COMPLIANCE – Nuclear Pharmacy Sterile & NON-Sterile Compounding[1] [2]

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Bureau of Health Professions Licensure

Board of Registration in Pharmacy
250 Washington Street, Boston, MA 02108-4619
(617) 973-0800
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DATE(S) OF INSPECTION:			INSPECTION #:	ISP-						
PHARMACY DBA NAME:										
STREET ADDRESS:										
CITY / STATE / ZIP:										
TELEPHONE:										
FAX:										
EMAIL:										
PHARMACY LIC. NUMBERS:										
PHARMACY LIC. EXPIRATION:										
DEA REG. NUMBER:										
DEA REG. EXPIRATION:										
PURPOSE OF INSPECTION:	☐ NEW STORE		☐ RELOCATION		☐ COMPLIANCE					
MANAGER OF RECORD (MOR):										
MOR REG. NUMBER:										
PHARMACY HOURS:	MON		TUE		WED		THU		FRI	
	SAT				SUN					
PRACTICE SETTING:	☐ RADIOPHARMACY		☐ PET MANUFACTURER		☐ BOTH					
DAILY PHARMACY VOLUME (RXs):	☐ LESS THAN 100		☐ 100 TO 500		☐ ABOVE 500					
PROCEDURAL:	☐ PATIENT SPECIFIC ☐ INTERVENTIONAL		☐ HOT-CELL ☐ SRPA		☐ INVESTIGATIONAL DRUGS ☐ NONSTERILE (CNSP) ☐ STERILE (CSP)					
SECURITY CAMERAS:	☐ YES ☐ NO									
SPECIAL LICENSE(S) ISSUED:	☐ YES ☐ NO									
OUT OF STATE LICENSE(S)?	☐ YES ☐ NO									

	White – Compliance Statement	**USP <825> Standards**	Question #s: 1.00 – 353.00
	Blue – Compliance Criteria		

[1] MA Board of Registration in Pharmacy: Compounding Pharmacy Practice Resources - https://www.mass.gov/lists/pharmacy-practice-resources (accessed 11.29.23)

[2] MA Board of Registration in Pharmacy: 247 CMR 13.00 - https://www.mass.gov/regulations/247-CMR-1300-registration-requirements-and-minimal-professional-standards-for-nuclear-pharmacies (accessed 12.4.2023)

Item #	Requirement	Y/N/N/A	Comment
A	**General Requirements**		
1.00	Does the pharmacy compound nonsterile radiopharmaceuticals? If so, list which of the following do they compound (e.g. Oral Capsules, oral solutions, other (if other, list those products in the notes)).		
2.00	Does the pharmacy obtain conventionally manufactured nonsterile drug products for dispensing? If so, list those products in the notes.		
3.00	Does the pharmacy obtain compounded nonsterile preparations from 503B-registered outsourcing facilities for dispensing? If so, list those products/outsourcers in the notes.		
4.00	Does the pharmacy compound sterile radiopharmaceuticals? If so, list which of the following compounds in the notes. (e.g., intravenous, intrathecal, intraperitoneal, subcutaneous, intradermal, inhalations, ophthalmics, intra-organ instillations)		
5.00	Does the pharmacy obtain conventionally manufactured sterile drug products for dispensing? If so, list those products in the notes.		
6.00	Does the pharmacy obtain compounded sterile preparations from 503B-registered outsourcing facilities for dispensing? If so, list those products/outsourcers in the notes.		
7.00	Does the pharmacy compound sterile preparations involving one or more nonsterile components?		
8.00	If the pharmacy compounds sterile preparations requiring a sterilization procedure, is testing (e.g. filtration with bubble point testing) performed prior to dispensing?		
9.00	If the pharmacy compounds injectable sterile preparations involving one or more components that are not certified to be pyrogen-free, is pyrogen testing performed prior to dispensing?		
10.00	Does the pharmacy prepare and dispense sterile radiopharmaceuticals in a patient care setting as immediate use?		

Item #	Requirement	Y/N/N/A	Comment
A	**General Requirements**		
11.00	Does the pharmacy prepare immediate use sterile radiopharmaceuticals in an ambient environment without primary or secondary engineering controls?		
12.00	Does handling for immediate use sterile radiopharmaceuticals in an ambient environment lacking primary and secondary engineering controls when intended for a single patient meet the following requirements? as applicable:		
12.01	Are preparations (including minor deviations) and/or dispensing limited to use for a single patient?		
12.02	Are preparation (including preparations with minor deviations) components sterile, conventionally manufactured drug products (e.g., NDA, ANDA)?		
12.03	Are dispensing of drug products produced under an approved IND or RDRC protocol?		
12.04	Are manipulations for any unit doses (e.g., decreasing the dosage, needle changes) or dispensing for one patient (e.g., withdrawing a dose)?		
12.05	Are preparations labeled for administration within 1 hour of the first container puncture or exposure of any critical site involved (e.g., syringe tip, needle hub or needle) to ambient air, whichever is first?		
12.06	Are all components involved (e.g., Tc-99m sodium pertechnetate syringe or vial, final prepared radiopharmaceutical kit vial, diluent vial) discarded within 1 hour of being punctured or after use for a single patient administration, whichever is first?		
12.07	Does the pharmacy indicate that dose pooling (combining doses from two or more syringes to meet one patient's need) is performed as immediate use? Is any residual activity that remains is immediately discarded and not utilized for any other patient?		
12.08	Does pharmacy staff follow proper hand hygiene and garbing?		
12.09	Does the pharmacy follow 10.4 Preparation of Radiolabeled Red Blood Cells for Immediate Use for red blood cell labeling?		
12.10	Does the pharmacy follow 12.2 Labeling for labeling?		

Item #	Requirement	Y/N/N/A	Comment
A	**General Requirements**		
12.11	Is area for sterile preparation and/or dispensing functionally separate from nonsterile compounding area (e.g., radiolabeling food) during the time of use?		
12.12	Does the pharmacy require a segregated radiopharmaceutical processing area (SRPA), classified area, or PEC?		
12.13	Are the number of steps or punctures limited?		
12.14	Does the pharmacy require personnel to complete the aseptic qualifications as detailed in 4.1 Aseptic Qualifications (e.g., aseptic technique training with documented assessment, media fill challenge, gloved fingertip testing)?		
12.15	Is adding non-radioactive, sterile, and commercially manufactured pharmaceutical(s) only applicable if performing immediate use. While adding a non-radioactive, sterile, and commercially manufactured pharmaceutical (e.g., lidocaine) to a unit dose is otherwise considered compounding, it is allowed for immediate use purposes if all the above are adhered to.		
12.16	Is dose splitting (splitting a unit dose for administration to more than one patient) performed as immediate use?		
12.17	If performed, is dose splitting done in an ISO class 5 PEC in either an SRPA or in an ISO class 8 or better buffer area? Note where this is performed.		
B	**Personnel Qualifications and Training**		
13.00	Are personnel trained to work with radiopharmaceuticals per policies and standard operating procedures (SOPs) authorized by an ANP or AU (e.g. physician)?		
14.00	Do personnel follow these policies or SOPs of the ANP or AU (e.g. physician) and work under their supervision?		
14.01	Are personnel trained in blood-borne pathogens (as appropriate)?		
15.00	Are individuals entering a handling area properly garbed and maintain proper personal hygiene to minimize the risk of contamination to the environment and/or radiopharmaceuticals?		

Item #	Requirement	Y/N/N/A	Comment
B	**Personnel Qualifications, and Training**		
15.01	Are individuals who have a condition that may pose a higher potential of contaminating the radiopharmaceutical and the environment with microorganisms (e.g., rashes, sunburn, recent tattoos, oozing sores, conjunctivitis, or active respiratory infection) reported to their supervisor?		
15.02	Is the designated person responsible for evaluating whether these individuals should be excluded from working in sterile processing areas before their conditions are resolved?		
16.00	Have all personnel of reproductive capability who handle, or compound radiopharmaceuticals/radioactive materials confirmed in writing they understand the risks of handling radiopharmaceuticals/radioactive materials?		
17.00	Is there documentation of training for other employees (including drivers, warehouse, receiving, administrative, clerks, etc.) who may have contact with radiopharmaceuticals/radioactive materials on handling the spills associated with these?		
18.00	Can personnel demonstrate knowledge and can verbalize the principles of the safe use of RAM – time (working quickly/efficiently), distance (not handling RAM directly, using tongs), and shielding (using lead containers and shields in work areas)?		
19.00	Can personnel demonstrate a knowledge of emergency procedures and are able to point out the locations of the eyewash station, emergency spill kit, and can verbalize how to handle contamination including reporting?		
20.00	Do personnel prove competency under the observation of a designated person, as applicable to their jobs, prior to performing radiopharmaceutical aseptic tasks (that are beyond immediate use). Note– these can be completed at a different site if all SOPs are identical for the applicable job function.		
21.00	Do the minimum qualifications include the following?		
21.01	Aseptic technique with a documented assessment (written or electronic)		
21.02	Garbing and hand hygiene, as defined by policies and SOPs		

Item #	Requirement	Y/N/N/A	Comment
B	**Personnel Qualifications and Training**		
21.03	PEC cleaning and disinfecting		
21.04	Gloved fingertip and thumb sampling		
21.05	Media-fill testing (not required for non-compounding personnel)		
22.00	Is gloved fingertip and thumb sampling required for all personnel who enter and perform tasks in an ISO Class 5 PEC (e.g., aseptic manipulations, cleaning the PEC)?		
23.00	Is gloved fingertip and thumb sampling performed initially on both hands, immediately following hand hygiene and garbing?		
23.01	Is successful completion of initial gloved fingertip and thumb sampling defined as zero colony- forming units (cfu)?		
24.00	Is subsequent gloved fingertip and thumb sampling after media-fill testing defined as ≤3 cfu (total for both hands)?		
25.00	Is the gloved fingertip and thumb sampling performed with touch plates or other devices (e.g., plates, paddles, or slides) that contain a general microbial growth agar [e.g., trypticase soy agar (TSA) soybean–casein digest media] supplemented with neutralizing additives (e.g., lecithin and polysorbate 80) which support both bacterial and fungal growth?		
26.00	Per P&P review, gloves are not disinfected immediately before touching the sampling device.		
27.00	Is a gloved fingertip and thumb sample from both hands collected by rolling finger pads and thumb pad over the agar surface, using a separate sampling device for each hand?		
28.00	Are the plates incubated in an incubator at 30°–35° C for no less than 48 h, and then at 20°–25° C for no less than 5 additional days?		
29.00	Is media-fill testing done for all personnel who prepare, compound, dispense, and repackage sterile radiopharmaceuticals?		
30.00	Is testing reflective of the actual manipulations to be carried out by the individual and simulate the most challenging and stressful conditions to be encountered in the worker's duties?		

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B	**Personnel Qualifications and Training**		
31.00	Are media-fill tests documented as defined by the facility's policies and SOPs?		
33.00	Are media-fill tests performed with a commercial source of soybean–casein digest medium?		
34.00	Do those performing sterile-to-sterile processing activities start with sterile media?		
35.00	Do those performing nonsterile-to-sterile compounding use a nonsterile soybean–casein digest powder to make a solution?		
35.01	Is dissolved nonsterile commercially available soybean–casein digest medium in nonbacteriostatic water to make a 3% nonsterile solution?		
35.02	Is the final media manipulated in a manner that simulates nonsterile-to-sterile compounding activities?		
35.03	Is the final media prepared with at least 1 container as the positive control to demonstrate growth promotion, which is indicated by visible turbidity upon incubation?		
36.00	Does the certificate of analysis (CoA) include documentation of growth promotion testing for each lot of media used?		
37.00	Once the media-fill simulation is completed and the final containers are filled with the test medium, are the media filled containers incubated for 7 days at 20°–25° C followed by 7 days at 30°–35° C to detect a broad spectrum of microorganisms? Note: Failure is indicated by visible turbidity or other visual manifestations of growth in the medium in 1 or more container–closure unit(s) on or before 14 days.		
38.00	In the event of failure, are results of the evaluation and corrective actions documented and the documentation maintained to provide a record and long-term assessment of personnel competency?		
39.00	Do media and components used include the following?		
39.01	manufacturer		
39.02	expiration date		
39.03	lot number		

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B	**Personnel Qualifications and Training**		
40.00	Does the documentation include at a minimum the following?		
40.01	starting temperature for each interval of incubation		
40.02	dates of incubation		
40.03	results		
40.04	name of the person evaluated		
40.05	evaluation date		
40.06	evaluation time		
41.00	Do personnel who fail visual observation of hand hygiene, garbing, and aseptic technique, gloved fingertip and thumb sampling, or media-fill testing successfully pass reevaluations in the deficient area(s) before they can resume processing of sterile radiopharmaceuticals?		
42.00	Are all failures, retraining, and re-evaluations documented?		
43.00	Do personnel successfully complete requalification in the core competencies via demonstrated through observation, written testing, and hands-on demonstration of skills?		
44.00	Visual observation: Are personnel visually observed while performing hand hygiene, garbing SOPs, and aseptic technique procedures both initially, and then at least once **every 12 months**?		
45.00	Gloved fingertip and thumb sampling: Do personnel perform fingertip and thumb sampling 3 times initially, and then **every 12 months** (in conjunction with media-fill testing).		
46.00	Media-fill testing: After initial qualification, is a media-fill test of all personnel engaged in sterile radiopharmaceutical processing performed **at least every 12 months** (in conjunction with gloved fingertip and thumb sampling)?		
47.00	Cleaning and disinfecting: Does the pharmacy retrain and requalify personnel in the cleaning and disinfecting of sterile processing areas **every 12 months** or in conjunction with any change(s) in cleaning and disinfecting SOPs, whichever is sooner?		

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B	**Personnel Qualifications and Training**		
48.00	After a pause in sterile radiopharmaceutical processing: Are personnel that have not performed radiopharmaceutical processing in more than **6 months** requalified in all core competencies before resuming duties?		
49.00	Sterile compounding using a nonsterile drug substance or components: Are personnel who perform sterile compounding using a nonsterile drug substance or components requalified in all core competencies **every 6 months**?		
C	**Hand Hygiene and Garbing for SRPA**		
55.00	Before entering the SRPA or buffer area, do personnel remove all the following (as applicable)? (Radiation dosimetry devices are allowed, as required by the RAM license).		
55.01	Outer garments (e.g., bandanas, coats, hats, jackets, sweaters, vests)		
55.02	All cosmetics		
55.03	All hand, wrist, and other exposed jewelry including piercings that could interfere with the effectiveness of the garbing		
55.04	Nail products (e.g., artificial nails, polish, extenders). {Natural nails kept neat and trimmed.}		
55.05	Ear buds		
55.06	Headphones		
56.00	Are electronic devices that are not necessary for compounding or other required tasks banned from the SRPA?		
57.00	Do personnel don shoe covers, head/hair/facial hair cover(s) and face masks? Note – these items are donned in an order that eliminates the greatest risk of contamination, as defined in facility SOPs.		
58.00	Does the process before entering the buffer area or SRPA include the following?		
58.01	Remove visible debris from underneath fingernails under warm running water using a disposable nail cleaner		
58.02	Wash hands and arms up the elbows with soap and water for at least 30 seconds and then dry using low-lint towels		
58.03	Electronic hand dryers are not permitted		

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C	**Hand Hygiene and Garbing for SRPA**		
58.04	Hand antisepsis cleansing is performed using a suitable alcohol-based hand rub		
58.05	Don a low-lint gown with sleeves that fit snugly around the wrist and enclosed at the neck. Note: Disposable gowns are preferred.		
58.06	If reusable gowns are used, a clean gown is donned **daily**.		
58.07	Aseptically don sterile, powder-free gloves. Gloves completely and snugly cover the ends of the gown cuffs so that skin on the wrists and upper hands is completely enveloped.		
59.00	Does the routine process include the following?		
59.01	Do personnel periodically apply sterile 70% IPA to gloves while balancing the risk of radioactivity contamination; due to touching or handling potentially nonsterile materials?		
59.02	Do personnel inspect the gloves they are wearing for holes, punctures, radioactivity contamination, or tears?		
59.03	If a defect, radioactivity contamination, or malfunction is detected, do personnel immediately do the following?		
59.04	Remove the gloves		
59.05	Repeat antiseptic hand cleansing using an alcohol-based hand rub		
59.06	Don new sterile gloves		
59.07	Personnel avoid touch contamination of container septa, needles, syringe and needle hubs, and other critical sites		
60.00	Do exiting processes for buffer area or SRPA include the following?		
60.01	Shoe covers, head/hair/facial hair cover(s), face masks and gloves are properly disposed of		
60.02	New PPE is used for each re-entry		
60.03	Gowns may be re-used within the same shift if maintained to minimize contamination (e.g. away from sinks)		
60.04	Gowns are in a classified area or,		
60.05	Gowns are kept in (or immediately outside of) the SRPA		

Item #	Requirement	Y/N/N/A	Comment
D	**Primary and Secondary Engineering Controls**		
61.00	Is the facility is designed to minimize airborne contamination (for sterile radiopharmaceutical facilities)?		
62.00	Is the facility being well-lighted?		
63.00	Are the refrigerator and freezer restricted to drug products only (no food)?		
64.00	Are the temperatures in classified areas and SRPA continuously maintained at 25 degrees C or cooler?		
65.00	Are the temperatures monitored in the classified areas and SRPA each day that they are used, either manually or by a continuous recording device?		
66.00	Are the temperature readings of the classified areas and SRPA documented **at least once daily** or stored in a continuous recording device and retrievable?		
67.00	Are the temperature readings reviewed as described in the facility's SOPs?		
68.00	Free-standing air conditioners are not used within the classified area or SRPA?		
69.00	Are temperature monitoring devices calibrated and verified for accuracy **at least every 12 months** or as required by the manufacturer?		
71.00	Is the humidity monitored in the classified areas and SRPA each day that it is used, either manually or by a continuous recording device?		
72.00	Are the humidity readings of the classified areas and SRPA documented **at least once daily** or stored in a continuous recording device and retrievable?		
73.00	Are the humidity readings reviewed as described in the facility's SOPs?		
74.00	Are free-standing humidifiers/dehumidifier not used within the classified area or SRPA?		
75.00	Are humidity monitoring devices calibrated and verified for accuracy **at least every 12 months** or as required by the manufacturer?		
76.00	Is the designated person responsible to ensure the following?		
76.01	Does each area related to sterile radiopharmaceutical processes meet the classified air quality standard appropriate for the activities to be conducted in that area?		
76.02	Are ISO Class 5 PECs located, operated, maintained, monitored, and certified to have appropriate air quality?		

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D	**Primary and Secondary Engineering Controls**		
77.00	Were placement of doors, door surfaces, and movement of the door, all of which can affect airflow, considered when designing doors for a sterile radiopharmaceutical processing facility?		
78.00	Are tacky surfaces not used in ISO-classified areas?		
79.00	Are the PEC located in a SEC?		
80.00	When the PEC is in an SEC which is an ISO-classified buffer room with an ante room, does all the following apply?		
80.01	Is the ISO-classified anteroom and buffer area separated from the surrounding unclassified areas of the facility with fixed walls and doors?		
80.02	Are facility design and controls in place to minimize the flow of lower-quality air into the more controlled areas?		
80.03	Is the air supplied to the classified areas introduced through HEPA filters that are in the ceiling?		
80.04	Are returns low on the wall unless a visual smoke study demonstrates an absence of stagnant airflow where particulate will accumulate?		
80.05	Is a smoke study of the PEC repeated whenever a change to the placement of the PEC within the area is made?		
80.06	Are the classified areas equipped with a pressure-differential monitoring system?		
80.07	Does the anteroom have a line of demarcation to separate the clean side from the less clean side?		
80.08	Is the anteroom entered through the less clean side, and the clean side is the area closest to the buffer area?		
80.09	Is required garb worn prior to crossing the line of demarcation?		
81.00	When the PEC is in an SEC, which is an unclassified area, without an ante room or buffer area (aka SRPA), the following apply:		
81.01	Only sterile radiopharmaceutical preparation, preparation with minor deviations, dispensing, and repackaging may be performed in an SRPA		
81.02	The SRPA is located away from unsealed windows, doors that connect to the outdoors, and traffic flow which may adversely affect the air quality in the PEC.		

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D	**Primary and Secondary Engineering Controls**		
81.03	A visible perimeter establishes the boundaries of the SRPA.		
81.04	Access to the SRPA is restricted to authorized personnel and required materials.		
81.05	An SRPA is not located adjacent to environmental control challenges		
81.06	If the SRPA meets ISO Class 8 total airborne particle count specifications, it can also be used for storage and elution of non-direct infusion radionuclide generators (e.g., Tc-99m)		
82.00	If a pass-through is used to prevent influx of contaminants, both doors are never opened at the same time.		
84.00	Is the PEC certified to meet ISO Class 5 or better conditions (3520 particle count (with limit ≥0.5 µm) per cubic meter) under dynamic operating conditions?		
85.00	Is the airflow in the PEC unidirectional (laminar flow)?		
86.00	Is "first air" at the face of the filter free from airborne particulate contamination?		
87.00	Is the HEPA-filtered air supplied in the direct processing area (DPA) at a velocity sufficient to sweep particles away from aseptic processing areas and maintain unidirectional airflow as much as possible during operations, given the limitations added from the radiation shielding in the DPA?		
88.00	Are in situ air pattern analyses via smoke studies conducted at the critical area to demonstrate unidirectional airflow and sweeping action under dynamic conditions?		
89.00	Does the placement of the PEC allow for cleaning around the PEC?		
90.00	Laminar airflow workbench (LAFW): Does a LAFW used for preparing radiopharmaceuticals provide vertical unidirectional HEPA-filtered airflow?		
91.00	In cases where the LAFW is located within the segregated containment area of a hot-cell, it is acceptable for a horizontal unidirectional HEPA-filtered airflow pattern to be utilized.		
92.00	Placement of PEC: Is the PEC located out of traffic patterns and away from area air currents that could disrupt the intended airflow patterns inside the PEC?		

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D	**Primary and Secondary Engineering Controls**		
92.01	If used only to prepare, prepare with minor deviations, dispense, or repackage sterile radiopharmaceuticals the ISO Class 5 PEC may be placed in an unclassified SRPA.		
92.02	If used to compound sterile radiopharmaceuticals, the PEC is located within an ISO Class 7 or better buffer area with an ISO Class 8 or better anteroom.		
93.00	Is a dynamic airflow smoke pattern test performed initially and **at least every 6 months** to ensure that the PEC is properly placed into the facility and that workers understand how to utilize the unidirectional airflow to maintain first air as much as possible given the limitations added from the radiation shielding in the DPA?		
94.00	For ISO-classified rooms, does the total ACPH maintain the ISO class under dynamic operating conditions?		
95.00	Are at least 15 ACPH of the total air change rate in a room come from the HVAC through HEPA filters located in the ceiling?		
96.00	Is there a minimum of 30 total HEPA-filtered ACPH supplied to ISO Class 7 areas?		
96.01	Does HEPA-filtered air from the PEC, added to the HVAC-supplied HEPA-filtered air, increase the total HEPA-filtered ACPH to at least 30 ACPH?		
96.02	If the PEC is used to meet the minimum total ACPH requirements, is the PEC not turned off except for maintenance?		
96.03	Are both the ACPH from HVAC contributed from the PEC, and the total ACPH documented on certification reports?		
97.00	Is a minimum of 20 ACPH of HEPA-filtered air supplied to ISO Class 8 areas?		
97.01	Are anterooms where activity levels are high, required more HEPA-filtered ACPH to maintain ISO Class 8 under dynamic operating conditions?		
97.02	Are the total ACPH documented on certification reports?		

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D	**Primary and Secondary Engineering Controls**		
98.00	Are the surfaces of ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets in the classified area smooth, impervious, free from cracks and crevices, and non-shedding, so they can be cleaned and disinfected, and to minimize spaces in which microorganisms and other contaminants can accumulate?		
100.00	Are junctures between the ceiling and the walls and between the wall and the floor sealed to eliminate cracks and crevices where dirt can accumulate?		
101.00	If ceilings consist of inlaid panels, are each panel caulked or otherwise sealed and secured to seal them to the support frame?		
102.00	Are walls constructed of or covered with a durable material (e.g., epoxy-painted walls or heavy-gauge polymer) and the integrity of the surface maintained?		
103.00	Are panels joined together and sealed to each other and the support structure?		
104.00	Do floors include coving to the sidewall or the juncture between the floor and wall are caulked?		
106.00	If overhangs or ledges are present, are they easily cleanable?		
107.00	Is the exterior lens surface of ceiling light fixtures smooth, mounted flush, and sealed?		
108.00	Are any other penetrations through the ceiling or walls sealed?		
109.00	Is the SRPA and all surfaces (e.g., walls, floors, counters, equipment) within the SRPA clean, uncluttered, and dedicated to sterile radiopharmaceutical processing activities?		
113.00	If overhangs or ledges are present, are they easily cleanable?		
E	**Water Sources**		
115.00	In facilities with an ante room and buffer room, is the sink placed inside or outside of the ante room? Note placement, inside or outside.		
115.01	If the sink is located outside of the anteroom, it is in a clean space to minimize the risk of bringing in contaminants into the anteroom.		
115.02	If the sink is located inside the anteroom, describe where it is located.		

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E	**Water Sources**		
115.03	The buffer area does not contain plumbed water sources [e.g., sink(s), eyewash(es), shower(s), or floor drain(s)].		
115.04	The ante room does not contain floor drain(s).		
117.00	In facilities with a SRPA design:		
117.01	Is the sink accessible but located at least 1 m from the PEC and generators, if present?		
117.02	Is the sink not located inside the perimeter of the SRPA?		
F	**Placement and Movement of Materials**		
118.00	Are only furniture, equipment, and other materials necessary permitted in the classified area or SRPA?		
118.02	Does the number, design, location, and manner of furniture, equipment and material installation not adversely impact environmental air quality and promote effective cleaning and disinfecting?		
119.00	Are shipping carton(s) or other corrugated or uncoated cardboard not allowed in the classified area or SRPA?		
120.00	Are carts used to transport components or equipment into classified areas constructed from nonporous materials with cleanable casters and wheels?		
121.00	In a classified area, are carts not moved from the dirty side to the clean side of the anteroom unless the entire cart, including casters, is cleaned, and disinfected?		
122.00	Are all items wiped with low-lint wipers and an appropriate disinfectant by personnel wearing gloves before they are brought into the clean side of anteroom(s), pass-through(s), into an SRPA or into an ISO 5 PEC?		
123.00	Are activities and tasks carried out within the buffer area limited to only those necessary?		
124.00	Are food and drinks exposed in patient care and treatment areas not in the anterooms or buffer areas?		
125.00	When processing activities require the manipulation of blood-derived or other biological material (e.g., radiolabeling patient's or donor's blood cells) do the following occur?		

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F	**Placement and Movement of Materials**		
125.01	Are the manipulations clearly separated from routine material-handling procedures and equipment used in radiopharmaceutical preparation activities?		
125.02	Are manipulations controlled by specific SOPs to avoid any cross-contamination?		
G	**Remote Aseptic Processing Involving a Hot-Cell**		
126.00	Does a hot-cell device provide an inherent physical segregation for the ISO Class 5 aseptic processing area?		
127.00	If the hot-cell is in an ISO-classified space, do personnel garb according to requirements of <825> for that environment?		
128.00	If hand and arm incursions into the interior of the hot-cell occur causing personnel to stage the required materials and supplies, do personnel garb in relation to the contamination risk associated with the individual hot-cell/ISO Class 5 relationship?		
129.00	For situations where a PEC device is located within a hot cell, all the following apply:		
129.01	Do dynamic airflow smoke pattern tests show that the staging of supplies and materials in the demarcated PEC area does not allow the influx of unclassified air into the PEC?		
129.02	For interventions that are outside of the PEC, do personnel garb in nonsterile gloves and a low-particulate lab coat?		
129.03	If the hot cell has failed the airflow smoke pattern test, are personnel required to garb differently?		
130.00	For situations where the hot cell is an integrated HEPA filtration system with a clear demarcated area that is a PEC, the following apply:		
130.01	Do dynamic airflow smoke pattern tests show that the staging of supplies and materials into the demarcated PEC area does not allow the influx of less than ISO Class 5 quality air into the PEC?		

Item #	Requirement	Y/N/N/A	Comment
G	**Remote Aseptic Processing Involving a Hot-Cell**		
130.02	If a failure of the airflow smoke pattern test requires personnel to garb in accordance with 4.5 Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Area for all incursions into the PEC.		
131.00	For other hot cell/PEC configurations and technologies that may exist, the following apply:		
131.01	Does verification (either by airflow smoke pattern tests or other manufacturer specified methods) ensure, upon each certification, that the staging of materials and supplies does not allow for the intrusion of less than ISO Class 5 air into the designated ISO Class 5 space?		
131.02	Does failure of the airflow smoke pattern test require personnel to garb in accordance with 4.5 Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Area for all incursions into the hot cell?		
H	**Pressure Differentials**		
133.00	Do positive pressure environments have a minimum differential positive pressure of 0.02-inch water column between each ISO-classified area (e.g., between the buffer area and anteroom)?		
134.00	Is the pressure differential between the anteroom and the unclassified area no less than a positive 0.02-inch water column?		
134.01	Is the buffer area, if present, positive pressure compared to the anteroom?		
134.02	Is the anteroom, if present, positive pressure compared to unclassified portions of the restricted area?		
135.00	Is the restricted area, in the presence of volatile or airborne radiopharmaceuticals, negative pressure compared to the unrestricted area?		
136.00	Is the SRPA negative pressure compared to unrestricted areas in the presence of volatile or airborne radiopharmaceuticals (e.g., I-131 sodium iodide and Xe-133 gas)?		
137.00	Any time a pressure differential is required, is there a pressure monitoring device?		

Item #	Requirement	Y/N/N/A	Comment
H	**Pressure Differentials**		
138.00	In a classified area, is a pressure differential monitoring system used to continuously monitor the pressure differential between the anteroom(s) and buffer area(s) and between the anteroom and the general environment outside the classified area(s) or area(s)?		
139.00	Are the results from the pressure monitoring system reviewed and documented **at least daily** on days the area is used?		
140.00	All pressure monitoring devices are tested for accuracy and required performance **at least every 6 months**.		
I	**Certification of PEC and SECs**		
146.00	Certification of the classified areas, including the PEC, is performed initially.		
147.00	Recertification is performed **at least every 6 months**.		
148.00	Procedures outlined in the current CETA certification guide for Sterile Compounding Facilities, or an equivalent guideline, are followed.		
149.00	Airflow testing is performed to determine acceptability of the air velocity, the air exchange rate, and area pressure cascade to ensure that air consistently flows from most to least clean areas, and that the appropriate quality of air is maintained under dynamic operating conditions.		
150.00	HEPA filter integrity testing is performed (HEPA filters are leak tested after installation and as part of recertification).		
151.00	Total Particle Counts testing is performed and conducted under dynamic operating conditions using calibrated electronic equipment.		
152.00	Smoke Visualization Studies are performed under either simulated or dynamic operating conditions to demonstrate unidirectional airflow and sweeping action over and away from the preparation(s).		
153.00	Are other equivalents for certifying the PEC performed and documented per facility SOPs, in cases where technologies exist for hot-cell and PEC configurations that are not consistent for certification by the current CETA standards?		
154.00	In this case, the PEC maintains the environmental equivalent for total particle counts and the protection of the ISO Class 5 area from intrusions of lesser controlled air.		

Item #	Requirement	Y/N/N/A	Comment
J	**Environmental Monitoring (Temp, Humidity, Viables, Total Particles)**		
155.00	The temperature and humidity are monitored in the SRPA or area containing a hot-cell, and if in a classified area the pressure is monitored, each day that radiopharmaceutical handling occurs, either manually or by a continuous recording device.		
156.00	Does Monitoring include the following?		
156.02	Are temperature continuous readings confirmed **daily** to have remained within the acceptable range?		
156.03	Are relative humidity continuous readings confirmed **daily** to have remained within the acceptable range?		
156.04	Are excursion documented and, if applicable, appropriate corrective actions taken?		
156.05	Are temperature monitoring devices verified for accuracy **every 12 months** or as required by the manufacturer?		
156.06	Are monitoring of pressure differentials performed?		
157.00	Has the pharmacy developed and implemented written air and surface monitoring procedures for all sterile radiopharmaceutical classified areas?		
158.00	Are air and surface monitoring results and the corrective actions documented, and records readily retrievable as required by jurisdictional laws and regulations?		
159.00	Is the air and surface monitoring program clearly described in the established SOPs of the facility and include a diagram of the sampling locations, SOPs for collecting samples, frequency of sampling, size of samples (e.g., surface area, volume of air), time of day of sampling in relation to activities in the classified areas, and action levels that will trigger corrective action?		
159.01	Are samples obtained from locations that pose the highest possible contamination risk to the sterile radiopharmaceuticals involved with the operation's processes and are likely to be representative of the conditions throughout the area?		

Item #	Requirement	Y/N/N/A	Comment
J	**Environmental Monitoring (Temp, Humidity, Viables, Total Particles)**		
160.00	Are personnel who operate the equipment trained in the proper operation of the air and surface sampling equipment to ensure accurate and reproducible sampling?		
161.00	Are all air sampling devices serviced and calibrated as recommended by the manufacturer?		
162.00	Does the microbiological air and surface monitoring program include viable impact volumetric airborne particulate sampling and surface sampling?		
163.00	Are air and surface sampling performed initially for PECs & classified areas in a facility to establish a baseline level of environmental quality?		
164.00	After initial sampling, are the PECs & classified area(s) monitored according to the minimum frequencies?		
165.00	Are air and surface sampling conducted during actual or simulated dynamic operating conditions to confirm that the required environmental quality in classified areas is maintained?		
166.00	Is sampling carried out at the conclusion of sterile radiopharmaceutical processing but prior to cleaning and disinfecting the surface area?		
167.00	Is sampling performed in all the following circumstances?		
167.01	In conjunction with the certification of new facilities and equipment?		
167.02	After any modification of facilities or equipment		
167.03	In response to identified problems (e.g., positive growth in sterility tests of compounded radiopharmaceuticals)?		
167.04	In response to identified trends (e.g., repeated positive gloved fingertip sampling results or failed media-fill testing involving more than one operator where a review of the operator technique shows no reasonable flaws in process; repeated observations of air or surface contamination)?		
167.05	In response to changes that could impact the controlled area environments (e.g., significant change in cleaning process or the agents involved)?		
168.00	Is regular review of the sampling data performed to detect trends such as elevated levels of microbial bioburden, elevated levels of nonviable particulates, or other adverse changes within the environment?		

Item #	Requirement	Y/N/N/A	Comment
J	**Environmental Monitoring (Temp, Humidity, Viables, Total Particles)**		
169.00	Are results reviewed in conjunction with personnel data (i.e., training records, visual observations, competency assessments) to assess the state of control and to identify potential risks of contamination?		
170.00	Is prompt corrective action in response to any adverse findings taken to maintain the necessary environmental quality for handling sterile radiopharmaceutical?		
171.00	Is data also reviewed following corrective actions to confirm that the actions taken have been effective in achieving the required air and surface quality levels?		
172.00	Volumetric active air sampling of all classified areas (e.g., ISO Class 5 PEC and ISO Class 7 and 8 areas) using an impaction device are conducted during dynamic operating or simulated operating conditions **at least every 6 months.**		
173.00	Does viable air sampling include the following?		
173.01	Following the manufacturer's instructions for operation of the air sampling device, including placement of media?		
173.02	Using the sampling device, test at least 1 cubic meter or 1000 liters of air from each location sampled?		
173.03	At the end of the sampling, retrieve the media plates/devices and cover?		
173.04	Invert the media and incubate at 30°–35° C for no less than 48 hours. Examine for growth. Record the total number of discrete colonies of microorganisms on each plate as cfu/m3 of air on an environmental sampling form based on sample type (i.e., viable air). Include sample location and date?		
173.05	Incubates the inverted media at 20°–25° C for no less than 5 additional days? Examines the media plates for growth? Records the total number of discrete colonies of microorganisms on each plate as cfu/m3 of air on an environmental sampling form based on sample type (i.e., viable air)? Includes sample location and date?		
174.00	To shorten the overall incubation period, can two samples be collected for each sample location and incubated concurrently?		

Item #	Requirement	Y/N/N/A	Comment
J	**Environmental Monitoring (Temp, Humidity, Viables, Total Particles)**		
175.00	Both samples could be TSA, or one sample could be TSA and the other fungal media [e.g., malt extract agar (MEA) or sabouraud dextrose agar (SDA)]. Describe samples in notes.		
176.00	Each sample is incubated in a separate incubator.		
177.00	One sample is incubated at 30°–35°C for no less than 48 hours and the other sample is incubated at 20°–25° C for no less than 5 days.		
178.00	Fungal media samples are incubated at 20°–25° C for no less than 5 days.		
179.00	The count of the total number of discrete colonies of microorganisms are done on each sample and these results are recorded as cfu per sample.		
180.00	Are the results of the sampling recorded on an environmental sampling form based on sample type (i.e., viable air) and include the sample location, and sample date?		
181.00	Are general microbiological growth medium that supports the growth of bacteria and fungi used (e.g., TSA medium)?		
182.00	Do CoA(s) from the manufacturer verify that the medium meets the expected growth promotion, pH, and sterilization requirements?		
183.00	Are samples incubated in a temperature monitored incubator with a calibrated measuring device?		
184.00	Is the incubator temperature monitored during incubation, either manually or by a continuous recording device, and the results reviewed and documented?		
185.00	Are the incubators used for microbiological testing placed in a location outside of any classified area or SRPA and kept away from areas where compounding or sterile processing activities are carried out?		
186.00	Air Sampling Action Levels (cfu/cubic meter (1000L) of air per plate) are within the appropriate range: **ISO Class 5 - >1** **ISO Class 7 - >10** **ISO Class 8 - >100**		
187.00	Are cfu counts evaluated against the action levels and in relation to previous data to identify adverse results and/or trends?		

Item #	Requirement	Y/N/N/A	Comment
J	**Environmental Monitoring (Temp, Humidity, Viables, Total Particles)**		
187.01	If two pieces of media were collected at a single location, are all recovered growth documented and action levels are applied individually to each plate/device (i.e., results from each cubic meter of air sampled are compared to the action level for that area)?		
188.00	If levels measured during the viable air monitoring program exceed the action levels for the ISO classification levels of the area sampled, is the cause investigated, and corrective action is taken?		
188.01	Is the corrective action plan dependent on the cfu count and the microorganism recovered?		
188.02	If levels measured during viable air sampling exceed the levels, is an attempt made to identify any microorganism recovered to the genus level with the assistance of a qualified individual?		
188.03	Is the corrective action plan documented?		
189.00	Are all sampling sites and procedures described in the facility's SOP?		
190.00	Is surface sampling of all classified areas and all PECs conducted **at least monthly** for the detection of microbial contamination?		
191.00	Is each classified area sampled?		
192.00	Is the DPA of the PEC, and any equipment permanently contained in the PEC, sampled?		
193.00	Are work surfaces in classified areas near the PEC, frequently touched surfaces in classified areas, and pass-through enclosure(s) for all classified areas evaluated to determine the locations that pose the greatest risk of harboring microbial contamination?		
194.00	Is surface sampling performed at the end of the radiopharmaceutical aseptic activities or shift, but before the area has been cleaned and disinfected?		
195.00	Do radiopharmaceutical personnel consider the appropriate exposure and contamination prevention measures prior to and while collecting samples?		
196.00	If the worker assesses that the risk for exposure is not in conformance with ALARA safety standards, are measures taken to eliminate the risk (e.g., implementation of appropriate shielding, performing the sampling later or alternate day)?		

Item #	Requirement	Y/N/N/A	Comment
J	**Environmental Monitoring (Temp, Humidity, Viables, Total Particles)**		
197.00	Are surface sampling devices (e.g., plates, paddles, or slides) containing microbial growth media used for sampling flat surfaces?		
198.00	Are CoAs from the manufacturer verified that the media meet the expected growth promotion, pH, and sterilization requirements?		
199.00	Do surface sampling devices contain general microbial growth media (e.g., TSA) supplemented with neutralizing additives (e.g., lecithin and polysorbate 80) to neutralize the effects of any residual disinfecting agents?		
200.00	If used, do contact plates have a raised convex surface?		
201.00	Are sterile swabs wetted with sterile water or a sterile neutralizing buffer used when sampling irregular surfaces and difficult-to-reach locations, such as crevices, corners, and spaces between surfaces?		
202.00	After sampling, is the sampled area thoroughly cleaned and disinfected?		
203.00	Are the following procedures for surface sampling on flat surfaces used?		
203.01	Remove the cover from the surface sampling device. Firmly press, using a rolling motion, if possible, the media surface onto the surface to be sampled. The surface sampling device will leave a residue of growth medium on the sample site. After sampling, use sterile 70% IPA to remove residue. Cover each surface sampling device.		
203.02	If using plates, invert the plates?		
203.03	Incubate the surface sampling devices at **30°–35° C for no less than 48 hours.** Examine for growth. Record the total number of discrete colonies of microorganisms on each media device as cfu/sample on an environmental sampling form based on sample type (i.e., surface). Include sample location and date.		
203.04	Incubate the sampling device at **20°–25° C for no less than 5 additional days.** Examine the media plates for growth. Record the total number of discrete colonies of microorganisms (cfu/sample) on the environmental sampling record based on sample type (i.e., surface). Include sample location and date.		
204.00	Does the facility use two samples for each sampling location?		
204.01	Are both TSA?		

Item #	Requirement	Y/N/N/A	Comment
J	**Environmental Monitoring (Temp, Humidity, Viables, Total Particles)**		
204.02	Is one TSA and one Fungal?		
204.03	Is each sample incubated in a separate incubator?		
204.04	Is one sample media incubated at **30°–35° C for no less than 48 hours**?		
204.05	If fungal media are used as one of the samples, is it fungal media sample incubated the at **20°–25° C or no less than 5 days**?		
204.06	Are the total number of discrete colonies of microorganisms on each sample counted as cfu per sample?		
204.07	Are the results of the sampling recorded?		
205.00	Surface Sampling Action Levels (cfu/device or swab) are within the appropriate range: **ISO Class 5 - >3** **ISO Class 7 - >5** **ISO Class 8 - >50**		
206.00	Are cfu counts evaluated against the action levels and in relation to previous data to identify adverse results and/or trends?		
206.01	If two pieces of media were collected at a single location, is all recovered growth on each documented and action levels are applied to each piece of media individually (i.e., results from each sampling device are compared to the action level for that area)?		
207.00	If levels measured during the viable air monitoring program exceed the action levels for the ISO classification levels of the area sampled, is the cause investigated, and corrective action is taken?		
207.01	Is data collected in response to corrective actions reviewed to confirm that the actions taken have been effective?		
207.02	Is the corrective action plan dependent on the cfu count and the microorganism recovered?		
207.03	If levels measured during surface sampling exceed the levels, is an attempt made to identify any microorganism recovered to the genus level with the assistance of a qualified individual?		
207.04	Is the corrective action plan documented?		

Item #	Requirement	Y/N/N/A	Comment
J	**Environmental Monitoring (Temp, Humidity, Viables, Total Particles)**		
208.00	Are all cleaning and disinfecting activities performed by trained and appropriately garbed personnel using facility approved agents and procedures described in written SOPs?		
209.00	Is cleaning performed in the direction of most to least clean areas?		
210.00	Are the frequency, method(s), and location(s) of cleaning, disinfecting, and sporicidal agent use established in written SOPs, in accordance with the manufacturer's instructions when available, or based on sound microbiological cleaning techniques when unavailable, and followed by all cleaning personnel?		
210.01	Is the manufacturer's direction or published data for the minimum contact time followed for the cleaning, disinfecting, and sporicidal agents used?		
210.02	When sterile 70% IPA is used, is it allowed to dry?		
K	**Cleaning and Disinfecting**		
211.00	Are all cleaning, disinfecting, and application of sporicidal agents documented according to facility SOPs?		
212.00	Are surfaces cleaned prior to being disinfected unless an Environmental Protection Agency (EPA)-registered (or equivalent) one-step disinfectant cleaner is used to accomplish both the cleaning and disinfection in one step?		
212.01	After cleaning and disinfecting or the application of a one-step disinfectant cleaner in a PEC, is sterile 70% IPA applied to remove any residue?		
213.00	Does cleaning and disinfecting surfaces occur at the minimum frequencies in Table 5 or if activities are not performed daily, cleaning and disinfecting completed before initiating activities?		
214.00	Is the act of reducing or removing radioactivity (radioactive decontamination) from an object or surface balanced with the risk of spreading radioactive contamination?		
214.02	Is this balance specified in SOPs (e.g., trigger levels for safe cleaning)?		
215.00	Does Cleaning of the PEC(s) and equipment inside the PEC(s) and/or PEC and the equipment inside the PEC(s) located in a hot cell occurs in the following situations?		

Item #	Requirement	Y/N/N/A	Comment
K	**Cleaning and Disinfecting**		
215.01	Prior to performing sterile processing of radiopharmaceuticals on each day that activities are carried out, are the walls, bars, torso shield and any exposed surface of equipment inside the PEC cleaned to the extent possible as specified by the equipment manufacturer or the assessment of a qualified individual (e.g., microbiologist or industrial hygienist)?		
215.02	Is radioactive contamination shielded with appropriate temporary material, providing the material is covered with low-lint absorbent pads or has equivalent low shedding properties?		
216.00	Does disinfecting of the PEC(s) and equipment inside the PEC(s) and/or PEC and the equipment inside the PEC(s) located in a hot cell occur in the following situations?		
216.01	Following cleaning on each day that activities are carried out, are exposed surfaces of the equipment disinfected to the extent possible as specified by the equipment manufacturer or the assessment of a qualified individual (e.g., microbiologist or industrial hygienist)?		
216.02	When used, are low-lint absorbent pads removed and the PEC surveyed for radioactive contamination prior to disinfecting?		
216.03	Are new pads replaced after disinfecting or as required after spills?		
217.00	Does Cleaning and Disinfecting occurs DAILY for the following?		
217.01	PEC(s) and equipment inside the PEC(s)		
217.02	Surface of sink(s)		
217.03	PEC and equipment inside the PEC(s) located in a hot cell.		
217.04	Hot cells (all interior surfaces, dependent on design, equipment, and shielding present)		
217.05	Work surface(s) outside the PEC		
217.06	Floor(s)		
218.00	Does Cleaning and Disinfecting occurs **MONTHLY** for the following?		
218.01	Ceiling(s)		
218.02	Wall(s), door(s), door frame(s), and other fixtures		
218.03	Storage shelving and storage bins		
219.00	Does Sporicidal application occur **MONTHLY** for the following?		

Item #	Requirement	Y/N/N/A	Comment
K	**Cleaning and Disinfecting**		
219.01	PEC(s) and equipment inside the PEC(s)		
219.02	Surface of sink(s)		
219.03	Hot cells (all interior surfaces, dependent on design, equipment, and shielding present)		
219.04	PEC and the equipment inside the PEC(s) located in a hot cell		
219.05	Work surface(s) outside the PEC		
219.06	Ceiling(s)		
219.07	Wall(s), door(s), door frame(s), and other fixtures		
219.08	Floor(s)		
219.09	Storage shelving and storage bins		
220.00	Are cleaning and disinfecting agents selected and used with careful consideration of compatibilities, effectiveness, and user safety?		
221.00	Are considerations when selecting and using disinfectants include their anti-microbial activity, inactivation by organic matter, residue, shelf life, preparation requirements of the agent, and suitability for surfaces being disinfected?		
221.01	After the disinfectant is applied on the surface to be disinfected, is the disinfectant allowed to dwell for the minimum contact time specified by the manufacturer, during which time the surface cannot be disturbed?		
222.00	Is only sterile 70% IPA used in the ISO Class 5 PEC?		
223.00	Are sporicidal agents used **at least monthly** on all surfaces in classified areas and SRPAs?		
224.00	Are all cleaning supplies (e.g., wipers and mop heads), except for tool handles and holders, low lint?		
225.01	If disposable cleaning supplies are used, are they discarded after each cleaning activity?		
226.00	Are reusable cleaning tools made of cleanable materials (e.g., no wooden handles) and are cleaned and disinfected before and after each use?		
227.00	Are reusable cleaning tools dedicated for use in the classified areas or SRPAs and are not removed from these areas except for disposal?		

Item #	Requirement	Y/N/N/A	Comment
K	**Cleaning and Disinfecting**		
228.00	Are reusable cleaning tools discarded after an appropriate amount of time, to be determined based on the condition of the tools?		
230.00	Are cleaning supplies used in the classified areas and SRPAs disposed in a manner that minimizes the potential for dispersing particulates into the air (e.g., with minimal agitation, away from work surfaces)?		
231.00	Is the PEC cleaned and disinfected at the minimum frequencies specified in Table 5?		
232.00	If the PEC contains a removable work tray, are all sides of the work tray and the area underneath the work tray cleaned and disinfected **at least monthly**?		
233.00	If necessary are all surfaces of the PEC surveyed for radioactive contamination and follow facility SOPs to decontaminate?		
234.00	If necessary, any particles, debris, or residue removed with an appropriate solution (e.g., Sterile Water for Injection or Sterile Water for Irrigation) using sterile, low-lint wipers?		
235.00	Is a cleaning agent applied followed by a disinfecting agent or an EPA-registered (or equivalent) one-step disinfectant cleaner and ensure that the contact time specified per manufacturer instructions is achieved?		
236.00	Is sterile 70% IPA applied?		
237.00	Are the surfaces allowed to dry completely before beginning activities?		
238.00	Is the PEC wiped with a sporicidal agent **at least monthly**?		
239.00	Are shipping carton(s) or other corrugated or uncoated cardboard prohibited in the classified area (e.g., clean side of anteroom) or within the perimeter of the SRPA?		
240.00	Before items are introduced into a classified area or SRPA, are they wiped with a sporicidal agent, EPA-registered (or equivalent) one-step disinfectant cleaner, or sterile 70% IPA using low-lint wipers?		
241.00	After the sporicidal or sterile disinfectant is applied onto the surface, is the agent allowed to dwell on the surface for the minimum contact time specified by the manufacturer?		

Item #	Requirement	Y/N/N/A	Comment
K	**Cleaning and Disinfecting**		
241.01	Is the agent used for disinfecting the packaging compatible with the packaging and not render the product label unreadable?		
242.00	Are any items to be transferred into the PEC from the classified area or SRPA disinfected with a sterile disinfectant (e.g., sterile 70% IPA)?		
243.00	If radiopharmaceuticals are being processed by remote means in a hot-cell, the opening of sterile packages (e.g., syringes, luer lock caps) may not be possible by remote means within the ISO Class 5 area.		
243.01	In this case, are the syringes opened and appropriately labeled outside of the ISO Class 5 environment and placed in disinfected shielding, immediately prior to the forthcoming dispensing cycle?		
244.00	Are critical sites (e.g., vial stoppers) wiped with sterile 70% IPA? Note: If the vial shield top is then closed, the septum is disinfected again with sterile 70% IPA prior to another needle puncture.		
245.00	Is the critical site wiped ensuring that both chemical and mechanical actions are used to remove contaminants?		
246.00	Is the sterile 70% IPA allowed to dry before piercing critical sites?		
247.00	Is the septum wiped with sterile 70% IPA frequently whenever multiple punctures are occurring (e.g., removing several individual doses from a multiple-dose container)?		
248.00	Is radiation shielding and equipment used in the classified area/SRPA or PEC that is exposed to patient care areas during the process of administration cleaned and disinfected before returning to any classified area (e.g., buffer or ante-room) or SRPA in accordance with the Centers for Disease Control and Prevention Guidelines 1 classified as noncritical equipment requiring low-risk disinfection?		
249.00	Are syringes that have been used in a patient care area not brought back into the classified area (e.g., buffer or anteroom) or SRPA for re-assaying or disposal unless the syringe is sealed inside an impervious container (e.g., sealed plastic bag) that is disinfected prior to entry into the classified area or SRPA?		

Item #	Requirement	Y/N/N/A	Comment
K	**Cleaning and Disinfecting**		
250.00	Is equipment that has been exposed to needles and syringes contaminated with blood-borne pathogens and RAMs considered mixed waste (e.g., syringe shields and syringe carrying containers)?		
250.01	Is this equipment cleaned and disinfected through actions regulated by the facility's SOPs?		
250.02	Is equipment that contained or was in contact with mixed waste cleaned and disinfected with an appropriate agent(s) for blood?		
L	**Assigning BUDs**		
251.00	Does the pharmacy have policies and SOPs appropriate to the assignment of BUD and maintain documentation of applicable study results and calculations?		
253.00	Does the pharmacy have SOPs to collect and evaluate complaints associated with the use of radiopharmaceuticals having assigned BUDs?		
255.00	Does the individual responsible for the manipulation assign the BUD based on established testing data, either performed in-house or obtained from peer reviewed literature?		
256.00	Preparation Conditions for Sterile Radiopharmaceuticals: Describe condition used at the pharmacy in notes section (Table 7).		
257.00	For compounded preparations (sterile and nonsterile) plus preparations with minor deviations, is BUD dependent on maintenance of quality and purity including radiochemical purity, radionuclidic purity and other applicable parameters as specified in individual monographs or as clinically appropriate?		
258.00	Assignment of BUD for a radiopharmaceutical considers several factors, as appropriate. Issues of concern include all but are not limited to the following:		
260.00	Radiochemical Purity - Is the assigned BUD based on stability studies in which these variables are controlled and are representative of the conditions of actual use?		

Item #	Requirement	Y/N/N/A	Comment
L	**Assigning BUDs**		
262.00	Radionuclidic purity - USP monographs for Tc-99m radiopharmaceuticals require that the radionuclidic impurity Mo-99 not exceed 0.15 µCi Mo-99 per mCi Tc-99m at the time of administration.		
263.00	Are calculations of radionuclidic purity at future times necessary to ensure compliance throughout the assigned BUD?		
264.00	Age of the generator eluate - Extension of the BUD for Tc-99m pertechnetate intended for radiolabeling of kits consider the build-up of Tc-99 and peroxides over time.		
265.00	Number of particles - For radiolabeled particulates, the number of particles per unit radioactivity increases over time as the radionuclide decays. Calculation of the number of MAA particles in the patient dose is conducted to ensure compliance with the prescribed particle range throughout the assigned BUD.		
266.00	Specific Activity - For some receptor-based radiopharmaceuticals, the mass quantity may influence uptake. In such situations, the assigned BUD ensures that the patient dose contains no more than the specified mass.		
267.00	Container Type – The assigned BUD is determined in the proper storage container.		
269.00	In the case of manufactured radiopharmaceuticals that are distributed to nuclear pharmacies or other healthcare facilities for terminal distribution/dispensing, the assigned BUD of the dispensed dose cannot exceed the expiration date/time of the manufactured radiopharmaceutical(s).		
270.00	In the case of radiopharmaceuticals prepared from kits, the BUD of a dispensed dose cannot exceed the assigned BUD of the finished kit preparation.		
271.00	A radiopharmaceutical may not exceed the shortest BUD of any of its components.		

Item #	Requirement	Y/N/N/A	Comment
M	**Documentation**		
272.00	Are applicable records (hard-copy or electronic), including policies and SOPs, maintained for all activities involved in repackaging, preparing, preparing with minor deviations, compounding, and dispensing radiopharmaceuticals?		
273.00	Do such records include all but are not limited to the following?		
273.01	Personnel training and testing including visual assessment of aseptic technique competency		
273.02	Validation		
273.03	Garbing		
273.04	Hand hygiene		
273.05	Equipment/environment cleaning and disinfecting		
273.06	Gloved fingertip and thumb sampling		
273.07	Media fill evaluation initially		
273.08	Media fill follow up testing at specified intervals		
273.09	Equipment maintenance and cleaning/disinfecting		
273.10	End product radiochemical purity and other testing, as applicable, results of preparations, preparations with minor deviations, and compounded preparations		
273.11	Master Formulation Record (MFR) for preparation with minor deviation(s) and compounding		
273.12	Validation of stability testing to support the assigned BUD from SOPs by the compounder or derived from accepted literature		
273.13	Investigations and corrective actions and tracking of events to closure.		
274.00	Do Testing and Monitoring of environmental controls include the following?		
274.01	ISO classification		
274.02	ACPH		
274.03	Pressure differentials		
274.04	Temperature		
274.05	Humidity		
274.06	Viable air		
274.07	Viable surface		

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

Item #	Requirement	Y/N/N/A	Comment
M	**Documentation**		
277.07	Name of vendor or manufacturer, lot numbers, and expiration dates of all ingredients and components		
277.08	Name of the person who prepared and name of the supervising personnel (e.g., ANP)		
277.09	Date and time of preparation		
277.10	Assigned internal identification number (e.g., lot number)		
277.11	Unique reference [e.g., prescription, order number(s)]		
277.12	Assigned BUD and storage requirements		
277.13	Documentation of QC results		
278.00	The individual responsible for preparing the radiopharmaceutical(s) ensures that the final preparation complies with quality and purity specifications throughout the assigned BUD.		
N	**Preparation of Radiopharmaceuticals**		
279.00	Do the quality and purity specifications include, as appropriate for the preparation, the following?		
279.01	Radionuclidic purity		
279.02	Radiochemical purity		
279.03	Chemical purity		
279.04	Physical and chemical properties		
280.00	For nonsterile preparations, manufacturer preparation instructions are followed (e.g., I-131 NaI capsules or solution), considering appropriate radiation safety considerations and environmental controls, if applicable (e.g., negative air pressure area, chemical fume hood, activated charcoal filters when handling a potentially volatile radionuclide).		
283.00	For sterile preparations (including intravascular devices), manufacturer preparation instructions are followed, considering appropriate radiation safety considerations, appropriate environmental controls, and aseptic handling practices to maintain sterility.		
284.00	The minimum environmental standard for the preparation of sterile radiopharmaceuticals beyond immediate use is within an ISO Classified area or device.		

Item #	Requirement	Y/N/N/A	Comment
N	**Preparation of Radiopharmaceuticals**		
285.00	In some cases, radiopharmaceuticals are prepared with minor deviations from manufacturer instructions that are necessary to accommodate circumstances not contemplated in the FDA-approved labeling.		
285.01	Deviations from manufacturer preparation instructions for radiopharmaceuticals maintain the same ingredients but may differ in their proportions.		
286.00	The minor deviations utilized require appropriate in-house QC testing, designed to validate the radiochemical purity of the product for the entirety of the BUD or are supported by appropriate peer-reviewed publications.		
287.00	Do the pharmacy radiopharmaceutical preparations with minor deviations include all the following when applicable?		
287.01	Altering the quantity of radioactivity or volume added to the vial		
287.02	Changes in step-by-step operations (e.g., dilute Tc-99m sodium pertechnetate after rather than before addition to the vial)		
287.03	Using alternative devices or equipment (e.g., a heating block rather than a hot water bath, using a different sized needle, different shielding materials)		
287.04	Using QC test methods other than those described in the product labeling (e.g., radiochemical purity)		
287.05	Filtering Tc-99m sulfur colloid		
287.06	Other, (if so, describe in the notes)		
288.00	The preparation BUD does not exceed 6 hours after the blood sample is obtained from the patient or blood bank.		
289.00	Equipment and supplies are never shared with other activities unless they are first thoroughly cleaned and disinfected.		
290.00	Do special precautions when radiolabeling of blood components for non-immediate use include the following?		

Item #	Requirement	Y/N/N/A	Comment
N	**Preparation of Radiopharmaceuticals**		
290.01	There is complete physical separation (either fixed or non-fixed wall) of areas where blood products are handled from areas where non-blood products are handled. An ISO Class 5 BSC located in an ISO Class 7 buffer area is required for blood-labeling processes. If more than one ISO Class 5 PEC is located within the ISO Class 7 buffer area, policies and SOPs are in place to include certification that the SEC meets conditions of air quality at maximum occupancy under dynamic operating conditions.		
290.02	One radiolabeling procedure per PEC at a time. Blood products from more than one patient are never manipulated at the same workstation at the same time. Each area has dedicated supplies, equipment, and waste disposal to eliminate sharing of these items or overlap in pathways.		
290.03	Thorough cleaning and disinfection of the ISO Class 5 BSC and all reusable equipment within, occurs prior to starting another blood component radiolabeling procedure.		
O	**Preparation of Radiolabeled Blood Components**		
290.04	If a dedicated dose calibrator is not available, then a means of preventing the blood container(s) from contaminating the dose calibrator is used or the dose calibrator dipper and liner is cleaned and disinfected following the radioassay.		
290.05	Centrifuge is located within the ISO Class 7 buffer area that is dedicated for blood component radiolabeling processes.		
290.06	Dedicated (per each radiolabeling procedure) consumable products (e.g., 0.9% sodium chloride injection, diluent, tubes, syringes, and other supplies) necessary for each individual patient radiolabeling procedure.		
290.07	All tubes and syringes in contact with the patient's blood components are clearly labeled with the patient's name and at least one additional identifier (e.g., date of birth, medical record number, barcode).		
290.08	Dedicated syringe shields and vial shields.		
290.09	Any garb that enters the ISO Class 5 BSC is removed and replaced before handling anything else not related to performing this procedure.		

Item #	Requirement	Y/N/N/A	Comment
O	**Preparation of Radiolabeled Blood Components**		
290.10	Removal of all disposable items from the ISO Class 5 BSC is utilized in each radiolabeling procedure.		
290.11	Cleaning and disinfection of all reusable equipment and components (e.g., BSC, centrifuge, dose calibrator, syringe shields, vial shields, syringe transport shields and delivery cases) is done after each radiolabeling procedure prior to any further use. Policies and SOPs address cleaning and disinfection processes including the use of an EPA-registered (or equivalent) one-step disinfectant cleaner with activity against blood-borne pathogens followed by sterile 70% IPA. Sterile 70% IPA alone is not sufficient.		
290.12	After the completion of blood radiolabeling procedures, 4.5 Hand Hygiene and Garbing requirements for Buffer Areas and segregated Radiopharmaceutical Processing Area are followed.		
P	**Compounding**		
292.00	Each compounding activity is based on a pre-established written procedure and includes maintenance of compounding records.		
292.01	The compounding record provides traceability for components and person(s) involved.		
293.00	All sterile compounding, using aseptic technique, is performed in an ISO 5 PEC. Compounding employees are using appropriate aseptic technique.		
294.00	Compounding is not performed for any radiopharmaceutical(s) that has been withdrawn from the market because of safety or lack of effectiveness unless part of an institutional review board approved investigational study.		
295.00	Radiopharmaceuticals that are essentially copies of marketed FDA-approved radiopharmaceuticals are not compounded unless there is a change that produces a clinical difference for an identified individual patient, as determined by a prescriber.		
296.00	Areas designated for nonsterile compounding are cleaned, uncluttered, and separated from areas designated for sterile radiopharmaceuticals.		
298.00	The placement of equipment and materials are designed to prevent cross-contamination.		

Item #	Requirement	Y/N/N/A	Comment
P	**Compounding**		
299.00	When feasible, disposable material is used to reduce the chance of cross-contamination.		
300.00	Each compound has a unique MFR.		
301.00	The preparation information is documented on a compounding record.		
302.00	The MFR details the selection of all components.		
303.00	The ingredients obtained from sources in this preferential order: FDA-approved product; FDA-registered facility; and lastly, if the ingredients for the compound are not available from either of these two sources, the MFR details the selection of a material that is suitable for the intended use.		
304.00	The MFR establishes the identity, strength, purity, and quality of the ingredients by validated means (e.g., CoA).		
305.00	Requirements for nonsterile oral meal components are limited to common food grade description and are not required to establish identity by validated means.		
306.00	A BUD for the nonsterile compounded radiopharmaceutical is validated, considering the stability of the ingredients, any intermediate containers, the final container, and the storage conditions.		
306.01	A BUD cannot be extended past the labeled expiration date of any component in the nonsterile compound.		
306.02	If the nonsterile compounded radiopharmaceutical(s) includes components from other preparations or preparations with minor deviations, the BUD of the final compounded radiopharmaceutical does not exceed the shortest remaining BUD of any of those components.		
307.00	Do personnel responsible for sterile compounding consider all possible interactions between the components, such as altered chemical stability, radiochemical stability, solubility, or other parameters (e.g., osmolality) related to changes in pH, excipients, or other factors, in determining an appropriate BUD?		

Item #	Requirement	Y/N/N/A	Comment
P	**Compounding**		
308.00	Do the sterile compounding activities involve the addition of a conventionally manufactured drug product (e.g., Ascorbic Acid Injection, Lidocaine Hydrochloride Injection, Sodium Bicarbonate Injection) approved by the appropriate regulatory agency to a radiopharmaceutical?		
309.00	Does the pharmacy split conventionally marketed sterile kits?		
310.00	Do personnel responsible for sterile compounding consider all possible interactions of kit components with these other containers (e.g., container walls, closures), as well as possible alterations in stability (e.g., physical stability, chemical stability) that may affect radiolabeling yields or performance parameters, when determining an appropriate BUD?		
310.01	Systematic QC testing is performed to validate the appropriateness of a particular BUD.		
311.00	Some sterile compounding activities involve the use of materials other than commercially marketed products, such as drug substances and/or radionuclides.		
311.01	If one or more materials or components are not certified to be sterile and pyrogen-free, a sterilization procedure (e.g., filtration with bubble point testing) and testing described in <85> is performed. Record calibration date of the bubble test pressure gauge, as applicable.		
312.00	The designated person for compounding is responsible for ensuring that the final preparation complies with pre-established standards or acceptance criteria for identity, quality, and purity.		
313.00	The designated person considers all possible interactions between the components, such as altered chemical stability, radiochemical stability, solubility, or other parameters (e.g., osmolality) related to changes in pH, excipients, or other factors, in determining an appropriate BUD.		
313.01	Testing to validate the appropriateness of a particular BUD may be required.		
314.00	If compounding involves a bulk drug substance, the radiopharmaceutical complies with standards of an applicable USP or NF monograph, if one exists, or be a component of an approved drug product.		

Item #	Requirement	Y/N/N/A	Comment
P	**Compounding**		
314.01	A bulk drug substance includes a radionuclide, a ligand, or other substance, such as a precursor that becomes an active ingredient in the final radiopharmaceutical.		
315.00	Each bulk drug substance is manufactured by drug establishments registered with FDA and be accompanied by a valid CoA or equivalent testing procedures.		
316.00	If compounding involves excipients or other inactive ingredients, the excipients or other inactive ingredients comply with standards of an applicable USP or NF monograph, if one exists.		
317.00	It is also acceptable that any excipients or other inactive ingredients be approved products, manufactured by a drug establishment registered with the FDA.		
318.00	Labeling of the final patient-ready dose or ordered amount of a radiopharmaceutical is also a component of the dispensing process.		
319.00	Except for an unopened manufacturer container, the final dose or ordered amount is radioassayed (i.e., in a dose calibrator).		
Q	**Labeling**		
323.00	Is the inner container (e.g. syringe, vial) labeled with all the following?		
323.01	Standard radiation symbol		
323.02	The words “Caution—Radioactive Material”		
323.03	For all therapeutic and blood-products, the patient name/identifier		
323.04	Radionuclide and chemical form (generic name)		
323.05	Radioactivity at the date and time of calibration		
324.00	Is the outer shielding (e.g., syringe or vial shielding) labeled with all the following?		
324.01	Standard radiation symbol		
324.02	The words “Caution—Radioactive Material”		
324.03	For all therapeutic and blood-products, the patient name/identifier		
324.04	The radionuclide and chemical form (generic name)		
324.05	Radioactivity with units at time of calibration and the calibration time		
324.06	Volume or number of units (e.g., 2 capsules), as applicable		

Item #	Requirement	Y/N/N/A	Comment
Q	**Labeling**		
324.07	Product expiration or BUD, as applicable, and any special storage and handling requirements for non-immediate use (e.g., refrigeration, resuspension)		
324.08	Route of administration		
R	**Direct Infusion Systems**		
325.00	Do the operations of the direct infusion systems follow the “Instructions for Use” in the device labeling?		
326.00	Are each of the following parameters considered by the operator of the system?		
326.01	Setup attachment or needle-puncture should be performed in a defined environment		
326.02	Aseptic handling in ambient air with a maximum BUD of 10 hours is allowed for these direct infusion systems		
326.03	The 0.9% sodium chloride bag attached to the device may only be punctured once and may be used for no more than 10 hours. The bag is labeled with the date and time of puncture and the BUD		
326.04	Any nonsterile parts of the device that may encounter the septum of the radiopharmaceutical vial is disinfected with sterile 70% IPA prior to puncturing the vial with the needle		
326.05	The septum of any vial and the ports of any diluent bag is wiped with sterile 70% IPA prior to puncturing		
326.06	When puncturing the vial in ambient air, it is only punctured once		
326.07	If there are problems with the infusion device, no sterile container(s) associated with the system is repunctured or transferred to a PEC for further manipulations and the container, with contents, is discarded		
S	**Transporting Generators Between Facilities**		
327.00	Are the following standards followed if transporting generators between facilities?		
327.01	The generator needle and/or ports are capped in ISO Class 8 air or better with sterile protectors		

Item #	Requirement	Y/N/N/A	Comment
S	**Transporting Generators Between Facilities**		
327.02	The generator is packaged and transported in a manner to maintain the integrity and sterility of the generator system		
T	**Repackaging**		
328.00	If the facility repackages, are the following applicable?		
328.01	Removes conventionally manufactured radiopharmaceutical(s) from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the product.		
328.02	Places the contents of multiple containers of the same finished drug product into one container, if the container does not include other ingredients		
329.00	Does the facility repackage nonsterile radiopharmaceuticals (e.g., I-131 sodium iodide oral capsules)?		
330.00	Does the facility repackage sterile radiopharmaceuticals (e.g., thallous chloride Tl 201 injection)?		
331.00	Unopened manufacturer dosage units (e.g., capsules, Xe-133 vials) are not radioassayed.		
332.00	The repackaged radiopharmaceutical is radioassayed (i.e., in a dose calibrator), if it is not an unopened manufacturer dosage unit.		
U	**Quality Assurance, Quality Control, and Reporting**		
335.00	QA and QC programs are formally established and documented in SOPs that ensure that all aspects of the handling of radiopharmaceuticals are conducted in accordance with this chapter and applicable federal, state, and local laws and regulations.		
336.00	A designated person ensures that the facility has formal, written QA and QC programs. List this person in the notes.		
337.00	Do QA and QC programs establish a system which include of all the following?		
337.01	Adherence to procedures		
337.02	Prevention and detection of errors and other quality problems		
337.03	Evaluation of complaints and adverse events		
337.05	Appropriate investigations and corrective actions		

Item #	Requirement	Y/N/N/A	Comment
U	**Quality Assurance, Quality Control, and Reporting**		
338.00	The SOPs describe the roles, duties, and training of the personnel responsible for each aspect of the QA program.		
339.00	The overall QA and QC program is reviewed at least once **every 12 months** by the designated person. List last date of review in notes.		
340.00	The results of the review are documented, and appropriate corrective action taken, if needed.		
341.00	If a radiopharmaceutical is dispensed or administered before the results of release testing are known, does the facility have all the following SOPs in place?		
341.01	Immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (e.g., sterility, strength, purity, bacterial endotoxin, or other quality attributes)		
341.02	Determine whether a recall is necessary		
342.00	Does the SOP for recall of out-of-specification dispensed radiopharmaceuticals contain all the following procedures?		
342.01	Determine the severity of the problem and the urgency for the implementation and completion of the recall		
342.02	Determine the distribution of any affected radiopharmaceutical, including the date and quantity		
342.03	Identify patients who have received the radiopharmaceutical		
342.04	Outline the disposition and reconciliation of the recalled radiopharmaceutical		
343.00	Does the facility document the implementation of the recall procedures?		
344.00	Is the recall is reported to appropriate regulatory bodies as required by laws and regulations of the applicable regulatory jurisdiction (e.g., state board of pharmacy, state health department)?		
345.00	Has the nuclear pharmacy developed and implemented SOPs for handling complaints? Note: Complaints may include concerns or reports on the quality and container labeling of, or possible adverse reactions to, a specific radiopharmaceutical.		
346.00	Does the designated person review all complaints to determine if they indicate potential quality problems with the radiopharmaceutical?		

Item #	Requirement	Y/N/N/A	Comment
U	**Quality Assurance, Quality Control, and Reporting**		
346.01	If a complaint indicates potential quality issues with radiopharmaceuticals, is an investigation into the potential cause of the issue completed?		
346.02	Does the investigation consider whether the quality problem could extend to other radiopharmaceuticals?		
346.03	Is corrective action, if necessary, implemented for all potentially affected radiopharmaceuticals?		
346.04	Does the investigation consider whether to initiate a recall of potentially affected radiopharmaceuticals and whether to cease sterile compounding until all underlying problems have been identified and corrected?		
347.00	Is a readily retrievable record (written or electronic) of each complaint kept by the facility, regardless of the source of the complaint (e.g., e-mail, telephone, mail)?		
348.00	Does the record contain all the following?		
348.01	The name of the complainant		
348.02	The date the complaint was received		
348.03	The nature of the complaint		
348.04	The response to the complaint		
348.05	If known, the name and strength of the radiopharmaceutical and the assigned internal identification number (e.g., prescription, order, or lot number).		
349.00	Does the record also include the findings of any investigation and any follow-up?		
350.00	Are records of complaints easily retrievable for review and evaluation for possible trends?		
351.00	Are records retained in accordance with the record keeping requirements?		
352.00	Is a radiopharmaceutical that is returned in connection with a complaint quarantined until it is destroyed after completion of the investigation and in accordance with applicable jurisdictional laws and regulations?		
353.00	Are adverse events potentially associated with the quality of radiopharmaceuticals reported in accordance with the facility's SOPs and all applicable jurisdictional laws and regulations?		

USP 825 Comments:

Additional Comments:

Plan of Correction Issued: ☐ Yes ☐ No

If yes, I will provide a plan of correction for all findings within 15 business days. **Due Date**: _____

Inspector: _____ **Date:** _____

Inspector: _____ **Date:** _____

Inspector: _____ **Date:** _____

Inspector: _____ **Date:** _____