	For all therapeutic and blood-products, the patient name/identifier	Choose an item.		12.2
324.04	The radionuclide and chemical form (generic name)	Choose an item.		12.2
324.05	Radioactivity with units at time of calibration and the calibration time	Choose an item.		12.2
324.06	Volume or number of units (e.g., 2 capsules), as applicable	Choose an item.		12.2
324.07	Product expiration or BUD, as applicable, and any special storage and handling requirements for non-immediate use (e.g., refrigeration, resuspension)	Choose an item.		12.2
324.08	Route of administration	Choose an item.		12.2
	Direct Infusion Systems			12.3
325.00	Do the operations of the direct infusion systems follow the "Instructions for Use" in the device labeling?	Choose an item.		12.3
326.00	Are each of the following parameters considered by the operator of the system?	Choose an item.		12.3
326.01	Setup attachment or needle-puncture should be performed in a defined environment	Choose an item.		12.3
326.02	Aseptic handling in ambient air with a maximum BUD of 10 hours is allowed for these direct infusion systems	Choose an item.		12.3

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Nuclear Pharmacy Inspection

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		Finding	Notes	USP Reference(s)
326.03	The 0.9% sodium chloride bag attached to the device may only be punctured once and may be used for no more than 10 hours. The bag is labeled with the date and time of puncture and the BUD	Choose an item.		12.3
326.04	Any nonsterile parts of the device that may encounter the septum of the radiopharmaceutical vial is disinfected with sterile 70% IPA prior to puncturing the vial with the needle	Choose an item.		12.3
326.05	The septum of any vial and the ports of any diluent bag is wiped with sterile 70% IPA prior to puncturing	Choose an item.		12.3
326.06	When puncturing the vial in ambient air, it is only punctured once	Choose an item.		12.3
326.07	If there are problems with the infusion device, no sterile container(s) associated with the system is repunctured or transferred to a PEC for further manipulations and the container, with contents, is discarded	Choose an item.		12.3
	Transporting Generators Between Facilities			12.4
327.00	Are the following standards followed if transporting generators between facilities?	Choose an item.		12.4
327.01	The generator needle and/or ports are capped in ISO Class 8 air or better with sterile protectors	Choose an item.		12.4
327.02	The generator is packaged and transported in a manner to maintain the integrity and sterility of the generator system	Choose an item.		12.4
	Repackaging			13
328.00	If the facility repackages, are the following applicable?	Choose an item.		13
328.01	Removes conventionally manufactured radiopharmaceutical(s) from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the product.	Choose an item.		13
328.02	Places the contents of multiple containers of the same finished drug product into one container, as long as the container does not include other ingredients	Choose an item.		13
329.00	Does the facility repackage nonsterile radiopharmaceuticals (e.g., I-131 sodium iodide oral capsules)?	Choose an item.		13
330.00	Does the facility repackage sterile radiopharmaceuticals (e.g., thallous chloride Tl 201 injection)?	Choose an item.		13
331.00	Unopened manufacturer dosage units (e.g., capsules, Xe-133 vials) are not radioassayed.	Choose an item.		13
332.00	The repackaged radiopharmaceutical is radioassayed (i.e., in a dose calibrator), if it is not an unopened manufacturer dosage unit.	Choose an item.		13
333.00	*Recommendation: The inner container is labeled with all of the following:*	Choose an item.		13
333.01	*Standard radiation symbol*	Choose an item.		13

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		Finding	Notes	USP Reference(s)
333.02	*The words "Caution—Radioactive Material"*	Choose an item.		13
333.03	*The radionuclide and chemical form (generic name)*	Choose an item.		13
333.04	*Radioactivity with units at time of calibration and the calibration time*	Choose an item.		13
334.00	*Recommendation: The outer container is labeled with all of the following:*	Choose an item.		13
334.01	*Standard radiation symbol*	Choose an item.		13
334.02	*The words "Caution—Radioactive Material"*	Choose an item.		13
334.03	*The radionuclide and chemical form (generic name)*	Choose an item.		13
334.04	*Radioactivity with units at time of calibration and the calibration time*	Choose an item.		13
334.05	*Volume, or number of units (e.g., capsules), as applicable*	Choose an item.		13
334.06	*Product expiration or BUD, as applicable*	Choose an item.		13
334.07	*Special storage and handling instructions*	Choose an item.		13
	Quality Assurance and Quality Control			14
335.00	QA and QC programs are formally established and documented in SOPs that ensure that all aspects of the handling of radiopharmaceuticals are conducted in accordance with this chapter and applicable federal, state, and local laws and regulations.	Choose an item.		14
336.00	A designated person ensures that the facility has formal, written QA and QC programs. *List this person in the notes.*	Choose an item.		14
337.00	Do QA and QC programs establish a system which include of all of the following?	Choose an item.		14
337.01	Adherence to procedures	Choose an item.		14
337.02	Prevention and detection of errors and other quality problems	Choose an item.		14
337.03	Evaluation of complaints and adverse events	Choose an item.		14
337.05	Appropriate investigations and corrective actions	Choose an item.		14
338.00	The SOPs describe the roles, duties, and training of the personnel responsible for each aspect of the QA program.	Choose an item.		14
339.00	The overall QA and QC program is reviewed at least once every 12 months by the designated person. *List last date of review in notes.*	Choose an item.		14
340.00	The results of the review are documented, and appropriate corrective action taken, if needed.	Choose an item.		14
	Notification About and Recall of Out-of-Specification Dispensed Radiopharmaceuticals			14.1
341.00	If a radiopharmaceutical is dispensed or administered before the results of release testing are known, does the facility have all of the following SOPs in place?			14.1

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		Finding	Notes	USP Reference(s)
341.01	Immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (e.g., sterility, strength, purity, bacterial endotoxin, or other quality attributes)	Choose an item.		14.1
341.02	Determine whether a recall is necessary	Choose an item.		14.1
342.00	Does the SOP for recall of out-of-specification dispensed radiopharmaceuticals contain all of the following procedures?	Choose an item.		14.1
342.01	Determine the severity of the problem and the urgency for the implementation and completion of the recall	Choose an item.		14.1
342.02	Determine the distribution of any affected radiopharmaceutical, including the date and quantity	Choose an item.		14.1
342.03	Identify patients who have received the radiopharmaceutical	Choose an item.		14.1
342.04	Outline the disposition and reconciliation of the recalled radiopharmaceutical	Choose an item.		14.1
343.00	Does the facility document the implementation of the recall procedures?	Choose an item.		14.1
344.00	Is the recall is reported to appropriate regulatory bodies as required by laws and regulations of the applicable regulatory jurisdiction (e.g., state board of pharmacy, state health department)?	Choose an item.		14.1
	Complaint Handling			14.2
345.00	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.	Choose an item.		14.2
346.00	Does the designated person review all complaints to determine if they indicate potential quality problems with the radiopharmaceutical?	Choose an item.		14.2
346.01	If a complaint indicates potential quality issues with radiopharmaceuticals, is an investigation into the potential cause of the issue completed?	Choose an item.		14.2
346.02	Does the investigation consider whether the quality problem could extend to other radiopharmaceuticals?	Choose an item.		14.2
346.03	Is corrective action, if necessary, implemented for all potentially affected radiopharmaceuticals?	Choose an item.		14.2
346.04	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?	Choose an item.		14.2
347.00	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)?	Choose an item.		14.2
348.00	Does the record contain all of the following?	Choose an item.		14.2
348.01	The name of the complainant	Choose an item.		14.2
348.02	The date the complaint was received	Choose an item.		14.2

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348.03	The nature of the complaint	Choose an item.		14.2
348.04	The response to the complaint	Choose an item.		14.2
348.05	If known, the name and strength of the radiopharmaceutical and the assigned internal identification number (e.g., prescription, order, or lot number).	Choose an item.		14.2
349.00	Does the record also include the findings of any investigation and any follow-up?	Choose an item.		14.2
350.00	Are records of complaints easily retrievable for review and evaluation for possible trends?	Choose an item.		14.2
351.00	Are records retained in accordance with the record keeping requirements?	Choose an item.		14.2
352.00	Is a radiopharmaceutical that is returned in connection with a complaint quarantined until it is destroyed after completion of the investigation and in accordance with applicable jurisdictional laws and regulations?	Choose an item.		14.2
	Adverse Event Reporting			14.3
353.00	Are adverse events potentially associated with the quality of radiopharmaceuticals reported in accordance with the facility's SOPs and all applicable jurisdictional laws and regulations?	Choose an item.		14.3
354.00	*Recommendation: Adverse events potentially associated with the quality of the radiopharmaceutical preparation are reported to the applicable jurisdictional regulatory body (e.g., state boards of pharmacy, state health departments, FDA's MedWatch program for human drugs).*	Choose an item.		14.3

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An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

PIC Signature _____ Date _____ Inspector Signature _____ Date _____