West Virginia Board of Pharmacy

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Charleston, West Virginia 25301

NUCLEAR PHARMACY PERMIT INSPECTION-USP STANDARDS

This form is intended to be used in conjunction with a state's regular pharmacy inspection form, and only covers the non-sterile compounding portion of an inspection. The inspection items in this form are based on USP Chapter <825>. An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Business or Corporation:				Day 1:				
Doing Business As (DBA):				Start Time:				
West Virginia License #				End Time:				
Address:								
City:				Day 2:				
State:		Zip Code:		Start Time:				
Telephone number:				End Time:				
Toll free number:				Pharmacist in Charge				
Fax number:				PIC e-mail				
Email address:				Non-Sterile Compounding Supervisor				
Hours of Compounding Operation (Check if 24/7) ☐								
Leave blank if closed	Sun	Mon	Tues	Wed	Thu	Fri	Sat	Hazardous Compounding Supervisor *(if applicable)*

Note if differ from regular facility hours:

Verified Pharmacy Program® Inspection Form

Nuclear Pharmacy Inspection

Facility Name:

Inspection Date:

		Finding	Notes
	General Pharmacy		
1.00	Is the PIC (or pharmacy manager/director) present for the inspection? *If no, list the pharmacist on duty.*	--	
2.00	Are photographs allowed during the inspection (no Protected Health Information (PHI))?	--	
	General Operations and Licensure		
3.00	Are pharmacy licenses, permits and registrations (state, controlled substance, DEA, etc.) posted?	--	
4.00	Is the RSO the same as is listed on the radioactive materials (RAM) license?	--	
5.00	Is the PIC an Authorized User (AU) on the RAM license? List all AUs.	--	
6.00	Is the most recent board of pharmacy inspection report available for review? *Record the date of the last inspection and how frequently the pharmacy is routinely inspected by the board.*	--	
6.01	Were any deficiencies noted? *Indicate the deficiencies and note whether they were corrected.*	--	
7.00	Is the most recent NRC (and/or state radiation control agency) inspection report available for review? *If yes, note the state and the date of the inspection and frequency of inspections by other states.*	--	
7.01	Were any deficiencies noted? *Indicate the deficiencies and note whether they were corrected.*	--	
8.00	Has this pharmacy been inspected by any other state for which it holds a license? *If yes, note the state and the date of the inspection and frequency of inspections by other states.*	--	
9.00	Is the pharmacy operating under an exemption or restriction granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the exemption or restriction.*	--	
10.00	Is the pharmacy operating under a waiver or variance granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the waiver or variance.*	--	
11.00	Has the pharmacy been inspected or visited by the DEA? *If yes, indicate the inspection/visit date and note any deficiencies. Also note how frequently the pharmacy is inspected/visited by the DEA.*	--	
12.00	Has the pharmacy been inspected by the FDA? *If yes, indicate the inspection date and note any deficiencies, significant correspondence, or if a "483" was issued and date, and response and date. Also note how frequently the pharmacy is inspected by the FDA.*	--	
13.00	Has the pharmacy been inspected by the Environmental Protection Agency (EPA), Department of Transportation (DOT) or any other outside agency? *If yes, indicate the inspection date and note any deficiencies related to pharmacy practice.*	--	
14.00	Does the pharmacy hold any accreditations or certifications? *If yes, indicate which and collect most recent date of survey.*	--	
15.00	Has the pharmacy held any accreditations or certifications in the past that they no longer hold? *Provide a list and the reasons for such.*	--	
16.00	Were any deficiencies detected on the last internal audit? *List date of last audit and note any deficiencies found and action plan to correct.*	--	

Facility Name:
Inspection Date:

17.00	Does this pharmacy handle IND radiopharmaceuticals? *Indicate percentage and which ones.*	--	
18.00	Does the pharmacy **distribute** compounded preparations to practitioners for "office use" or "physician use"? *If yes, indicate volume or percentage provided within this state, and volume or percentage provided in other states.*	--	
19.00	Does the pharmacy **distribute** compounded preparations to hospitals, clinics, or surgery centers? *If yes, indicate volume or percentage provided within this state, and volume or percentage provided in other states.*	--	
20.00	When the pharmacy **delivers** or **distributes** radiopharmaceuticals, does the pharmacy maintain a copy of each customer's current RAM license/registration? *Verify by viewing examples in customer files.*	--	
21.00	Does the pharmacy provide compounded preparations to other pharmacies for dispensing? *If yes, indicate if the pharmacies have common ownership or if the pharmacy has central fill contracts or agreements with these pharmacies for patient-specific preparations.*	--	
22.00	Does the pharmacy purchase any compounded products from other entities for dispensing to patients? *If yes, describe which products and from where they are purchase (collect name and license of other entity).*	--	
23.00	Does the pharmacy only make essential copies of a commercially available drug product on the Drug Shortage List or that is justified by a documented medical need of the individual patient as determined by the prescribing practitioner? *If yes, indicate name and volume/percent compounded currently.*	--	
23.01	If yes, products are verified as appearing on the Drug Shortage List in effect under 506E of the Federal Act at the time of compounding, distribution, and dispensing.	--	
23.02	If yes, the Drug Shortage List is monitored and when a drug product is no longer on the list, any remaining stock is quarantined and not available for distribution or dispensing. *Note: Per FDA guidance, 503B facilities may continue to distribute for 60 days following drug shortage list removal for existing orders.*	--	
24.00	**Nonsterile Compounding:** Does the pharmacy compound oral preparations (capsules, liquids, etc.)? *If yes, indicate which in notes.*	--	
25.00	**Sterile Compounding:** Does the pharmacy compound parenteral preparations? *Provide List.*	--	
26.00	**Sterile Compounding:** Does the pharmacy compound parenteral suspensions? *Provide List.*	--	
27.00	**Sterile Compounding:** Does the pharmacy compound inhalation preparations? *Provide List.*	--	
28.00	Does the pharmacy perform testing in-house (such as purity, radiochemical purity, potency, sterility, endotoxin, environmental monitoring)? *If yes, what testing is performed in house?*	--	
29.00	Does the pharmacy send samples to an outside lab to perform testing? *If yes, provide the name of the lab performing testing for the pharmacy and what testing is performed.*	--	
	Policy and Management		
30.00	Policies and procedures for the program are maintained in the pharmacy in an immediately retrievable form. *Indicate if hard copy, electronic, or both.*	--	
31.00	Do the P&Ps include the prescription processing, compounding, dispensing, delivery, receipt and storage, and the handling of HD, and handling infectious waste or spills?	--	
32.00	Are the P&Ps reviewed and updated regularly? *Indicate the review frequency and who performs the reviews.*	--	
33.00	Are systems in place for the ongoing monitoring of state and federal laws/regulations for changes? *Give details of the system and resources, or indicate if it is a corporate process and who is responsible overall as well as at the site.*	--	
34.00	Is there a statement in the P&P, or are other means used to ensure that the most stringent laws/regulations are followed? *Describe system details.*	--	
35.00	Does the pharmacy maintain all required records, including but not limited to prescription files and invoices on site? *Record how long records are kept. If not on site, where?*	--	

36.00	Does the pharmacy have access to appropriate law references including state and federal regulations (including state regulations for all states in which the facility is licensed and NRC)? *Indicate if they are hard copies or are accessed online (demonstrate access) or both.*	--	
37.00	Does the pharmacy have access to appropriate dosage and toxicology references? *Indicate if they are hard copies or are accessed online or both.*	--	
38.00	Does the pharmacy have access to appropriate practice specific references? Nuclear, geriatric, pediatric, etc. *List and indicate if hard copy or online or both.*	--	
39.00	Are Safety Data Sheets (SDS) [formerly known as Material Safety Data Sheets (MSDS)] available to personnel for drugs and chemicals used in the pharmacy (including those for compounding, if applicable)? *Verify that personnel can access them and are familiar with the format.*	--	
40.00	Does the pharmacy have a hazardous waste handling and collection system? *Indicate how often waste is collected and the vendor(s) used.*	--	
	Quality Assurance/Quality Improvement (QA/QI)		
41.00	Is there a documented continuous quality improvement (CQI) Program for the purpose of detecting, documenting, assessing, and preventing quality related events (QREs)? *If yes, list who oversees the program.*	--	
42.00	Is QA data kept on site? *If not, where?*	--	
43.00	Are quality self-audits performed? *How often?*	--	
44.00	Is Quality Related Event (QRE) defined? *May also be referred to as "incidents" or "errors".*	--	
44.01	Is there a form to fill out for a QRE? *Indicate if paper or electronic, or both, and who fills it out.*	--	
44.02	**Reporting**: Incidents of QREs are reported to a nationally recognized error reporting program, an outside peer review committee, or a patient safety organization. *Indicate which organizations are reported including if the pharmacy reports QREs to the board of pharmacy.*	--	
45.00	Are external errors documented and tracked? *View example documentation.*	--	
46.00	Are internal errors documented and tracked? *View example documentation.*	--	
47.00	Are complaints documented, tracked, and investigated as appropriate and the information is used as part of the CQI program?	--	
48.00	Are reports of contamination or instability of compounded preparations documented, investigated, and tracked, and is there a recall system in place?	--	
49.00	Does the pharmacy continuous quality improvement program include viable environmental testing?	--	
49.01	Does the facility QA program identify action limits or thresholds and the appropriate follow-up mechanisms when action limits or thresholds are exceeded, including a recall system?	--	
49.02	Are deficiencies in compounding, labeling, packaging, and quality testing and inspection identified and corrected?	--	
50.00	Are pharmacy information systems and technology performance issues measured and tracked? *Such as computers, etc.*	--	
51.00	Are any other measurements tracked and analyzed? *Indicate in Notes.*	--	
52.00	QRE data collected is analyzed to assess causes and any contributing factors (root cause). *Indicate who performs the analysis and frequency (with each event, weekly, monthly, quarterly, etc).*	--	
53.00	Is data trended over time (eg, against previous years' data)?	--	
54.00	Quality meetings are held at least annually by staff members of the pharmacy to consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.	--	
55.00	Have process or policy changes or improvements been made based upon other data collected in the QA/QI program? *Provide an example.*	--	

56.00	Improvements or changes made are evaluated for performance to measure the effectiveness of the CQI program.	--	
	Animal Compounding Compliance		
	Total Non-Compliant (Includes Unknowns)	**0**	
57.00	**For animal compounding:** The compounding meets the same standards as compounding for human patients.	--	
58.00	The pharmacist is knowledgeable or has references regarding the individual species' limitations in physiology and metabolic capacity that can result in toxicity when certain drugs or excipients are used. *(Example: xylitol is contraindicated for dogs).*	--	
59.00	For therapy doses, the pharmacy obtains appropriate information to assess correct dosage such as animal species, breed or weight?	--	
60.00	It is determined and documented if the animal is used for food (meat, milk, eggs, etc.) or that the animal is a pet.	--	
61.00	The facility has a list of drugs and components not allowed when compounding for food-producing animals.	--	
62.00	The pharmacist is familiar with, or has a reference regarding drug residues in the food chain and withdrawal times if compounding for food-producing animals.	--	
63.00	The pharmacist is familiar with, or has a reference regarding regulations for drug use in performance animals (e.g., race or show horses, racing dogs).	--	
	Personnel Information		
64.00	Is there a process for periodic verification of validity of personnel licenses (registrations)? *Describe the process.*	--	
65.00	Are all personnel wearing name tags that clearly identify if they are a pharmacist or a technician? *What about other positions?*	--	
66.00	If the pharmacy uses relief personnel from outside agencies to perform sterile compounding, the training and certifications are verified. *View documentation.*	--	
67.00	Does the pharmacy have Visiting Authorized Nuclear Pharmacist(s)?	--	
67.01	Do the visiting nuclear pharmacist(s) have written authorization on file?	--	
67.02	Are the visiting nuclear pharmacist(s) licenses on file in the pharmacy?	--	
67.03	Are visiting nuclear pharmacists limited to 60 days per year or less?	--	
67.04	Are all records associated with the visiting nuclear pharmacist maintained for at least five (5) years after the last visit?	--	
68.00	Does the pharmacy have a technician policy that specifies what a technician is allowed and not allowed to do?	--	
69.00	Does the pharmacy maintain the proper technician-to-pharmacist ratio? *Indicate ratio used and the maximum number of staff who work at the same time.*	--	
70.00	Do employees undergo background checks upon hire? *Indicate if performed periodically for existing employees.*	--	
71.00	Do employees undergo drug testing upon hire? *Indicate if performed periodically for existing employees and if it is random, for cause, or both.*	--	
72.00	Is new hire training, including orientation, general pharmacy procedures, HIPAA, Radiation Safety/ALARA, Occupational Safety and Health Administration (OSHA) blood borne pathogen, or hazardous materials handling performed and documented? *View the documentation.*	--	
73.00	Is ongoing annual training performed and documented, including topics such as HIPAA, Radiation Safety/ALARA, OSHA blood borne pathogen, or HAZCOM ? *View the documentation.*	--	
74.00	Is there a performance review process and is it documented? *If yes, how often?*	--	
75.00	Is a procedure for corrective or disciplinary action in place and documented?	--	

Facility Name:
Inspection Date:

Personnel Compliance

	Total Non-Compliant (Includes Unknowns)	**0**	
76.00	Have all personnel of reproductive capability who handle or compound radiopharmaceuticals/radioactive materials confirmed in writing they understand the risks of handling radiopharmaceuticals/radioactive materials?	--	
77.00	Is there documentation of training for other employees (including drivers, warehouse, receiving, administrative, clerks, etc.) who may have contact with radiopharmaceuticals/radioactive materials on handling the spills associated with these?	--	
78.00	Personnel demonstrate knowledge and can verbalize the principles of the safe use of RAM – time (working quickly/efficiently), distance (not handling RAM directly, using tongs), and shielding (using lead containers and shields in work areas).	--	
79.00	Personnel demonstrate a knowledge of emergency procedures and are able to point out the locations of the eyewash station, emergency spill kit, and can verbalize how to handle contamination including reporting.	--	
80.00	**Nonsterile Compounding:** There is documentation that the training includes cleaning and disinfection, garb, manipulation of ingredients including quality testing, labeling, and RAM handling.	--	
81.00	**Nonsterile Compounding:** There is documentation that the training process for the preparation of compounds includes demonstration of the compounding procedure first, followed by the trainee performing the procedure under supervision successfully before trainee is allowed to perform compounding independently.	--	
82.00	**Nonsterile Compounding:** There is documentation that training includes the operation of any equipment that may be used when preparing compounded products. *Documentation includes operation and troubleshooting.*	--	
83.00	**Nonsterile Compounding:** There is documentation that employees performing nonsterile compounding are evaluated at least annually on compounding competency, including compounding technique, equipment, and materials handling.	--	
84.00	**Sterile Compounding:** There is documentation that all compounding personnel have passed initial and subsequent annual written exams that include QA procedures for the appropriate compounding risk levels including RAM.	--	
85.00	**Sterile Compounding:** There is documentation that all compounding personnel have passed initial and subsequent annual competency assessments of aseptic compounding skills using observational audit tools including handling RAM.	--	
86.00	**Sterile Compounding:** There is documentation that new compounding personnel have passed initial observed gowning procedure and three gloved fingertip sampling tests. *Personnel must pass the tests upon initial validation before being allowed to compound. Action required if the tests yield any garbing deficiencies, or if the sampling results are >0 colony-forming units (CFU)/plate on the three initial validations.*	--	
87.00	**Sterile Compounding:** There is documentation that compounding personnel preparing low or medium risk-level products have passed an annual observed gowning procedure and gloved fingertip sampling test. *Action required if the tests yield any garbing deficiencies, or if the fingertip sampling results are >3 CFU (total both hands, all 10 fingers). Documentation to include type of media used, COA on media, incubation time and temperature and interpretation of results. Indicate frequency, if testing more than annually.*	--	

88.00	**Sterile Compounding:** There is documentation that a media fill test procedure is performed for each compounding employee at least annually for individuals that prepare low or medium risk-level products. *The test conditions must closely simulate the most challenging or stressful conditions encountered during compounding of the highest risk level product and include any automation used in compounding. Media-filled vials are incubated and failure is indicated by visible turbidity in the medium on or before 14 days . Indicate frequency, if testing more than annually.*	--	
89.00	**Sterile Compounding:** The media-fill testing procedures include:		
89.01	Media selection (including obtaining COAs or growth promotion certificates from suppliers);	--	
89.02	Fill Volume;	--	
89.03	Incubation time and temperature (Media-filled vials are generally incubated at 20° to 25° or at 30° to 35° for a minimum of 14 days. If two temperatures are used for incubation of media-filled samples, then these filled containers should be incubated for at least 7 days at each temperature.);	--	
89.04	Inspection of filled units;	--	
89.05	Documentation;	--	
89.06	Interpretation of results; and	--	
89.07	Action levels set with the corrective actions required.	--	
90.00	**High-Risk Sterile Compounding:** There is documentation that compounding personnel have passed an observed gowning procedure and gloved fingertip sampling test every six (6) months. *Action required if the tests yield any garbing deficiencies, or if the sampling results are >3 CFU on both hands upon revalidation. Documentation to include type of media used, COA on media, incubation time and temperature and interpretation of results. Indicate frequency, if testing more than every 6 months.*	--	
91.00	**High-Risk Sterile Compounding:** There is documentation that a media fill test procedure is performed for each compounding employee at least every six (6) months for individuals that prepare high risk-level products. *The test conditions must closely simulate the most challenging or stressful conditions encountered during compounding of the highest risk level product and include any automation used in compounding. Media-filled vials are generally incubated at 20° to 25° or at 30° to 35° for a minimum of 14 days. If two temperatures are used for incubation of media-filled samples, then these filled containers should be incubated for at least 7 days at each temperature.*	--	
92.00	**Sterile and Nonsterile Compounding:** Are all personnel that perform cleaning activities in the compounding areas appropriately trained (including housekeeping or other outside personnel if used for cleaning)?	--	
	Facility and Security		
93.00	Is entry to prescription product storage and processing areas limited to task-critical employees?	--	
94.00	Is entry into the compounding areas limited to task-critical employees (limited to only the pharmacist(s) and other trained and authorized pharmacy personnel)?	--	
95.00	Are drugs secured to prevent unauthorized removal or access?	--	
96.00	Does the pharmacy have a working security/alarm system in place? *If yes, describe.*	--	
97.00	Does the pharmacy have cameras? *If yes, record how long images are retained.*	--	
98.00	Does anyone have access to the pharmacy after hours in the absence of the pharmacist? *Explain.*	--	
99.00	Do pharmacy staff remain in the pharmacy if the pharmacist is absent on a meal break? ***If so, is there a policy regarding what activities may or may not be allowed during the pharmacist's absence?***	--	

Facility Name:

Inspection Date:

100.00	Is the "Notice to Workers" posted? *Includes regulations and P&P (or where to find them), license and amendments, and NRC Notices of Violation involving radiological working conditions.*	--	
101.00	Is the "Notice to Employees" posted? *(NRC Form 3)*	--	
102.00	If the facility performs both sterile and nonsterile compounding, the areas are separated and distinct.	--	
103.00	Is the blood compounding area separate and distinct from the general compounding area?	--	
103.01	Are components used in compounding with blood products restricted to the blood compounding area (not used in other compounding areas)?	--	
104.00	Are chemicals stored in the appropriate manner (e.g. per SDS)? *Indicate how/where stored.*	--	
105.00	Are all volatile products (e.g. Xe-133 gas, liquid I-131 NaI) stored and manipulated in a negative pressure environment? *Indicate storage and manipulation room and PEC description.*	--	
105.01	If the pharmacy handles radioactive gases, are the clearance time and safety procedures posted?	--	
106.00	Are there housekeeping standards to ensure the environment is professional, safe, neat, and clean?	--	
107.00	Is the pharmacy clean and is there appropriate space for the prescription volume?	--	
108.00	Is there a heating and air conditioning system? Indicate which or both, and if they are operational.	--	
109.00	Temperature monitoring is performed in **drug storage areas** (if separate from the compounding areas) and maintained within 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements.	--	
109.01	Temperature monitoring in the drug storage area is performed at least once daily and documented. *Temperature records are maintained.*	--	
109.02	Excursion action plan is in place including evaluating excursion effects on drug product integrity.	--	
110.00	Humidity monitoring is performed in **drug storage areas** (if separate from the compounding areas) to provide humidity in the ranges warranted by specific drug product storage requirements. *If drug products require storage in a "dry place", humidity is not to exceed 40%. Generally recommended range is 35-60%.*	--	
110.01	Humidity monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. *Humidity records are maintained.*	--	
110.02	Excursion action plan in place including evaluating excursion effects on drug product integrity.	--	
111.00	Are the refrigerator and freezer restricted to drug products only (no food)?	--	
112.00	Temperature monitoring in the refrigerator is performed at least once daily and documented. Additionally, compounding personnel shall note the storage temperature when placing the product into or removing the product from the storage unit in order to monitor any temperature aberration. Alternatively, continuous monitoring or retroactive detection using min/max may be used. *Temperature records are maintained.*	--	
112.01	Is the temperature in the refrigerator within the USP range (2°-8°C or 36°-46 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the refrigerator at the time of inspection.*	--	
113.00	Temperature monitoring in the freezer is performed at least once daily and documented. Additionally, compounding personnel shall note the storage temperature when placing the product into or removing the product from the storage unit in order to monitor any temperature aberration. *Temperature records are maintained.*	--	
113.01	Is the temperature in the freezer within the USP range (between −25° to −10°C or −13° to 14 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the freezer at the time of inspection.*	--	
114.00	Are there contingency plans in the event of power outage or refrigerator/freezer failure? *Describe process.*	--	

115.00	Are there contingency plans in the event of heating or air conditioning failure? *Describe process.*	--	
	Environmental Monitoring Compliance		
	Total Non-Compliant (Includes Unknowns)	**0**	
116.00	**Nonsterile Compounding:** All PECs have been certified within the last six months.	--	
117.00	**Sterile Compounding:** The most recent PEC and room certification report is available. ***Obtain a copy and submit with inspection report.***	--	
117.01	All ISO Class 7 and 8 SECs (clean/buffer rooms and anterooms) have been certified within the last 6 months. *If non-compliant, record the date of the last certification.*	--	
117.02	All ISO Class 5 PECs (laminar airflow workbenches or areas, BSCs, CAIs, CACIs, and barrier isolators) have been certified within the last 6 months. *If non-compliant, record the date of the last certification.*	--	
117.03	Certification is performed at least every six months (view date of previous certification) and whenever a device or room is relocated or altered, or major service to the facility is performed. *If non-compliant, record the date of the previous certification.*	--	
117.04	Certification is performed to the Controlled Environment Testing Association (CETA) guide (USP: CETA CAG-003-2006 Certification Guide for Sterile Compounding Facilities) and is noted on the report.	--	
117.05	The PIC/compounding supervisor is familiar with what testing is required and interpretation of results, ensures all testing is performed appropriately (under dynamic conditions where appropriate), has action levels identified, evaluates results to detect issues or trends, and action levels are further customized based on trended data of performance.	--	
118.00	The certification report includes information about the equipment used for performing each test including: identification of the equipment used by model, serial number, last calibration date (or date when next calibration is due).	--	
118.01	The equipment used had not exceeded its calibration date at the time of certification.	--	
119.00	The HEPA filtered air changes per hour (ACPH) were measured for the compounding rooms.	--	
119.01	Is the ISO Class 7 sterile compounding room certified as having a minimum of 30 ACPH with at least 15 ACPH from outside air sources? ***Recirculated air from the PECs may account for up to 15 ACPH.***	--	
119.02	Is the ISO Class 8 anteroom certified as having the recommended minimum of 20 ACPH?	--	
119.03	If a CACI is used in a non-HEPA-filtered room, the room is certified to maintain a minimum of 12 ACPH?	--	
120.00	Air pattern analysis using smoke testing was performed under dynamic conditions (people working in the PECs and rooms). *The smoke flow is described in the report for the various tests such as turbulent, sluggish, smooth, etc.*	--	
120.01	Air pattern analysis was conducted at the critical area (direct compounding area inside the ISO Class 5 PEC) to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions (personnel compounding or simulating compounding in PEC).	--	
120.02	Air pattern analysis was conducted to confirm positive pressure (and negative pressure into required compounding rooms) at all points around all openings, doorways, and pass-throughs.	--	
120.03	Air pattern analysis conducted around particle generating equipment while the equipment was in operation to confirm air flow.	--	
121.00	Differential air pressure between rooms was measured.	--	
121.01	Was the differential pressure measured to be at least 0.02" water column positive from the clean room to the anteroom and between the anteroom and all adjacent spaces with the doors closed? NOTE: Radioactive licensing may prohibit ante room from being positive to unrestricted general area.	--	

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121.02	Was the differential pressure measured to be at least 0.01" water column negative from the room containing volatile products to the adjacent room with the doors closed?	--	
122.00	Displacement airflow between rooms or areas was measured. *This is for a clean/buffer room without a door that closes to the anteroom - may be an open space or may have plastic strips in doorways.*	--	
122.01	Displacement airflow (for low and medium-risk non-hazardous rooms only) was measured at a minimum differential velocity of 40 feet per minute from the cleanroom to the anteroom. *Note that it is very important to maintain this velocity across the entire opening and the report should indicate multiple points of measure across all openings.*	--	
123.00	Particle counts of particles 0.5um and larger were measured under dynamic conditions.	--	
123.01	ISO Class 5 areas and PECs are certified as having less than 3,520 particles per cubic meter of air (100 particles per cubic foot).	--	
123.02	ISO Class 7 areas are certified as having less than 352,000 particles per cubic meter of air (10,000 particles per cubic foot).	--	
123.03	ISO Class 8 areas are certified as having less than 3,520,000 particles per cubic meter of air (100,000 particles per cubic foot).	--	
124.00	HEPA filter tests were performed.	--	
124.01	All room HEPA filters were leak tested and if leaks found, they were fixed.	--	
124.02	All PEC HEPA filters were leak tested and if leaks found, they were fixed.	--	
125.00	Viable air (every six months) and surface sampling (periodically) tests have been conducted as required. *Document frequency.*	--	
125.01	PECs with failed tests are not used for compounding until the conditions are corrected and verified by subsequent testing.	--	
125.02	Appropriate growth media used (containing tryptic soy agar medium with polysorbate and lecithin (TSApl) added to neutralize cleaning agents for surface sampling) with appropriate corresponding incubation time and temperature used. *Required to use media that supports both bacterial and fungal growth for high risk compounding.*	--	
125.03	Viable air sampling by active impaction using a volumetric air sampling device. *NOTE: Passive air sampling or settling plates are not compliant with USP Chapter <797>.*	--	
125.04	Air samples were taken in each ISO Class 5 PEC, and in each sterile compounding room and anteroom and volume sufficient volume of air (400-1000L) was collected? *Note: 1000L must be collected in ISO Class 5 PECs to be able to detect the action level. Room samples can be 400-1000L.*	--	
125.05	Surface samples performed on all direct compounding areas inside of each ISO 5 PEC, in each ISO classified room, inside any pass-throughs, and on surfaces likely to be contaminated due to position relative to doorways, etc.	--	
125.06	Viable air and surface samples did not exceed USP action levels (or internal action levels if more restrictive). ***Classification Air Sample Surface Sample*** ***ISO Class 5 >1 CFU/m3 >3 CFU/plate*** ***ISO Class 7 >10 CFU/m3 >5 CFU/plate*** ***ISO Class 8 >100 CFU/m3 >100 CFU/plate*** *CFUs are TOTAL of bacterial plus fungal/mold plates. If air sampling volume is less than 1000 liters (one cubic meter), the raw total microbial count must be multiplied by the appropriate factor to determine the number of CFU/cubic meter.*	--	
125.07	CFUs detected by any means (viable air or surface sampling, gloved fingertip testing, failed sterility tests, etc.) are identified to the genus level. *All CFUs detected must be identified even if the number of CFUs does not exceed an action level.*	--	

125.08	If any highly pathogenic microbes (e.g. mold, yeast, coagulase positive staphylococcus, or gram negative rods) were detected (whether or not the number of CFUs exceeds action levels), begin immediate remediation (e.g. recleaning and retesting); and conduct investigation into the source(s) of the contamination.	--	
126.00	**Materials Tests:** Molybdenum-99 breakthrough tests are performed and records kept for at least five years.	--	
	Product Ordering, Receipt and Inventory		
127.00	Is the pharmacy restricted to buying prescription drugs from certain WDs or manufacturers?	--	
127.01	If restricted, does the PIC approve the vendors? *If not, who does approve (corporate)?*	--	
128.00	Are all orders received when the pharmacy is open? *Verify the orders are brought directly to the pharmacy still sealed and not delivered before the pharmacy is open.*	--	
129.00	Does the pharmacy purchase any compounded products from other entities for dispensing to patients? *If so, describe which products and from where they are purchase (collect name and license of other entity).*	--	
130.00	Does the pharmacy make any sterile or nonsterile compounded preparations using bulk powder or liquid Active Pharmaceutical Ingredients (APIs) such as I-131 for capsules or solutions? *Indicate bulk products and vendors used.*	--	
130.01	Does the pharmacy verify that the manufacturer/repackager of the API is an FDA-registered facility? *If so, list how this verified*	--	
130.02	Does the pharmacy use active ingredients that are not from an FDA facility? *If so, indicate sources.*	--	
131.00	Does the computer system track on-hand quantities of products? *Who can adjust the on-hand quantities, and are adjustments tracked?*	--	
132.00	Are orders generated and sent by the computer for prescription products, including controlled substances? *Who can alter the orders before they are sent?*	--	
133.00	Does the pharmacy maintain required inventories (such as change in PIC, theft/loss, etc)? *Indicate which.*	--	
134.00	Are incidents of diversion or resignation/termination of personnel for cause reported? *Indicate agencies/law enforcement to whom reports are made.*	--	
135.00	Does the pharmacy have a complete physical inventory of products performed at least once yearly? *If cycle counting, indicate the process.*	--	
136.00	Does the pharmacy have a system in place to track prescription drug products in order to detect diversion or theft? *Describe process (for example, inventory or shrink report tools used, perpetual inventory in computer, etc).*	--	
137.00	Are all products inspected upon receipt to detect any packaging issues, damage, etc.? *Describe what happens if products are damaged.*	--	
138.00	How are outdated, damaged, or recalled products segregated? *Indicate how often the pharmacy checks for out-of-date products.*	--	
139.00	Are non-RAM expired or damaged products destroyed on site? *View documentation. If "no", note the name of the reverse distributor.*	--	
	Components		
140.00	Certificates of analysis (COAs) are obtained for all bulk APIs (such as I-131 for making capsules and solutions) and for media used for viable testing.	--	
141.00	Certificates for each sealed source are kept on file. *It will show the original activity and date of calibration.*	--	
142.00	USP- or NF-grade substances used, if available.	--	

143.00	APIs or other components have labeling indicating use for pharmaceutical compounding or manufacturing. Labels do not indicate "For Research Purposes Only," or "Not for Drug Use," or "Veterinary Use Only," or are handwritten labels from other pharmacies. *Photograph and describe if found. Request copies of the invoices for products with questionable labels.*	--	
144.00	All substances and components have a complete label including a batch control or lot number, and an expiration date.	--	
145.00	For APIs without an expiration date assigned by the manufacturer or supplier, the pharmacy assigns a conservative expiration date. *The expiration date assigned is not greater than one (1) year, unless it is supported with data and/or testing. Note: purity and quality testing may be performed to extend.*	--	
146.00	All APIs are labeled with the date they were received.	--	
147.00	If the pharmacy repackages APIs into smaller containers for ease of use, the expiration date assigned is conservative (typically the lesser of one year or the actual expiration from the original container). *Product may be tested to extend the expiration date but may not exceed the original package expiration date.*	--	
148.00	Containers are labeled with appropriate OSHA hazard communication labels and are stored correctly.	--	
149.00	**Nonsterile compounding:** Is water an ingredient? If so, what type is used?	--	
150.00	Does the pharmacy use nonsterile empty vials and vial stoppers, or closures and terminally sterilize them with an on-site autoclave?	--	
	Prescription/Order Processing		
151.00	Are any portions of the prescription processing performed at a different location? *If so, explain. Indicate whether there is a central fill/central processing agreement in place.*	--	
152.00	Does the pharmacy obtain a copy or verify of the RAM license (of the facility to which the radiopharmaceutical will be delivered) issued by the State Radiation Control Agency or the NRC?	--	
153.00	Does the pharmacy verify the state medical license of the physician identified on the facility RAM license?	--	
154.00	Is there a procedure to follow a RAM license for the facility or the prescriber cannot be obtained or verified?	--	
155.00	Does the pharmacy have electronic prescription capability? *Indicate whether it is for non-controlled substances, controlled substances, or both.*	--	
156.00	Is the pharmacy computer system provided routine maintenance and is the information backed up? *Indicate the frequency of backup and if the backup data is stored off site.*	--	
157.00	Is there a continuity plan should the system become inoperable? *Describe how data will be retrieved.*	--	
	Patient Profiles and Communication		
158.00	Does the patient information gathered include patient contact information, age or date of birth, and gender?	--	
159.00	For therapy doses, does the pharmacy receive appropriate information to assess correct dosage, such as geriatric or pediatric weight-based doses?	--	
160.00	Does the pharmacist perform an evaluation of the dose, safety, and intended use of the preparation to be compounded?	--	
161.00	Does the pharmacy take back prescription drugs from customers? If so, describe.	--	
162.00	Are providers instructed on the signs of product instability or contamination (as appropriate) and to report any changes in the physical characteristics of the product to the pharmacy?	--	
163.00	Does the after-hours voicemail message have instructions on whom to contact based on urgency of issue? *For example, "if this is an emergency, please dial 911; leave message if not urgent; alternative number to call for advice after hours such as a nurse line, etc."*	--	

Facility Name:
Inspection Date:

	Patient Confidentiality		
164.00	Is the PIC also the HIPAA Privacy Officer? *If not, indicate privacy officer in Note.*	--	
165.00	Is there a HIPAA policy in place for employees, vendors, and contractors?	--	
166.00	Do employees deemed nonessential to patient care have access to confidential patient information, such as delivery services, etc.?	--	
167.00	Is access to the pharmacy system limited to appropriate personnel? *Password protected, access limited by job type, access revoked as appropriate such as upon termination, access to patient information in the computer is tracked.*	--	
168.00	Are confidential documents shredded? *Indicate if In-house or by a service and list service in notes if applicable.*	--	
169.00	Does the pharmacy destroy PHI including labeled prescription vials?	--	
170.00	Does the crisis plan includes security of paper and electronic patient information?	--	
	Prescription Packing and Transporting		
171.00	Does the pharmacy utilize employee drivers to deliver prescriptions to patients and/or after and facilities?	--	
172.00	Does the pharmacy utilize other services/carriers to deliver prescriptions to patients and/or facilities? *Indicate carriers used.*	--	
173.00	There is a tracking system in place to verify delivery of prescription products. *Indicate if signatures obtained or how tracked.*	--	
174.00	Deliveries of RAM are directly to a secure location at a health care facility.	--	
175.00	Is only authorized packaging used?	--	
175.01	Are DOT-7A performance test records on file for each type of packaging used by the pharmacy? *View documentation.*	--	
175.02	Is the packaging tamper-evident?	--	
	Equipment		
	Total Non-Compliant (Includes Unknowns)	**0**	
176.00	Appropriate equipment and utensils are available, clean, and in good working order. *Automated, mechanical, or electronic equipment (including capsule machines, autoclaves, ovens, etc.) are periodically inspected and calibrated yearly or in accordance with the equipment manufacturer guidelines.*	--	
177.00	Appropriate instruments and meters (Geiger-Mueller survey meters, rate meters, Cutie Pie survey meters, etc) are available including documentation for use (P&P and operating instructions).	--	
178.00	PEC (hood) prefilters are checked and replaced regularly. *View replacement log or documentation of check and replacement by certification company.*	--	
179.00	Is all equipment thoroughly cleaned promptly after each use to prevent cross contamination?	--	
180.00	Automated Compounding Devices (ACDs) are used for sterile compounding (such as repeater pumps) and there is a P&P for the use and calibration.	--	
180.01	There is documentation of the ACD tubing being changed or discarded every 24 hours.	--	
180.02	The ACD is used when performing media fill testing.	--	
	Nonsterile Compounding -- Beyond-Use Dating (BUD)		
	Total Non-Compliant (Includes Unknowns)	**0**	
181.00	BUDs are assigned from the day of preparation.	--	

182.00	BUDs are assigned based on dispensing in tight, light-resistant containers/overpacks.	--	
184.00	Extended BUDs are assigned and the facility has performed its own stability testing. *View records, preparation must exactly match the preparation tested by the facility including concentration of all active ingredients, excipients, etc.*	--	
185.00	BUDs for nonaqueous formulations are not later than the remaining time until the earliest expiration date of any API and not later than six (6) months.	--	
186.00	BUDs for water-containing oral formulations are not later than 14 days when stored at controlled cold temperatures (refrigerated).	--	
187.00	BUDs for water-containing semisolid formulations are not later than 30 days.	--	
	Nonsterile Compounding -- Environment		
	Total Non-Compliant (Includes Unknowns)	**0**	
188.00	The non-sterile compounding area is a controlled environment and separate from the general pharmacy.	--	
189.00	The pharmacy performs non-sterile compounding in a ventilated cabinet.	--	
190.00	Ventilated cabinet(s) used for non-sterile compounding is certified or tested periodically.	--	
191.00	There is sufficient space available for the type and amount of compounding performed and the space is orderly to prevent mix-ups between ingredients, containers, labels, in-process materials, and finished preparations.	--	
192.00	Only one preparation is compounded at a time.	--	
193.00	The compounding area is well lit.	--	
194.00	Appropriate protective attire (gowns, gloves, masks, etc.) is available.	--	
195.00	There is a sink for the nonsterile compounding area with hot and cold potable water, soap or detergent, and air-driers or single-use towels. *This cannot be the same one for the sterile area.*	--	
196.00	**Temperature** in the compounding area is maintained to provide controlled room temperature of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements.	--	
196.01	If drugs are stored in the compounding area, temperature monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. *Temperature records are maintained.*	--	
196.02	Excursion action plan is in place including evaluating excursion effects on drug product integrity.	--	
197.00	**Humidity** in the compounding area is maintained to provide humidity in the ranges warranted by specific drug product storage requirements. *If drug products require storage in a "dry place", humidity is not to exceed 40%. Generally **recommended** range is 35-60%.*	--	
197.01	Humidity monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. *Humidity records are maintained.*	--	
197.02	Excursion action plan is in place including evaluating excursion effects on drug product integrity.	--	
198.00	All components, equipment, and containers are stored off the floor, and handled and stored to prevent contamination.	--	
199.00	All components and packaging containers and closures are properly rotated to use oldest first.	--	
	Nonsterile Compounding -- Documentation		
	Total Non-Compliant (Includes Unknowns)	**0**	
200.00	The pharmacy creates a Master Formulation record the first time before compounding a new preparation.	--	
201.00	Every formulation is evaluated for incompatibilities and the potential for being ineffective or toxic.	--	

202.00	The **master formulation record** includes:		
202.01	Official or assigned name, strength, and dosage form;	--	
202.02	All necessary calculations;	--	
202.03	Description of all ingredients and their quantities;	--	
202.04	Compatibility and stability information including references (when available);	--	
202.05	Equipment used for the preparation;	--	
202.06	Mixing instructions (order of mixing, temperatures, duration of mixing, and other pertinent factors);	--	
202.07	Container used and packaging requirements;	--	
202.08	Assigned BUD information;	--	
202.09	Labeling information including the name of and quantity or concentration of each active ingredient;	--	
202.10	Description of the finished preparation;	--	
202.11	Storage requirements; and	--	
202.12	Quality control procedures and expected results (e.g. dose measurement of capsule in the dose calibrator).	--	
203.00	The pharmacy creates a compounding record for each compound prepared.	--	
204.00	The **compounding record** includes:		
204.01	Official or assigned name, strength and dosage of the preparation;	--	
204.02	Master Formulation Record reference;	--	
204.03	Sources, lot numbers, and expiration dates of all components;	--	
204.04	Total quantity or number of dosage units compounded;	--	
204.05	Person compounding the preparation;	--	
204.06	Person performing the quality control procedures;	--	
204.07	Person who approved the preparation;	--	
204.08	Date of compounding;	--	
204.09	Assigned internal identification number or prescription number;	--	
204.10	Description of the final preparation;	--	
204.11	Assigned BUD;	--	
204.12	Duplicate label;	--	
204.13	Results of quality control procedures (weight range of filled capsules, pH of aqueous liquids, etc.); and	--	
204.14	Documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver including investigation and recall, if appropriate.	--	

Nonsterile Compounding -- Compounding Procedures

	Total Non-Compliant (Includes Unknowns)	**0**	
205.00	The Master Formulation Record and the Compounding Record has been reviewed by the compounder to ensure it is error free.	--	
206.00	Compounding personnel ascertain that ingredients for compounded preparations are of the correct identity and appropriate quality including a unit-by-unit inspection of the components.	--	
207.00	The containers and closures selected meet USP standards (from container supplier).	--	

208.00	Container selection determined by physical and chemical properties of the preparation.	--	
209.00	Compounding personnel maintain good hand hygiene and wear clean and appropriate clothing for the compounding being performed.	--	
210.00	Personnel don appropriate protective garb when performing compounding.	--	
211.00	Routine compounding procedures for batch preparation completed and verified according to written procedures, including: c*alculations correct, weighing and measuring performed correctly, order of mixing correct, compounding techniques performed correctly.*	--	
212.00	Procedures for in-process checks followed. *These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists that includes visual inspection of product, and documentation of the compounding accuracy is performed to ensure proper measurement, reconstitution and component usage.* ***Recommended:*** *compounding accuracy checked by a person other than the compounder.*	--	
213.00	There are no deviations from the master formulation record, unless they are approved and deemed appropriate by a pharmacist and a new master formulation record is created.	--	
214.00	There is a procedure for cleaning which is followed. *After each preparation, daily tasks, monthly tasks, etc.*	--	
215.00	Personnel are appropriately garbed for protection when cleaning.	--	

Nonsterile Compounding -- Release Checks

	Total Non-Compliant (Includes Unknowns)	**0**	
216.00	The finished preparation is observed to appear as expected in the master formulation record and documented.	--	
217.00	As appropriate, the final completed preparation assessed for weight, mixing, clarity, color, consistency, pH, and strength/activity and documented.	--	
217.01	Batch preparations (in anticipation of prescriptions) are of an appropriate volume and batch products in stock are all within their BUD (not outdated).	--	
217.02	Labels on batch preparations include the name and quantity of all contents, date and time of preparation (or internal code/lot number indicating this information), preparer and verification pharmacist identifiers, stability (BUD), and any auxiliary labels indicated including appropriate packaging and labeling of hazardous materials.	--	
218.00	The immediate container shall be labeled with:		
218.01	The standard radiation symbol;	--	
218.02	The words “Caution — Radioactive Material”;	--	
218.03	The name of the pharmacy; and	--	
218.04	The prescription number.	--	
219.00	Does the labeling on patient-specific containers include:		
219.01	State required prescription label information;	--	
219.01	Identifiers for the persons preparing the compound and performing the final verification;	--	
219.03	BUD;	--	
219.04	An indication that this is a compounded preparation; and	--	
219.05	Any additional special handling requirements.	--	
220.00	The immediate outer container of a radioactive drug to be dispensed shall also be labeled with:		
220.01	The standard radiation symbol;	--	
220.02	The words “Caution — Radioactive Material”;	--	

220.03	The name of the radionuclide;	--	
220.04	The chemical form;	--	
220.05	The amount of RAM contained, in millicuries or microcuries;	--	
220.06	If the radioactive drug is a liquid, the volume in milliliters;	--	
220.07	The requested calibration time for the amount of radioactivity contained.	--	

Sterile Compounding -- Environment

	Total Non-Compliant (Includes Unknowns)	**0**	
221.00	The anteroom has a line of demarcation or other separation of the dirty to the clean side. *Note: the line of demarcation may NOT be the doorway between the anteroom and the clean/buffer room.*	--	
221.01	Carts used to bring supplies from the storeroom are kept on the outside of the line of demarcation.	--	
221.02	Carts used in the clean/buffer room are kept on the clean side of the line of demarcation.	--	
222.00	All surfaces of the sterile product compounding area carts, shelves, stools, chairs, and other items are resistant to disinfectants, non-permeable, non-carpeted or upholstered, and low particulate generating.	--	
223.00	Walls are constructed of durable material, which is cleanable, such as epoxy-coated or heavy-gauge polymer material. If panels are used, they are locked together and sealed.	--	
224.00	The ceiling surface shall be impervious and hydrophobic. If tiles are used, they shall be locked and the seams between the tiles and where they meet the walls shall be caulked and sealed.	--	
225.00	The floor overlaid with wide sheet flooring and seamless or with heat welded seams, with coving to the sidewall, and a sealed seam where the coving meets the wall.	--	
226.00	The clean/buffer room or anteroom does not have dust collecting overhangs.	--	
227.00	The exposed surfaces of:		
227.01	PEC are free of dirt, rust, chips and particulate matter.	--	
227.02	Light fixtures are smooth, mounted flush, and sealed.	--	
228.00	A working sink, located on the clean side of the line of demarcation, is available that enables pharmacy personnel to wash hands and enter the sterile compounding area without contaminating his/her hands and is away from/not adjacent to any PEC(s).	--	
229.00	There is no sink or drain in the clean/buffer room.	--	
230.00	All air ducts controlling air flow into the sterile compounding area are equipped with HEPA-filtered air that maintains the clean/buffer room with at least an ISO Class 8 environment.	--	
231.00	Incoming air ducts through HEPA filters are on or near the ceiling and air return ducts are low on the walls in the anteroom and clean/buffer room.	--	
232.00	Beverages including drinking water, chewing gum, candy, or food items are prohibited from the clean/buffer room or anteroom.	--	
233.00	If compounding occurs using nonsterile ingredients, products, components, or devices (for example compounding with non-sterile APIs or using nonsterile vials and closures), the pharmacy has appropriate equipment to sterilize the finished product.	--	
233.01	Pre-sterilization procedures for high risk level CSPs (such as weighing and mixing) are performed in no worse than an ISO Class 8 environment.	--	
234.00	Does the ISO Class 8 clean room or buffer area door lead into an ISO Class 8 anteroom?	--	
235.00	Completely enclosed anteroom and clean/buffer room (with a door) are equipped with monitors or gauges to measure differential pressure.	--	
235.01	Anteroom is at least 0.02" wc positive pressure to general pharmacy areas.	--	
235.02	Clean/buffer room is at least 0.02" wc positive pressure to general pharmacy areas.	--	

235.03	Hazardous compounding room and drug storage area is at least 0.01" wc negative pressure to ISO Class 7 anteroom.	--	
235.04	Pressures are reviewed and documented on a log at least every work shift (minimum of once daily) or monitored by a continuous recording device. *View logs*	--	
235.05	Written plan in place to detect and react to pressure differentials outside of limits.	--	
236.00	If the clean/buffer room and anteroom are not fully enclosed (open or with plastic strips - no door that closes), the air flow is measured across the openings.	--	
236.01	The air flow is at least 40 feet per minute across the entire opening.	--	
236.02	Airflow is read and recorded each shift (minimum of once daily) or continuously recorded. *View logs.*	--	
236.03	Written plan in place to detect and react to air flow measurements outside of limits.	--	
236.04	This area is used only for low- and medium-risk compounding (HD and high-risk not allowed).	--	
237.00	The doors into the anteroom from the general pharmacy area and from the anteroom into the clean room are prevented from both being open at the same time. By interlocking, training of personnel, or signage.	--	
238.00	The inside and outside doors of a pass-through are prevented from both being open at the same time. *By interlocking, training of personnel, or signage.*	--	
239.00	**If the PEC is a BSC or LAFW that is NOT located in an ISO Class 7 clean/buffer room**: BSC or LAFW has been certified to maintain ISO Class 5 during compounding activities.	--	
239.01	If low risk, are the compounds located in segregated area are BUD 12 hours or less? *If yes, list percentage.*	--	
239.02	All garbing requirements are adhered to.	--	
239.03	Located in an area that is maintained under sanitary conditions and only traveled by persons engaging in the compounding of sterile preparations.	--	
239.04	Location does not contain any unsealed windows or doors that connect to the outdoors or areas of high traffic flow, and is not adjacent to construction sites, warehouses, or food preparation areas.	--	
240.00	**If the CAI/CACI that is *not* located in an ISO Class 7 clean/buffer room:** CAI/CACI has been certified to maintain ISO Class 5 under dynamic conditions including transferring of ingredients, components and devices, and during preparation of Compounded Sterile Preparation (CSP).	--	
240.01	The pharmacy has documentation from the manufacturer that the CAI or CACI will meet this standard when located in worse than ISO Class 7 environments.	--	
240.02	The CAI or CACI is located in an area that is maintained under sanitary conditions and only traveled by persons engaging in the compounding of sterile preparations.	--	
240.03	The sink is separated from the immediate area of the ISO Class 5 BSC or LAFW (not adjacent).	--	
241.00	**Temperature** in the compounding area is maintained to provide controlled room temperature of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements.	--	
241.01	Temperature monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. *Temperature records are maintained.*	--	
241.02	Excursion action plan is in place including evaluating excursion effects on drug product integrity.	--	
242.00	**Humidity** in the compounding area is maintained to provide humidity in the ranges warranted by specific drug product storage requirements. *If drug products require storage in a "dry place", humidity is not to exceed 40%. Generally **recommended** range is 35-60%.*	--	
242.01	Humidity monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. *Humidity records are maintained.*	--	
242.02	Excursion action plan is in place including evaluating excursion effects on drug product integrity.	--	
243.00	Are the blowers on PECs operated continuously during compounding activity, including during interruptions of less than eight hours?	--	

244.00	When the ISO 5 PEC blower is turned off and before other personnel enter to perform compounding activities, is only one garbed person allowed to enter the buffer area for the purposes of turning on the blower (for at least 30 minutes) and sanitizing the work surfaces?	--	
	Sterile Compounding -- Cleaning and Disinfection		
	Total Non-Compliant (Includes Unknowns)	**0**	
245.00	Are all personnel performing cleaning appropriately garbed?	--	
246.00	Is the sterile compounding area equipped with appropriate nonshedding cleaning equipment and supplies? *All cleaning tools, such as wipers, sponges, and mops, must be nonshedding, dedicated to and labeled for use in either the buffer or clean area (no wooden handles are allowed).*	--	
247.00	If cleaning tools are reused, is there a procedure to rinse and sanitize the tools?	--	
248.00	Are reusable tools appropriately labeled to prevent them from being used inappropriately?	--	
249.00	For cleaning and sanitizing agents that are not "ready-to -use" formulations, Aare there formulas and instructions for mixing or diluting the cleaning and sanitizing agents prior to use and is the preparation of cleaning supplies agents documented?	--	
250.00	Are cleaning and sanitizing agents appropriately labeled including expiration dates? *Verify no expired agents present.*	--	
251.00	Are appropriate cleaning agents used that are effective for bacteria, viruses, fungi, and spores?	--	
252.00	Is the ISO 5 PEC cleaned at the beginning of each shift, between compounding different preparations, at least every 30 minutes while compounding and after spills or suspected surface contamination?	--	
253.00	Does sanitizing of the ISO 5 PEC include sanitizing with sterile 70% IPA using a nonlinting wipe?	--	
253.01	If heavily soiled, cleaning includes the appropriate agent. *List agent(s) used.*	--	
254.00	Does daily cleaning and sanitizing include counters and easily cleanable work surfaces?	--	
255.00	Does daily cleaning include the floors starting from the clean room and working outwards? *Floor cleaning is not to occur during compounding.*	--	
256.00	If fatigue mats are used in the clean room or anteroom, are they cleaned daily and left to dry on both sides?	--	
257.00	Is a tacky mat used, and if so, is there a procedure in place regarding replacement?	--	
258.00	Are the ceilings, walls, all shelving, bins, carts, chairs, and the tops and sides of the PECs thoroughly cleaned monthly? *(This includes removing everything from shelves and bins before cleaning, cleaning the undersides of cart surfaces and stools, wheels, etc.) Check inside bins and shelving for dust in clean room if you are garbed.*	--	
259.00	Is enough time allocated for cleaning activities, including contact/dwell times for the cleaning/disinfection agents?	--	
	Sterile Compounding -- Garbing		
	Total Non-Compliant (Includes Unknowns)	**0**	
260.00	Personnel are prohibited from compounding, or entering the clean/buffer room or anteroom if they have a rash, sunburn, weeping sores, conjunctivitis, or an active respiratory infection.	--	
261.00	Personnel are required to remove all personal outer garments such as hats, scarves, sweaters, vests, coats, or jackets and any makeup or cosmetics before entering compounding areas. *Include observations in the comments.*	--	
262.00	Personnel are required to remove all hand and wrist jewelry, and all visible jewelry or piercings such as earrings, lip or eyebrow piercings, etc. before entering clean/buffer room.	--	
263.00	Personnel are prohibited from wearing artificial nails or extenders, and required to keep natural nails neat and trimmed.	--	

264.00	Garbing with dedicated shoes or shoe covers that are donned as the line of demarcation is crossed (with the dedicated or covered shoe never touching the same side of the line of demarcation as the dirty shoe).	--	
265.00	Garbing includes head and facial hair covers and masks? *Note that facial hair requires both a facial hair cover AND a mask. Eye shields are optional unless using cleaning agents as indicated on SDS. There is a method available to assure that all hair is covered.*	--	
266.00	Hand cleaning is performed in the anteroom and includes removing debris from under the nails with a nail cleaner followed by a vigorous washing of the hands and forearms with soap for at least 30 seconds with hands and arms then dried with lint-free disposable towels, or an electronic or HEPA filtered hand dryer. *Scrub brushes are NOT recommended as they cause skin irritation and damage.*	--	
267.00	The gown is nonshedding with sleeves that fit snugly around the wrists and enclosed at the neck.	--	
268.00	All bare skin is covered on the arms and the legs (no bare ankles, wrists, etc).	--	
269.00	Prior to donning sterile gloves, a waterless alcohol based surgical hand scrub with persistent activity is used and hands allowed to dry. *Note: regular Purell Hand Sanitizer is NOT appropriate. Purell or other brand surgical hand scrub is appropriate - must have residual activity.*	--	
270.00	Upon leaving the sterile product compounding area, gowns are taken off and disposed of, or if used for nonhazardous compounding they are left in the anteroom and not reused for longer than one shift.	--	
271.00	Pharmacists or other personnel do NOT enter the anteroom and cross the line of demarcation without donning shoe covers or dedicated shoes. *Watch for personnel traversing back and forth across the line of demarcation without doffing and donning new shoe covers or dedicated shoes.*	--	
272.00	Pharmacists or other personnel do NOT enter the clean/buffer room without fully washing and garbing (wearing just a mask to check technician's work, for example).	--	

Sterile Compounding -- Compounding Procedures

	Total Non-Compliant (Includes Unknowns)	**0**	
273.00	Gloves are disinfected with adequate frequency with an approved disinfectant, such as sterile 70% isopropyl alcohol (IPA).	--	
274.00	Nonessential objects that shed particles are prohibited in the buffer or clean area, including pencils, cardboard cartons, paper towels, reading material, and cotton items (e.g., gauze pads)?	--	
275.00	Essential paper related products (syringe overwraps, work records contained in a protective plastic sleeve) are wiped down with sterile 70% IPA before being brought into the buffer or clean area.	--	
276.00	Supplies required for the scheduled operations of the shift are prepared by wiping the outer surface with sterile 70% IPA (or removing the outer wrap as the item is introduced into the aseptic work area) and brought into the buffer or clean area in a bin or on a movable cart.	--	
277.00	Compounding employees are using appropriate aseptic technique. *May require inspector to garb and enter clean/buffer room. Pay attention to first air, entry and exit of materials in ISO Class 5 PEC, appropriate frequent sanitization of gloves, appropriate cleaning and cleanliness of the direct compounding area (DCA).* ***Compounding MUST be observed****, if compounding is not being performed at the time of survey mark item as "Non-Compliant".*	--	
277.01	If compounding is not being performed at the time of survey, ask that a compounding pharmacist or technician prepare a compound for you to observe the compounding process. *If the pharmacy staff refuses or is unable to perform compounding for you to observe, document on the "* ***Denial of Authorization****" form. List individual who signs the Denial of Authorization.*		
278.00	Compounding personnel ascertain that ingredients for CSPs are of the correct identity and appropriate quality by reading vendors' labels, and a unit-by-unit physical inspection of the product before use.	--	

279.00	All rubber stoppers, of vials and bottles and the necks of ampules are disinfected with sterile 70% IPA waiting for at least 10 seconds before they are used to prepare CSPs.	--	
280.00	Are opened or needle punctured single-dose containers (bags, bottles, syringes, or vials) that are opened or punctured in worse than ISO Class 5 air used within one hour and the remaining contents discarded?	--	
281.00	Single-dose vials exposed to ISO Class 5 or cleaner air are used within six (6) hours of the initial puncture and any remaining contents discarded. *If exposed to less than ISO Class 5 air, used within 1 hour and discarded.*	--	
282.00	Multiple-dose vials formulated for removal of portions on multiple occasions are used within 28 days (or the manufacturer's specific BUD if less) after the initial entry or puncture and any remaining contents discarded.	--	
283.00	The compounding record is complete. *View several completed compounding records and answer each of the following questions. List records reviewed.*	--	
283.01	Official or assigned name, strength and dosage of the preparation;	--	
283.02	Names, lot numbers and expiration dates of all components;	--	
283.03	Total quantity or number of units compounded;	--	
283.04	Person compounding the preparation;	--	
283.05	Person performing the quality control procedures;	--	
283.06	Person who approved the preparation;	--	
283.07	Date of compounding;	--	
283.08	Assigned internal identification number or prescription number;	--	
283.09	Assigned BUD and reference if extended beyond USP guidelines;	--	
283.10	Duplicate label;	--	
283.11	Sterilization method (if applicable); and	--	
283.12	Indication of the quality control procedures to perform (testing, filter integrity, etc.) and results of the testing, quality control issues, and investigation/recall if applicable.	--	
284.00	Are procedures for in-process checks followed? *These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists that includes visual inspection of product, and documentation of the compounding accuracy is by someone other than the compounder to ensure proper measurement, reconstitution, and component usage.*	--	
285.00	Labels on BATCH preparations include the name and quantity of all contents, date, and time of preparation (or internal code indicating this information), preparer and verification pharmacist identifiers, stability (BUD), and any auxiliary labels indicated including appropriate packaging and labeling.	--	
286.00	The immediate container shall be labeled with:		
286.01	The standard radiation symbol;	--	
286.02	The words “Caution — Radioactive Material”;	--	
286.03	The name of the pharmacy; and	--	
286.04	The prescription number.	--	
287.00	Does the labeling on patient-specific containers include:		
287.01	State required prescription label information;	--	
287.02	Identifiers for the persons preparing the compound and performing the final verification;	--	
287.03	BUD;	--	

287.04	Route of administration and flow rate (if applicable); and	--	
287.05	Any additional special handling requirements?	--	
288.00	The immediate outer container of a radioactive drug to be dispensed shall also be labeled with:		
288.01	The standard radiation symbol;	--	
288.02	The words “Caution — Radioactive Material”;	--	
288.03	The name of the radionuclide;	--	
288.04	The chemical form;	--	
288.05	The amount of RAM contained, in millicuries or microcuries;	--	
288.06	If the radioactive drug is a liquid, the volume in milliliters;	--	
288.07	The requested calibration time for the amount of radioactivity contained.	--	
289.00	All manufacturer-supplied products are stored in original manufacturers containers.	--	
290.00	BUDs assigned that are greater than 12 hours are documented with justification based on USP guidelines, testing, or literature. *Verify documentation and list at least three products reviewed (where applicable).*	--	
291.00	If BUDs are set according to manufacturers’ package insert recommendation(s), the products are prepared **exactly** according to package insert. *Verify documentation and list at least three products reviewed (where applicable).*	--	
292.00	Appropriate sterilization methods are used and documented. *Ensure P&Ps are in place that address determining the appropriate type of sterilization method, equipment to be used, documentation to be kept, and testing to be performed.*	--	

Sterile Compounding -- Release Checks and Tests

	Total Non-Compliant (Includes Unknowns)	**0**	
293.00	For suspensions, is the particle size measured (where applicable)?	--	
294.00	Are products visually checked for particulates or other foreign matter against both a light and a dark colored background as a condition of release?	--	
295.00	Are there checks for container, closure integrity and any other apparent visual defects?	--	
296.00	Is compounding accuracy documented by verification of steps?	--	
297.00	Is verification of ingredient identity and quantity verified? *Is there a reconciliation of components?*	--	
298.00	Are labels verified as being correct and is a copy of the label included in the record? *Complies to regulation, contains the correct names and amounts or concentrations of ingredients, total volumes, BUDs, storage conditions, and route of administration.*	--	
299.00	**Sterility testing (USP <71>).** *If testing is performed to a higher standard than the minimums below, describe.*		
299.01	Sterility testing includes both bacterial and fungal testing.	--	
299.02	Sterility testing is performed for all CSPs that have extended BUDS.	--	
299.03	Sterility testing is performed for high-risk CSPs prepared in batches of more than 25 identical containers.	--	
299.04	Sterility testing is performed for CSPs exposed longer than 12 hours at 2°C-8°C or longer than six hours at warmer than 8°C before being sterilized.	--	

Facility Name:

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299.05	The appropriate quantities of units are sterility tested. Parenterals, number of units in the batch is: 1. Not more than 100, test 10% or four units, whichever is greater 2. More than 100 but more than 500, test 10 units 3. More than 500, test 2% or 20 units, whichever is less For large volume parenterals: 2% or 10 containers, whichever is less. For non-parenterals (eye drops, inhalation, etc.): 1. Not more than 200 containers, test 5% or 2 containers, whichever is greater 2. More than 200, test 10 containers 3. If the product is packaged in unit doses, use the parenteral testing above.	--	
299.06	For products failing testing, product is quarantined, and an investigation is performed including microbial identification and action taken. *View testing records and note any products with failed results and actions taken.*	--	
299.07	If items are dispensed or distributed prior to sterility testing completion, there is a written procedure requiring daily observation of the incubated media. If there is any evidence of microbial growth, there is an immediate recall and both the patient and the physician/prescriber of the patient to whom a potentially contaminated CSP was administered are notified of the potential risk. *View testing records and note any products with failed results and actions taken.*	--	
300.00	The appropriate quantity of units is used for sterility testing?	--	
301.00	**Endotoxin testing (USP <85>).** *If testing is performed to a higher standard than the minimums below, describe.*		
301.01	Is endotoxin testing performed for all high-risk level CSPs for administration by injection prepared in groups of more than 25 single-dose packages (such as ampules, bags, syringes, vials).	--	
301.02	High-risk CSPs prepared in multiple dose vials for administration to multiple patients.	--	
301.03	High-risk CSPs exposed longer than 12 hours at 2°C-8°C (25°F-46°F) or longer than six (6) hours at warmer than 8°C (46°F) before they are sterilized.	--	
301.04	For products failing testing, product is quarantined, and an investigation is performed and action taken. *View testing records and note any products with failed results and actions taken.*	--	
302.00	**Purity testing:** CSPs are tested for radiochemical purity.	--	
303.00	View a sampling of testing records. Products that have been dispensed or distributed that failed testing (e.g. sterility, endotoxin, or radiochemical purity) have been appropriately recalled and investigated.	--	

The information and comments obtained in the nonsterile and sterile compounding sections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

P.I.C. Signature Date

Inspector Signature Date