NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Radiopharmaceuticals Compounding Inspection: Instruction Sheet and Form

The NVBOP's established self-assessment inspection process provides management the opportunity to review the standards by which the board inspects your operation. The process recognizes you as the responsible person to implement and review policies and procedures necessary to provide a quality standard of pharmaceutical services.

Please have the self-assessment form completed and available for review by the first day of the month listed on your inspection notice. An inspector will review the form with you and inspect your facility during the month listed on your inspection notice.

To minimize any disruption to your facility during the inspection process please have the following available:

1. Completed radiopharmaceuticals compounding Inspection form along with prior year inspection form
2. Most recent certification report for ISO classified areas. Documentation of corrective action taken by facility for any failures documented on the certification report
3. Prior 12 months of glove finger-tip testing results. Documentation of corrective action taken by facility for any failures
4. Prior 12 months of media fill testing results. Documentation of corrective action taken by facility for any failures
5. Prior 12 months of competency documentation for compounding personnel
6. Examples of compounding records
7. SOP's relevant to the radiopharmaceuticals compounding process

Pharmacy Information	
Date Completed:	
Pharmacy Name:	
Pharmacy License #:	
Pharmacy Address:	
Pharmacy Telephone #:	
Pharmacy Fax #:	
Pharmacy Email:	
Managing Pharmacist Name:	
Managing Pharmacist start date:	
Designated Person:	

List of compounding personnel approved to compound radiopharmaceutical products (Make copies of this page if additional space is needed)			
#	Name (First, Last)	License Number	Position
1			
2			
3			
4			
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General Information				
Citation	**Question**	**Yes**	**No**	**NA**
USP 825	Location compounds sterile radiopharmaceuticals for immediate use and follows all of the requirements as outlined in USP 825?			

Personnel Training and Evaluation Documentation				
Citation	**Question**	**Yes**	**No**	**NA**
The following records for employees are completed prior to sterile compounding and at frequencies listed in USP 825				
USP 825 Section 4.2 – 4.5	Performs aseptic hand hygiene?			
	Selects and appropriately don's protective garb?			
	Gowns are only garbing material that is reused?			
	Visual observation while performing hand hygiene, garbing SOPs, and aseptic technique procedures and cleaning and disinfection reevaluation is performed every 12 months?			
	Personnel that have not performed radiopharmaceutical processing in more than 6 months are requalified in all core competencies before resuming duties?			
USP 825 Section 4.2 – 4.5	Personnel who perform sterile compounding using a nonsterile drug substance or component are requalified in all core competencies every 6 months?			
USP 825 Section 4.2 – 4.5	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 procession of sterile preparations?			
USP 825 Section 4.2 – 4.5	All failures, retraining, and reevaluations are documented?			
USP 825 Section 4.2 – 4.5	Personnel who are authorized to be in 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?			
USP 825 Section 4.2 – 4.5	Personnel use sterile, powder free gloves for all sterile compounding activities?			
Media-Fill Testing				
USP 825 Section 4.1	Pharmacy is following all requirements listed in USP 825 for media-fill testing?			
	Pharmacy is performing media-fill testing initially and then every 12 months thereafter?			
	Documentation of any failure and re-testing is maintained?			
Gloved Finger-tip Testing				
USP 825 Section 4.1	Pharmacy is following all requirements listed in USP 825 for gloved finger-tip testing?			
	Sampled immediately after gowning/garbing for initial testing?			
	Employees must successfully pass 1 test with zero cfu's for initial testing? (immediately following hand-hygiene and garbing)			
	Employees must successfully pass 1 test with less than 3 cfu's for annual training? (completed post media-fill test)			
	Documentation of any failure and re-testing is maintained?			

Facilities and Engineering Controls				
Citation	**Question**	**Yes**	**No**	**NA**
USP 825 Section 5.1	The designated person is responsible for ensuring that each area related to sterile radiopharmaceutical processed 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?			
	The PEC is located in a SEC, which is either an ISO-classified buffer room or a segregated radiopharmaceutical processing area (SRPA)?			
	The ISO classified ante-room and buffer area are separated from the surrounding unclassified areas of the facility with fixed walls and doors?			
	Air supplied to the classified areas is introduced through HEPA filters that are located in the ceiling?			
	Air returns are located low on the wall?			
	The classified areas are equipped with a pressure-differential monitoring system?			
	The ante-room has a line of demarcation to separate the clean side from the less clean side?			
	Required garb is worn prior to crossing the line of demarcation?			
	A PEC may be located within an unclassified area, without an ante-room or buffer area (SRPA). Does the location utilize a SRPA?			
	If using a SRPA only sterile radiopharmaceutical preparation, preparation with minor deviations, dispensing, and repackaging are performed in the SRPA?			
	A visible perimeter establishes the boundaries of the SRPA?			
	Access to the SRPA is restricted to authorized personnel and required materials?			
	The PEC is certified to meet ISO Class 5 or better conditions?			
	The airflow in the PEC is unidirectional?			
	If used to compound sterile radiopharmaceuticals, the PEC is located within an ISO Class 7 or better buffer area with an ISO Class 8 or better ante-room?			
USP 825 Section 5.1	A minimum of 30 total HEPA-filtered ACPH is supplied to ISO Class 7 areas?			
USP 825 Section 5.1	At least 15 ACPH of the total air exchange in a room comes from HVAC?			
USP 825 Section 5.1	If the PEC is used to meet the minimum total ACPH requirements, the PEC is not turned off?			
USP 825 Section 5.1	A minimum of 20 total HEPA-filtered ACPH is supplied to ISO Class 8 areas?			
USP 825 Section 5.1	Location meets all requirements listed in USP 825 related to creating areas to achieve easily cleanable conditions?			
USP 825 Section 5.3	If the location is using a SRPA design, the sink is located at least 1 meter from the PEC and generators?			
USP 825 Section 5.7	RAM users are complying with the conditions specified in their approved RAM license application and regulations?			
USP 825 Section 5.7	Positive pressure environments have a minimum differential positive pressure of 0.02-inch water column between each ISO-classified area?			
USP 825 Section 5.7	The results from the pressure monitoring devices are documented daily on the days the area is used?			
USP 825 Section 5.7	Certification of the classified areas, including the PEC are performed initially and recertification is performed at least every 6 months?			
USP 825 Section 5.7	Recertification includes airflow testing, HEPA filter integrity testing, total particle count testing, and smoke visualization studies?			

Microbiological Air and Surface Monitoring				
Citation	**Question**	**Yes**	**No**	**NA**
USP 825 Section 6.2	Volumetric air sampling of all classified areas using an impaction device is conducted during dynamic operating or simulated operating conditions at least every 6 months?			
USP 825 Section 6.2	Air samples are incubated at 30-35 degrees for no less than 48 hours and then incubated at 20-25 degrees for no less than 5 additional days?			
USP 825 Section 6.2	Incubators used for microbiological testing are placed in a location outside of any classified area or SRPA?			
USP 825 Section 6.2	If levels measured during the viable air monitoring program exceed the levels listed in USP 825 the cause is investigated and corrective action is taken?			
USP 825 Section 6.3	Surface sampling of all classified areas and all PECs is conducted at least monthly for the detection of microbial contamination?			
USP 825 Section 6.3	The DPA of the PEC and any equipment permanently contained in the PEC is sampled?			
USP 825 Section 6.3	Surface sampling is performed at the end of the radiopharmaceutical aseptic activities or shift, but before the area has been cleaned and disinfected?			
USP 825 Section 6.3	Surface samples are incubated at 30-35 degrees for no less than 48 hours and then incubated at 20-25 degrees for no less than 5 additional days?			
USP 825 Section 6.3	If levels measured during the viable surface monitoring program exceed the levels listed in USP 825 the cause is investigated and corrective action is taken?			

Cleaning and Disinfecting				
Citation	**Question**	**Yes**	**No**	**NA**
USP 825 Section 7 – 7.6	Cleaning and disinfecting takes place in all classified areas and SRPAs based on the frequencies listed in USP 825?			
USP 825 Section 7 – 7.6	All cleaning and disinfecting activities are performed by trained and appropriately garbed personnel using facility approved agents and procedures that are described in written SOPs?			
USP 825 Section 7 – 7.6	Cleaning is performed in the direction of most to least clean areas?			
USP 825 Section 7 – 7.6	All cleaning, disinfecting, and application of sporicidal agents is documented according to the facility SOPs?			
USP 825 Section 7 – 7.6	All products used are allowed to dwell for the minimum contact time specified by the manufacturer?			
USP 825 Section 7 – 7.6	The 70% IPA used in the ISO Class 5 PEC is sterile?			
USP 825 Section 7 – 7.6	Sporicidal agents are used at least monthly in classified areas and SRPAs?			
USP 825 Section 7 – 7.6	All cleaning supplies are low-lint?			
USP 825 Section 7 – 7.6	All surfaces in the PEC are surveyed for radioactive contamination and decontaminated per facility SOP's?			
USP 825 Section 7 – 7.6	All items transferred into the PEC from the classified area or SRPA are disinfected with a sterile disinfectant?			
USP 825 Section 7 – 7.6	Critical sites are wiped with sterile 70% IPA?			

Assigning BUDs				
Citation	**Question**	**Yes**	**No**	**NA**
USP 825 Section 8	Is pharmacy following all BUD (in hours) listed in USP 825?			
	Is pharmacy assigning any BUDs that are longer in duration than those listed in USP 825?			
	If assigning extended BUDs does the pharmacy have evidence to support the extended date?			

Documentation				
Citation	**Question**	**Yes**	**No**	**NA**
USP 825 Section 9	Are records (hard-copy or electronic) maintained for all of the following? Policies and procedures, repackaging, preparing, preparing with minor deviations, compounding, and dispensing radiopharmaceuticals.			

Master Formulation Record				
Citation	**Question**	**Yes**	**No**	**NA**
USP 825 Section 9.1 – 9.2	Pharmacy has a MFR for all preparations with minor deviations or compounded products?			
	MFR meets all of the requirements listed in USP 825?			
	A record for preparation with minor deviations or compounding meets all of the requirements listed in USP 825?			

Dispensing				
Citation	**Question**	**Yes**	**No**	**NA**
USP 825 Section 12.1	Except for an unopened manufacturer container, the final dose of ordered amount is assayed?			
	The activity at calibration time is always within federal, state, and local variance limits?			

Labeling				
Citation	**Question**	**Yes**	**No**	**NA**
USP 825 Section 12.2	The inner container is labeled with all of the requirements listed in USP 825?			
	The outer shielding is labeled with all of the requirements listed in USP 825?			

Repackaging				
Citation	**Question**	**Yes**	**No**	**NA**
USP 825 Section 13	The pharmacy is following all of the repackaging requirements listed in USP 825?			

Quality Assurance and Quality Control				
Citation	**Question**	**Yes**	**No**	**NA**
USP 825 Section 14	The pharmacy has an established and documented QA and QC program?			
	Designated person reviews the QA and QC program on an annual basis?			

Notes

Your location will be inspected by an agent of the Nevada Board of Pharmacy. Any noted unsatisfactory conditions that require action will be sent to the email you indicate below. **All unsatisfactory conditions must be corrected within the time frames stated to ensure compliance with laws and regulations governing your business. Please attach a copy of any documentation and corrective action you have taken to this inspection form for future review on inspection.**

Date:	
Pharmacist Printed Name:	
Pharmacist Signature:	
Email address for correspondence:	