



**WA Pharmacy Quality Assurance Commission  
2026 Responsible Pharmacy Manager  
Pharmacy Self-Inspection Worksheet  
USP 825 – Radiopharmaceuticals –  
Preparation, Compounding,  
Dispensing, and Repackaging Addendum**

**ATTENTION: Responsible Pharmacy Manager or Equivalent**

Washington law holds the responsible manager and all pharmacists on duty responsible for ensuring pharmacy compliance with all state and federal laws governing the practice of pharmacy. Failure to complete this addendum within the month of March and within 30 days of becoming responsible manager (as required by WAC 246-945-005) may result in disciplinary action. **The following addendum is required to be filled out and kept on file with the General Pharmacy or Hospital Pharmacy Self-Inspection Worksheet. Do not send to the commission office.**

The primary objective of this report, and your self-inspection, is to provide an opportunity to identify and correct areas of non-compliance with state and federal law. This worksheet does not replace **U.S. Pharmacopeia (USP) <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging**. (NOTE: Neither the self-inspection nor a Commission inspection evaluates your complete compliance with all laws and rules of the practice of pharmacy.)

By answering the questions and referencing the appropriate laws/rules/CFR provided, you can determine whether you are compliant with many of the rules and regulations. If you have corrected any deficiencies, please write corrected and the date of correction by the appropriate question.

**This self-inspection worksheet applies only to activities performed by pharmacy personnel. Other healthcare professionals are regulated by their own boards and commissions.**

**Date responsible manager/change of responsible manager inspection was completed:** \_\_\_\_\_

**Signature of responsible pharmacy manager:** \_\_\_\_\_

To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email [doh.information@doh.wa.gov](mailto:doh.information@doh.wa.gov).

2026 Radiopharmaceuticals Self-Inspection Addendum

General Rule Reference - Applies to all questions throughout the worksheet.  
 RCW 18.64.270(2) "Any medicinal products that are compounded for patient administration or distribution to a licensed practitioner for patient use or administration shall, at a minimum, meet the standards of the official United States pharmacopeia as it applies to nonsterile products and sterile administered products."

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
<b>INTRODUCTION</b>						
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1.	Do prepared or compounded nonsterile preparations comply with applicable identity, quality, and purity standards?	<b>USP Chapter 825 – 1.1 Nonsterile Radiopharmaceuticals</b> For prepared or compounded preparations, such preparations must comply with applicable identity, quality, and purity standards, as described in manufacturer labeling, USP monographs, or other appropriate sources.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2.	Do prepared or compounded sterile preparations comply with applicable identity, quality, and purity standards?	<b>USP Chapter 825 – 1.2 Sterile Radiopharmaceuticals</b> Examples of sterile radiopharmaceuticals include injectables (e.g., intravenous, intrathecal, intraperitoneal, subcutaneous, and intradermal), inhalations, ophthalmics, and intra-organ instillations. For conventionally marketed products, see 12.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	3.	If nonsterile components are used for sterile compounded preparations, is sterilization performed prior to dispensing?	Dispensing. For prepared or compounded preparations, such preparations must comply with applicable identity, quality, and purity standards. For compounded preparations involving one or more nonsterile components, a sterilization procedure (e.g., filtration with bubble point testing) must be performed prior to dispensing. For injectable compounded preparations involving one or more components that are not certified to be pyrogen-free, bacterial endotoxin testing, as defined in Bacterial Endotoxins Test <85>, must be performed prior to dispensing. The most important factor for maintaining sterility is the avoidance of touch contamination. Wipe the vial septum with sterile 70% isopropyl alcohol (IPA) prior to initial needle puncture. If the vial shield top is then closed, the septum must be disinfected again with sterile 70% IPA prior to another needle puncture. Some vial shields are constructed such that the vial septum is recessed and difficult to access. One approach for disinfecting the vial septum in this type of vial shield is to use right-angle forceps to hold a sterile 70% IPA wipe and apply direct contact with the vial septum. It is also acknowledged that such vial shields disrupt first air contacting the vial	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	4.	If non-pyrogen-free components are used for sterile compounded preparations, is bacterial endotoxin testing performed prior to dispensing?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	5.	Are vial septa wiped with sterile 70% isopropyl alcohol prior to initial needle puncture?		

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
					septum during certain handling conditions. Wipe the septum with sterile 70% IPA frequently whenever multiple punctures are occurring (e.g., removing several individual doses from a multiple-dose container).	
<b>RADIATION SAFETY CONSIDERATIONS</b>						
			6.	Are aseptic handling practices balanced with radiation safety considerations, based on the following:	<b>USP Chapter 825– 2 RADIATION SAFETY CONSIDERATIONS</b> The handling of radiopharmaceuticals necessitates meeting the radiation regulatory agency requirements for worker safety. This involves licensing commitments to keep all exposure levels for the workers involved as low as reasonably achievable (ALARA) practices. Principles of radiation safety involve time, distance, shielding, and contamination control. Moreover, radiation detection and measuring devices are necessary. Aseptic handling practices must be balanced with radiation safety considerations, based on the following: Knowledge, training, experience, and professional judgment related to the type, abundance, and energy of the radioactive emissions; The quantity of radioactivity, volume, handling steps, and timing; Other factors, which can vary on a case-by-case basis.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	6.	a Knowledge, training, experience, and professional judgment related to the type, abundance, and energy of the radioactive emissions		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	6.	b The quantity of radioactivity, volume, handling steps, and timing		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	6.	c Other factors, which can vary on a case-by-case basis		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	7.	If used, are disposable absorbent pads clean and low-lint?	<b>USP Chapter 825– 2.4 Radiation Contamination Control</b> RAM contamination (e.g., spills, drips, sprays, volatility) is an important concern for radiation protection. Therefore, various techniques and materials may be used by handlers of radiopharmaceuticals to minimize radioactive contaminations. For example, container contents are maintained at neutral or negative pressure, because positive pressure in a container is a common cause of radioactive contamination. Disposable absorbent pads are commonly used to contain such radioactive contamination and, when used in an ISO Class 5 PEC, the pads must be clean and low-lint. Vertical air flow, not horizontal, in a PEC is used to control contamination. When exposure to blood and other potentially infectious material is reasonably anticipated,	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8.	Are policies implemented for handling biohazardous radioactive sharps while minimizing contamination?		

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
					some engineered needlestick prevention devices may pose a radiation hazard to employees. Policies must be implemented for handling biohazardous radioactive sharps while minimizing contamination.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	9.	Do individuals wear body and, as required, extremity dosimeters for long-term monitoring of personnel radiation exposure?	<b>USP Chapter 825– 2.4 Radiation Contamination Control- RADIATION DETECTORS AND MEASURING DEVICES</b> Radiopharmaceuticals require measurement with a suitable radiation measuring device (e.g., dose calibrator). These and other necessary equipment, (e.g., monitors, bar code scanner, label printer) may be placed inside an ISO Class 5 PEC but should be placed in a manner that minimizes disruptions of airflow. As per RAM license requirements, individuals must wear body and, as required, extremity dosimeters (e.g., a ring worn on a finger) for long-term monitoring of personnel radiation exposure. The body dosimeter should be worn underneath the gown. Any extremity dosimeter must be worn underneath gloves and must not interfere with proper fit of gloves.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	10.	Are extremity dosimeters worn underneath gloves that do not interfere with proper fit of gloves?		
<b>IMMEDIATE USE OF STERILE RADIOPHARMACEUTICALS</b>						
			11.	When preparing radiopharmaceuticals under immediate use practice in an ambient environment that lacks primary and secondary engineering controls when intended for a single patient, are the following met:	<b>USP Chapter 825– 3 IMMEDIATE USE OF STERILE RADIOPHARMACEUTICALS</b> The preparation and dispensing of sterile radiopharmaceuticals in a patient care setting may be handled as an immediate use practice. The information below describes the appropriate handling requirements for immediate use sterile radiopharmaceuticals in an ambient environment that lacks primary and secondary engineering controls (SEC) when intended for a single patient. Strict aseptic technique and limited beyond-use date (BUD) must be adhered to given the lack of engineering controls. Appropriate for preparation (including minor deviations) and/or dispensing that is limited to use for a single patient; Preparation (including preparations with minor deviations) components must be sterile, conventionally manufactured drug products (e.g., NDA, ANDA); Dispensing of drug	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11.	a Strict aseptic technique and limited beyond-use date must be adhered to given the lack of engineering controls.		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11.	b Appropriate for preparation (including minor deviations) and/or dispensing that is limited to use for a single patient.		

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11.	c	Preparation (including preparations with minor deviations) components must be sterile, conventionally manufactured drug products.	products produced under an approved IND or RDRC protocol is allowed; Manipulations for any unit doses (e.g., decreasing the dosage, needle changes) or dispensing for one patient (e.g., withdrawing a dose) is allowed; Must be administered 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; All components involved (e.g., Tc-99m sodium pertechnetate syringe or vial, final prepared radiopharmaceutical kit vial, diluent vial) must be discarded within 1 hour of being punctured or after use for a single patient administration, whichever is first. Dose pooling (combining doses from two or more syringes to meet one patient's need) may be performed as immediate use. Any residual activity that remains must be immediately discarded and not utilized for any other patient; Follow hand hygiene and garbing in 4.4 Hand Hygiene and Garbing for Immediate Use Preparations; Follow 10.4 Preparation of Radiolabeled Red Blood Cells for Immediate Use for red blood cell labeling. Follow 12.2 Labeling for labeling; Area for sterile preparation and/or dispensing must be functionally separate from nonsterile compounding area (e.g., radiolabeling hood) during the time of use; Does not require a segregated radiopharmaceutical processing area (SRPA), classified area, or PEC. The number of steps or punctures is not limited; Does not 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); 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. Dose splitting (splitting a unit dose for administration to more than one patient) may not be performed as immediate use; if performed, dose splitting must be done in an ISO class 5 PEC in either an SRPA or in an ISO class 8 or better buffer area.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11.	d	Dispensing of drug products produced under an approved IND or RDRC protocol is allowed.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11.	e	Manipulations for any unit doses or dispensing for one patient is allowed.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11.	f	Must be administered within 1 hour of the first container puncture or exposure of any critical site involved to ambient air, whichever is first.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11.	g	All components involved must be discarded within 1 hour of being punctured or after use for a single patient administration, whichever is first.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11.	h	Dose pooling may be performed as immediate use. Any residual activity that remains must be immediately discarded and not utilized for any other patient.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11.	i	Follow hand hygiene and garbing in 4.4 Hand Hygiene and Garbing for Immediate Use Preparations.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11.	j	Follow 10.4 Preparation of Radiolabeled Red Blood Cells for Immediate Use for red blood cell labeling.	

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11.	k	Follow 12.2 Labeling for labeling.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11.	l	Area for sterile preparation and/or dispensing must be functionally separate from nonsterile compounding area during the time of use.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11.	m	Does not require a segregated radiopharmaceutical processing area, classified area, or PEC.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11.	n	The number of steps or punctures is not limited.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11.	o	Does not require personnel to complete the aseptic qualifications as detailed in 4.1 Aseptic Qualifications.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11.	p	While adding a non-radioactive, sterile and commercially manufactured pharmaceutical 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.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11.	q	Dose splitting may not be performed as immediate use; if performed, dose splitting must be done in an ISO class 5 PEC in either an SRPA or in an ISO class 8 or better buffer area.	
<b>PERSONNEL QUALIFICATIONS, TRAINING, AND HYGIENE</b>						
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	12.	Are personnel trained to work with radiopharmaceuticals per the	<b>USP Chapter 825– 4 PERSONNEL QUALIFICATIONS, TRAINING, AND HYGIENE</b>	

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				policies and SOPs authorized by an ANP or AU physician?	Personnel must be trained to work with radiopharmaceuticals per the policies and standard operating procedures (SOPs) authorized by an ANP or AU physician. These individuals (e.g., nuclear medicine technologists or nuclear pharmacy technicians) must follow these policies and SOPs of the ANP or AU physician and work under their supervision. As appropriate, this should include blood-borne pathogens training. Individuals entering a compounding area must be properly garbed and must maintain proper personal hygiene to minimize the risk of contamination to the environment and/or radiopharmaceuticals. 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) must report these conditions to their supervisor. The designated person is responsible for evaluating whether these individuals should be excluded from working in sterile processing areas before their conditions are resolved.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	13.	Do personnel follow the policies and SOPs of the ANP or AU physician?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	14.	Do personnel work under the supervision of the ANP or AU physician?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	15.	Are individuals entering the compounding area properly garbed?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	16.	Are individuals maintaining proper personal hygiene?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	17.	Do individuals who have a condition that may pose a higher potential of contamination with microorganisms report these conditions to their supervisor?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	18.	Do personnel prove competency, as applicable to their job functions, prior to performing radiopharmaceutical aseptic tasks that are beyond immediate use?		<b>USP Chapter 825– 4.1 Aseptic Qualifications</b> Personnel must prove competency, as applicable to their job functions, prior to performing radiopharmaceutical aseptic tasks that are beyond immediate use. These qualifications may be conducted at a different site if all SOPs are identical for the applicable job function. These qualifications must be completed and documented initially, and then successfully repeated at intervals described below in Timing of Reevaluation and Requalification under the observation of a designated person and include the following: Aseptic technique training with a documented assessment (written or electronic); Garbing and hand hygiene, as defined by the policies and SOPs; PEC cleaning and disinfecting; Gloved fingertip and thumb sampling; Media-fill testing.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	19.	Are these qualifications completed and documented initially?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	20.	Are these qualifications completed and documented at repeated intervals?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	21.	Are these qualifications completed and documented under the observation of a designated person?		

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			22.	Do the qualifications include the following:		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	22.	a Aseptic technique training with a documented assessment		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	22.	b Garbing and hand hygiene, as defined by the policies and SOPs		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	22.	c PEC cleaning and disinfecting		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	22.	d Gloved fingertip and thumb sampling		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	22.	e Media-fill testing		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	23.	Do personnel that perform tasks in an ISO Class 5 PEC prove their competency in appropriate garbing?	<b>USP Chapter 825– 4.1 Aseptic Qualifications - GLOVED FINGERTIP AND THUMB SAMPLING</b> Appropriate garbing, including sterile gloves, is necessary for personnel who enter and perform tasks in an ISO Class 5 PEC (e.g., aseptic manipulations, cleaning the PEC). Personnel that perform such functions must prove their competency in this process. Gloved fingertip and thumb sampling must be performed initially on both hands, immediately following hand hygiene and garbing. Successful completion of initial gloved fingertip and thumb sampling is defined as zero colony-forming units (cfu) and subsequent gloved fingertip and thumb sampling after media-fill testing is defined as ≤3 cfu (total for both hands). The gloved fingertip and thumb sampling must be 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) as this supports both bacterial and fungal growth; Gloves must not be disinfected immediately before touching the sampling device, as this could cause a false-negative result; Using a separate sampling device for each hand, a gloved fingertip and thumb sample from both hands must be collected by rolling finger pads and thumb pad over	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	24.	Is gloved fingertip and thumb sampling performed initially on both hands, immediately following hand hygiene and garbing?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	25.	Do touch plates or other devices contain general microbial growth agar supplemented with neutralizing additives?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	26.	Are gloves not disinfected immediately before touching the sampling device?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	27.	Are gloved fingertip and thumb samples from both hands collected by rolling finger pads and thumb pad over the agar surface, using a separate sampling device for each hand?		

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	28.	Are plates incubated in an incubator at 30°–35° for no less than 48 hours and then at 20°–25° for no less than 5 additional days?	the agar surface; The plates must be incubated in an incubator at 30°–35° for no less than 48 h, and then at 20°–25° for no less than 5 additional days.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	29.	Is media-fill testing reflective of actual manipulations carried out by the individual?	<b>USP Chapter 825– 4.1 Aseptic Qualifications - MEDIA-FILL TESTING</b> Media-fill testing is necessary for all personnel who prepare, compound, dispense, and repackage sterile radiopharmaceuticals. This testing must be reflective of the actual manipulations to be carried out by the individual and must simulate the most challenging and stressful conditions to be encountered in the worker’s duties. Media-fill tests must be documented as defined by the facility’s policies and SOPs. Media-fill tests should be performed at the end of a work session in the PEC. Media-fill tests must be performed with a commercial source of soybean–casein digest medium. Those performing sterile-to-sterile processing activities must start with sterile media. Those performing nonsterile-to-sterile compounding must use a nonsterile soybean–casein digest powder to make a solution. Dissolve nonsterile commercially available soybean–casein digest medium in nonbacteriostatic water to make a 3% nonsterile solution. Manipulate it in a manner that simulates nonsterile-to-sterile compounding activities. Prepare at least 1 container as the positive control to demonstrate growth promotion, which is indicated by visible turbidity upon incubation. The certificate of analysis (CoA) must include documentation of growth promotion testing for each lot of media used. Once the media-fill simulation is completed and the final containers are filled with the test medium, incubate media-filled containers in an incubator for 7 days at 20°–25° followed by 7 days at 30°–35° to detect a broad spectrum of microorganisms. 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. In the event of failure, results of the evaluation and corrective actions must be documented and the documentation	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	30.	Does media-fill testing simulate the most challenging and stressful conditions encountered in the worker’s duties?		
			31.	Does media-fill testing meet the following:		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	31.	a Are media-fill tests documented as defined by the facility’s policies and SOPs?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	31.	b Performed with a commercial source of soybean–casein digest medium		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	31.	c For sterile-to-sterile processing, activities start with sterile media		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	31.	d For nonsterile-to-sterile compounding, use a nonsterile soybean–casein digest powder to make a solution		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	32.	Does the certificate of analysis include documentation of growth promotion testing for each lot of media used?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	33.	In the event of failure, are results of the evaluation and corrective actions documented?		

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	34.	Is the documentation maintained to provide a record and long-term assessment of personnel competency?	maintained to provide a record and long-term assessment of personnel competency. Documentation must at a minimum include the name of the person evaluated, evaluation date/time, media and components used including manufacturer, expiration date and lot number, starting temperature for each interval of incubation, dates of incubation, and the results.	
			35.	Does documentation meet the following:		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	35.	a Name of the person evaluated		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	35.	b Evaluation date/time		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	35.	c Media and components used including manufacturer		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	35.	d Expiration date and lot number		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	35.	e Starting temperature for each interval of incubation		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	35.	f Dates of incubation		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	35.	g Results		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	36.	Do personnel successfully pass reevaluations in deficient area(s) before they can resume processing of sterile preparations?	<b>USP Chapter 825– 4.2 Reevaluation, Retraining, and Qualification - REQUALIFICATION AFTER FAILURE</b> Personnel who fail visual observation of hand hygiene, garbing, and aseptic technique, gloved fingertip and thumb sampling, or media-fill testing must successfully pass reevaluations in the deficient area(s) before they can resume processing of sterile preparations. All failures, retraining, and reevaluations must be documented.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	37.	Are all failures, retraining, and reevaluations documented?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	38.	Do personnel successfully complete requalification in the core competencies?	<b>USP Chapter 825– 4.2 Reevaluation, Retraining, and Qualification - REQUALIFICATION PROGRAM</b> Personnel must successfully complete requalification in the core competencies listed in 4.1 Aseptic Qualifications. Successful completion must be demonstrated through observation, written testing, and hands-on demonstration of skills.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	39.	Is successful completion demonstrated through observation, written testing, and hands-on demonstration of skills?		

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	40.	Are personnel visually observed while performing hand hygiene, garbing SOPs, and aseptic technique procedures initially, and then at least once every 12 months?	<b>USP Chapter 825– 4.2 Reevaluation, Retraining, and Qualification - TIMING OF REEVALUATION AND REQUALIFICATION</b> Visual observation: Personnel must be visually observed while performing hand hygiene, garbing SOPs, and aseptic technique procedures initially, and then at least once every 12 months. Gloved fingertip and thumb sampling: Personnel must perform fingertip and thumb sampling 3 times initially, and then every 12 months (in conjunction with media-fill testing). Media-fill testing: After initial qualification, conduct a media-fill test of all personnel engaged in sterile radiopharmaceutical processing at least every 12 months (in conjunction with gloved fingertip and thumb sampling). Cleaning and disinfecting: Retrain and requalify personnel in the cleaning and disinfecting of sterile processing areas every 12 months or in conjunction with any change(s) in cleaning and disinfecting SOPs, whichever is sooner. After a pause in sterile radiopharmaceutical processing: Personnel that have not performed radiopharmaceutical processing in more than 6 months must be requalified in all core competencies before resuming duties. Sterile compounding using a nonsterile drug substance or components: Personnel who perform sterile compounding using a nonsterile drug substance or components (see 11.3 Sterile Compounding Using a Nonsterile Drug Substance or Components) must be requalified in all core competencies every 6 months.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	41.	Do personnel perform fingertip and thumb sampling 3 times initially, and then every 12 months?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	42.	Are personnel that have not performed radiopharmaceutical processing in more than 6 months requalified in all core competencies before resuming duties?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	43.	Are personnel who perform sterile compounding using a nonsterile drug substance or components requalified in all core competencies every 6 months?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	44.	Do other personnel or visitors comply with garbing and gloving SOPs? <b>**These individuals do not need to prove competency.**</b>		<b>USP Chapter 825– 4.3 Ancillary Personnel</b> Personnel who are authorized to be within the sterile processing area and do not handle sterile preparations are not required to complete training on media-fill testing but are required to complete all other training and testing. Other personnel or visitors (e.g., auditors, regulators, student observers) must comply with garbing and gloving SOPs but do not need to prove competency.
			45.	For immediate use preparations, do precautions related to personal hygiene include the following:	<b>USP Chapter 825– 4.4 Hand Hygiene and Garbing for Immediate Use Preparations</b>	

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	45.	a	Hand hygiene	Radiopharmaceuticals may be prepared and dispensed as immediate use, and the precautions related to personal hygiene to be followed must include the following: Hand hygiene: 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. Garbing: Immediately after hand hygiene, 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. [NOTE—A different lab coat must be worn to care for a patient than the coat/gown used for radiopharmaceutical preparation.]
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	45.	b	Garbing	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	45.	c	Different lab coat worn for patient care than preparation	
			46.	For activities in an ISO Class 5 PEC, precautions related to personal hygiene include the following:		<p><b>USP Chapter 825– 4.5 Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Area</b></p> <p>In situations involving repackaging, dispensing, preparation, preparation with minor deviations, or compounding of sterile radiopharmaceuticals in an ISO Class 5 PEC, the following precautions related to personal hygiene are to be followed: Before entering the SRPA or buffer area, personnel must remove outer garments (e.g., bandanas, coats, hats, jackets, sweaters, vests); all cosmetics; all hand, wrist, and other exposed jewelry including piercings that could interfere with the effectiveness of the garbing (e.g., the fit of gloves, cuffs of sleeves, and eye protection). Nail products (e.g., artificial nails, polish, extenders) are prohibited. Natural nails must be kept neat and trimmed. Remove ear buds and headphones. Radiation dosimetry devices are allowed, as required by the RAM license. Do not bring electronic devices that are not necessary for compounding or other required tasks. Immediately before entering the SRPA or buffer area, remove visible debris from underneath fingernails under warm running water using a disposable nail cleaner. Personnel must wash hands and arms up the elbows with soap and water for at least 30 s and then dry hands using low-lint towels. Alternatively, hand washing may</p>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	46.	a	Remove outer garments, cosmetics, exposed jewelry, and piercings that could interfere with garbing	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	46.	b	Nail products prohibited	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	46.	c	Natural nails kept neat and trimmed	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	46.	d	Ear buds and headphones removed	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	46.	e	Wash hands and arms up the elbows with soap and water for at least 30 seconds	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	46.	f	Dry hands using low-lint towels	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	46.	g	Don shoe covers, head/hair/facial hair covers, and face mask	

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	46.	h	Don a low-lint gown with sleeves that fit snugly around the wrists and enclosed at the neck	be performed after donning shoe covers, head/hair covers, and face mask, as described below. Personnel must don the following garb—shoe covers, head/hair/facial hair covers, face mask—in an order that eliminates the greatest risk of contamination, as defined in facility SOPs. If not already performed, remove visible debris from underneath fingernails under warm running water using a disposable nail cleaner. Personnel must then wash hands and arms up to the elbows with soap and water for at least 30 s and then dry hands using low-lint towels. Electronic hand dryers are not permitted. Personnel must then perform hand antisepsis cleansing using a suitable alcohol-based hand rub. Personnel must then don a low-lint gown with sleeves that fit snugly around the wrists and enclosed at the neck. Disposable gowns are preferred. If reusable gowns are used, a clean gown must be donned daily. Personnel must then aseptically don sterile, powder-free gloves. Gloves must completely and snugly cover the ends of the gown cuffs so that skin on the wrists and upper hands is completely enveloped. Because gloves may not remain sterile due to touching or handling potentially nonsterile materials, personnel must periodically apply sterile 70% IPA to gloves while balancing the risk of radioactivity contamination. Personnel must also routinely inspect the gloves that they are wearing for holes, punctures, radioactivity contamination, or tears. If a defect, radioactivity contamination, or malfunction is detected, personnel must immediately remove the gloves, repeat antiseptic hand cleansing using an alcohol-based hand rub, and don new sterile gloves. Direct personnel touch contamination is the most common source of microorganisms, so personnel must avoid touch contamination of container septa, needles, syringe and needle hubs, and other critical sites. When personnel exit the buffer area or SRPA, shoe covers, head/hair covers, face masks, and gloves must be properly disposed of and new ones donned for each reentry into the buffer area or SRPA. Gowns may be re-used within the same shift if the gown is maintained in a classified area or in (or immediately outside of) the SRPA that minimizes contamination (e.g., away from sinks).
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	46.	i	Clean reusable gown donned daily	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	46.	j	Aseptically don sterile, powder-free gloves	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	46.	k	Gloves completely and snugly cover the ends of the gown cuffs	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	46.	l	Periodically apply sterile 70% IPA to gloves	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	46.	m	Routinely inspect the gloves for holes, punctures, radioactivity contamination, or tears	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	46.	n	Immediately remove gloves if defective, radioactivity contamination, or malfunction and repeat antiseptic hand cleansing	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	46.	o	Avoid touch contamination of container septa, needles, syringe and needle hubs, and other critical sites	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	46.	p	Upon exit of the SRPA or buffer area donned items are properly disposed of	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	46.	q	New items are donned for reentry into the buffer area or SRPA	

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#	USP Reference	Notes/Corrective Actions
Yes	No	N/A			
<b>FACILITIES AND ENGINEERING CONTROLS</b>					
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	47.	Are sterile radiopharmaceutical facilities designed and controlled to minimize airborne contamination provide a well-lighted as well as a comfortable working environment?	<b>USP Chapter 825– 5.1 Facility Design and Environmental Controls</b> In addition to minimizing airborne contamination, sterile radiopharmaceutical facilities must be designed and controlled to provide a well-lighted and comfortable working environment (see Physical Environments That Promote Safe Medication Use <1066>). The classified areas and SRPA must be continuously maintained at a temperature of 25° or cooler and should be continuously maintained at a relative humidity (RH) below 60% to minimize the risk for microbial proliferation and provide comfortable conditions for personnel attired in the required garb. The temperature and humidity must be monitored in the classified areas each day that it is used, either manually or by a continuous recording device. The results of the temperature and humidity readings must be documented at least once daily or stored in the continuous recording device, and must be retrievable. The temperature and humidity readings must be reviewed as described in the facility’s SOPs. Free-standing humidifiers/dehumidifiers and air conditioners must not be used within the classified area or SRPA. Temperature and humidity monitoring devices must be verified for accuracy at least every 12 months or as required by the manufacturer. The designated person is responsible for ensuring that each area related to sterile radiopharmaceutical processes meets the classified air quality standard appropriate for the activities to be conducted in that area. They must also ensure that the ISO Class 5 PECs are located, operated, maintained, monitored, and certified to have appropriate air quality.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	48.	Are classified areas and SRPA continuously maintained at a temperature of 25° or cooler?	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	49.	Is temperature and humidity monitored in the classified areas each day that it is used? <b>**Either manually or by a continuous recording device is acceptable.**</b>	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	50.	Are results of the temperature and humidity readings documented at least once daily or stored in the continuous recording device, and retrievable?	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	51.	Are documented results of the temperature and humidity readings retrievable?	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	52.	Are temperature and humidity readings reviewed as described in the facility’s SOPs?	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	53.	Are free-standing humidifiers/dehumidifiers and air conditioners not used within the classified area or SRPA?	

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	54.	Are temperature and humidity monitoring devices verified for accuracy at least every 12 months or as required by the manufacturer?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	55.	Does the designated person ensure that each area related to sterile radiopharmaceutical processes meet the classified air quality standard appropriate for the activities to be conducted in that area?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	56.	Does the designated person ensure that ISO Class 5 PECs are located, operated, maintained, monitored, and certified to have appropriate air quality?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	57.	Are tacky surfaces not used in ISO-classified areas?	<b>USP Chapter 825– 5.1 Facility Design and Environmental Controls -TYPES OF SECONDARY ENGINEERING CONTROLS AND DESIGN</b> Due to the interdependence of the various areas or areas that make up a sterile radiopharmaceutical processing facility, it is essential to define and control the dynamic interactions permitted between areas. When designing doors, consider the placement of door closures, door surfaces, and the movement of the door, all of which can affect airflow. Tacky surfaces must not be used in ISO-classified areas. The PEC must be located in a SEC, which may be either an ISO-classified buffer room with ante-room or an SRPA, in a manner that minimizes conditions that could increase the risk of microbial contamination. For example, strong air currents from opened doors, personnel traffic, or air streams from the HVAC system(s) can disrupt the unidirectional airflow of an open-faced PEC such as a laminar airflow workbench (LAFW) or biological safety cabinet (BSC). The ISO-classified ante-room and buffer area	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	58.	Is the PEC located in a SEC in a manner that decreases the risk of microbial contamination? <b>**Either an ISO-classified buffer room with ante-room or an SRPA is acceptable.**</b>		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	59.	Are ISO-classified ante-rooms and buffer areas separated from surrounding unclassified areas of the facility with fixed walls and doors?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	60.	Are facility designs and controls in place to minimize flow of lower-quality air into more controlled areas?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	61.	Is air supplied to classified areas introduced through HEPA filters located in the ceiling?	<p>must be separated from the surrounding unclassified areas of the facility with fixed walls and doors. Facility design and controls must be in place to minimize the flow of lower-quality air into the more controlled areas. Air supplied to the classified areas must be introduced through HEPA filters that are located in the ceiling. Returns must be low on the wall unless a visual smoke study demonstrates an absence of stagnant airflow where particulate will accumulate. A smoke study of the PEC must be repeated whenever a change to the placement of the PEC within the area is made. The classified areas must be equipped with a pressure-differential monitoring system. The ante-room must have a line of demarcation to separate the clean side from the less clean side. The ante-room is entered through the less clean side, and the clean side is the area closest to the buffer area. Required garb must be worn prior to crossing the line of demarcation (see 4. Personnel Qualifications, Training, and Hygiene).</p> <p>A PEC may be located within an unclassified area, without an ante-room or buffer area. This type of design is called an SRPA. Only sterile radiopharmaceutical preparation, preparation with minor deviations, dispensing, and repackaging may be performed in an SRPA. 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). The SRPA must be located away from unsealed windows, doors that connect to the outdoors, and traffic flow which may adversely affect the air quality in the PEC. The impact of activities that will be conducted around or adjacent to the SRPA must be considered carefully when designing such an area. A visible perimeter must establish the boundaries of the SRPA. Access to the SRPA must be restricted to authorized personnel and required materials. An SRPA must not be located adjacent to environmental control challenges. It is also critical to control materials (e.g., supplies and equipment) as they move from classified areas of lower quality to those of higher quality (e.g., ISO Class 8 ante-room</p>	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	62.	Are returns low on the wall unless a visual smoke study demonstrates an absence of stagnant airflow where particulate will accumulate?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	63.	Are smoke studies of the PEC repeated when a change to the placement of the PEC is made within the area?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	64.	Are classified areas equipped with a pressure-differential monitoring system?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	65.	Do ante-rooms have a line of demarcation to separate the clean side from the less clean side?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	66.	Is required garb worn prior to crossing the line of demarcation?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	67.	Is the SRPA located away from unsealed windows, doors that connect to the outdoors, and traffic flow?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	68.	Is the impact of activities conducted around or adjacent to the SRPA considered when designing the area?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	69.	Does a visible perimeter establish the boundaries of the SRPA?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	70.	Is access to the SRPA restricted to authorized personnel and required materials?		

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions	
Yes	No	N/A					
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	71.	Is the SRPA not located adjacent to environmental control challenges?	to ISO Class 7 buffer area to ISO Class 5 PEC) to prevent the influx of contaminants. Airlocks and interlocking doors can be used to facilitate better control of air flow between areas of differing ISO classification (e.g., between the buffer area and ante-room), or between a classified area and an unclassified area (e.g., between the ante-room and an unclassified area such as a hallway) See 5.7 Environmental Controls for a description of air pressure differentials. If a pass-through is used, both doors must never be opened at the same time, which may be achieved using interlocking mechanisms.		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	72.	Are both pass-through doors never opened at the same time?			
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	73.	Are PECs certified to meet ISO Class 5 or better conditions?	<b>USP Chapter 825– 5.1 Facility Design and Environmental Controls – THE RADIOPHARMACEUTICAL PROCESSING ENVIRONMENT</b> The PEC must be certified to meet ISO Class 5 or better conditions (see Table 1) and must be designed to minimize microbial contamination during processing of radiopharmaceuticals under dynamic operating conditions. The airflow in the PEC must be unidirectional (laminar flow), and because of the particle collection efficiency of the filter, the “first air” at the face of the filter is, for the purpose of aseptic processing, free from airborne particulate contamination. HEPA-filtered air must be supplied in the direct processing area (DPA) (ISO Class 5; see Table 1) 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. Proper design and control prevents turbulence and stagnant air in the DPA. In situ air pattern analysis via smoke studies must be conducted at the critical area to demonstrate unidirectional airflow and sweeping action under dynamic conditions.		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	74.	Are PECs designed to minimize microbial contamination during processing of radiopharmaceuticals under dynamic operating conditions?			
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	75.	Is airflow in PECs unidirectional?			
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	76.	Is HEPA-filtered air supplied in the direct processing area at a velocity sufficient to sweep particles away from aseptic processing areas?			
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	77.	Does HEPA-filtered air maintain unidirectional airflow during operations?			
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	78.	Are smoke studies conducted at the critical area to demonstrate unidirectional airflow and sweeping action under dynamic conditions?			
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	79.	Does placement of PECs allow for cleaning around the PECs?		<b>USP Chapter 825– 5.1 Facility Design and Environmental Controls - TYPES OF PECS AND PLACEMENT</b>	

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	80.	Do LAFWs used for preparing radiopharmaceuticals provide vertical unidirectional HEPA-filtered airflow? <b>**If LAFWs are located within the segregated containment area of a hot-cell, it is acceptable to have horizontal unidirectional HEPA-filtered airflow patterns.**</b>	Proper placement of the PEC is critical to ensuring an ISO Class 5 environment for preparing radiopharmaceuticals. Placement of the PEC must allow for cleaning around the PEC. PEC provides an ISO Class 5 or better environment for sterile radiopharmaceuticals. The unidirectional airflow within the PEC helps protect the DPA from process-generated contamination of an aseptic processing environment. The unidirectional airflow within the PEC helps protect the DPA from process-generated contamination (e.g., opening wrappings of sterile containers, worker movement, etc.) as well as from outside sources. Laminar airflow workbench (LAFW): An LAFW used for preparing radiopharmaceuticals must provide vertical unidirectional HEPA-filtered airflow. In cases where the LAFW is located within the segregated containment area of a hot-cell, it is acceptable for a horizontal unidirectional HEPA-filtered airflow pattern to be utilized. Biological safety cabinet (BSC) Class II: A BSC Class II is a cabinet with an open front, inward airflow, downward unidirectional HEPA-filtered airflow, and HEPA-filtered exhaust. The BSC is designed to provide worker protection from exposure to biohazardous material and to provide an ISO Class 5 or better environment for preparing sterile radiopharmaceuticals. Placement of PEC: The PEC must be located out of traffic patterns and away from area air currents that could disrupt the intended airflow patterns inside the PEC. If used only to prepare, prepare with minor deviations, dispense, or repackage sterile radiopharmaceuticals the ISO Class 5 PEC may be placed in an unclassified SRPA. If used to compound sterile radiopharmaceuticals, the PEC must be located within an ISO Class 7 or better buffer area with an ISO Class 8 or better anteroom. <b>*See also Table 7. Preparation Conditions for Sterile Radiopharmaceuticals on Page 70 of this worksheet.*</b> A dynamic airflow smoke pattern test must be 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.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	81.	Are PECs located out of traffic patterns and away from area air currents?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	82.	If used to compound sterile radiopharmaceuticals, are PECs located within an ISO Class 7 or better buffer area with an ISO Class 8 or better anteroom? (Refer to Table 7)		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	83.	Are dynamic airflow smoke pattern tests performed initially and at least every 6 months?		

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	84.	Is a minimum of 30 total HEPA-filtered ACPH supplied to ISO Class 7 areas?	<b>USP Chapter 825– 5.1 Facility Design and Environmental Controls - AIR-EXCHANGE REQUIREMENTS</b> For classified areas, adequate HEPA-filtered airflow to the buffer area(s) and ante-room(s) is required to maintain the appropriate ISO classification during processing activities. Airflow is measured in terms of the number of HEPA-filtered air changes per hour (ACPH). The ACPH may need to be higher to maintain the required ISO classification and microbial state of control depending on these factors: the number of personnel permitted to work in the area, the number of particulates that may be generated from activities and processes in the area, the equipment located in the area, the area pressure, and the effects of temperature. The summary of ACPH requirements is listed in Table 2. A minimum of 30 total HEPA-filtered ACPH must be supplied to ISO Class 7 areas. The total HEPA-filtered air change rate must be adequate to maintain ISO Class 7 under dynamic operating conditions considering factors listed above; At least 15 ACPH of the total air change rate in a room must come from the HVAC through HEPA filters located in the ceiling; The HEPA-filtered air from the PEC, when added to the HVAC-supplied HEPA-filtered air, increases the total HEPA-filtered ACPH to at least 30 ACPH; If the PEC is used to meet the minimum total ACPH requirements, the PEC must not be turned off except for maintenance; The ACPH from HVAC, ACPH contributed from the PEC, and the total ACPH must be documented on certification reports; A minimum of 20 ACPH of HEPA-filtered air must be supplied to ISO Class 8 areas; The total HEPA-filtered air change rate must be adequate to maintain ISO Class 8 under dynamic operating conditions considering factors listed above; At least 15 ACPH of the total air change rate in a room must come from the HVAC through HEPA filters located in the ceiling; Ante-rooms where activity levels are high may require more HEPA-filtered ACPH to maintain ISO Class 8 under dynamic operating conditions; The total ACPH must be documented on certification reports.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	85.	Is the total HEPA-filtered air change rate adequate to maintain ISO Class 7 under dynamic operating conditions?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	86.	Does at least 15 ACPH of the total air change rate in a room come from the HVAC through HEPA filters located in the ceiling?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	87.	If the PEC is used to meet the minimum total ACPH requirements, is the PEC not turned off except for maintenance?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	88.	Are the ACPH from HVAC, ACPH from the PEC, and total ACPH documented on certification reports?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	89.	Is a minimum of 20 ACPH of HEPA-filtered air supplied to ISO Class 8 areas?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	90.	Is the total HEPA-filtered air change rate adequate to maintain ISO Class 8 under dynamic operating conditions?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	91.	Does at least 15 ACPH of the total air change rate in a room come from the HVAC through HEPA filters located in the ceiling?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	92.	Is the total ACPH documented on certification reports?		

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	93.	Are 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?	<b>USP Chapter 825– 5.2 Creating Areas to Achieve Easily Cleanable Conditions - CLASSIFIED AREAS</b> The surfaces of ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets in the classified area must be 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. Junctures between the ceiling and the walls and between the wall and the floor must be sealed to eliminate cracks and crevices where dirt can accumulate. If ceilings consist of inlaid panels, each panel must be caulked or otherwise sealed and secured to seal them to the support frame. Surfaces should be resistant to damage by cleaning agents, disinfectants, and tools used to clean. Walls must be constructed of or covered with a durable material (e.g., epoxy-painted walls or heavy-gauge polymer) and the integrity of the surface must be maintained. Panels must be joined together and sealed to each other and the support structure. Floors must include coving to the sidewall or the juncture between the floor and wall must be caulked. Floors must include coving to the sidewall. Classified areas should minimize dust-collecting overhangs such as utility pipes and ledges such as windowsills. If overhangs or ledges are present, they must be easily cleanable. The exterior lens surface of ceiling light fixtures must be smooth, mounted flush, and sealed. Any other penetrations through the ceiling or walls must be sealed.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	94.	Are junctures between the ceiling and the walls and between the wall and the floor sealed to eliminate cracks and crevices?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	95.	Is each inlaid ceiling panel caulked or otherwise sealed and secured?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	96.	Are walls constructed of or covered with a durable material?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	97.	Are walls constructed of or covered so the integrity of the surface is maintained?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	98.	Are panels joined together and sealed to each other and the support structure?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	99.	Do floors include coving to the sidewall?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	100.	Are junctures between the floor and walls caulked?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	101.	Do floors include coving to the sidewall?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	102.	Are overhangs or ledges easily cleanable?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	103.	Is the exterior lens surface of ceiling light fixtures smooth, mounted flush, and sealed?		

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	104.	Are penetrations through the ceiling or walls sealed?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	105.	Are SRPA and all surfaces within the SRPA clean, uncluttered, and dedicated to sterile radiopharmaceutical processing activities?	<b>USP Chapter 825– 5.2 Creating Areas to Achieve Easily Cleanable Conditions - SRPA</b> The SRPA and all surfaces (e.g., walls, floors, counters, equipment) within the SRPA must be clean, uncluttered, and dedicated to sterile radiopharmaceutical processing activities. Surfaces in the SRPA should be 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. Surfaces should be resistant to damage by cleaning agents, disinfectants, and tools used to clean. Dust-collecting overhangs such as utility pipes and ledges such as windowsills should be minimized. If overhangs or ledges are present, they must be easily cleanable.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	106.	Are overhangs or ledges easily cleanable?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	107.	Is the facility where sterile radiopharmaceuticals are prepared designed so that activities such as hand hygiene and garbing do not adversely affect the ability of the PEC to function as designed?		<b>USP Chapter 825– 5.3 Water Sources</b> The facility where sterile radiopharmaceuticals are prepared must be designed so that activities such as hand hygiene and garbing should not adversely affect the ability of the PEC to function as designed. Sinks should enable hands-free use with a closed system of soap (i.e., non-refillable) to minimize the risk of extrinsic contamination. In facilities with an ante-room and buffer area, the sink used for hand hygiene may be placed either inside or outside of the ante-room. If the sink is located outside of the ante-room, it must be located in a clean space to minimize the risk of bringing in contaminants into the anteroom. If the sink is located inside the ante-room, it may be placed on either the clean side or the less-clean side of the anteroom. [NOTE—The order of hand washing and garbing would depend on the placement of the sink (see 4.5 Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Area).] The buffer area must not contain plumbed water sources [e.g., sink(s), eyewash(es), shower(s), or floor drain(s)]. The ante-room must not contain floor drain(s). If installed, sprinkler systems in classified areas should be
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	108.	If the sink is located outside of the ante-room, is the sink located in a clean space to minimize the risk of bringing in contaminants into the anteroom?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	109.	Does the buffer area not contain plumbed water sources?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	110.	Does the ante-room not contain floor drains?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	111.	In a facility with a SRPA design, is the sink accessible but located at least 1 m from the PEC and generators?		

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	112.	Is the sink not located inside the perimeter of the SRPA?	recessed and covered, and should be easily cleanable. In a facility with an SRPA design, the sink must be accessible but located at least 1 m from the PEC and generators, if present. The sink must not be located inside the perimeter of the SRPA.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	113.	For furniture, equipment, and other materials, does the number, design, location, and manner of installation not adversely impact environmental air quality?	<b>USP Chapter 825– 5.4 Placement and Movement of Materials</b> Only furniture, equipment, and other materials necessary are permitted in the classified area or SRPA and they should be low-shedding and easily cleaned and disinfected. Their number, design, location, and manner of installation must not adversely impact environmental air quality and must promote effective cleaning and disinfecting. No shipping carton(s) or other corrugated or uncoated cardboard are allowed in the classified area or SRPA. Carts used to transport components or equipment into classified areas must be constructed from nonporous materials with cleanable casters and wheels. All items must be 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. However, constraints that would lead to excessive radiation exposure to radiation for workers and thereby be contradictory to following ALARA safety principles (e.g., the wiping of unshielded sources of radioactive material) might preclude this from occurring. In a classified area, carts must not be moved from the dirty side to the clean side of the anteroom unless the entire cart, including casters, is cleaned and disinfected.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	114.	For furniture, equipment, and other materials, does the number, design, location, and manner of installation promote effective cleaning and disinfecting?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	115.	Are carts used to transport components or equipment into classified areas constructed from nonporous materials with cleanable casters and wheels?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	116.	Are items wiped with low-lint wipers and an appropriate disinfectant by personnel wearing gloves before they are brought into the clean side of ante-rooms, pass-throughs, into an SRPA or into an ISO 5 PEC?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	117.	Are carts cleaned and disinfected if they are moved from the clean side to the dirty side of the anteroom?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	118.	Are activities and tasks carried out within the buffer area limited to only those necessary?	<b>USP Chapter 825– 5.5 Classified Areas</b> Activities and tasks carried out within the buffer area must be limited to only those necessary. Food, drinks, and	

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	119.	Are food, drinks, and materials kept out of patient care, treatment areas, ante-rooms, and buffer areas if exposed in patient care and treatment areas?	materials exposed in patient care and treatment areas must not enter ante-rooms or buffer areas. When processing activities require the manipulation of blood-derived or other biological material (e.g., radiolabeling patient’s or donor’s blood cells), the manipulations must be clearly separated from routine material-handling procedures and equipment used in radiopharmaceutical preparation activities, and they must be controlled by specific SOPs to avoid any cross-contamination.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	120.	Are activities that require the manipulation of blood-derived or other biological material separated from routine material-handling procedures and equipment used in radiopharmaceutical preparation activities?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	121.	Are activities that require the manipulation of blood-derived or other biological material separated from routine material-handling procedures and equipment controlled by specific SOPs to avoid cross-contamination?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	122.	If the hot-cell is located in an ISO-classified space, do personnel garb according to requirements listed in 4.5 Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Area?	<b>USP Chapter 825– 5.6 Remote Aseptic Processing Involving a Hot-Cell</b> A hot-cell device provides an inherent physical segregation for the ISO Class 5 aseptic processing area. If the hot-cell is located in an ISO-classified space, personnel must garb according to requirements listed in 4.5 Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Area. 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 4.5 Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Area to carry out these aseptic manipulations or to perform other routine tasks in the general area where the hot-cell is located. If hand and arm incursions into the interior of the hot-cell	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	123.	When the PEC is located within a hot-cell, do dynamic airflow smoke pattern tests show that the staging of supplies and materials in the demarcated PEC area do not allow the influx of unclassified air into the PEC?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	124.	When the hot-cell is an integrated HEPA filtration system with a clear		

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				demarcated area that is a PEC, 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?	might be necessary for personnel to stage the required materials and supplies, the personnel must garb in relation to the contamination risk associated with the individual hot-cell/ISO Class 5 relationship. For situations where a PEC device is located within a hot-cell, dynamic airflow smoke pattern tests must show that the staging of supplies and materials in the demarcated PEC area does not allow the influx of unclassified air into the PEC. Personnel may be garbed in nonsterile gloves and a low-particulate lab coat for interventions that are outside of the PEC. A failure of the airflow smoke pattern test requires 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. For situations where the hot-cell is an integrated HEPA filtration system with a clear demarcated area that is a PEC, dynamic airflow smoke pattern tests must 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. Personnel may be garbed in nonsterile gloves and a low particulate lab coat for interventions that are outside of the PEC. A failure of the airflow smoke pattern test requires 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.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	125.	Does verification by either 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?	Does verification by either 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. A failure of the airflow smoke pattern test requires 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.	

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	126.	Do all RAM users comply with the conditions specified in their approved RAM license application and regulations?	<p><b>USP Chapter 825– 5.7 Environmental Controls</b>                      All RAM users must 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 described in this section. Passthrough enclosures for transferring radiopharmaceuticals from controlled handling areas (e.g., buffer area) should be designed to provide reasonable balance between maintenance of air quality and other worker safety concerns (e.g., radiation exposure, physical injury from lifting heavy shielded cases). At a minimum, there must be a mechanical system or SOP in place that ensures that both doors cannot be open at the same time. There may be both positive and negative air pressure within the facility; positive pressure to minimize the potential of microbial contamination in sterile drug preparation areas, and negative pressure to minimize potential radioactive contamination from volatile or airborne radiopharmaceuticals. Positive pressure environments must 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). The pressure differential between the ante-room and the unclassified area must be no less than a positive 0.02-inch water column. Refer to the RAM license for negative pressure requirements. For preparation of sterile radiopharmaceuticals, consideration of both concerns could be addressed as follows: 1. Buffer area, if present, must be positive pressure compared to the ante-room 2. Ante-room, if present, must be positive pressure compared to unclassified portions of the restricted area 3. Restricted area, in the presence of volatile or airborne radiopharmaceuticals, must be negative pressure compared to the unrestricted area 4. SRPA must be negative pressure compared to unrestricted areas in the presence of volatile or airborne radiopharmaceuticals (e.g., I-131 sodium iodide and Xenon). Various environmental controls for various preparation scenarios (see Table 7 for maximum BUDs for differing environments) are described in the following sections. Table 1 details the limits for particle counts for each specific ISO classification.</p>	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	127.	Is there a mechanical system or SOP in place that ensures that both passthrough doors cannot be open at the same time?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	128.	Do positive pressure environments have a minimum differential positive pressure of 0.02-inch water column between each ISO-classified area?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	129.	Is the pressure differential between the ante-room and the unclassified area no less than a positive 0.02-inch water column?		

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	130.	In a classified area, is a pressure differential monitoring system used to continuously monitor the pressure differential between the ante-rooms and buffer areas and between the ante-room and the general environment outside the classified areas?	<b>USP Chapter 825– 5.7 Environmental Controls - ESTABLISHING AND MAINTAINING PRESSURE DIFFERENTIALS</b> Any time a pressure differential is required, a pressure monitoring device is required. In a classified area, a pressure differential monitoring system must be 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). The results from the pressure monitoring system must be reviewed and documented at least daily on days the area is used. All pressure monitoring devices must be tested for accuracy and required performance at least every 6 months.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	131.	Are the results from the pressure monitoring system reviewed and documented at least daily on days the area is used?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	132.	Are all pressure monitoring devices tested for accuracy and performance at least every 6 months?		
			133.	Do SRPAs with vertical ISO Class 5 PECs meet the following:	<b>USP Chapter 825– 5.7 Environmental Controls - SRPA WITH VERTICAL FLOW ISO CLASS 5 PEC(S) FOR RADIOPHARMACEUTICAL PREPARATIONS</b> An SRPA with vertical ISO Class 5 PECs must meet the following requirements: Area surrounding the PEC may be ambient (unclassified) atmosphere; Area must be clean, uncluttered, and dedicated to the processing of radiopharmaceuticals; Appropriate for preparation, preparation with minor deviations, repackaging, and dispensing of radiopharmaceuticals. An area that meets ISO Class 8 total airborne particle-count specifications may be used to store and elute non-direct infusion radionuclide generators (e.g., Tc-99m).	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	133. a	Area surrounding the PEC may be ambient (unclassified) atmosphere		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	133. b	Area is clean, uncluttered, and dedicated to the processing of radiopharmaceuticals		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	133. c	Appropriate for preparation, preparation with minor deviations, repackaging, and dispensing of radiopharmaceuticals		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	134.	Is certification of the classified areas, including PECs, performed initially and at least every 6 months using procedures outlined in the current Controlled Environment Testing	<b>USP Chapter 825– 5.7 Environmental Controls - CERTIFICATION OF PECS AND ENVIRONMENT IN WHICH THE PEC IS LOCATED</b> Certification of the classified areas, including the PEC, must be performed initially and recertification must be performed	

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				Association (CETA) certification guide for Sterile Compounding Facilities, or an equivalent guideline?	at least every 6 months using procedures outlined in the current Controlled Environment Testing Association (CETA) certification guide for Sterile Compounding Facilities, or an equivalent guideline, and must include the following: Airflow testing: To determine acceptability of the air velocity, the air exchange rate, and area pressure cascade to ensure that air consistently flows from most to least clean areas, and that the appropriate quality of air is maintained under dynamic operating conditions; HEPA filter integrity testing: HEPA filters must be leak tested after installation and as part of recertification; Total particle counts testing: Conducted under dynamic operating conditions using calibrated electronic equipment; Smoke visualization studies: Performed under either simulated or dynamic operating conditions to demonstrate unidirectional airflow and sweeping action over and away from the preparation(s). In cases where technologies exist for hot-cell and PEC configurations that are not consistent for certification by the current CETA standards, other equivalent means for certifying the PEC may be performed and documented per facility SOPs. In this case, the PEC must maintain the environmental equivalent for total particle counts and the protection of the ISO Class 5 area from intrusions of lesser controlled air.	
			135.	Does certification of the classified areas, including PECs, include the following:		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	135.	a Airflow testing		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	135.	b HEPA filter integrity testing		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	135.	c Total particle counts testing		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	135.	d Smoke visualization studies		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	136.	When technologies exist for hot-cell and PEC configurations that are not consistent for certification by the current CETA standards or other equivalent means for certifying, does the PEC maintain the environmental equivalent for total particle counts and the protection of the ISO Class 5 area from intrusions of lesser controlled air?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	137.	Is temperature and humidity monitored in the SRPA or area containing a hot-cell?	<b>USP Chapter 825– 5.7 Environmental Controls - DAILY MONITORING OF ENVIRONMENT</b> The temperature and humidity must be monitored in the SRPA or area containing a hot-cell, and if in a classified area the pressure must monitored, each day that preparations are made, either manually or by a continuous recording device. These include: Relative humidity should be kept at 60% or lower; Temperature and relative humidity continuous readings must be confirmed daily to have remained within the acceptable range; Excursions must be documented and, if applicable, appropriate corrective	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	138.	If in a classified area, is pressure monitored, each day that preparations are made, either manually or by a continuous recording device?		
			139.	Does environmental control include the following:		

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions	
Yes	No	N/A					
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	139.	a	actions taken; Temperature monitoring devices must be verified for accuracy every 12 months or as required by the manufacturer; Monitoring of pressure differentials must be performed. See Packaging and Storage Requirements <659> for information on controlled area temperature and allowable excursions.		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	139.	b		Excursions documented and, if applicable, appropriate corrective actions taken	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	139.	c		Temperature monitoring devices verified for accuracy every 12 months or as required by the manufacturer	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	139.	d		Monitoring of pressure differentials are performed	

**MICROBIOLOGICAL AIR AND SURFACE MONITORING**

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	140.	Does the facility develop and implement written air and surface monitoring procedures for all sterile radiopharmaceutical classified areas?	<b>USP Chapter 825– 6 MICROBIOLOGICAL AIR AND SURFACE MONITORING</b> An effective air and surface monitoring program provides information on the environmental quality of the classified areas where sterile radiopharmaceuticals are processed. The program identifies environmental quality trends over time, potential routes of microbiological contamination, and allows for implementation of corrective actions to prevent microbiological contamination of the radiopharmaceuticals. Facilities must develop and implement written air and surface monitoring procedures for all sterile radiopharmaceutical classified areas. Air and surface monitoring results and the corrective actions must be documented, and records must be readily retrievable as required by jurisdictional laws and regulations.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	141.	Are air and surface monitoring results and corrective actions documented?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	142.	Are records readily retrievable?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	143.	Does the microbiological air and surface monitoring program include viable impact volumetric airborne		<b>USP Chapter 825– 6.1 General Monitoring Requirements</b> The goals of an air and surface monitoring program are to determine whether microbiological contamination is present

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				particulate sampling and surface sampling?	at unacceptable levels and to assess whether proper personnel practices are being followed, cleaning and disinfecting agents are effective, and environmental quality is maintained. The microbiological air and surface monitoring program must include viable impact volumetric airborne particulate sampling and surface sampling. Air and surface sampling must be performed initially for classified areas in a facility to establish a baseline level of environmental quality. After initial sampling, the classified areas must be monitored according to the minimum frequencies described in this section to ensure that the environment remains in a suitable state for aseptic processing tasks. The air and surface monitoring program involves the collection and evaluation of samples from various air and surface locations to detect viable microbiological contaminants. The data are then used to assess risks for contamination, potential routes of contamination, and the adequacy of cleaning and disinfection techniques and agents specified in the facility SOPs. Regular review of the sampling data must be performed to detect trends such as elevated levels of microbial bioburden, elevated levels of nonviable particulates, or other adverse changes within the environment. Evaluating results collected over a period of time can be useful in identifying trends or determining that a significant change has occurred, even when the results fall within the specified limits. In addition, results must be 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. Prompt corrective action in response to any adverse findings is required to maintain the necessary environmental quality for handling sterile radiopharmaceutical. Data must also be reviewed following corrective actions to confirm that the actions taken have been effective in achieving the required air and surface	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	144.	Is air and surface sampling performed initially for classified areas in the facility?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	145.	After initial sampling, are the classified areas monitored according to the minimum frequencies?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	146.	Is regular review of the sampling data performed to detect trends?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	147.	Are results reviewed in conjunction with personnel data?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	148.	Is data reviewed following corrective actions?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	149.	Is air and surface sampling conducted during actual or simulated dynamic operating conditions?		
			150.	Is sampling performed in the following circumstances:		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	150.	a In conjunction with the certification of new facilities and equipment		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	150.	b After any modification of facilities or equipment		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	150.	c In response to identified problems		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	150.	d In response to identified trends		

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	150.	e	In response to changes that could impact the controlled area environments	<p>quality levels (see Table 3 and Table 4). Air and surface sampling must be conducted during actual or simulated dynamic operating conditions to confirm that the required environmental quality in classified areas is maintained. Due to radiation exposure concerns for the workers involved, it is permissible for sampling to be carried out at the conclusion of sterile radiopharmaceutical processing but prior to cleaning and disinfecting the surface area. In this case, simulated tasks that are reflective of the routine aseptic activities are performed. In addition to the specific sampling frequencies described in this section, sampling must be performed in any of the following circumstances: In conjunction with the certification of new facilities and equipment; After any modification of facilities or equipment; In response to identified problems (e.g., positive growth in sterility tests of compounded radiopharmaceuticals); In response to identified trends (e.g., repeated positive gloved fingertip sampling results or failed media-fill testing involving more than one operator where a review of the operator technique shows no reasonable flaws in process; repeated observations of air or surface contamination); In response to changes that could impact the controlled area environments (e.g., significant change in cleaning process or the agents involved). To obtain an air and surface sample that is representative of the typical aseptic operating conditions at the facility, air and surface sampling must be conducted under dynamic or simulated dynamic operating conditions in all PECs and classified areas. If conducted during actual sterile processing, the monitoring program must be designed and conducted in a manner that minimizes the chance that the sampling itself will contribute to contamination of the sterile radiopharmaceutical(s) or the environment. The air and surface monitoring program must be clearly described in the established SOPs of the facility and must 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. The locations</p>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	150.	f	Is air and surface sampling conducted under dynamic or simulated dynamic operating conditions in all PECs and classified areas?	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	150.	g	If conducted during actual sterile processing, is the monitoring program designed and conducted to minimize the chance that sampling would contribute to contamination of the sterile radiopharmaceuticals or the environment?	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	150.	h	Is the air and surface monitoring program described in the established SOPs of the facility?	
			151.		Does the air and surface monitoring program include the following:	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	151.	a	Diagram of the sampling locations	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	151.	b	SOPs for collecting samples	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	151.	c	Frequency of sampling	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	151.	d	Size of samples	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	151.	e	Time of day of sampling in relation to activities in the classified areas	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	151.	f	Action levels that would trigger corrective action	

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	152.	Are air sampling devices serviced and calibrated as recommended by the manufacturer?	of sampling should be carefully selected based on their relationship to the activities performed in the area. It is important to obtain samples from locations that pose the highest possible contamination risk to the sterile radiopharmaceuticals involved with the operation's processes and that are likely to be representative of the conditions throughout the area. Evaluating results collected over a period of time can be useful in identifying trends or determining that a significant change has occurred, even when the results fall within the specified limits. It is important that personnel who operate the equipment be trained in the proper operation of the air and surface sampling equipment to ensure accurate and reproducible sampling. All air sampling devices must be serviced and calibrated as recommended by the manufacturer.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	153.	Is a monitoring program for viable airborne particles developed and implemented to assess microbiological air quality in all classified areas?	<b>USP Chapter 825– 6.2 Monitoring Air Quality for Viable Airborne Particles</b> A monitoring program for viable airborne particles must be developed and implemented to assess microbiological air quality in all classified areas.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	154.	Is volumetric active air sampling of all classified areas using an impaction device conducted during dynamic operating or simulated operating conditions at least every 6 months?	<b>USP Chapter 825– 6.2 Monitoring Air Quality for Viable Airborne Particles - VIABLE AIR SAMPLING: TIMING AND LOCATIONS</b> 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 must be conducted during dynamic operating or simulated operating conditions at least every 6 months. Air sampling sites must be selected in all classified areas. When conducting sampling of the PEC, care should be taken to avoid disturbing unidirectional airflow if taken during actual sterile processing activities. Viable air sampling must include: 1. Follow the manufacturer's instructions for operation of the air sampling device, including placement of media. 2. Using the sampling device, test at least 1 cubic meter or 1000 liters of air from each location sampled. 3. At the end of	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	155.	Are air sampling sites selected in all classified areas?		
			156.	Does viable air sampling include the following:		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	156.	a Follow the manufacturer's instructions for operation of the air sampling device, including placement of media.		

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	156.	b	Using the sampling device, test at least 1 cubic meter or 1000 liters of air from each location sampled.	<p>the sampling, retrieve the media plates/devices and cover. 4. Invert the media and incubate at 30°–35° 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. 5. Then incubate the inverted media at 20°–25° for no less than 5 additional days. Examine the media plates 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. Alternatively, to shorten the overall incubation period, two samples may be collected for each sample location and incubated concurrently. 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)]. Incubate each sample in a separate incubator. Incubate one sample at 30°–35° for no less than 48 hours, and incubate the other sample at 20°–25° for no less than 5 days. Fungal media samples must be incubated at 20°–25° for no less than 5 days. Count the total number of discrete colonies of microorganisms on each sample, and record these results as cfu per sample. Record the results of the sampling on an environmental sampling form based on sample type (i.e., viable air) and include the sample location, and sample date. A general microbiological growth medium that supports the growth of bacteria and fungi must be used (e.g., TSA medium). CoA(s) from the manufacturer must verify that the medium meets the expected growth promotion, pH, and sterilization requirements. Samples must be incubated in a temperature monitored incubator with a calibrated measuring device. The incubator temperature must be monitored during incubation, either manually or by a continuous recording device, and the results must be reviewed and documented. Incubators used for microbiological testing must be placed in a location</p>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	156.	c	At the end of the sampling, retrieve the media plates/devices and cover.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	156.	d	Invert the media and incubate at 30°–35° 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. Include sample location and date.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	156.	e	Then incubate the inverted media at 20°–25° for no less than 5 additional days. Examine the media plates 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. Include sample location and date.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	157.		Are fungal media samples incubated at 20°–25° for no less than 5 days?	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	158.		Is a general microbiological growth medium that supports the growth of bacteria and fungi used?	

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	159.	Do CoAs from the manufacturer verify that the medium meets the expected growth promotion, pH, and sterilization requirements?	outside of any classified area or SRPA and kept away from areas where compounding or sterile processing activities are carried out. All sampling activities must be performed by trained individuals.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	160.	Are samples incubated in a temperature monitored incubator with a calibrated measuring device?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	161.	Is the incubator temperature monitored during incubation, either manually or by a continuous recording device?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	162.	Are incubator temperature results reviewed and documented?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	163.	Are incubators used for microbiological testing placed in a location outside of any classified area or SRPA?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	164.	Are incubators used for microbiological testing kept away from areas where compounding or sterile processing activities are carried out?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	165.	Are sampling activities performed by trained individuals?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	166.	If two pieces of media were collected at a single location, is all recovered growth on each documented?	<b>USP Chapter 825– 6.2 Monitoring Air Quality for Viable Airborne Particles - DATA EVALUATION AND ACTION LEVELS</b> Evaluate cfu counts against the action levels in Table 3 and in relation to previous data to identify adverse results and/or trends. If two pieces of media were collected at a single location, all recovered growth on each must be documented and action levels are applied individually to	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	167.	If two pieces of media were collected at a single location, are action levels applied individually to each plate/device?		

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	168.	If levels measured during the viable air monitoring program exceed the levels in Table 3 for the ISO classification levels of the area sampled, is the cause investigated?	<p>each plate/device (i.e., results from each cubic meter of air sampled must be compared to the action level for that area). If levels measured during the viable air monitoring program exceed the levels in Table 3 for the ISO classification levels of the area sampled, the cause must be investigated and corrective action must be taken. The corrective action plan must be dependent on the cfu count and the microorganism recovered. Some examples of corrective action include process or facility improvements, personnel training, cleaning and disinfecting, or HEPA filter replacement and/or repair, or reducing the BUD of the radiopharmaceutical during investigation and while carrying out the corrective action plan. The extent of the investigation should be consistent with the deviation and should include an evaluation of trends. The corrective action plan must be documented. If levels measured during viable air sampling exceed the levels in Table 3, an attempt must be made to identify any microorganism recovered to the genus level (see Microbial Characterization, Identification, and Strain Typing &lt;1113&gt;) with the assistance of a qualified individual (e.g., microbiologist or industrial hygienist).</p> <p><b>USP Chapter 825– 6.3 Monitoring Surfaces for Viable Particles</b>                      Surface sampling is an important component of the maintenance of a suitably controlled environment for sterile radiopharmaceutical processing, especially because transfer of microbial contamination from improperly disinfected work surfaces (e.g., via inadvertent touch contact by personnel) is a potential source of contamination of the radiopharmaceutical(s). Surface sampling is useful for evaluating facility cleaning and material handling procedures, work surface cleaning and disinfecting procedures, and personnel competency in work practices such as proper cleaning and disinfection. All sampling sites and procedures must be described in the facility’s SOP.</p>	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	169.	If levels measured during the viable air monitoring program exceed the levels in Table 3 for the ISO classification levels of the area sampled, is corrective action taken?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	170.	Is a corrective action plan dependent on the cfu count and the microorganism recovered?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	171.	Is the corrective action plan documented?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	172.	If levels measured during viable air sampling exceed the levels in Table 3, is an attempt made to identify any microorganism recovered to the genus level with the assistance of a qualified individual?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	173.	Are sampling sites and procedures described in the facility’s SOP?		

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	174.	Is surface sampling of classified areas and PECs conducted at least monthly?	<p><b>USP Chapter 825– 6.3 Monitoring Surfaces for Viable - SURFACE SAMPLING: TIMING AND LOCATIONS</b>                      Surface sampling of all classified areas and all PECs must be conducted at least monthly for the detection of microbial contamination. Each classified area must be sampled (see Microbiological Control and Monitoring of Aseptic Processing Environments &lt;1116&gt;). The DPA of the PEC, and any equipment permanently contained in the PEC, must be sampled. Staging or work surfaces in classified areas near the PEC, frequently touched surfaces in classified areas, and pass-through enclosure(s) for all classified areas are to be evaluated to determine the locations that pose the greatest risk of harboring microbial contamination. Surface sampling must be performed at the end of the radiopharmaceutical aseptic activities or shift, but before the area has been cleaned and disinfected. However, radiopharmaceutical personnel must also consider the appropriate exposure and contamination prevention measures prior to and while collecting samples. If the worker assesses that the risk for exposure is not in conformance with ALARA safety standards, measures must be taken to eliminate the risk (e.g., implementation of appropriate shielding, performing the sampling at a later time or alternate day).</p>	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	175.	Is each classified area sampled?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	176.	Is the DPA of the PEC, and any equipment permanently contained in the PEC, sampled?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	177.	Is surface sampling performed at the end of radiopharmaceutical aseptic activities or shift, but before the area has been cleaned and disinfected?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	178.	Do radiopharmaceutical personnel consider the appropriate exposure and contamination prevention measures prior to and while collecting samples?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	179.	If the worker assesses that risk for exposure is not in conformance with ALARA safety standards, are measures taken to eliminate the risk?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	180.	Are surface sampling devices containing microbial growth media used for sampling flat surfaces?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	181.	Do CoAs from the manufacturer verify that the media meets expected growth promotion, pH, and sterilization requirements?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	182.	Do surface sampling devices contain general microbial growth media supplemented with neutralizing additives?		

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	183.	If used, do contact plates have a raised convex surface?	water or a sterile neutralizing buffer may be used when sampling irregular surfaces and difficult-to-reach locations, such as crevices, corners, and spaces between surfaces. After sampling, the sampled area must be thoroughly cleaned and disinfected. Use the following procedures for surface sampling on flat surfaces: 1. 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. 2. If using plates, invert the plates. 3. Incubate the surface sampling devices at 30°–35° 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. 4. Incubate the device at 20°–25° 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. Alternatively, to shorten the overall incubation period, two samples may be collected for each sample location. 1. Both samples could be TSA or one sample could be TSA and the other fungal media (e.g., MEA or SDA). 2. Incubate each sample in a separate incubator. Incubate one sample at 30°–35° for no less than 48 hours, and incubate the other sample at 20°–25° for no less than 5 days. 3. If fungal media are used as one of the samples, incubate the fungal media sample at 20°–25° for no less than 5 days. 4. Count the total number of discrete colonies of microorganisms on each sample, and record these results as cfu per sample. Record the results of the sampling. 5. Record the results of the sampling.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	184.	After sampling, is the sampled area cleaned and disinfected?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	185.	If two devices were collected at a single location, is all recovered growth on each documented?	<b>USP Chapter 825– 6.3 Monitoring Surfaces for Viable - DATA EVALUATION AND ACTION LEVELS</b>	

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	186.	If two devices were collected at a single location, are action levels applied to each piece of media individually?	Evaluate cfu counts against the action levels in Table 4 and examine counts in relation to previous data to identify adverse results or trends. If two devices were collected at a single location, all recovered growth on each must be documented and action levels are applied to each piece of media individually (i.e., results from each sampling device must be compared to the action level for the area). If levels measured during surface sampling exceed the levels in Table 4 for the ISO classification levels of the area sampled, the cause must be investigated and corrective action must be taken. Data collected in response to corrective actions must be reviewed to confirm that the actions taken have been effective. The corrective action plan must be dependent on the cfu count and the microorganism recovered. Examples of corrective action include process or facility improvements, personnel training, cleaning and disinfecting, or HEPA filter replacement and/or repair, or reducing the BUD of the radiopharmaceutical(s) during investigation and while carrying out the corrective action plan. The extent of the investigation should be consistent with the deviation and should include an evaluation of trends. The corrective action plan must be documented. If levels measured during surface sampling exceed the levels in Table 4, an attempt must be made to identify any microorganism recovered to the genus level (see <1113>) with the assistance of a qualified individual (e.g., microbiologist or industrial hygienist).	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	187.	If levels measured during surface sampling exceed the levels in Table 4 for the ISO classification levels of the area sampled, is the cause investigated?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	188.	If levels measured during surface sampling exceed the levels in Table 4 for the ISO classification levels of the area sampled, is corrective action taken?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	189.	Is data collected in response to corrective actions reviewed?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	190.	Is the corrective action plan dependent on the cfu count and the microorganism recovered?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	191.	Is the corrective action plan documented?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	192.	If levels measured during surface sampling exceed the levels in Table 4, is an attempt made to identify any microorganism recovered to the genus level with the assistance of a qualified individual?		
<b>CLEANING AND DISINFECTING</b>						
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	193.	Are surfaces cleaned prior to being disinfected? <b>**Using an Environmental Protection Agency (EPA)-registered (or equivalent) one-step disinfectant cleaner to</b>	<b>USP Chapter 825-7 CLEANING AND DISINFECTING</b> Cleaning and disinfecting are important because surfaces in classified areas and SRPAs are a potential source of microbial contamination of sterile radiopharmaceuticals. The process of cleaning involves removing organic and	

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				<b>accomplish both the cleaning and disinfection in one step is acceptable.**</b>	inorganic residues from surfaces, usually with a manual or mechanical process and a cleaning agent. The process of disinfecting involves destruction of microorganisms, usually with a chemical or physical agent. Surfaces must be cleaned prior to being disinfected unless an Environmental Protection Agency (EPA)-registered (or equivalent) one-step disinfectant cleaner is used to accomplish both the cleaning and disinfection in one step. After cleaning and disinfecting or the application of a one-step disinfectant cleaner in a PEC, apply sterile 70% IPA to remove any residue. Cleaning and disinfecting surfaces should occur at the minimum frequencies specified in Table 5 or if activities are not performed daily, cleaning and disinfecting must be completed before initiating activities. The act of reducing or removing radioactivity (radioactive decontamination) from an object or surface must be balanced with the risk of spreading radioactive contamination. At times the best approach may be to shield the area until the radiation exposure levels are lower. This balance must be specified in SOPs (e.g., trigger levels for safe cleaning). The PEC should be checked for radioactive contamination prior to cleaning and disinfecting to prevent spreading radioactive contamination in the PEC. All cleaning and disinfecting activities must be performed by trained and appropriately garbed personnel using facility-approved agents and procedures that must be described in written SOPs. Cleaning must be performed in the direction of most to least clean areas. The frequency, method(s), and location(s) of cleaning, disinfecting, and sporicidal agent use must be established in written SOPs, in accordance with the manufacturer’s instructions when available, or based on sound microbiological cleaning techniques when unavailable, and must be followed by all cleaning personnel. The manufacturer’s direction or published data for the minimum contact time must be followed for the	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	194.	If sterile processing of radiopharmaceuticals are not performed daily, is cleaning and disinfecting completed before initiating these activities?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	195.	Is reducing or removing radioactivity from an object or surface balanced with the risk of spreading radioactive contamination?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	196.	Is the balance of reducing or removing radioactivity from an object or surface and risk of spreading radioactive contamination specified in SOPs?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	197.	Are cleaning and disinfecting activities performed by trained and appropriately garbed personnel?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	198.	Are cleaning and disinfecting activities performed using facility-approved agents?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	199.	Are cleaning and disinfecting activities performed using procedures described in written SOPs?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	200.	Is cleaning performed in the direction of most to least clean areas?		

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	201.	Is the frequency, method(s), and location(s) of cleaning, disinfecting, and sporicidal agent used established in written SOPs, in accordance with the manufacturer's instructions when available, or based on sound microbiological cleaning techniques when unavailable?	cleaning, disinfecting, and sporicidal agents used. When sterile 70% IPA is used, it must be allowed to dry. All cleaning, disinfecting, and application of sporicidal agents must be documented according to facility SOPs.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	202.	Are written SOPs followed by cleaning personnel?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	203.	Is the manufacturer's direction or published data for the minimum contact time followed for the cleaning, disinfecting, and sporicidal agents used?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	204.	When sterile 70% IPA is used, is it allowed to dry?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	205.	Is cleaning, disinfecting, and application of sporicidal agents documented according to facility SOPs?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	206.	Are cleaning and disinfecting agents selected and used with careful consideration of compatibilities, effectiveness, and user safety?	<b>USP Chapter 825-7.1 Cleaning, Disinfecting, and Sporicidal Agents</b> Cleaning and disinfecting agents must be selected and used with careful consideration of compatibilities, effectiveness, and user safety. 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 (see <i>Disinfectants and Antiseptics</i> <1072>). After the disinfectant is applied on the surface to be disinfected, the disinfectant must be allowed to dwell for the minimum contact time specified by the manufacturer,	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	207.	Is the disinfectant allowed to dwell on the applied surface for the minimum contact time specified by the manufacturer without being disturbed?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	208.	Is sterile 70% IPA used in the ISO Class 5 PEC?		

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	209.	Are sporicidal agents used at least monthly on all surfaces in classified areas and SRPAs?	during which time the surface cannot be disturbed. Only the 70% IPA used in the ISO Class 5 PEC must be sterile. Sporicidal agents must be used at least monthly on all surfaces in classified areas and SRPAs. Some EPA-registered (or equivalent) one-step disinfectant cleaners may have sporicidal properties. See Table 6 for a summary of the purpose of the cleaning, disinfecting, and sporicidal agents.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	210.	Are all cleaning supplies, with the exception of tool handles and holders, low-lint?	<b>USP Chapter 825-7.2 Cleaning Supplies</b> All cleaning supplies (e.g., wipers and mop heads), with the exception of tool handles and holders, must be low-lint and should be disposable. If disposable cleaning supplies are used, they must be discarded after each cleaning activity. Reusable cleaning tools must be made of cleanable materials (e.g., no wooden handles) and must be cleaned and disinfected before and after each use. Reusable cleaning tools must be dedicated for use in the classified areas or SRPAs and must not be removed from these areas except for disposal. They must be discarded after an appropriate amount of time, to be determined based on the condition of the tools. Cleaning supplies and solutions used in the classified areas and SRPAs should be monitored for radioactive contamination after use and prior to disposal, as per facility SOPs. Dispose of cleaning supplies used in the classified areas and SRPAs in a manner that minimizes the potential for dispersing particulates into the air (e.g. with minimal agitation, away from work surfaces).	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	211.	Are disposable cleaning supplies discarded after each cleaning activity?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	212.	Are reusable cleaning tools made of cleanable materials?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	213.	Are reusable cleaning tools cleaned and disinfected before and after each use?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	214.	Are reusable cleaning tools dedicated for use in the classified areas or SRPAs and not removed from these areas except for disposal?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	215.	Are reusable cleaning tools discarded after an appropriate amount of time, to be determined based on the condition of the tools?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	216.	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?		<b>USP Chapter 825– 7.3 Cleaning and Disinfecting the PEC</b> Clean and disinfect the PEC at the minimum frequencies specified in Table 5. If the PEC contains a removable work tray, all sides of the work tray and the area underneath the work tray must be cleaned and disinfected at least monthly.

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	217.	Is the PEC wiped with a sporicidal agent at least monthly?	1. Survey all surfaces of the PEC for radioactive contamination and follow facility SOPs to decontaminate, if necessary. 2. Remove, if necessary, any particles, debris, or residue with an appropriate solution (e.g., Sterile Water for Injection or Sterile Water for Irrigation) using sterile, low-lint wipers. 3. Apply a cleaning agent followed by a disinfecting agent or apply an EPA-registered (or equivalent) one-step disinfectant cleaner and ensure that the contact time specified per manufacturer instructions is achieved. 4. Apply sterile 70% IPA 5. Allow the surface to dry completely before beginning activities. 6. The PEC must be wiped with a sporicidal agent at least monthly.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	218.	Are all shipping carton(s), corrugated or uncoated cardboard kept out of the classified areas and kept out of the perimeter of the SRPA?	<b>USP Chapter 825– 7.4 Disinfecting Supplies for Classified Areas and SRPAs</b> No shipping carton(s) or other corrugated or uncoated cardboard are allowed in the classified area (e.g., clean side of ante-room) or within the perimeter of the SRPA.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	219.	Are items wiped with a sporicidal agent, EPA-registered (or equivalent) one-step disinfectant cleaner, or sterile 70% IPA using low-lint wipers before they are introduced into a classified area or SRPA?	Before items are introduced into a classified area or SRPA, they must be wiped with a sporicidal agent, EPA-registered (or equivalent) one-step disinfectant cleaner, or sterile 70% IPA using low-lint wipers. After the sporicidal or sterile disinfectant is applied onto the surface, the agent must be allowed to dwell on the surface for the minimum contact time specified by the manufacturer (see 6.1 General Monitoring Requirements). The agent used for disinfecting the packaging must be compatible with the packaging and must not render the product label unreadable. Any item to be transferred into the PEC from the classified area or SRPA must be disinfected with a sterile disinfectant (e.g., sterile 70% IPA). In the case of radiopharmaceuticals 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. In this case, the syringes may be opened and appropriately labeled outside of the ISO	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	220.	Are sporicidal or sterile disinfectant agents allowed to dwell on the applied surface for the minimum contact time specified by the manufacturer?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	221.	Is the agent used for disinfecting the packaging compatible with the packaging and not render the product label unreadable?		

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	222.	Is each item transferred into the PEC from the classified area or SRPA disinfected with a sterile disinfectant?	Class 5 environment and placed in disinfected shielding, immediately prior to the forthcoming dispensing cycle.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	223.	Are critical sites wiped with sterile 70% IPA?	<b>USP Chapter 825-7.5 Disinfecting Critical Sites</b> Critical sites (e.g., vial stoppers) must be wiped with sterile 70% IPA. The critical site must be wiped ensuring that both chemical and mechanical actions are used to remove contaminants. The sterile 70% IPA must be allowed to dry before piercing critical sites.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	224.	Is the critical site wiped ensuring that both chemical and mechanical actions are used to remove contaminants?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	225.	Is sterile 70% IPA allowed to dry before piercing critical sites?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	226.	Are radiation shielding and equipment that is exposed to patient care areas during the process of administration cleaned and disinfected before returning to any classified area or SRPA?	<b>USP Chapter 825– 7.6 Cleaning and Disinfecting Items from Patient Care Area</b> Radiation shielding and equipment used in the classified area/SRPA or PEC that is exposed to patient care areas during the process of administration must be 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 <sup>1</sup> as noncritical equipment requiring low-risk disinfection. Syringes that have been used in a patient care area must not be 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. Equipment that has been exposed to needles and syringes contaminated with blood-borne pathogens and RAMs are considered mixed waste (e.g., syringe shields and syringe carrying containers). This equipment must be cleaned and disinfected through actions regulated by the facilities' SOPs. Equipment that contained or was in contact with mixed waste must be cleaned and disinfected with an appropriate agent(s) for blood.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	227.	Are syringes that have been used in a patient care area not brought back into the classified area or SRPA for re-assaying or disposal? <b>**A syringe may reenter a classified area or SRPA, if it is sealed inside an impervious container that is disinfected prior to entry.**</b>		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	228.	Is equipment cleaned and disinfected through actions regulated by the facilities' SOPs?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	229.	Is equipment that contained or was in contact with mixed waste cleaned and disinfected with an appropriate agent(s) for blood?		

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
<b>ASSIGNING BUD</b>						
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	230.	If assigning a BUD longer than the manufacturer-stated/suggested use-by time interval, is there evidence to support the maintenance of appropriate quality and purity?	<b>USP Chapter 825– 8. Assigning BUD</b> BUDs are based on the risk of microbial contamination with the assumption that the radiopharmaceutical(s) should remain chemically and physically stable, and its container–closure system should maintain its integrity for the duration of the BUD (Table 7). The time starts at the moment of the first sterile vial puncture or exposure of a critical site (e.g., syringe tip, needle hub, or needle) to ambient air, whichever is first. The BUDs stated in Table 7 are maximum values in the absence of sterility testing, and the assigned BUD may be shorter for a variety of reasons discussed below. The individual responsible for the manipulation assigns the BUD based on established testing data, either performed in-house or obtained from peer reviewed literature. For compounded preparations (sterile and nonsterile), the BUD is also dependent on maintenance of appropriate quality and purity, including radiochemical purity, radionuclidic purity, and other applicable parameters as specified in individual monographs or as clinically appropriate. For preparations with minor deviations involving conventionally manufactured kits (sterile and nonsterile), the kit may state or suggest a use-by time in the package insert. For certain radiopharmaceuticals transportation time, radionuclide availability, and other factors may necessitate extending manufacturer-stated/suggested use-by time to meet patient needs. Assigning a BUD longer than the manufacturer-stated/suggested use-by time interval must be supported by evidence of the maintenance of appropriate quality and purity, including radiochemical purity and radionuclidic purity as specified in individual monographs, and other applicable parameters as clinically appropriate. Assignment of a BUD for a radiopharmaceutical(s) must consider several factors, as applicable. Issues of concern include, but are not limited to, the following: Sterility: Maintenance of sterility is a major concern for any sterile preparation or product. Good aseptic handling practices in an appropriate	
			231.	When assigning a BUD for a radiopharmaceutical(s), are the following considered:		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	231.	a Sterility		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	231.	b Radiochemical purity where the assigned BUD is based on stability studies		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	231.	c Radionuclidic purity		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	231.	d Age of generator eluate		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	231.	e Number of particles including the increasing ratio over time of the number of particles per unit radioactivity.		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	231.	f The specific activity of the patient dose contains no more than the specified maximum mass when radioactivity decays over time and the specific activity decreases resulting in more mass per unit radioactivity		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	231.	g Container type that ensures proper storage		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	231.	h Cell viability		

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	231.	i	Expiration date assigned for manufactured radiopharmaceuticals that is distributed to nuclear pharmacies or other healthcare facilities for terminal distribution/dispensing	environmentally-controlled area are the most critical factors in ensuring sterility. See Table 7 for maximum BUD. The assigned BUD should not exceed the sterility-related times listed in Table 7, unless a longer time is justified by Sterility Tests <71>. Radiochemical purity: Maintenance of radiochemical purity is affected by a variety of factors including, but not limited to, storage temperature, quantity of radioactivity, radioactivity concentration, presence or absence of antioxidants or other stabilizing agents, and container type (e.g., glass vial vs. plastic syringe). The assigned BUD must be based on stability studies in which these variables are controlled and are representative of the conditions of actual use. For factors that allow a range of values (e.g., storage temperature, quantity of radioactivity, radioactivity concentration), studies should be conducted at the extremes of the ranges. Radionuclidic purity: Because radionuclidic impurities may decay away more slowly than the primary radionuclide, the radionuclidic purity may decrease over time. For example, the ratio of Mo-99 (half-life of about 66 hours) to Tc-99m (half-life of about 6 hours) continuously increases over time. 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. Calculation of radionuclidic purity at future times is necessary to ensure compliance throughout the assigned BUD. Age of generator eluate: As a generator eluate decays, the desired daughter radionuclide decays to form other nuclides and potential radiolytic products, which may interfere with radiolabeling of kits. For example, Tc-99m undergoes decay to Tc-99. More importantly, increasing amounts of peroxides formed as radiation interacts with water molecules. Increased amounts of Tc-99 and peroxides can interfere with the radiolabeling of many kits. Extension of the BUD for Tc-99m pertechnetate intended for radiolabeling of kits must take into account the build-up of Tc-99 and peroxides over time. Number of particles: For radiolabeled particulates, the number of particles per unit radioactivity increases over time as the radionuclide decays. For example, the BUD for Tc-99m albumin aggregated
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	231.	j	The assigned BUD of radiopharmaceuticals prepared from kits	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	231.	k	The shortest BUD of any component.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	232.		Does the facility have SOPs to collect and evaluate complaints associated with the use of radiopharmaceuticals having assigned BUDs?	

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#	USP Reference	Notes/Corrective Actions
Yes	No	N/A			
				<p>[macroaggregated albumin (MAA)] must take into account the increasing ratio over time of the number of particles per unit radioactivity. For example, if an MAA kit is prepared such that the radioactive patient dose is 200,000 particles at the time of calibration, the same patient dose will contain 700,000 particles at 10.85 hours after calibration. Calculation of the number of MAA particles in the patient dose is necessary to ensure compliance with the prescribed particle range throughout the assigned BUD. Specific activity: For some receptor-based radiopharmaceuticals, the mass quantity may influence uptake (i.e., too much mass may result in saturation of receptor sites and reduce target uptake of the radiopharmaceutical). As radioactivity decays over time, specific activity decreases resulting in more mass per unit radioactivity. In such situations, the assigned BUD must ensure that the patient dose contains no more than the specified maximum mass. Container type: Because radiochemical stability or other quality attributes of a radiopharmaceutical may be affected by its container characteristics, the BUD for a radiopharmaceutical dose dispensed in a plastic syringe may be different than the BUD of that same radiopharmaceutical maintained in a glass vial. The assigned BUD must be determined in the proper storage container. Cell viability: The viability of radiolabeled blood cells (e.g., leukocytes) decreases over time, and may also be affected by other factors such as the suspending medium, temperature, and agitation. The assigned BUD should be as short as circumstances reasonably allow so as to maximize cell viability. 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). In the case of radiopharmaceuticals prepared from kits, the BUD of a dispensed dose cannot exceed the assigned BUD of the finished kit preparation. A radiopharmaceutical may not exceed the shortest BUD of any of its components. The facility must have policies and SOPs appropriate to the assignment of BUD and maintain documentation of</p>	

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#	USP Reference	Notes/Corrective Actions
Yes	No	N/A			
				applicable study results and calculations. Studies of radiolabeling efficiency and radiochemical stability should employ quality control (QC) testing methods described in the manufacturer’s package insert, USP monographs and general chapters, or other equivalent testing methods and be sufficiently rigorous to allow statistical confidence in the results. The facility must have SOPs to collect and evaluate complaints associated with the use of radiopharmaceuticals having assigned BUDs. Policies and SOPs should also be 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.	

**DOCUMENTATION**

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	233.	<p>Are applicable records, including policies and SOPs, maintained for all activities involved in repackaging, preparing, preparing with minor deviations, compounding, dispensing radiopharmaceuticals?</p> <p><b>USP Chapter 825– 9. Documentation</b> Applicable records (hard-copy or electronic), including policies and SOPs, must be maintained for all activities involved in repackaging, preparing, preparing with minor deviations, compounding, and dispensing radiopharmaceuticals. Such records include, but are not limited to: Personnel training and testing, including visual assessment of aseptic technique competency, validation, garbing, hand hygiene, equipment/environment cleaning and disinfecting, gloved fingertip and thumb sampling, and media fill evaluation initially and follow up testing at specified intervals; Testing and monitoring of environmental controls, including ISO classification, ACPH, pressure differentials, temperature, humidity and viable air/surface and total airborne particle test results; Equipment maintenance and cleaning/disinfecting; End product radiochemical purity and other testing, as applicable, results of preparations, preparations with minor deviations, and compounded preparations; Master Formulation Record (MFR) for preparation with minor deviation(s) and compounding; Validation of stability testing to support the assigned BUD from SOPs by the compounder or derived from accepted literature; Investigations and corrective actions and tracking of events to closure.</p>	
--------------------------	--------------------------	--------------------------	------	--	--

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			234.	Is the following data included in the MFR when a minor deviation or compounding occurs:	<b>USP Chapter 825– 9.1 Master Formulation Record</b> A MFR is required only for a preparation with minor deviations or compounding, as described in 11. Compounding. A MFR is not required for a preparation following the manufacturer’s instructions. Data that must be included in the MFR are as follows: Name of the radiopharmaceutical; Name, identity, strength, purity, quality, and quantity of ingredients with validated documentation (e.g., CoA); Detailed procedure (e.g., heating, components, incubation time); Range of radioactivity; Range of volume; Equipment to be used; PEC and SEC to be used, if applicable; Quality control tests to be performed for final release of the radiopharmaceutical (e.g., radiochemical purity, pH); Procedures for depyrogenation and sterility procedures and validations, as applicable, including limits; Trained personnel; Garbing procedure, if different than standard procedure; Container(s); Reference source of the BUD assignment and storage conditions.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	234.	a Name of the radiopharmaceutical		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	234.	b Name, identity, strength, purity, quality, and quantity of ingredients with validated documentation		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	234.	c Detailed procedure		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	234.	d Range of radioactivity		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	234.	e Range of volume		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	234.	f Equipment to be used		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	234.	g PEC and SEC to be used		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	234.	h Quality control tests to be performed for final release of the radiopharmaceutical		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	234.	i Procedures for depyrogenation and sterility procedures and validations, as applicable, including limits		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	234.	j Trained personnel		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	234.	k Garbing procedure, if different than standard procedure		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	234.	l Container(s)		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	234.	m Reference source of the BUD assignment and storage conditions		

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			235.	Does a record for preparation with minor deviation or compounding include the following:	<b>USP Chapter 825– 9.2 Records for Preparation with Minor Deviations/Compounding</b> A record for preparation with minor deviation or compounding must include the following: Name of the radiopharmaceutical; Physical form (e.g., capsule or solution); Name and quantity of ingredients including calibration time for radioactive ingredients (e.g., 100 mCi Tc 99m sodium pertechnetate @ 1300); Total volume; Reference to the MFR; Any deviation from the MFR, if applicable; Name of vendor or manufacturer, lot numbers, and expiration dates of all ingredients and components; Name of the person who prepared and name of the supervising personnel (e.g., ANP or AU physician); Date and time of preparation; Assigned internal identification number (e.g., lot number); Unique reference [e.g., prescription, order number(s)]; Assigned BUD and storage requirements; Documentation of QC results.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	235.	a Name of the radiopharmaceutical		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	235.	b Physical form		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	235.	c Name and quantity of ingredients including calibration time for radioactive ingredients		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	235.	d Total volume		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	235.	e Reference to the MFR		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	235.	f Any deviation from the MFR, if applicable		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	235.	g Name of vendor or manufacturer, lot numbers, and expiration dates of all ingredients and components		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	235.	h Name of the person who prepared and name of the supervising personnel		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	235.	i Date and time of preparation		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	235.	j Assigned internal identification number		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	235.	k Unique reference [e.g., prescription, order number(s)]		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	235.	l Assigned BUD and storage requirements		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	235.	m Documentation of QC results		

**PREPARATION**

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	236.	Does the individual responsible for preparing the radiopharmaceutical(s) ensure that the final preparation complies with quality and purity specifications throughout the assigned BUD?	<b>USP Chapter 825– 10. Preparation</b> The individual responsible for preparing the radiopharmaceutical(s) must ensure that the final preparation complies with quality and purity specifications throughout the assigned BUD. This includes, as appropriate for the reparation, radionuclidic purity, radiochemical purity, chemical purity, and physical and chemical properties.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	237.	Do deviations from manufacturer preparation instructions for radiopharmaceuticals maintain the same ingredients but may differ in their proportions?	<b>USP Chapter 825– 10.2 Preparation with Minor Deviations</b> 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. Note that General Notices, 5.20.20.1 In Compounded Preparations includes the statement: “Deviation from the specified processes or methods of compounding, although not from the ingredients or proportions thereof, may occur provided that the finished preparation conforms to the relevant standards and to preparations produced by following the specified process.” However, except for a few receptor-based radiopharmaceuticals where specific activity is an important parameter, there is a very broad range of acceptable values for specific activity and for proportions of ingredients. Deviations from manufacturer preparation instructions for radiopharmaceuticals must maintain the same ingredients but may differ in their proportions. This requires appropriate in-house QC testing, designed to validate the radiochemical purity of the product for the entirety of the BUD or is supported by appropriate peer-reviewed publications for the minor deviation utilized. Examples of minor deviations include, but are not limited to, the following: Altering the quantity of radioactivity or volume added to the vial; Changes in step-by-step operations (e.g., dilute Tc-99m sodium pertechnetate after rather than before addition to the vial); Using alternative devices or equipment (e.g., a heating block rather than a hot water bath, using a different sized needle, different shielding materials); Using QC test methods other than those described in the product labeling (e.g., radiochemical purity); Filtering Tc-99m sulfur colloid.	

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	238.	Are blood and blood components handled with required precautions using aseptic technique?	<b>USP Chapter 825– 10.3 Preparation of Radiolabeled Blood Components</b> Handling blood and radiolabeling of blood components requires special attention to biological risks and must be handled with standard precautions using aseptic technique to prevent the introduction of new microorganisms into the preparation that will be administered. Due to the potential presence of microorganisms in the original blood sample, the preparation must be administered as soon as possible but no later than 6 hours after the blood sample is obtained from the patient or blood bank. The presence of microorganisms in a blood sample may present a risk to the individual performing the preparation as well as cross-contamination to other blood samples or other non-blood related radiopharmaceuticals. Equipment and supplies should never be shared with other activities unless they are first thoroughly cleaned and disinfected. Special precautions when radiolabeling of blood components for non-immediate use include: There must be 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 must be in place to include certification that the SEC meets conditions of air quality at maximum occupancy under dynamic operating conditions; One radiolabeling procedure per PEC at a time. Blood products from more than one patient must never be manipulated at the same workstation at the same time. Each area should have dedicated supplies, equipment (including dose calibrator), and waste disposal to eliminate sharing of these items or overlap in pathways; Thorough cleaning and disinfection of the ISO Class 5 BSC and all reusable equipment within, prior to starting another blood component radiolabeling procedure; If a dedicated dose calibrator is not available, then a means of preventing the	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	239.	Are blood sample preparations administered within 6 hours of receipt?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	240.	Is there complete physical separation between where blood products are handled and non-blood products?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	241.	Are blood products labeled in ISO Class 5 BSC in an ISO Class 7 buffer area?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	242.	If more than one ISO class 5 PEC is located within the ISO Class 7 buffer area, are policies and SOP's in place?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	243.	Are certifications in place that the SEC meets air quality at maximum occupancy under dynamic operating conditions?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	244.	Is there only one radiolabeling procedure per PEC at a time?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	245.	Are blood products from only one patient manipulated at each workstation at a time?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	246.	If a dedicated dose calibrator is not available, is a dedicated dose calibrator available to prevent the blood containers from contaminating the calibrator?		

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	247.	If a dedicated dose calibrator is not available, are dose calibrator dippers and liners cleaned and disinfected prior to the radioassay?	blood container(s) from contaminating the dose calibrator must be used or the dose calibrator dipper and liner must be cleaned and disinfected following the radioassay; Centrifuge should be located within the ISO Class 7 buffer area that is dedicated for blood component radiolabeling processes; Dedicated (per each radiolabeling procedure) consumable products (e.g., 0.9% sodium chloride injection, diluent, tubes, syringes, and other supplies) necessary for each individual patient radiolabeling procedure; All tubes and syringes in contact with the patient's blood components must be clearly labeled with the patient's name and at least one additional identifier (e.g., date of birth, medical record number, barcode); Dedicated syringe shields and vial shields; Remove and replace any garb that enters the ISO Class 5 BSC before handling anything else not related to performing this procedure; Removal of all disposable items from the ISO Class 5 BSC utilized in each radiolabeling procedure; 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) after each radiolabeling procedure prior to any further use. Policies and SOPs must address cleaning and disinfection processes including the use of an EPA-registered (or equivalent) one-step disinfectant cleaner with activity against blood-borne pathogens followed by sterile 70% IPA. Sterile 70% IPA alone is not sufficient; After the completion of blood radiolabeling procedures, follow all requirements in 4.5 Hand Hygiene and Garbing for Buffer Areas and segregated Radiopharmaceutical Processing Area.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	248.	Are all tubes and syringes in contact with patient blood components clearly labeled?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	249.	Do SOP's address cleaning and disinfection process as required for blood-borne pathogens?		
			250.	Is in vitro red blood cell labeling prepared under the following conditions:	<b>USP Chapter 825-10.4 Preparation of Radiolabeled Red Blood Cells for Immediate Use</b> In vitro red blood cell labeling must be prepared while following the conditions below: A dedicated space for blood handling must be designated through the entirety of the blood radiolabeling process. This area must be free from clutter and not used for any other radiopharmaceutical	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	250.	a A dedicated space for blood handling throughout the entirety of the blood radiolabeling process		

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions	
Yes	No	N/A					
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	250.	b	Area free from clutter and not used for any other preparations or handling prior to cleaning and disinfection	preparation or handling until the completion of cleaning and disinfection; Perform only one radiolabeling procedure at a time or have documented processes that maintain the integrity of samples and environment; Dedicated equipment must be used for blood radiolabeling procedure (e.g., L-block, syringe shield, vial shield, forceps, needle recapper); If a dedicated dose calibrator is not available, then a means of preventing the blood container(s) from contaminating the dose calibrator or a cleaning and disinfecting procedure with an appropriate product must be used to decontaminate the dipper and liner of the dose calibrator following the radioassay; A cleaning and disinfecting procedure with an appropriate agent(s) must be used to decontaminate the area and equipment prior to and after the radiolabeling is complete and all disposable components have been discarded; Follow all requirements in 4.4 Hand Hygiene and Garbing for Immediate Use Preparations; The start time of the preparation must begin 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; BUD of 1 hour (see Table 7).	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	250.	c	Only one procedure labeled at a time or a documented process to maintain integrity of samples and environment		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	250.	d	Equipment dedicated for radiolabeling procedure		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	250.	e	Prevention of blood containers contaminating a dose calibrator if a dedicated dose calibrator is not available		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	250.	f	Dose calibrator cleaned and disinfected if a dedicated calibrator is not available		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	250.	g	Procedure for cleaning and disinfecting with appropriate products used to decontaminate the dipper and liner of the dose calibrator following the radioassay		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	250.	h	Cleaning and disinfecting procedure followed to decontaminate the area and equipment prior to and after the radiolabeling is complete		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	250.	i	Hand hygiene and garbing for immediate use followed		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	250.	j	The start time of the preparation begins with initial container puncture or exposure of critical site		

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions	
Yes	No	N/A					
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	250.	k	A BUD of 1 hour is used for expiration		
<b>COMPOUNDING</b>							
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	251.		<b>USP Chapter 825-11 COMPOUNDING</b> Each compounding activity must be based on a pre-established written procedure and must include maintenance of compounding records. The compounding record must provide traceability (see 9. Documentation). All sterile compounding, using aseptic technique, must be performed in an ISO 5 PEC. Refer to 5.7 Environmental Controls and Table 7 for further clarification on the location of the PEC and the applicability of the radiopharmaceutical BUD. Compounding must 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. Radiopharmaceuticals that are essentially copies of marketed FDA-approved radiopharmaceuticals must not be compounded unless there is a change that produces a clinical difference for an identified individual patient, as determined by a prescriber.		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	252.	Are there written procedures for maintenance of compounding records that provide traceability?			
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	253.	Is sterile compounding performed in an ISO 5 PEC?			
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	254.	Is compounding not performed with any radiopharmaceuticals that have been withdrawn from the market because of safety, lack of effectiveness, unless an institutional review board had approved for investigational study?			
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	255.	Are radiopharmaceuticals not compounded that are essentially copies of FDA-approved radiopharmaceuticals unless there is a change that produces a clinical difference identified by the patient or prescriber?			
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	256.	Are areas designated for nonsterile compounding clean, uncluttered, and separated from sterile radiopharmaceuticals?		<b>USP Chapter 825-11.1 Compounding Nonsterile Radiopharmaceuticals</b> 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. Examples of compounding nonsterile radiopharmaceuticals include: changing the dosage form of a capsule to a solution, changing an	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	257.	Does the placement of equipment and materials take into account a design that prevents cross-contamination?			

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	258.	Does each compound have a unique MFR?	intravenous dosage form to an oral dosage form, and radiolabeling a food for oral administration (e.g., Tc-99m sulfur colloid in eggs). Areas designated for nonsterile compounding must be cleaned and uncluttered and separated from areas designated for sterile radiopharmaceuticals. Compounding should take into account RAM licensing requirements for appropriate radiation safety considerations and utilize appropriate environmental controls, if applicable (e.g., chemical fume hood, activated charcoal filters when handling potentially volatile radionuclides). The placement of equipment and materials must take into account a design that prevents cross-contamination. When feasible, disposable material should be used to reduce the chance of cross-contamination. Each compound must have a unique MFR (see 9.1 Master Formulation Record). The preparation information is documented on a compounding record (see 9.2 Records for Preparation with Minor Deviations/Compounding). The MFR details the selection of all components. The ingredients must be 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 must detail the selection of a material that is suitable for the intended use. The MFR must establish the identity, strength, purity, and quality of the ingredients by validated means (e.g., CoA). Requirements for nonsterile oral meal components are limited to common food grade description and are not required to establish identity by validated means. A BUD for the compounded radiopharmaceutical must be validated, taking into account the stability of the ingredients, any intermediate containers, the final container, and the storage conditions. A BUD cannot be extended past the labeled expiration date of any component in the compound. If the compounded radiopharmaceutical(s) includes components from other preparations or preparations with minor deviations, the BUD of the final compounded radiopharmaceutical must not exceed the shortest remaining BUD of any of those components.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	259.	Are the ingredients obtained from the preferred sources?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	260.	Does the MFR detail ingredients obtained from other sources that are suitable for the intended use?		
			261.	Does the MFR establish the following for non-preferred sources by validated means:		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	261.	a Identity		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	261.	b Strength		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	261.	c Purity		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	261.	d Quality		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	262.	Are BUD's for the compounded radiopharmaceuticals validated?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	263.	Does the BUD not extend past the shortest BUD of any components?		

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	264.	Do personnel responsible for compounding consider all possible interactions between components?	<b>USP Chapter 825-11.2 Sterile Compounding</b> Personnel responsible for compounding must 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. In some cases, this may require systematic QC testing over time to validate the appropriateness of a particular BUD. Another activity that is considered a compounding activity is the splitting of conventionally marketed kits. Kit-splitting (also referred to as "fractionation") may be used to meet patient need. For example, the contents of a kit vial can be reconstituted with 0.9% sodium chloride injection and aliquoted into other containers for storage and subsequent radiolabeling. The individual responsible must consider all possible interactions of kit components with these other containers (e.g., container walls, closures), as well as possible alterations in stability (e.g., physical stability, chemical stability) that may affect radiolabeling yields or performance parameters, when determining an appropriate BUD. Systematic QC testing is required to validate the appropriateness of a particular BUD.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	265.	Does the individual responsible consider all the possible interactions and alteration of stability for kit components if kit-splitting is used?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	266.	If nonsterile components are used is a sterilization and testing procedure performed?	<b>USP Chapter 825-11.3 Sterile Compounding Using a Nonsterile Drug Substance or Components</b> Some sterile compounding activities involve the use of materials other than commercially marketed products, such as drug substances and/or radionuclides. 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) must be performed. 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, and must 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. This may require testing to validate the	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	267.	Does the designated person for compounding consider all possible interactions between components, such as stability, radiochemical stability, solubility, and other parameter?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	268.	Does compounding of bulk drug substances comply with USP and NF monograph standards?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	269.	Does compounding with excipients or other inactive ingredients comply		

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				with USP and NF monograph standards?	appropriateness of a particular BUD. If compounding involves a bulk drug substance, the radiopharmaceutical must comply with standards of an applicable USP or NF monograph, if one exists, or be a component of an approved drug product. For this chapter, 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. Each bulk drug substance should be manufactured by drug establishments registered with FDA and be accompanied by a valid CoA or equivalent testing procedures. If compounding involves excipients or other inactive ingredients, the excipients or other inactive ingredients must comply with standards of an applicable USP or NF monograph, if one exists. It is also acceptable that any excipients or other inactive ingredients be approved products, manufactured by a drug establishment registered with the FDA.	
<b>DISPENSING</b>						
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	270.	Are all opened or final dose form not from the manufacturer radioassayed?	<b>USP Chapter 825-12.1 Dispensing and Radioassay</b> Except for an unopened manufacturer container, the final dose or ordered amount must be radioassayed (i.e., in a dose calibrator). The measured activity should be mathematically corrected for radioactive decay to the time of scheduled administration (calibration time) (refer to 14. Quality Assurance and Quality Control). The activity at calibration time must always be within federal, state, and local variance limits.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	271.	Is the activity at calibration within limits?		
			272.	Does the inner container labeling of radiopharmaceuticals meet the following minimum requirements?	<b>USP Chapter 825-12.2 Labeling</b> The labeling of radiopharmaceuticals can fall under the jurisdiction of numerous regulatory agencies. Individual boards of pharmacy and other regulatory bodies may have very specific statutes and/or regulations concerning this process. The requirements specified in this chapter must be considered the minimum requirements for the labeling	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	272.	a Standard radiation symbol		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	272.	b The words "Caution—Radioactive Material"		

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	272.	c	For all therapeutic and blood-products, the patient name/identifier	<p>of the inner container (e.g., syringe, vial) and the outer shielding (e.g., syringe or vial shielding). Therefore, all personnel distributing and/or dispensing radiopharmaceuticals should verify that any labeling is in compliance with regulatory agencies.</p> <p>The inner container must be labeled with the following: Standard radiation symbol; The words "Caution—Radioactive Material"; For all therapeutic and blood-products, the patient name/identifier; Radionuclide and chemical form (generic name); Radioactivity at the date and time of calibration.</p> <p>The outer shielding must be labeled with the following: Standard radiation symbol; The words "Caution—Radioactive Material"; For all therapeutic and blood-products, the patient name/identifier; Radionuclide and chemical form (generic name); Radioactivity at the date and time of calibration; Volume or number of units dispensed (e.g., 2 capsules), as applicable; Product expiration or BUD (see Table 7), as applicable, and any special storage and handling instructions for nonimmediate use (e.g., refrigeration, resuspension); Route of administration.</p>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	272.	d	Radionuclide and chemical form (generic name)	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	272.	e	Radioactivity at the date and time of calibration	
			273.		Does the outer shielding labeling of radiopharmaceuticals meet the following minimum requirements:	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	273.	a	Standard radiation symbol	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	273.	b	The words "Caution—Radioactive Material"	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	273.	c	For all therapeutic and blood-products, the patient name/identifier	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	273.	d	Radionuclide and chemical form (generic name)	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	273.	e	Radioactivity at the date and time of calibration	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	273.	f	Volume or number of units dispensed, as applicable	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	273.	g	Product expiration or BUD (see Table 7), as applicable, and any special storage and handling instructions for nonimmediate use	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	273.	h	Route of administration	

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
<b>Direct Infusion Systems – Pharmacies that do not utilize Direct Infusion Systems and answer “No” to question 274 may skip question numbers 275-278</b>						
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	274.	Does the facility use radiopharmaceutical direct infusion systems under the guidelines that are described in USP <825> 12.3?	<b>USP Chapter 825-12.3 Direct Infusion Systems</b> The information in this section is limited to the sterility and aseptic technique for direct infusion systems. The described infusion systems are FDA-cleared medical devices or FDA-approved direct infusion generators without an ISO-5 environment. The manner in which all necessary solutions (e.g., radiopharmaceutical and eluant/diluent) are used in conjunction with the system was a consideration in the overall approval process for the system. Therefore, all operators of the direct infusion systems must follow the “Instructions for Use” in the device labeling. Direct infusion generators (e.g., rubidium chloride Rb 82 injection) may employ a container of eluant (e.g., bag of 0.9% sodium chloride injection) to allow administration of the eluate directly to patient(s); Direct infusion devices (e.g., portable PET patient-infusion system) provide a method for dispensing and administration from a multiple-dose container of the radiopharmaceutical (e.g., fludeoxyglucose F 18 injection) and the diluent (e.g., 0.9% sodium chloride injection) directly to patients to reduce the radiation exposure to personnel. In each of these situations, the radiopharmaceutical container must be attached to or be needle-punctured by the respective direct infusion system. Given that such direct infusion systems are intended for multiple patients over the course of several hours, there could be a sterility concern if not operated properly. Therefore, the following parameters must be considered by the operator of the system: Setup attachment or needle-puncture should be performed in a defined environment; Aseptic handling in ambient air with a maximum BUD of 10 hours is allowed for these direct infusion systems (see Table7). The 0.9% sodium chloride	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	275.	Do all operators of the direct infusion systems follow the “Instructions for Use” in the device labeling?		
			276.	In the following situations, is the radiopharmaceutical container attached to or needle-punctured by the respective direct infusion system:		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	276. a	Direct infusion generators that employ a container of eluant to allow administration of the eluate directly to patient(s)		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	276. b	Direct infusion devices that provide a method for dispensing and administration from a multiple-dose container of the radiopharmaceutical directly to patients to reduce the radiation exposure to personnel		
			277.	Are the following parameters considered by the operator of the system if it is intended for multiple patients over the course of several hours:		

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	277.	a	Setup attachment or needle-puncture should be performed in a defined environment	bag attached to the device may only be punctured once and may be used for no more than 10 hours. The bag must be labeled with the date and time of puncture and the BUD; Any nonsterile parts of the device that may encounter the septum of the radiopharmaceutical vial must be disinfected with sterile 70% IPA prior to puncturing the vial with the needle; The septum of any vial and the ports of any diluent bag must be wiped with sterile 70% IPA prior to puncturing; When puncturing the vial in ambient air, it must only be punctured once; If there are problems with the infusion device, no sterile container(s) associated with the system can be repunctured or transferred to a PEC for further manipulations and the container, with contents, must be discarded.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	277.	b	Aseptic handling in ambient air with a maximum BUD of 10 hours is allowed for these direct infusion systems (see Table 7)	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	277.	c	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 must be labeled with the date and time of puncture and the BUD	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	277.	d	Any nonsterile parts of the device that may encounter the septum of the radiopharmaceutical vial must be disinfected with sterile 70% IPA prior to puncturing the vial with the needle	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	277.	e	The septum of any vial and the ports of any diluent bag must be wiped with sterile 70% IPA prior to puncturing	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	277.	f	When puncturing the vial in ambient air, it must only be punctured once	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	277.	g	If there are problems with the infusion device, no sterile container(s) associated with the system can be repunctured or transferred to a PEC for further manipulations and the container, with contents, must be discarded	

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			278.	Are the following standards followed if transporting generators between facilities:	<b>USP Chapter 825- 12.4 Transporting Generators Between Facilities</b> The following standards must be followed if transporting generators between facilities: The generator needle and/or ports must be capped in ISO Class 8 air or better with sterile protectors; The generator must be packaged and transported in a manner to maintain the integrity and sterility of the generator system.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	278.	a The generator needle and/or ports capped in ISO Class 8 air or better with sterile protectors		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	278.	b The generator is packaged and transported in a manner to maintain the integrity and sterility of the generator system		

**REPACKAGING**

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	279.	Are opened or repackaged radiopharmaceuticals radioassayed?	<b>USP Chapter 825-13 REPACKAGING</b> Repackaging refers to the act of removing 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. Repackaging also includes the act of placing the contents of multiple containers of the same finished drug product into one container, as long as the container does not include other ingredients. Repackaging may be performed for nonsterile radiopharmaceuticals (e.g., I-131 sodium iodide oral capsules) and for sterile radiopharmaceuticals (e.g., thallous chloride Tl 201 injection). Except for unopened manufacturer dosage units (e.g., capsules, Xe-133 vials), the repackaged radiopharmaceutical must be radioassayed (i.e., in a dose calibrator). The inner container should be labeled with the following: Standard radiation symbol; The words "Caution—Radioactive Material"; The radionuclide and chemical form (generic name); Radioactivity with units at time of calibration and the calibration time The outer shielding should be labeled with the following: Standard radiation symbol; The words "Caution—Radioactive Material"; The radionuclide and chemical form (generic name); Radioactivity with units at time of calibration and the calibration time; Volume, or number of units (e.g.,	
--------------------------	--------------------------	--------------------------	------	---	---	--

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
					capsules), as applicable; Product expiration or BUD (see Table 7), as applicable; Special storage and handling instructions.	
<b>QUALITY ASSURANCE AND QUALITY CONTROL</b>						
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	280.	Do the facility's QA and QC programs establish and document in SOPs that all aspects of the handling of radiopharmaceuticals are conducted in accordance with this chapter and applicable laws and regulations?	<b>USP Chapter 825-14 QUALITY ASSURANCE AND QUALITY CONTROL</b> Quality assurance (QA) is a system of procedures, activities, and oversight that ensures that radiopharmaceutical processing consistently meets quality standards (see Quality Assurance in Pharmaceutical Compounding 1163). Quality control (QC) is the sampling, testing, and documentation of results that, taken together, ensure that specifications have been met before release of the radiopharmaceutical(s). A facility's QA and QC programs must be 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. A designated person must ensure that the facility has formal, written QA and QC programs that establish a system of: 1. Adherence to procedures, 2. Prevention and detection of errors and other quality problems, 3. Evaluation of complaints and adverse events, and 4. Appropriate investigations and corrective actions. The SOPs must describe the roles, duties, and training of the personnel responsible for each aspect of the QA program. The overall QA and QC program must be reviewed at least once every 12 months by the designated person. The results of the review must be documented and appropriate corrective action taken, if needed.	
			281.	Does a designated person ensure that the facility has written QA and QC programs that establish a system of the following:		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	281.	a Adherence to procedures		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	281.	b Prevention and detection of errors and other quality problems		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	281.	c Evaluation of complaints and adverse events		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	281.	d Appropriate investigations and corrective actions		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	282.	Do the SOPs describe the roles, duties, and training of the personnel responsible for each aspect of the QA program?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	283.	Is the overall QA and QC program reviewed at least once every 12 months by the designated person?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	284.	Are the results of the review documented and appropriate corrective action taken, if needed?		

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	285.	Does the facility have SOPs if a radiopharmaceutical is dispensed or administered before the results of release testing are known?	<b>USP Chapter 825-14.1 Notification About and Recall of Out-of-Specification Dispensed Radiopharmaceuticals</b> If a radiopharmaceutical is dispensed or administered before the results of release testing are known, the facility must have SOPs in place to: 1. 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), and 2. Determine whether a recall is necessary. The SOP for recall of out-of-specification dispensed radiopharmaceuticals must contain procedures to: Determine the severity of the problem and the urgency for the implementation and completion of the recall; Determine the distribution of any affected radiopharmaceutical, including the date and quantity; Identify patients who have received the radiopharmaceutical; Outline the disposition and reconciliation of the recalled radiopharmaceutical The facility must document the implementation of the recall procedures. The recall must be 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).	
			286.	Does the facility's SOPs include the following:		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	286.	a Immediately notify the prescriber of a failure of specifications with the potential to cause patient harm		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	286.	b Determine whether a recall is necessary		
			287.	Does the SOP for recall of out-of-specification dispensed radiopharmaceuticals contain procedures to:		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	287.	a Determine the severity of the problem and the urgency for the implementation and completion of the recall		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	287.	b Determine the distribution of any affected radiopharmaceutical, including the date and quantity		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	287.	c Identify patients who have received the radiopharmaceutical		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	287.	d Outline the disposition and reconciliation of the recalled radiopharmaceutical		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	288.	Does the facility document the implementation of recall procedures?		

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	289.	Are recalls reported to appropriate regulatory bodies as required by laws and regulations of the applicable regulatory jurisdiction?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	290.	Has the radiopharmaceutical facility developed and implemented SOPs for handling complaints?	<b>USP Chapter 825-14.2 Complaint Handling</b> Radiopharmaceutical facilities must develop and implement SOPs for handling complaints. Complaints may include concerns or reports on the quality and container labeling of, or possible adverse reactions to, a specific radiopharmaceutical.  A designated person must review all complaints to determine if they indicate potential quality problems with the radiopharmaceutical. If a complaint does, an investigation into the potential cause of the problem must be completed. The investigation must consider whether the quality problem could extend to other radiopharmaceuticals. Corrective action, if necessary, must be implemented for all potentially affected radiopharmaceuticals. 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. A readily retrievable record (written or electronic) of each complaint must be kept by the facility, regardless of the source of the complaint (e.g., e-mail, telephone, mail). The record must contain the name of the complainant, the date the complaint was received, the nature of the complaint, the response to the complaint, and, if known, the name and strength of the radiopharmaceutical and the assigned internal identification number (e.g., prescription, order, or lot number). The record must also include the findings of any investigation and any follow-up. Records of complaints must be easily retrievable for review and evaluation for possible trends and must be retained in accordance with the record keeping requirements in 9. Documentation. A radiopharmaceutical that is returned in connection with a complaint must be quarantined until it is destroyed after	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	291.	Does a designated person review all complaints?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	292.	Is an investigation into the potential cause of the problem completed if a complaint indicates potential quality problems with the radiopharmaceutical?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	293.	Does the investigation consider whether the quality problem could extend to other radiopharmaceuticals?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	294.	Is a corrective action implemented, if necessary, for all potentially affected radiopharmaceuticals?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	295.	Is a readily retrievable record (written or electronic) of each complaint kept by the facility, regardless of the source of the complaint?		
			296.	Does the record contain the following:		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	296.	a The name of the complainant		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	296.	b The date the complaint was received		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	296.	c The nature of the complaint		

2026 Radiopharmaceuticals Self-Inspection Addendum

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	296.	d	The response to the complaint	completion of the investigation and in accordance with applicable jurisdictional laws and regulations.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	296.	e	The name and strength of the radiopharmaceutical (if known)	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	296.	f	The assigned internal identification number	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	296.	g	The findings of any investigation	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	296.	h	Any follow-up of any investigation	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	297.		Are records of complaints retrievable for review and evaluation for a possible trend?	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	298.		Are records of complaints retained in accordance with the record keeping requirements in 9. Documentation?	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	299.		Are returned radiopharmaceutical in connection with a complaint quarantined until it is destroyed after completion of the investigation and in accordance with applicable laws and regulations?	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	300.		Are adverse events potentially associated with the quality of radiopharmaceuticals reported in accordance with the facility's SOPs and all applicable laws and regulations?	<b>USP Chapter 825-14.3 Adverse Event Reporting</b> Adverse events potentially associated with the quality of radiopharmaceuticals must be reported in accordance with the facility's SOPs and all applicable jurisdictional laws and regulations. In addition, adverse events potentially associated with the quality of the radiopharmaceutical preparation should be reported to the applicable jurisdictional regulatory body (e.g., state boards of pharmacy, state health departments, FDA's MedWatch program for human drugs).

**Table 7. Preparation Conditions for Sterile Radiopharmaceuticals<sup>1</sup>**

Preparation Conditions			
Manipulation	PEC	SEC	BUD (hours)
Immediate use	--	--	1
Direct infusion system, one puncture only (e.g., PET patient infusion system, Rb-82 generator)	--	--	10
Dispensing, repackaging, preparation, and preparation with minor deviations	ISO Class 5	SRPA	12
Radionuclide generator storage/ elution (e.g., non-direct infusion system; Tc-99m or Ga-68)	--	SRPA with ISO Class 8 total airborne particle count	12
Radionuclide generator storage/ elution (e.g., non-direct infusion system; Tc-99m or Ga-68)	--	ISO Class 8 or better buffer area with ISO Class 8 or better ante-room	24
Dispensing, repackaging, preparation, and preparation with minor deviations	ISO Class 5	ISO Class 8 or better buffer area with ISO Class 8 or better ante-room	24
Dispensing, repackaging, preparation, preparation with minor deviations, and compounding using sterile components	ISO Class 5	ISO Class 7 or better buffer area with ISO Class 8 or better ante-room	96
Dispensing, repackaging, preparation, preparation with minor deviations, and compounding using a nonsterile component and performing sterilization procedure (e.g., filtration with bubble point testing) but without performing <i>Sterility Tests (71)</i> testing	ISO Class 5	ISO Class 7 or better buffer area with ISO Class 8 or better ante-room	24
Radiolabeled blood components for immediate use [e.g., Tc 99m red blood cells (RBC)]	--	--	1
Radiolabeled blood components (e.g., radiolabeled leukocytes)	ISO Class 5 BSC	ISO Class 7 or better buffer area with ISO Class 8 or better ante-room	6 h after the blood sample is obtained

<sup>1</sup> The United States pharmacopeia. National formulary. General Chapter <825>. Rockville (MD): United States Pharmacopeial Convention; 2020. Table 7; p.17.  
DOH 690-369 (January 2026)