Kentucky Board of Pharmacy
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USP <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging

Pharmacy: _____ Permit: _____ Inspection Date: ____
Address: _____ City: _____ State: _____

List of other states pharmacy permitted by:

1.	6.
2.	7.
3.	8.
4.	9.
5.	10.

Document any waivers under 201 KAR 2:076 Section 2:

Designated Person(s):

Policies and Procedures/Standard Operating Procedures (SOP)	**Compliant**	**Non-Compliant**	**N/A**	**Not Inspected**
Purchase, receipt, storage, manipulation, compounding, distribution and disposal of radioactive materials. *201 KAR 2:215 Section 2 (3)*				
Personnel training and testing. *USP <825> 4. Personnel Qualifications, Training, and Hygiene and 9. Documentation*				
Garbing and hand hygiene. *USP <825> 4.1 Aseptic Qualifications; and 4.5 Hand Hygiene and Garbing for Buffer Areas and SRPA*				
Cleaning and disinfecting. *USP <825> 4.2 Reevaluation, Retraining, and Requalification and 7. Cleaning and Disinfecting*				
Monitoring for radioactive contamination and decontamination of those surfaces. *USP <825> 7.2 Cleaning Supplies and 7.3 Cleaning and Disinfecting the PEC*				
Handling and manipulation of blood-derived or other biological material and biohazardous radioactive sharps to avoid contamination. *USP <825> 2.4 Radiation Contamination Control, 5.5 Classified Areas, 7.6 Cleaning and Disinfecting Items from Patient Care Area and 10.3 Preparation of Radiolabeled Blood Components*				
Testing and monitoring of environmental controls. *USP <825> 5.1 Facility Design and Environmental Controls and 9. Documentation*				
Environmental monitoring: Viable air and surface sampling. *USP <825> 6. Microbiological Air and Surface Monitoring and 9. Documentation*				
Equipment maintenance. *USP <825> 9. Documentation*				
Assignment of BUD *USP <825>8. Assigning BUD*				
End product radiochemical purity and other testing, as applicable. *USP <825> 9. Documentation*				
Master Formulation Record (MFR). *USP <825> 9. Documentation*				
Quality assurance and quality control programs. *USP <825> 9. Documentation and 14. Quality Assurance and Quality Control*				
Dispensing prior to results of release testing. *USP <825> 14.1 Notification About and Recall of Out-of-Specification Dispensed Radiopharmaceuticals*				

Recalls, Complaints, and Adverse Events. *USP <825> 8. Assigning BUD, 14.1 Notification About and Recall of Out-of-Specification Dispensed Radiopharmaceuticals, 14.2 Complaint Handling, and 14.3 Adverse Event Reporting*				
Policies and Procedures reviewed and revised annually. *201 KAR 2:076 Section 1 (3)*				
Comments:				

Nonsterile Radiopharmaceuticals	**Compliant**	**Non-Compliant**	**N/A**	**Not Inspected**
Personnel trained per facility policy. *USP <825> 4. Personnel Qualifications, Training, and Hygiene*				
Personnel garbed per facility policy. *USP <825> 4. Personnel Qualifications, Training, and Hygiene*				
Nonsterile processing area has appropriate environmental controls, if applicable: • Negative air pressure area • Chemical fume hood • Activated charcoal filters *USP <825> 10.1 Preparation Following Manufacturer Instructions, 11.1 Compounding Nonsterile Radiopharmaceuticals, 12.1 Dispensing and Radioassay, and 13. Repackaging*				
Nonsterile processing area is clean and uncluttered. *USP <825> 10.1 Preparation Following Manufacturer Instructions, 11.1 Compounding Nonsterile Radiopharmaceuticals, 12.1 Dispensing and Radioassay, and 13. Repackaging*				
Nonsterile processing area is separate from sterile processing area. *USP <825> 10.1 Preparation Following Manufacturer Instructions, 11.1 Compounding Nonsterile Radiopharmaceuticals, 12.1 Dispensing and Radioassay, and 13. Repackaging*				
Documented process for cleaning nonsterile processing area between preparation cycles of different nonsterile products. *USP <825> 10.1 Preparation Following Manufacturer Instructions, 11.1 Compounding Nonsterile Radiopharmaceuticals, 12.1 Dispensing and Radioassay, and 13. Repackaging*				
Documented master formulation record and preparation record for all compounded preparations or preparations with minor deviations. *USP <825> 9.1 Master Formulation Record and 9.2 Records for Preparation with Minor Deviations/Compounding*				
Master formulation record documents: • Name of the radiopharmaceutical • Name, identity, strength, purity, and quantity of ingredients • Detailed procedure • Range of radioactivity and range of volume • Equipment to be used including PEC or SEC, if applicable • Required quality control tests • Trained personnel and required garbing if different from SOP • Container • Reference for BUD assignment and storage conditions *USP <825> 9.1 Master Formulation Record*				
Preparation record for preparations with minor deviations or compounded preparations documents: • Name of the radiopharmaceutical • Physical form or dosage form • Name and quantity of ingredients including calibration time for radioactive ingredients • Total volume				

• Reference to MFR and any deviations from MFR • Name of manufacturer/vendor, lot numbers and expiration dates of all ingredients and components • Name of compounder and verifying/supervising pharmacist • Date and time of preparation • Assigned lot number and/or prescription/order number • BUD and storage requirements • Quality control results *USP <825> 9.2 Records for Preparations with Minor Deviations/Compounding*				
Nonsterile radiopharmaceuticals appropriately radioassayed. *USP <825> 12.1 Dispensing and Radioassay*				
Inner container appropriately labeled with: • Standard radiation symbol • "Caution-Radioactive Material" • Patient name/identifier for all therapeutic products • Radionuclide and chemical form • Radioactivity at the date and time of calibration *USP <825> 12.2 Labeling*				
Outer container/shielding appropriately labeled with: • Standard radiation symbol • "Caution-Radioactive Material" • Patient name/identifier for all therapeutic products • Radionuclide and chemical form • Radioactivity at the date and time of calibration • Volume or number of units dispensed • Product expiration or BUD and any special storage and handling instructions • Route of administration *USP <825> 12.2 Labeling*				
Comments:				

Sterile Training: *For those facilities not performing sterile compounding from nonsterile drug substances or components.*	**Compliant**	**Non-Compliant**	**N/A**	**Not Inspected**
Documentation all applicable personnel passed initial and annual written exam including: • Cleaning and disinfecting; • Hand hygiene and garbing; and • Aseptic technique. *USP <825> 4.1 Aseptic Qualifications and 4.2 Reevaluation, Retraining, and Requalification*				
Observed and appropriately documented cleaning and disinfection qualification, initially, with any change in SOPs, and annually. Includes ancillary, non-compounding personnel, if applicable. *USP <825> 4.1 Aseptic Qualifications and 4.2 Reevaluation, Retraining, and Requalification*				
Observed and appropriately documented hand hygiene and garbing qualification, initially and annually. Includes ancillary, non-compounding personnel, if applicable. *USP <825> 4.1 Aseptic Qualifications and 4.2 Reevaluation, Retraining, and Requalification*				
Observed and appropriately documented aseptic technique qualification, initially and annually. *USP <825> 4.1 Aseptic Qualifications and 4.2 Reevaluation, Retraining, and Requalification*				
Observed and appropriately documented three initial gloved fingertip and thumb samplings, performed immediately following hand hygiene and garbing, with zero				

growth. Includes ancillary, non-compounding personnel, if applicable. *USP <825> 4.1 Aseptic Qualifications and 4.2 Reevaluation, Retraining, and Requalification*				
Observed and appropriately documented annual gloved fingertip and thumb samplings, performed after media fill, with ≤ 3 total CFUs. *USP <825> 4.1 Aseptic Qualifications and 4.2 Reevaluation, Retraining, and Requalification*				
Observed and appropriately documented initial and annual media fill test simulating the most challenging and stressful work conditions. *USP <825> 4.1 Aseptic Qualifications and 4.2 Reevaluation, Retraining, and Requalification*				
Observations performed by designated person(s). USP <825> *4.1 Aseptic Qualifications*				
Documentation of retraining, reevaluation and retesting of personnel who fail any testing or qualifications. *USP <825> 4.2 Reevaluation, Retraining, and Requalification*				
Personnel that have not performed sterile radiopharmaceutical processing for more than 6 months are requalified prior to resuming duties. *USP <825> 4.2 Reevaluation, Retraining, and Requalification*				
Comments:				

Garbing in Buffer Areas and Segregated Radiopharmaceutical Processing Area (SRPA)	**Compliant**	**Non-Compliant**	**N/A**	**Not Inspected**
Personnel remove outer garments, make-up, all hand, wrist and other exposed jewelry including piercings that can interfere with effectiveness of garbing. Radiation dosimetry devices are allowed. *USP <825> 4.5 Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Area*				
Personnel keep nails natural and short. *USP <825> 4.5 Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Area*				
Personnel report conditions that may pose a higher potential of contaminating environment with microorganisms (e.g. rashes, sunburn, recent tattoos, oozing sores, conjunctivitis, or active respiratory infection) and designated person evaluates whether individual may enter buffer area or SRPA. *USP <825> 4. Personnel Qualifications, Training, and Hygiene*				
Garb with shoe covers, head/hair/facial hair covers and facemask in order per facility SOPs and to minimize risk of contamination. *USP <825> 4.5 Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Area*				
Performs hand hygiene appropriately up to the elbows for 30 seconds and under nails. *USP <825> 4.5 Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Area*				
Use appropriate alcohol-based hand rub. *USP <825> 4.5 Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Area*				
Sterile gloves donned appropriately. *USP <825> 4.5 Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Area*				
Dispose of disposable gowns when leaving buffer area or SRPA or may re-use gown for one shift if maintained properly. Disposable gowns preferred, if re-usable gowns used - clean gown must be donned daily. *USP <825> 4.5 Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Area*				
Non-garbed personnel are not entering buffer area or SRPA. *USP <825> 4. Personnel Qualifications, Training, and Hygiene*				
Comments:				

Ante and Buffer Areas	**Compliant**	**Non-Compliant**	**N/A**	**Not Inspected**
Floor is smooth, impervious, free from cracks and crevices, non-shedding and sealed and coved where it meets the walls. *USP <825> 5.2 Creating Areas to Achieve Easily Cleanable Conditions*				
Ceilings are smooth, impervious, free from cracks and crevices, non-shedding and sealed where it meets the walls. Ceiling tiles are caulked or otherwise sealed to support frame. *USP <825> 5.2 Creating Areas to Achieve Easily Cleanable Conditions*				
Walls are constructed of or covered with a durable material (i.e. epoxy paint). smooth, impervious, free from cracks and crevices, non-shedding and sealed. *USP <825> 5.2 Creating Areas to Achieve Easily Cleanable Conditions*				
Accessories and furniture are easily cleanable, smooth, impervious, free from cracks and crevices, and non-shedding. Limited to necessary equipment in ante and buffer areas. *USP <825> 5.2 Creating Areas to Achieve Easily Cleanable Conditions and 5.4 Placement and Movement of Materials*				
Sink appropriately located. *USP <825> 5.3 Water Sources*				
Buffer area has no sink, drain, or water source. *USP <825> 5.3 Water Sources*				
Temperature recorded daily. Ante and buffer area temperature maintained at 25 C or cooler. *USP <825> 5.1 Facility Design and Environmental Controls and 5.7 Environmental Controls*				
Drugs stored at appropriate controlled storage temperatures: Controlled room temperature per USP <659>, generally 68-77 F or 20-25 C. *USP <825> 5.7 Environmental Controls*				
Drugs stored at appropriate controlled storage temperatures: Controlled cold temperature per USP <659>, generally 36-46 F or 2-8 C. *USP <825> 5.7 Environmental Controls*				
Drugs stored at appropriate controlled storage temperatures: Freezer temperature per USP <659>, generally -13 to 14 F or -25 to -10 C. *USP <825> 5.7 Environmental Controls*				
Humidity recorded daily. Relative humidity should be maintained below 60%. *USP <825> 5.7 Environmental Controls*				
Temperature and humidity monitoring devices verified for accuracy every 12 months or as required by manufacturer. *USP <825> 5.1 Facility Design and Environmental Controls and 5.7 Environmental Controls*				
Pressure is record daily. *USP <825> 5.7 Environmental Controls*				
Buffer room is positive pressure of at least 0.02-inch water column to ante room. *USP <825> 5.7 Environmental Controls*				
Ante room is positive pressure of at least 0.02-inch water column to unclassified portions of the restricted area. *USP <825> Environmental Controls*				
Restricted area is negative pressure compared to unrestricted area, if applicable per RAM license (i.e. volatile or airborne radiopharmaceuticals: I-131 or Xenon). *USP <825> 5.7 Environmental Control*				
No tacky surfaces or mats inside ISO classified areas. *USP <825> 5.1 Facility Design and Environmental Controls*				
Proper use of line of demarcation. *USP <825> 5.1 Facility Design and Environmental Controls*				
Comments:				
Segregated Radiopharmaceutical Processing Area (SRPA)	**Compliant**	**Non-Compliant**	**N/A**	**Not Inspected**

All surfaces (e.g., walls, floors, counters, equipment) clean, uncluttered and dedicated to sterile processing activities. *USP <825> 5.2 Creating Areas to Achieve Easily Cleanable Conditions*				
All surfaces (e.g., walls, floors, counters, equipment) smooth, impervious, free from cracks and crevices, and non-shedding. *USP <825> Creating Areas to Achieve Easily Cleanable Conditions*				
Accessories and furniture are easily cleanable, smooth, impervious, free from cracks and crevices, and non-shedding. Limited to necessary equipment in SRPA. *USP <825> 5.2 Creating Areas to Achieve Easily Cleanable Conditions and 5.4 Placement and Movement of Materials*				
Sink appropriately located. *USP <825> 5.3 Water Sources*				
Temperature recorded daily. SRPA temperature maintained at 25 C or cooler. *USP <825> 5.1. Facility Design and Environmental Controls and 5.7 Environmental Controls*				
Drugs stored at appropriate controlled storage temperatures: Controlled room temperature per USP <659>, generally 68-77 F or 20-25 C. *USP <825> 5.7 Environmental Controls*				
Drugs stored at appropriate controlled storage temperatures: Controlled cold temperature per USP <659>, generally 36-46 F or 2-8 C. *USP <825> 5.7 Environmental Controls*				
Drugs stored at appropriate controlled storage temperatures: Freezer temperature per USP <659>, generally -13 to 14 F or -25 to -10 C. *USP <825> 5.7 Environmental Controls*				
Humidity recorded daily. Relative humidity should be maintained below 60%. *USP <825> 5.7 Environmental Controls*				
Temperature and humidity monitoring devices verified for accuracy every 12 months or as required by manufacturer. *USP <825> 5.1 Facility Design and Environmental Controls and 5.7 Environmental Controls*				
Restricted area is negative pressure compared to unrestricted area, if applicable per RAM license (i.e. volatile or airborne radiopharmaceuticals: I-131 or Xenon). *USP <825> 5.7 Environmental Control*				
Non-direct infusion radionuclide generators stored and eluted in area that meets ISO Class 8 particle count classification. *USP <825> 5.7 Environmental Controls*				
Comments:				

Cleaning: Sterile Processing Areas	**Compliant**	**Non-Compliant**	**N/A**	**Not Inspected**
Personnel appropriately garbed when cleaning. *USP <825> 7. Cleaning and Disinfecting*				
Cleaning and disinfecting agent (may be EPA registered one-step disinfectant cleaner) appropriate for bacteria, fungi and viruses. *USP <825> 7. Cleaning and Disinfecting*				
Cleaning equipment is low-linting, disposable or dedicated. Reusable cleaning equipment cleaned and disinfected before and after each use. *USP <825> 7.2 Cleaning Supplies*				
Daily cleaning and disinfecting of Ante and Buffer area or SRPA including work surfaces, sink and floors. *USP <825> 7. Cleaning and Disinfecting*				
Daily cleaning and disinfecting of hot-cell. *USP <825> 7. Cleaning and Disinfecting*				
Daily cleaning and disinfecting of ISO 5 PEC and all equipment within PEC. *USP <825> 7. Cleaning and Disinfecting*				
Cleaning and disinfecting of ISO 5 PEC includes the following: • Survey for radioactive contamination				

• Removal of any particles, debris, or residue with appropriate solution (i.e. sterile water) and sterile, low-lint wipers. • Cleaning and disinfecting agent applied for specified contact time. • Sterile 70% IPA applied. • Surface allowed to dry completely before beginning activity. • Sporicidal agent used at least monthly. *USP <825> 7.3 Cleaning and Disinfecting the PEC*				
Monthly cleaning of ceilings, walls, and storage shelving and storage bins within Ante and Buffer area or SRPA. *USP <825> 7. Cleaning and Disinfecting*				
Monthly use of appropriate sporicidal agent on all surfaces and PEC within Ante and Buffer area and SRPA. *USP <825> 7. Cleaning and Disinfecting*				
Cleaning, disinfecting and sporicidal agents allowed to dwell based on manufacturer specified minimum contact time. *USP <825> 7.1 Cleaning, Disinfecting, and Sporicidal Agents*				
Radiation shielding and other equipment used in ante and buffer area, SRPA, or PEC exposed to patient care areas cleaned and disinfected before returning to processing areas. *USP <825> 7.6 Cleaning and Disinfecting Items from Patient Care Area*				
Comments:				

Environmental Monitoring and Certification of Ante and Buffer Areas	**Compliant**	**Non-Compliant**	**N/A**	**Not Inspected**
All ISO Class 5 PECs and ISO Class 7 and/or ISO Class 8 rooms have been certified as required. *USP <825> 5.7 Environmental Controls*				
Review report from certifier. **Certifier: Date:**				
Certification performed to CETA standards or equivalent standards. *USP <825> 5.7 Environmental Controls*				
Certifier's equipment calibrated to manufacturer standards. *USP <825> 5.7 Environmental Controls*				
Ante room has HEPA filtered air certified to ISO Class 8 or better. *USP <825> 5.7 Environmental Controls*				
Ante room has appropriate ACPH: ISO Class 8 minimum 20 ACPH, ISO Class 7 minimum 30 ACPH. *USP <825> 5.1 Facility Design and Environmental Controls and 5.7 Environmental Controls*				
Minimum 0.02-inch water column positive pressure differential from ante room to unclassified portions of restricted area. *USP <825> 5.7 Environmental Controls*				
Buffer room has HEPA filtered air certified to ISO Class 7 or better. *USP <825> 5.7 Environmental Controls*				
Buffer room has minimum 30 ACPH, 15 ACPH must be supplied by room HVAC. *USP <825> 5.1 Facility Design and Environmental Controls and 5.7 Environmental Controls*				
Minimum 0.02-inch water column positive pressure differential from buffer room to ante room. *USP <825> 5.7 Environmental Controls*				
ISO Class 7 areas not more than 352,000 particles per cubic meter of air, taken under dynamic conditions. *USP <825> 5.1 Facility Design and Environmental Controls and 5.7 Environmental Controls*				
ISO Class 8 area not more than 3,520,000 particles per cubic meter of air, taken under dynamic conditions. *USP <825> 5.1 Facility Design and Environmental Controls and 5.7 Environmental Controls*				
Room HEPA filters leak tested and repaired if needed. *USP <825> 5.7 Environmental Controls*				
PEC(s) certified to meet ISO Class 5 or better conditions. *USP <825> 5.1 Facility Design and Environmental Controls and 5.7 Environmental Controls*				

ISO Class 5 area not more than 3,520 particles per cubic meter of air, taken under dynamic conditions. *USP <825> 5.1 Facility Design and Environmental Controls and 5.7 Environmental Controls*				
Smoke visualization study performed at least every 6 months in direct processing area to demonstrate unidirectional airflow under simulated or dynamic conditions. *USP <825> 5.1 Facility Design and Environmental Controls and 5.7 Environmental Controls*				
PEC HEPA filters leak tested and repaired if needed. *USP <825> 5.7 Environmental Controls*				
PEC airflow velocity measured. *USP <825> 5.7 Environmental Controls*				
Radionuclide storage and elution area certified to ISO Class 8 or better. *USP <825> 5.7 Environmental Controls and 8.Assigning BUD*				
Air and surface microbial sampling performed in all classified areas under simulated or dynamic conditions. *USP <825> 6.1 General Monitoring Requirements*				
Air and surface monitoring program includes documentation of: • Date and time of sampling; • Sampling locations; • Method of collection; • Frequency of sampling; • Size of samples (e.g., surface area, volume of air); • Time of day in relation to processing activities; and • Action levels. *USP <825> 6. Microbiological Air and Surface Monitoring*				
Viable air sampling of all classified areas and PECs performed at least every 6 months using active impaction device during dynamic or simulated operating conditions with 1000 liters of air sampled. *USP <825> 6.2 Monitoring Air Quality for Viable Airborne Particles*				
Viable air sampling performed with appropriate growth media and proper incubation of media to support growth of bacteria and fungi. *USP <825> 6.2 Monitoring Air Quality for Viable Airborne Particles*				
Viable air microbial action levels: • ISO Class 5: >1 CFU • ISO Class 7: >10 CFU • ISO Class 8: >100 CFU *USP <825> 6.2 Monitoring Air Quality for Viable Airborne Particles*				
Surface sampling performed at least monthly in: • All classified areas, including frequently touched surfaces; • PEC; • Direct processing area and any permanent equipment in PEC; • Staging and work surfaces near the PEC; and • Pass through. *USP <825> 6.3 Monitoring Surfaces for Viable Particles*				
Surface sampling performed at end of activities or shift and prior to cleaning and disinfecting in conformance with ALARA standards. *USP <825> 6.3 Monitoring Surfaces for Viable Particles*				
Surface sampling performed with appropriate microbial growth media supplemented with neutralizing additives (e.g., TSA with lecithin and polysorbate 80) and media properly incubated to support bacteria and fungi growth. *USP <825> 6.3 Monitoring Surfaces for Viable Particles*				
Surface sampling microbial action levels: • ISO Class 5: >3 CFU • ISO Class 7: >5 CFU • ISO Class 8: >50 CFU *USP <825> 6.3 Monitoring Surfaces for Viable Particles*				
Incubators located outside of any classified area or SRPA and temperature recorded daily during incubation with calibrated measuring device. *USP <825> 6.2*				

Monitoring Air Quality for Viable Airborne Particles and 6.3 Monitoring Surfaces for Viable Particles				
If action levels for either air or surface sampling exceeded, CFU to be identified to the genus level. *USP <825> 6.2 Monitoring Air Quality for Viable Airborne Particles and 6.3 Monitoring Surfaces for Viable Particles*				
Documented investigation and corrective action plan when air or surface sampling action levels exceeded to include evaluation of personnel practices, effectiveness of cleaning and environmental quality. *USP <825> 6.1 General Monitoring Requirements, 6.2 Monitoring Air Quality for Viable Airborne Particles, and 6.3 Monitoring Surfaces for Viable Particles*				
Comments:				

Environmental Monitoring and Certification of PEC (SRPA and Hot-Cell)	**Compliant**	**Non-Compliant**	**N/A**	**Not Inspected**
All ISO Class 5 PECs and/or ISO Class 8 rooms been certified as required. *USP <825> 5.7 Environmental Controls*				
Review report from certifier. **Certifier: Date:**				
Certification performed to CETA standards or equivalent standards. *USP <825> 5.7 Environmental Controls*				
Certifier's equipment calibrated to manufacturer standards. *USP <825> 5.7 Environmental Controls*				
Radionuclide storage and elution area certified to ISO Class 8 total airborne particle count. *USP <825> 5.7 Environmental Controls and 8.Assigning BUD*				
Radionuclide storage and elution area and ISO Class 8 area not more than 3,520,000 particles per cubic meter of air, taken under dynamic conditions. *USP <825> 5.1 Facility Design and Environmental Controls, 5.7 Environmental Controls and 8. Assigning BUD*				
ISO Class 8 ante/buffer room has HEPA filtered air and a minimum of 20 ACPH. *USP <825> 5.1 Facility Design and Environmental Controls and 5.7 Environmental Controls*				
Room HEPA filters leak tested and repaired if needed. *USP <825> .7 Environmental Controls*				
SRPA negative differential pressure to unrestricted area per RAM license and in the presence of volatile or airborne radiopharmaceutical. *USP <825> 5.7 Environmental Controls*				
PEC(s) certified to meet ISO Class 5 or better conditions. *USP <825> 5.1 Facility Design and Environmental Controls and 5.7 Environmental Controls*				
ISO Class 5 area not more than 3,520 particles per cubic meter of air, taken under dynamic conditions. *USP <825> 5.1 Facility Design and Environmental Controls and 5.7 Environmental Controls*				
Smoke visualization study performed at least every 6 months in direct processing area to demonstrate unidirectional airflow under simulated or dynamic conditions. *USP <825> 5.1 Facility Design and Environmental Controls and 5.7 Environmental Controls*				
Dynamic airflow smoke pattern tests within hot-cell shows staging of supplies and materials does not allow influx of unclassified or less than ISO Class 5 air into PEC. *USP <825> 5.6 Remote Aseptic Processing Involving a Hot-Cell*				
PEC HEPA filters leak tested and repaired if needed. *USP <825> 5.7 Environmental Controls*				
PEC airflow velocity measured. *USP <825> 5.7 Environmental Controls*				
Air and surface microbial sampling performed in all classified areas under simulated or dynamic conditions. *USP <825> 6.1 General Monitoring Requirements*				

Air and surface monitoring program includes documentation of: • Date and time of sampling; • Sampling locations; • Method of collection; • Frequency of sampling; • Size of samples (e.g., surface area, volume of air); • Time of day in relation to processing activities; and • Action levels. *USP <825> 6. Microbiological Air and Surface Monitoring*				
Viable air sampling of all classified areas and PECs performed at least every 6 months using active impaction device during dynamic or simulated operating conditions with 1000 liters of air sampled. *USP <825> 6.2 Monitoring Air Quality for Viable Airborne Particles*				
Viable air sampling performed with appropriate growth media and proper incubation of media to support growth of bacteria and fungi. *USP <825> 6.2 Monitoring Air Quality for Viable Airborne Particles*				
Viable air microbial action levels: • ISO Class 5: >1 CFU • ISO Class 7: >10 CFU • ISO Class 8: >100 CFU *USP <825> 6.2 Monitoring Air Quality for Viable Airborne Particles*				
Surface sampling performed at least monthly in: • All classified areas, including frequently touched surfaces; • PEC; • Direct processing area and any permanent equipment in PEC; • Staging and work surfaces near the PEC; and • Pass through. *USP <825> 6.3 Monitoring Surfaces for Viable Particles*				
Surface sampling performed at end of activities or shift and prior to cleaning and disinfecting in conformance with ALARA standards. *USP <825> 6.3 Monitoring Surfaces for Viable Particles*				
Surface sampling performed with appropriate microbial growth media supplemented with neutralizing additives (e.g., TSA with lecithin and polysorbate 80) and media properly incubated to support bacteria and fungi growth. *USP <825> 6.3 Monitoring Surfaces for Viable Particles*				
Surface sampling microbial action levels: • ISO Class 5: >3 CFU • ISO Class 7: >5 CFU • ISO Class 8: >50 CFU *USP <825> 6.3 Monitoring Surfaces for Viable Particles*				
Incubators located outside of any classified area or SRPA and temperature recorded daily during incubation with calibrated measuring device. *USP <825> 6.2 Monitoring Air Quality for Viable Airborne Particles and 6.3 Monitoring Surfaces for Viable Particles*				
If action levels for either air or surface sampling exceeded, CFU to be identified to the genus level. *USP <825> 6.2 Monitoring Air Quality for Viable Airborne Particles and 6.3 Monitoring Surfaces for Viable Particles*				
Documented investigation and corrective action plan when air or surface sampling action levels exceeded to include evaluation of personnel practices, effectiveness of cleaning and environmental quality. *USP <825> 6.1 General Monitoring Requirements, 6.2 Monitoring Air Quality for Viable Airborne Particles, and 6.3 Monitoring Surfaces for Viable Particles*				
Comments:				

Sterile Processing Procedures	Compliant	Non-Compliant	N/A	Not Inspected
No shipping cartons or other corrugated or uncoated cardboard allowed in classified areas or within SRPA. *USP <825> 7.4 Disinfecting Supplies for Classified Areas and SRPAs*				
Food, drinks, and materials exposed in patient care and treatment areas do not enter ante or buffer areas. *USP <825> 5.5. Classified Areas*				
All items are wiped with sporicidal agent, EPA-registered one-step disinfectant cleaner, or sterile 70% IPA using low-lint wipers prior to introduction into ante room or SRPA. *USP <825> 7.4 Disinfecting Supplies for Classified Areas and SRPAs*				
Any item transferred into the ISO 5 PEC disinfected with sterile disinfectant (sterile 70% IPA). *USP <825> 7.4 Disinfecting Supplies for Classified Areas and SRPAs*				
Critical sites wiped with sterile 70% IPA that is allowed to dry prior to piercing. *USP <825> 7.5 Disinfecting Critical Sites*				
Personnel use correct aseptic technique. *USP <825> 4.5 Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Area and 10 Preparation*				
Gloves routinely checked for holes, punctures, radioactivity contamination or tears and replaced. *USP <825> 4.5 Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Area*				
Gloves routinely disinfected with sIPA in line with ALARA safety standards. *USP <825> 4.5 Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Area*				
Disposable, absorbent pad clean and low-lint. *USP <825> 2.4 Radiation Contamination Control*				
Preparations, preparations with minor deviations, and compounded radiopharmaceuticals undergo appropriate in-house quality control testing. *USP <825> 10 Preparation and 11.2 Sterile Compounding*				
Sterile radiopharmaceutical final doses appropriately radioassayed. *USP <825> 12.1 Dispensing and Radioassay*				
Documented master formulation record and preparation record for all compounded preparations or preparations with minor deviations. *USP <825> 9.1 Master Formulation Record and 9.2 Records for Preparation with Minor Deviations/Compounding*				
Master formulation record documents: • Name of the radiopharmaceutical • Name, identity, strength, purity, and quantity of ingredients • Detailed procedure • Range of radioactivity and range of volume • Equipment to be used including PEC or SEC, if applicable • Required quality control tests • Trained personnel and required garbing if different from SOP • Container • Reference for BUD assignment and storage conditions *USP <825> 9.1 Master Formulation Record*				
Preparation record for preparations with minor deviations or compounded preparations documents: • Name of the radiopharmaceutical • Physical form or dosage form • Name and quantity of ingredients including calibration time for radioactive ingredients • Total volume • Reference to MFR and any deviations from MFR • Name of manufacturer/vendor, lot numbers and expiration dates of all ingredients and components • Name of compounder and verifying/supervising pharmacist				

• Date and time of preparation • Assigned lot number and/or prescription/order number • BUD and storage requirements • Quality control results *USP <825> 9.2 Records for Preparations with Minor Deviations/Compounding*				
In the absence of sterility testing, radiopharmaceuticals assigned a maximum BUD based on preparation conditions. (*see USP <825> Table 7)* • SRPA: 12 hours • ISO Class 8 ante and buffer room: 24 hours • ISO Class 7 or 8 ante and ISO Class 7 buffer room: 96 hours *USP <825> 8. Assigning BUD*				
Inner container appropriately labeled with: • Standard radiation symbol • "Caution-Radioactive Material" • Patient name/identifier for all therapeutic products • Radionuclide and chemical form • Radioactivity at the date and time of calibration *USP <825> 12.2 Labeling*				
Outer container/shielding appropriately labeled with: • Standard radiation symbol • "Caution-Radioactive Material" • Patient name/identifier for all therapeutic products • Radionuclide and chemical form • Radioactivity at the date and time of calibration • Volume or number of units dispensed • Product expiration or BUD and any special storage and handling instructions • Route of administration *USP <825> 12.2 Labeling*				
Comments:				

Remote Aseptic Processing Involving a Hot-Cell	**Compliant**	**Non-Compliant**	**N/A**	**Not Inspected**
Personnel garb according to contamination risk. *USP <825> 5.6 Remote Aseptic Processing Involving a Hot-Cell*				
Temperature of area containing hot-cell recorded daily. *USP <825> 5.7 Environmental Controls*				
Drugs stored at appropriate controlled storage temperatures: Controlled room temperature per USP <659>, generally 68-77 F or 20-25 C. *USP <825> 5.7 Environmental Controls*				
Drugs stored at appropriate controlled storage temperatures: Controlled cold temperature per USP <659>, generally 36-46 F or 2-8 C. *USP <825> 5.7 Environmental Controls*				
Drugs stored at appropriate controlled storage temperatures: Freezer temperature per USP <659>, generally -13 to 14 F or -25 to -10 C. *USP <825> 5.7 Environmental Controls*				
Humidity recorded daily. Relative humidity should be maintained below 60%. *USP <825> 5.7 Environmental Controls*				
Temperature monitoring devices verified for accuracy every 12 months or as required by manufacturer. *USP <825> 5.7 Environmental Controls*				
If sterile packages not opened remotely in hot-cell – syringes may be opened and labeled outside of ISO 5 environment and placed in disinfected shielding. *USP <825> 7.4 Disinfecting Supplies for Classified Areas and SRPAs*				

Critical sites wiped with sterile 70% IPA that is allowed to dry prior to piercing. *USP <825> 7.5 Disinfecting Critical Sites*				
Personnel use correct aseptic technique. *USP <825> 4.5 Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Area and 10 Preparation*				
Staging of supplies and materials in PEC does not allow influx of unclassified air into PEC. *USP <825> 5.6 Remote Aseptic Processing Involving a Hot-Cell*				
Preparations, preparations with minor deviations, and compounded radiopharmaceuticals undergo appropriate in-house quality control testing. *USP <825> 10 Preparation and 11.2 Sterile Compounding*				
Sterile radiopharmaceutical final doses appropriately radioassayed. *USP <825> 12.1 Dispensing and Radioassay*				
Documented master formulation record and preparation record for all compounded preparations or preparations with minor deviations from manufacturer instructions. *USP <825> 9.1 Master Formulation Record and 9.2 Records for Preparation with Minor Deviations/Compounding*				
Master formulation record documents: • Name of the radiopharmaceutical • Name, identity, strength, purity, and quantity of ingredients • Detailed procedure • Range of radioactivity and range of volume • Equipment to be used including PEC or SEC, if applicable • Required quality control tests • Trained personnel and required garbing if different from SOP • Container • Reference for BUD assignment and storage conditions *USP <825> 9.1 Master Formulation Record*				
Preparation record for preparations with minor deviations or compounded preparations documents: • Name of the radiopharmaceutical • Physical form or dosage form • Name and quantity of ingredients including calibration time for radioactive ingredients • Total volume • Reference to MFR and any deviations from MFR • Name of manufacturer/vendor, lot numbers and expiration dates of all ingredients and components • Name of compounder and verifying/supervising pharmacist • Date and time of preparation • Assigned lot number and/or prescription/order number • BUD and storage requirements • Quality control results *USP <825> 9.2 Records for Preparations with Minor Deviations/Compounding*				
In the absence of sterility testing, radiopharmaceuticals assigned a maximum BUD based on preparation conditions. (*see USP <825> Table 7)* • SRPA: 12 hours • ISO Class 8 ante and buffer room: 24 hours • ISO Class 7 or 8 ante and ISO Class 7 buffer room: 96 hours *USP <825> 8. Assigning BUD*				
Inner container appropriately labeled with: • Standard radiation symbol • "Caution-Radioactive Material" • Patient name/identifier for all therapeutic products • Radionuclide and chemical form • Radioactivity at the date and time of calibration *USP <825> 12.2 Labeling*				
Outer container/shielding appropriately labeled with:				

• Standard radiation symbol • "Caution-Radioactive Material" • Patient name/identifier for all therapeutic products • Radionuclide and chemical form • Radioactivity at the date and time of calibration • Volume or number of units dispensed • Product expiration or BUD and any special storage and handling instructions • Route of administration *USP <825> 12.2 Labeling*				
Comments:				

Radiolabeling Blood Components	**Compliant**	**Non-Compliant**	**N/A**	**Not Inspected**
Physical separation with either fixed or non-fixed wall from areas where non-blood products are handled. *USP <825> 10.3 Preparation of Radiolabeled Blood Components*				
Blood labeling performed in ISO Class 5 BSC in an ISO Class 7 buffer area. *USP <825> 10.3 Preparation of Radiolabeled Blood Components*				
Only one radiolabeling procedure per BSC at a time. *USP <825> 10.3 Preparation of Radiolabeled Blood Components*				
Maximum of 6 hour BUD after blood sample obtained. *USP <825> 8. Assigning BUD*				
BSC and all reusable equipment and components cleaned and disinfected after each radiolabeling procedure. *USP <825> 10.3 Preparation of Radiolabeled Blood Components*				
Dedicated supplies including consumable products and syringe shields and vial shields for each patient. *USP <825> 10.3 Preparation of Radiolabeled Blood Components*				
All tubes and syringes in contact with patient's blood components clearly labeled with patient name and additional identifier. *USP <825> 10.3 Preparation of Radiolabeled Blood Components*				
Removal and replacement of any garb that enters BSC before handling of anything not related to a radiolabeling procedure. *USP <825> 10.3 Preparation of Radiolabeled Blood Components*				
Complete hand hygiene and garbing procedures upon completion of blood radiolabeling procedures. *USP <825>10.3 Preparation of Radiolabeled Blood Components*				
Comments:				

Quality Assurance (QA) and Quality Control (QC)	**Compliant**	**Non-Compliant**	**N/A**	**Not Inspected**
Formally established QA and QC programs overseen by a designated person. *USP <825> 14. Quality Assurance and Quality Control*				
QA and QC programs include system of: • Adherence to procedures; • Prevention and detection of errors; • Evaluation of complaints and adverse events; and • Investigation and correct actions. *USP <825> 14. Quality Assurance and Quality Control*				

Documented annual review of QA and QC programs. *USP <825> 14. Quality Assurance and Quality Control*				
If radiopharmaceutical dispensed before results of release testing, prescriber notified of any specification failures with the potential to cause patient harm. *USP <825> 14.1 Notification About and Recall of Out-of-Specification Dispensed Radiopharmaceuticals*				
Designated person reviews all complaints and investigates any complaints that indicate a potential quality problem with a radiopharmaceutical. *USP <825> 14.2 Complaint Handling*				
Documented record of all complaints and investigation results. *USP <825> 14.2 Complaint Handling*				
Comments:				