STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV365 - Nuclear Pharmacy

File #
Insp #

NAME	PERMIT NUMBER	DATE OF INSPECTION	
DOING BUSINESS AS			
STREET ADDRESS		TELEPHONE #	EXT
CITY	COUNTY	STATE/ZIP	

Additional Information

Basic License Data - PSD

DEA Reg #	

Business Operation Hours

M-T-W-TH-F	Weekly Hours
Monday	Tuesday
Wednesday	Thursday
Friday	Saturday
Saturday Hours	Sunday
Sunday Hours	

Optional Information

License Relations

Pharmacy Affiliate

	License #

RX DPT MGR/COR/POR

	License #

Special Sterile Compounding

	License #

INV 365 - Nuclear Pharmacy

Nuclear Pharmacy Requirements

Current nuclear pharmacy permit. [465.0193, F.S.]	
A licensed nuclear pharmacist is in charge and personally supervises the operation of only one nuclear pharmacy during all times when radiopharmaceutical services are being performed[64B16-28.901(1), F.A.C.] [465.0193, F.S.]	
Pharmacy has secured radioactive storage and decay area. [64B16-28.901(4), F.A.C.]	
Nuclear pharmacy area secured from access by unauthorized personnel. [64B16-28.901(2), F.A.C.]	
Pharmacy technicians and interns properly identified and supervised. [64B16-27.100 (2) F.A.C.] [64B16-27.4001 F.A.C.] [64B16-27.410 F.A.C.] [64B16-26.400(4) F.A.C.] [64B16-27.420 F.A.C.]	
Radiopharmaceuticals are distributed only upon a prescription from an authorized medical practitioner or his agent. [64B16-28.901(6), F.A.C.]	
Oral prescription reduced to writing contains at least the following: The name of the user or his agent, date of distribution and the time of calibration of the radiopharmaceutical; name of the procedure; name of the radiopharmaceutical; dose or quantity of the radiopharmaceutical; specific instructions; and the initials of the person who received the prescription order. [64B16-28.901(8), F.A.C.]	
All outdated, damaged, deteriorated, misbranded, or adulterated drugs and pharmaceuticals shall be removed or quarantined from active stock [64B16-28.110 F.A.C.]	
The immediate inner container label of a radiopharmaceutical to be distributed has standard radiation symbol, "Caution Radioactive Material," radionuclide, chemical form, and the prescription number of the radiopharmaceutical. [64B16-28.901(10), F.A.C.]	

Area for storage, compounding, distribution, and disposal of radiopharmaceuticals is adequate to separate them from areas that contain non-radioactive medicinal drugs. [64B16-28.902(1)(a), F.A.C.]	
Minimum equipment: fume hood with an air sampler, shielded radiation containment drawing station, dose calibrator, well scintillation counters, area rate meters, Geiger-Mueller (GM) survey meters, refrigerator, microscope, syringe shields, personnel radiation detection devices. [64B16-28.902(2), F.A.C.]	
Minimum supplies: syringes and vials, disposable gloves and protective lab coats, appropriate supplies to perform thin layer chromatography, lead transport shields for syringes and vials, DOT type 7A transport containers for shipping radioactive materials. [64B16-28.902(3), F.A.C.]	
CQI Policy and Procedures and proof of quarterly meetings protected under [766.101, F.S.] [64B16-27.300, F.A.C.]	
Each nuclear pharmacist maintains accurate records of the acquisition, inventory, distribution, and disposal of all radiopharmaceuticals. [64B16-28.901 (3), F.A.C.]	
Only a pharmacist may receive therapy or blood product procedures in a permitted nuclear pharmacy and the patient's name must be obtained and recorded prior to dispensing if the prescription order is for a therapeutic or blood product radiopharmaceutical. 64B16-27.420(3), F.A.C.] [64B16-28.901(8), F.A.C.	
Policy and procedure available showing utilization of pharmacy technician. [64B16-27.440, F.A.C.]	
Minimum current references: [10 CFR - FL], [49 CFR - DOT], [USP/NF, USP - DI], [404, F.S.], [465, F.S.] [893, F.S.], [64B16, F.A.C], [64E-5, F.A.C.], [64B16-28.902(4), F.A.C.]	
The immediate outer container shield of a radiopharmaceutical to be dispensed is labeled with:(a) The name of and address of the pharmacy;(b) The name of the prescriber;(c) The date of the original filling;(d) The standard radiation symbol;(e) The words "Caution Radioactive Material";(f) The name of the procedure;(g) The prescription order number of the radiopharmaceutical;(h) The radionuclide and chemical form;(i) The amount of radioactivity and the calibration date and time;(j) The expiration date and time;(k) The volume if a liquid;(l) The number of items or weight, if a solid;(m) The number of ampules or vials, if a gas;(n) Molybdenum 99 content to USP limits, applies only to Tc 99m products; and, the words "Physician's Use Only" for diagnostic radiopharmaceuticals. The initials of the pharmacist who dispensed the medication. [64B16-28.901(9), F.A.C.]	

USP General Chapter <825> Radiopharmaceuticals-Preparation, Compounding, Dispensing and Repackaging

A. Personnel Qualifications, Training, and Hygiene

DESIGNATED PERSON: The facility has designated one or more individuals (i.e., the designated person(s)) to be responsible and accountable for performance and operation of the facility and for personnel who prepare, compound, dispense and repackage radiopharmaceuticals. [USP 825 section 4]	
PERSONNEL: Prior to entering SEC's, personnel remove personal outer garments, cosmetics, artificial nails, hand, wrist, and exposed jewelry including piercings that can interfere with the effectiveness. [USP 825 section 4.5]	
PERSONNEL: Earbuds, headphones, and electronic devices not required for processing are not taken into the cleanroom. [USP 825 section 4.5]	
PERSONNEL GARBING: Personnel don shoe covers, head/hair/facial hair covers, face mask—in an order that eliminates the greatest risk of contamination, as defined in facility SOPs. [USP 825 section 4.5]	
PERSONNEL HAND WASHING: Personnel remove debris from under nails using a disposable nail cleaner. Personnel wash hands and arms up to the elbows with soap and water for at least 30s and dry hands using low lint towels. [USP 825 section 4.5]	
LOW LINT GOWNS: Don low lint gowns that fit snugly at the wrist and are enclosed at the neck. If gowns are re-used within the same shift, the gown is maintained in a classified area or in (or immediately outside of) the SRPA. [USP 825 section 4.5]	
HAND WASHING: Personnel perform hand antisepsis cleaning using a suitable alcohol- based hand rub. [USP 825 section 4.5]	
STERILE POWDER FREE GLOVES: Personnel aseptically don sterile powder free gloves which completely cover gown sleeves. [USP 825 section 4.5]	
PERSONNEL OBSERVATIONAL ASSESSMENTS: Personnel have passed observational assessments in aseptic technique, garbing and hand hygiene as defined by SOP's and PEC cleaning and disinfecting prior to performing compounding. Results are documented. [USP 825 section 4.1]	
GLOVED FINGERTIP SAMPLING: Prior to compounding, staff have completed gloved fingertip and thumb sampling three times on both hands, immediately following hand- hygiene and garbing. Successful completion of initial gloved fingertip and thumb sampling is defined as zero colony-forming units (cfu). [USP 825 section 4.1]	
INCUBATION: The plates are incubated in an incubator at 30°–35° for no less than 48 h, and then at 20°– 25° for no less than 5 additional days. Results are documented. [USP 825 section 4.1]	
MEDIA FILL: Prior to processing, staff have completed a media-fill test that closely simulates the most challenging or stressful conditions encountered by the individual during processing. Results are documented. [USP 825 section 4.1]	
FAILURES, RETRAINING AND REEVALUATIONS: Personnel who fail visual observation of hand hygiene, garbing, aseptic technique, gloved fingertip and thumb sampling or media fill testing pass reevaluations prior to processing. All failures, retraining and reevaluations are documented. [USP 825 section 4.2]	
ANNUAL GLOVED FINGERTIP SAMPLING: Re-evaluation of glove fingertip testing onto appropriate agar plates [Trypticase soy agar (TSA) with lecithin and polysorbate 80] for all processing personnel occurs at least annually and is done in conjunction with media fill as applicable. [USP 825 section 4.1]	
ANNUAL MEDIA FILLS: Media fills are completed at least annually by processing personnel and incubated at 20-25 for 7 days followed by 30-35 for 7 days. Results are documented. [USP 825 section 4.1]	
PERSONNEL REQUALIFICATION: Personnel are requalified in hand hygiene, garbing and aseptic technique every twelve months, and every six months for personnel engaging in compounding using a non- sterile drug or component. [USP 825 section 4.2]	
PERSONNEL REQUALIFICATION CLEANING AND DISINFECTING: Personnel are requalified 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. Records maintained. [USP 825 section 4.2	
GLOVES: Routinely disinfected with sterile 70% IPA after contacting nonsterile objects. [USP 825 section 4.5]	
EXTREMITY DOSIMETERS: Personnel wear body and extremity dosimeters. [USP 825 section 2.4]	

B. Facilities and Engineering Controls

CERTIFICATION OF THE CLASSIFIED AREAS: Including the PEC, is performed initially and recertification is performed at least every 6 months using procedures outlined in the current Controlled Environment Testing Association (CETA) certification guide for Sterile Compounding Facilities, (CAG-003-2006) under dynamic operating conditions. The designated person is responsible for ensuring that each area related to sterile radiopharmaceutical processes meets the classified air quality standard appropriate for the activities to be conducted in that area. [USP 825 section 5.7]	
TOTAL PARTICLE COUNT TESTING: Particle count testing is conducted initially and every 6 months, under dynamic operating conditions. [USP 825 section 5.7]	

ALL HEPA FILTERS: HEPA filters are leak tested after installation and every six months thereafter. [USP 825 section 5.7]	
CERTIFICATION REPORTS: Reports state ACPH from HVAC, ACPH contributed from the PEC, and the total ACPH's. [USP 825 section 5.7]	
SMOKE STUDIES: In situ air pattern analysis via smoke studies is conducted initially and every 6 months at the critical area to demonstrate unidirectional airflow and sweeping action under dynamic conditions. [USP 825 section 5.7]	
FACILITY TEMPERATURE: Temperature is maintained at 25 degrees C or cooler. [USP 825 section 5.7]	
TEMPERATURE AND HUMIDITY: Temperature and humidity are monitored and documented at least daily or are stored in a continuous monitoring device. Records are retrievable. [USP 825 section 5.7]	
TACKY SURFACES: No tacky surfaces in ISO-classified areas. [USP 825 section 5.1]	
LOW LINT DISPOSABLE ABSORBENT PADS: Used to contain radioactive contamination inside ISO 5 PEC. [USP 825 section 2.4]	

SRPA

ISO 5 PEC located in a SRPA is for preparation, preparation with minor deviations, repackaging, and dispensing of radiopharmaceuticals. [USP 825 section 5.1]	
THE PEC IS LOCATED OUT OF TRAFFIC PATTERNS and away from area air currents that could disrupt the intended airflow patterns inside the PEC. [USP 825 section 5.1]	
SRPA IS USED FOR ELUTION OF RADIONUCLIDE GENERATORS: SRPA meets ISO Class 8 airborne particle count specifications. [USP 825 section]	
SURFACES WITHIN THE SRPA: Clean, uncluttered and dedicated to sterile radiopharmaceutical processing activities. Overhangs or ledges are easily cleanable. [USP 825 section 5.2]	
SINK LOCATION: In a facility with an SRPA design, THE SINK IS ACCESSIBLE and located at least 1 meter from the PEC and generators. [USP 825 Section 5.3]	

Facility has Hot Cell

PRIOR TO STAGING MATERIALS and supplies into the interior of the hot cell, personnel garb prior to hand and arm incursions based on ISO 5 contamination risk described in facility SOP's. [USP 825 section 5.6]	
DYNAMIC SMOKE STUDIES demonstrate staging of supplies and materials into the demarcated PEC area does not allow for the influx of less than ISO Class 5 air into the PEC. [USP 825 section 5.6]	

C. Secondary Engineering Controls

THE ISO-CLASSIFIED ANTEROOM AND BUFFER AREA are separated from the surrounding unclassified areas of the facility with FIXED WALLS AND DOORS. [USP 825 section 5.1]	
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. [USP 825 section 5.3]	
LINE OF DEMARCATION: Anteroom has a line of demarcation. [USP 825 section 5.1]	
PRESSURE DIFFERENTIALS: Continuously monitored and documented daily on days of use. Pressures are maintained at +0.02" w.c. or better. [USP 825 section 5.7]	
PRESSURE GAUGES: Calibrated every 6 months. [USP 825 section 5.7]	
ISO CLASS 7 AREAS: Minimum of 30 total HEPA-FILTERED ACPH. A minimum of 15 ACPH of the total air change rate comes from the HVAC through HEPA filters located in the ceiling and returns are low on the wall. [USP 825 section 5.1 Table 2]	
ISO CLASS 8 AREAS: Minimum of 20 ACPH of HEPA-filtered air. [USP 825 section 5.1 Table 2]	
SMOOTH SURFACES: The surfaces of ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets in the classified area are smooth, impervious, free from cracks and crevices, and non-shedding, so they can be cleaned and disinfected. [USP 825 section 5.2]	
JUNCTURES AND COVING: Junctures between the ceiling and the walls and between the wall and floor are sealed. Floors include coving to the sidewall or the juncture between the floor and wall is caulked. [USP 825 section 5.2]	
CEILINGS: If ceilings consist of inlaid panels, each panel is caulked or otherwise sealed and secured to seal them to the support frame. The exterior lens surface of ceiling lighting fixtures is smooth, mounted flush, and sealed. All other penetrations through the ceiling or walls are sealed. [USP 825 section 5.2]	
CLEANROOM WALLS: are covered with a durable material (e.g., epoxy-painted walls or heavy-gauge polymer). Panels are joined together and sealed to each other. [USP 825 section 5.2]	
BUFFER ROOM: Only the furniture, equipment, supplies, and other material required for the compounding activities to be performed are brought into the buffer room. [USP 825 section 5.4]	
SINKS OR DRAINS: The buffer area does not contain sources of water (sinks) or floor drains. [USP 825 section 5.3]	
PASS THROUGH DOORS: A mechanical system or an SOP is in place to ensure both doors of pass throughs cannot be opened at the same time. [USP 825 section 5.1]	
NEGATIVE PRESSURE is maintained in restricted areas or SRPA which contain volatile or airborne radiopharmaceuticals (e.g., I-131 sodium iodide and Xenon). [USP 825 section 2.4]	

D. Microbiological Air and Surface Monitoring

ENVIRONMENTAL MONITORING PROGRAM: A written environmental monitoring program is established and includes volumetric air and surface monitoring procedures for all classified areas. Sampling is conducted under dynamic or simulated operating conditions in all PEC's and classified areas; Program includes diagram of sampling locations, SOPs for collecting samples, frequency of sampling, size of samples, time of day in relation to activities, and action levels. [USP 825 section 6.1]	
AIR AND SURFACE MONITORING: Results are documented and are readily retrievable. Investigations are conducted and corrective actions are taken when results exceed action levels. Results are reviewed to detect trends. [USP 825 section 6.1]	
AIR SAMPLING DEVICES: Serviced and calibrated as required by manufacturer. [USP 825 section 6.1]	
AIR AND SURFACE SAMPLING: Is done in conjunction with the certification of new facilities and equipment and/or after any modification of facilities or equipment. [USP 825 section 6.1]	

SAMPLING DATA: Is reviewed in conjunction with personnel data to assess the state of control and to identify potential risks of contamination. [USP 825 section 6.1]	
AIR SAMPLING: Volumetric air sampling is performed every six months and includes collection of at least 1 cubic meter or 1000 liters or air from each location. [USP 825 section 6.2]	
SURFACE SAMPLING: Is performed monthly in all classified areas including equipment and occurs at the end of aseptic activities or shift and prior to cleaning and disinfecting. Surface sampling devices contain TSA and are supplemented with neutralizing additives (e.g., lecithin and polysorbate 80). Contact plates have a raised convex surface. [USP 825 section 6.3]	
INCUBATION OF SAMPLES: Air and surface devices are incubated in an incubator at 30– 35 degrees C no less than 48 hours then at 20– 25 degrees C for no less than five days. Results are recorded and documented after each stage of incubation as colony forming units (cfu) per sample. [USP 825 section 6.3]	

E. Cleaning and Disinfecting

STERILE IPA: 70% IPA used to clean PEC is sterile. [USP 825 section 7.1]	
CONTACT TIME: The manufacturer's direction or published data for the minimum contact time is followed for the cleaning, disinfecting, and sporicidal agents used. When sterile 70% IPA is used, it is allowed to dry. [USP 825 section 7.1]	
CLEANING SUPPLIES: All cleaning supplies are low lint. Reusable cleaning tools are dedicated for use in the classified areas or SRPAs and are not removed from these areas except for disposal. [USP 825 section 7.2]	
CRITICAL SITES: Critical sites (e.g., vial stoppers) are wiped with sterile 70% IPA ensuring both chemical and mechanical actions are used to remove contaminants. The sterile 70% IPA is allowed to dry before piercing critical sites. [USP 825 section 1.2, 7.5]	
CLEANING OF WORK SURFACES: Work surfaces outside the PEC's are cleaned and disinfected daily, including surfaces of sink, and are documented. [USP 825 section 7 Table 5]	
CLEANING OF FLOORS: Floors in classified areas and within the perimeter of the SRPA are cleaned and disinfected daily and are documented. [USP 825 section 7 Table 5]	
MONTHLY SPORICIDAL AGENT: Sporicidal agent is applied to all surfaces in classified areas and SRPA's monthly. (Shelving, walls, floors surfaces of sinks and ceilings) USP 825 Cleaning, Disinfecting and Sporicidal Agents. [USP 825 section 7 Table 5]	
ITEMS INTRODUCED INTO A CLASSIFIED AREA OR SRPA: Items are wiped with low lint wipers by gloved personnel using a sporicidal agent, EPA-registered (or equivalent) one-step disinfectant cleaner, or sterile 70% IPA. The agent is allowed to dwell on the surface for the minimum contact time specified by the manufacturer. [USP 825 section 7.4]	
CLEANING AND DISINFECTING: All cleaning and disinfecting activities are performed by trained and appropriately garbed personnel using facility-approved agents and procedures described in written SOPs. SOPs include frequency, methods, and locations of cleaning, disinfecting and use of sporicidal agents. [USP 825 section 7]	

F. Assigning BUD

SOPs FOR BEYOND USE TIMES: SOPs and policies are established for appropriate beyond use times and are based on established testing data, either performed in-house or obtained from peer-reviewed literature. [USP 825 section 8]	
EXTENDED BEYOND USE TIMES: Beyond use times which extend manufacturer-stated/suggested use-by times are supported by evidence including radiochemical purity and radionuclide purity. [USP 825 section 8]	
COMPLAINTS: The facility has SOPs to collect and evaluate complaints associated with the use of radiopharmaceuticals having assigned BUDs and SOPs to reevaluate the assigned BUD based on complaints, which may include repeating studies and/or performing additional studies on radiolabeling efficiency and/or radiochemical stability. [USP 825 section 8]	
RADIONUCLIDE GENERATOR ELUTION: Beyond use time for radionuclide generator elution (e.g., Tc-99m or Ga-68) does not exceed 24 hours in ISO 8 or better buffer room, with an ISO 8 or better ante room or 12 hours in SRPA with a total airborne particle count of ISO Class 8 conditions or better. [USP 825 section 8, Table 7]	
ISO 5 IN SRPA: Beyond use time for Radiopharmaceuticals dispensed, repackaged, prepared, and prepared with minor deviations in ISO 5 located in SRPA does not exceed 12 hours. [USP 825 section 8, Table 7]	
ISO 5 LOCATED IN ISO 8 OR BETTER: Beyond use time for Radiopharmaceuticals dispensed, repackaged, prepared, and prepared with minor deviations in ISO 5 located in ISO 8 or better buffer room with an ISO 8 or better ante room does not exceed 24 hours. [USP 825 section 8, Table 7]	
ISO 5 LOCATED IN ISO 7 OR BETTER: Beyond use time for Radiopharmaceuticals dispensed, repackaged, prepared, prepared with minor deviations and compounded using sterile components in ISO 5 located in ISO 7 or better buffer area with ISO 8 or better ante area, does not exceed 96 hours. [USP 825 section 8, Table 7]	
RADIOLABELED LEUKOCYTES: Radiolabeled leukocytes prepared in an ISO 5 hood located in ISO 7 or better buffer area with ISO 8 or better anteroom are assigned 6 hours after blood sample is obtained. [USP 825 section 8, Table 7]	
IN HOUSE QC TESTING: For the minor deviation utilized, appropriate in-house QC testing, designed to validate the radiochemical purity of the product for the entirety of the BUD is required, or BUD is supported by appropriate peer-reviewed publications. [USP 825 section 10.2]	
NON-STERILE COMPONENTS: Radiopharmaceuticals compounded using a nonsterile component and performing sterilization without sterility testing are compounded in an ISO 5 hood located in ISO 7 or better buffer area with ISO 8 or better anteroom and are assigned BUD no more than 24 hours. [USP 825 section 8, Table 7]	
NON-STERILE COMPOUNDING AREAS: Areas designated for nonsterile compounding are separated from areas designated for sterile radiopharmaceuticals. [USP 825 section 11.1]	
NON- STERILE COMPONENTS: Ingredients are obtained from either FDA-approved product; FDA- registered facility; or if not available from either of these two sources, the MFR details the selection of a material that is suitable for the intended use. The MFR establishes the identity, strength, purity, and quality of the ingredients by validated means (e.g., CoA). [USP 825 section 11.3]	
VALIDATION OF BUD: The BUD for the compounded radiopharmaceutical is validated and is not extended past the labeled expiration date of any component. [USP 825 section 8, Table 7]	

G. Documentation

MASTER FORMULATION RECORDS (MFR): MFR include name identity, strength, purity, quality, and quantity of ingredients with validated documentation (e.g., CoA); detailed procedures, range of radioactivity and volumes, equipment to be used including PEC' and SEC; quality control tests (e.g., radiochemical purity, pH), sterility procedures if applicable; trained personnel, containers, reference source of BUD, and storage conditions. [USP 825 section 9.1]	

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COMPOUNDING RECORDS: Compounding records include name of radiopharmaceutical, physical form, name, and quantity of ingredients including calibration time; total volume, MFR reference and any deviations from the MFR, manufacturer, lot numbers and expiration dates of all ingredients and components; name of preparer and pharmacist; date and time of preparation; lot number, prescription number, assigned BUD and storage requirements and QC results. [USP 825 section 9.2]	
MFR FOR MINOR DEVIATIONS OR COMPOUNDED RP: An MFR is maintained for radiopharmaceutical prepared with minor deviations or compounded. [USP 825 section 9.1]	
COMPOUNDING RECORD: A record is maintained for preparation with minor deviations or compounding. [USP 825 section 9.2]	
COMPOUNDING RECORDS: Compounding records are maintained and are traceable. [USP 825 section 9.2]	

H. Preparation

CONFORMANCE TO RELEVANT STANDARDS: When preparations with minor deviations from specified processes or methods occur such as altering the quantity of radioactivity or volume added, changes in step-by-step operations, using alternative devices or equipment (e.g., heating block vs hot water bath, needle size, shielding materials), QC method, filtering Tc-99m sulfur colloid, the finished product conforms to relevant standards (i.e., in-house QC testing). [USP 825 section 10.2]	

Preparation of radiolabeled blood components red blood cells

RADIOLABELING PROCEDURES: If radiolabeling procedure of blood components is not limited to one at a time, labeling occurs in separate BSC. Each workstation contains dedicated supplies, equipment (including dose calibrator), and waste disposal. [USP 825 section 10.3]	
PHYSICAL SEPARATION: 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. [USP 825 section 10.3]	
BLOOD COMPONENTS: Tubes and syringes in contact with patient's blood components are clearly labeled with the patient's name and at least one additional identifier (e.g., DOB, medical record number, barcode). [USP 825 section 10.3]	
RADIOLABELING OF BLOOD COMPONENTS: Policies and SOP's describe cleaning and disinfecting of all equipment (e.g., BSC, centrifuge, dose calibrator, syringe and vial shields, transport shields, delivery cases) and includes use of EPA registered or equivalent one-step disinfectant cleaner followed by 70% sIPA. [USP 825 section 10.3]	
BIOHAZARDOUS MATERIALS: Procedures are established and followed for handling of biohazardous materials. An ISO Class 5 BSC located in an ISO Class 7 or better buffer area in an ISO 8 or better ante room is used for blood-labeling processes. Equipment used to manipulate blood are clearly separated from routine material handling procedures. SOPs are in place and are followed. [USP 825 section 10.3]	

I. Compounding

FDA APPROVED RADIOPHARMACEUTICALS: are not compounded unless prescriber determines such RP produces a clinical difference for an identified patient. [USP 825 section 11]	
KIT SPLITTING: When kit splitting is done, QC testing is performed to validate the BUD in all containers. [USP 825 section 11.2]	
NON- STERILE COMPONENTS: Sterilization procedures (e.g., filtration with bubble point testing) and USP 85 endotoxin testing is performed when one or more materials or components are not certified sterile or pyrogen-free. [USP 825 section 11.3]	

J. Repackaging

FINAL DOSES AND REPACKAGED RADIOPHARMACEUTICALS: Are radio assayed in a dose calibrator. [USP 825 section 15]	

K. Quality Assurance and Quality Control

A QA AND QC PROGRAM: Program is established and is documented in SOPs. [USP 825 section 14]	
DESIGNATED PERSON: Ensures the written QA and QC program includes adherence to procedures, prevention and detection of errors, evaluation of complaints and adverse events, and appropriate investigations and corrective actions are in place. [USP 825 section 14]	
REVIEW OF QA AND QC PROGRAM: The QA and QC program is reviewed at least every 12 months by designated person. Results are documented and appropriate action is taken if needed. [USP 825 section 14]	
SOP's FOR RELEASE PRIOR TO TEST RESULTS: SOPs are in place when RPs are dispensed prior to release of test results. Procedures include prescriber notification and if necessary, recall procedures. [USP 825 section 14.1]	
SOP IS ESTABLISHED FOR RECALL OUT-OF-SPECIFICATION DISPENSED RPS: Procedures include what determines severity and urgency for the implementation of the recall; the distribution including date and quantity, patient identification, and disposition and reconciliation of the recalled RP. [USP 825 section 14.1]	
COMPLAINTS: Facility has established SOPs for handling complaints and a designated person reviews all complaints. [USP 825 section 14.2]	
INVESTIGATIONS: Investigations are initiated when the designated person determines a complaint indicates there is a problem with the RP. Corrective actions are implemented. [USP 825 section 14.2]	
COMPLAINTS: Records of complaints are kept by the facility and are readily retrievable. Records include investigational findings and follow ups. [USP 825 section 14.2]	
ADVERSE EVENT REPORTING: SOPs are established for adverse event reporting and are followed. [USP 825 section 14.3]	

Remarks:

I have read and have had this inspection report and the laws and regulations concerned herein explained and do affirm that the information given herein is true and correct to the best of my knowledge.

Inspector Signature: Representative:

Date: Date: