# SNMMI Detailed Comments on USP<825>

| Line Numbers | Existing text | Comment | Suggested |
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| 146-147 | Furthermore, these standards apply to sterile intravascular radioactive devices (e.g., radioactive microspheres for intravascular brachytherapy). | Misleading -Take out – beyond scope of chapter | These standards apply to preparation of sterile compounded preparations that are administered via FDA-approved medical devices as directed by manufacturer instructions. |
| 150-152 | Radiopharmaceuticals manufactured in FDA-registered manufacturing establishments according to §510 of the Food, Drug, and Cosmetic Act | Include PET Manufactured products | Radiopharmaceuticals manufactured in FDA-registered manufacturing establishments according to §510 & §212 of the Food, Drug, and Cosmetic Act |
| 156-158 | Aspects of positron emission tomography (PET) drug preparation, as defined in Positron Emission Tomography Drugs for Compounding, Investigational, and Research Uses ⟨823⟩ | The manufacture of all investigational radiopharmaceuticals (not just PET tracers addressed in USP 823) should be excluded from the scope of this Chapter. Production of investigational agents is manufacturing regulated by the FDA, not a state licensed activity performed under the auspices of practice of medicine or pharmacy. The manufacturing controls are described in the CMC section of every individual IND. | Production or Manufacture of Investigational Radiopharmaceuticals is excluded when produced under an FDA-approved IND. |
| 159 | Administration to patients | Inadequate for current practice | Preparing a conventionally manufactured sterile product in accordance with the directions contained in approved labeling provided by the product's manufacturer is not compounding if the product is prepared for an individual patient and follows the provisions for administration below.<br><br>Administration includes the direct and immediate application of a conventionally manufactured product or a CSR to a patient by injecting, infusing, or otherwise providing a sterile medication in its final radiological dose adjusted form. |

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| | | | Administration includes radiological dose adjustment via needle change.<br>For guidance on administration of radiopharmaceuticals, see the Centers for Disease Control and Prevention's (CDC) Safe Injection Practices to Prevent Transmission of Infections to Patients.<br>Preparation of radiopharmaceuticals for a single patient using only sterile starting ingredients when administration will begin within 1 hour of beginning the preparation (e.g., within 1 hour of initial entry into or puncture of a single-dose container) is not required to meet the standards in this chapter. Any unused starting ingredient that is not labeled as a multiple-dose container must be discarded after preparation is complete.<br>Additionally, preparation of sterile medications for immediate administration should be performed in accordance with evidence-based information for physical and chemical compatibility of the drugs administered.<br>Aseptic technique must be followed for preparing any sterile medication intended for immediate use. Procedures must be in place to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other products. |
| 189-196 | Safety with radiation protection practices (worker safety). This chapter describes appropriate strategies that provide a reasonable assurance of maintaining, while also ensuring the safety of individuals performing these activities. Because radiopharmaceuticals represent a unique class of prescription drugs, the use of technologies, techniques, materials, and procedures other than those described in this chapter are not prohibited so long as they are | Due to the wide scope of radiopharmaceutical preparation practice areas and sites that this chapter will affect it is imperative that scientifically valid and defensible processes and procedures that are equivalent and or superior to the practices described and contained within this chapter are acknowledged as satisfying the intent of this chapter. It also imperative that it is recognized that radiopharmaceuticals exist in a special environment where evolution and development of new methods and procedures based on scientifically valid and defensible practices must be acknowledged as integral to existing practice as well as to the continued progress and | Add the following to end of line 196:<br>It is beyond the scope of this chapter to delineate the appropriate procedures or process required in each and every practice site where radiopharmaceuticals are prepared.<br>Equivalent or superior strategies may be developed and followed with historical environmental control data, documented within a quality system that incorporates a historical valid master plan for any specific preparation area or facility area that satisfies recognized standards *(FDA ICH WHO PICS)* for achieving end points of product sterility and safety according to the risk level associated with the intended use of |

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| | documented to be equivalent or superior to those described herein. | improvement in quality for existing and new radiopharmaceuticals and how they are prepared. | the specific product and adheres to established quality practices that include routine and ongoing monitoring and assessment of risk attributes for sterile products produced in that facility. |
| 198-199 | Examples of nonsterile radiopharmaceuticals include oral capsules and oral solutions. | Incomplete | Examples of nonsterile radiopharmaceuticals include liquid, solid, or semi-solid dosage forms including oral capsules, oral solutions, oral meals or suppositories. (need to reference Remington's/USP general chapter) |
| 213-216 | For compounded preparations involving one or more components that are not certified to be pyrogen-free, bacterial endotoxin testing, as defined in Bacterial Endotoxins Test ⟨85⟩ must be performed prior to dispensing. | Should be non-limiting and specific | For compounded preparations involving any components that are not certified to be pyrogen-free, bacterial endotoxin testing, as defined in Bacterial Endotoxins Test ⟨85⟩, must be performed prior to dispensing. |
| 217-230 | Disinfection of the vial septum with sterile 70% isopropyl alcohol (IPA) must be performed prior to needle puncture. If the vial shield top is then closed or the vial septum otherwise covered with a piece of radiation shielding, the septum must be redisinfected with sterile 70% IPA prior to another needle puncture. | The section describes the requirement for drawing the activity out of a vial located within a shielded container located in an open system (i.e. BSC). This is a common practice in nuclear medicine departments where relatively small amounts of radioactivity are handled. However, large scale (e.g. 10 Ci) dispensing of FDG is not described. In this scenario, the shielding is provided by the hot cell and materials are manipulated remotely. Special considerations such as dispensing from inverted vial (where the septum is downstream of LAF) and inability to decontaminate with sterile IPA prior to every septum puncture should be described. | ADD: This requirement may not apply when dispensing PET radiopharmaceuticals using an isolated dispensing process in a dispensing hot cell. |
| 228-230 | Handling conditions. Hence, disinfection of the septum with sterile 70% IPA should be performed frequently whenever multiple punctures are occurring (e.g., removing several individual doses from a multiple-dose vial). | Does not adequately address residual disinfectant hazard nor adequately establish frequency. Frequency should not pose unreasonable burden | IPA disinfection should be performed on a frequent basis whenever multiple punctures occur (e.g., removing several individual doses from a multiple-dose vial) with an adequate time period established to allow for evaporation of the disinfecting agent between applications. |
| Line 281 | Measuring device (e.g., dose calibrator). These and other necessary equipment, (e.g., monitors, | Labels and equipment must be qualified for controlled environment with respect to particulate generation and construction (non-porous resilient | These and other necessary equipment, (e.g., monitors, bar-code scanner, label printer) may be placed inside an ISO Class 5 PEC if qualified to be used in controlled environment and if they do |

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| | bar code scanner, label printer) may be placed inside an ISO Class 5 PEC. | material that is compatible with commonly used disinfection agents such as 70% IPA). | not pose additional challenges to the critical area. PEC critical must still pass Certification requirements for critical area. (CETACAG-003-2006 & ISO 14644-1) |
| 293-295 | Employees (e.g., nuclear medicine technologists or nuclear pharmacy technicians) must follow these policies and procedures of the ANP or AU physician and work under their supervision. | Include other allied professionals<br><br>The level of required supervision must be clearly defined. Does the designated responsible person (i.e. AU physician or pharmacist) need to be in the same campus, same building, same room, physically observing, signing off, etc.<br><br>These requirements will have a major impact on operations and staffing.<br><br>This is especially important in "hot lab" setting where ANP may not be available and nuclear medicine technologists handle radiopharmaceuticals under the "supervision" of nuclear medicine physician. | Employees (e.g., nuclear medicine technologists, nuclear pharmacy technicians, and scientists working in the field of radiopharmaceutical preparation ) must follow these policies and procedures of the ANP or AU physician and work under their direct or indirect supervision as established by approved institutional work place policy and procedures. |
| 305 - 309 | Personnel must prove competency, as applicable to their job functions, prior to performing radiopharmaceuticals aseptic tasks that are beyond immediate use. These qualifications must be completed and documented initially, and then successfully repeated every 6 months thereafter under the observations of a trained individual and include the following: | Assign as to risk | Not required for Immediate use<br><br>Initial 3x, Annual (with routine visual assessment by supervisor or designated trained individual) |
| | | Re-establish Low/Medium & High Risk activities for appropriate standards. See SNMMI COR recommendations in general comment letter | Immediate Use.<br><br>Low Risk = preparation according to PI ISO-5 in Non-Classified SCRA.<br><br>Medium Risk = Compounding with minor deviations.<br><br>High Risk = Compounding with Non-Sterile components, compounding with bulk |

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| | | | components, Non-FDA approved label drugs, complex compounding activities (i.e. Lyophilization). |
| 328 | Testing, with NMT 3 cfu total for both hands | Use of non-defined abbreviation ”NMT” | Provide initial full definition “No More Than” and include in definitions |
| 342-343 | Media-fill challenges are necessary for all personnel who prepare, compound, dispense, and repackage sterile radiopharmaceuticals. | Incompatible with lines 305-7 immediate use exclusion, creates confusion as to requirements. | Include or reference immediate use exclusion |
| 340 | The plates must be incubated in a temperature-controlled incubator for 30°–35° for 48–72 h, and then at 20°–25° for 5–7 additional days | Add alternative methods | Add to end of line 340:<br>Manufacturer recommendations as well as alternate methods and media shown to be equivalent or superior are acceptable for environmental and aseptic operator monitoring. |
| 344-347 | This testing must be reflective of the actual manipulations to be carried out by the individual radiopharmaceutical worker and it must simulate the most challenging and stressful conditions to be encountered in the worker’s duties | The requirements for the number of media fills must defined. For example, if the facility is performing both preparation and dispensing, are two separate media fills required for each operation? | Add:<br>Media fill processes simulating worst case conditions according to risk are sufficient. |
| 359-362 | Once the media-fill simulation is completed and the final containers are filled with the test medium, incubate media-filled containers in an incubator for 7 days at 20°–25° followed by 7 days at 30°–35° to 362 detect a broad spectrum of microorganisms. | Alternative incubation condition (specifically 14 days at 20°–25°C or as recommended by the media manufacturer should be included | Add:<br>Alternative methods may be utilized if shown to be equivalent or superior to suggested incubation methods. |
| 366 | 3.2 Re-evaluation, Retraining, and Requalification | Re-evaluate and classify according to risk | Section 3.2: Need rewrite to classify according to risk (see 305-309 Comment and Suggested) |
| 370 | | | A prequalified operator may be allowed to continue work with re-training and education pending results of re-qualification testing. |
| 376-377 | Personnel must successfully complete requalification every 6 months in the core competencies listed in 3.1 Aseptic Qualifications. | Re-evaluate and classify according to risk | Section 3.2:<br>Need rewrite to classify according to risk (see 305-309 Comment and Suggested)<br>“Annually ” |
| 383, 385, 388, | Once every 6 months | The requirement of retraining every 6 months will increase the financial burden and not increase the | Annually |

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| | | safety of the radiopharmaceutical production operations. It will be an undue burden for current facilities to increase the frequency of reevaluation and requalification from annually to every 6 months. There is a large body of historic supporting data that shows there is not an increased risk to perform these retraining's annually in a typical radiopharmaceutical production facility. | |
| 394 | Processing in more than 6 months | Similar to 383, 386 and 388 above | Processing in more than 12 months |
| 405 | Provided to a single patient in a timely manner | Immediate use should not be restricted to a single-patient if all patient unit doses are administered within 1-hour post first septum penetration time. The reasoning that only one septum penetration is permitted is also not applicable for radiopharmaceuticals as multiple penetrations are required in order to get the dose into the right activity range, even for a single dose. | No more than 2 punctures per vial in ambient condition, and multiple punctures allowed under ISO-5 conditions. |
| 409 | | Add personnel hygiene | Personnel should remove: outer garments (e.g., bandanas, coats, hats, jackets, scarves, sweaters, vests); all cosmetics; and visible jewelry or piercings that can interfere with the effectiveness of the garb (e.g., rings with protruding elements that may cause tears in gloves). Artificial nails, polish, or extenders are prohibited. Natural nails must be kept neat and trimmed. Remove ear buds and headphones or other similar devices. |
| 409 | Hand hygiene: Wash hands and arms up the elbows with soap and | Inappropriate for immediate use standard practice: Presents increased burden on provision of patient care inappropriate to risk level,<br>Elbow access hand hygiene is a standard compounding procedure where scrubs are indicated. Immediate use practice is intended to occur in standard health care practice environments where health care apparel does not routinely require scrub or other apparel allowing access to elbows. | Hand hygiene: Wash hands with soap |
| 416-418 | 416 disinfect the gloves with sterile 70% IPA. [NOTE—A different lab coat | Reinforce lab coat hygiene | Disinfect the gloves with sterile 70% IPA. [NOTE—A different lab coat must be worn to care for a patient than the coat/gown used for |

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| | must be worn to care for a patient than the coat/gown used for radiopharmaceutical preparation.] | | radiopharmaceutical preparation.] Lab Coats should be designated for radiopharmaceutical preparation only and may be used on a weekly basis if clean. |
| 419-420 | 3.5 Hand Hygiene and Garbing for Buffer Rooms and Segregated Radiopharmaceutical Processing Area | Need to establish compounding level according to risk: Simple prep / prep with minor deviation / nonsterile or according to BUD | |
| 454 | Personnel must then aseptically don sterile, powder-free gloves. | The requirements for donning of sterile gloves must be more clearly defined. Specifically, donning of the sterile gloves should be done (over the non-sterile decontaminated gloves) immediately prior to hands entering the PEC. Otherwise, there is a risk of contamination with organisms (including spores which are not inactivated by IPA) as both unclassified and ISO Class 7 spaces are not sterile. If operator hands do not enter sterile PEC and aseptic technique operations are not performed, then there is no reason to don sterile gloves in the first place. ISO 7 is not an aseptic environment. | Personnel must don non-sterile powder-free gloves when entering and working in SRPA's or buffer rooms. Sterile gloves must be donned over the disinfected non-sterile gloves prior beginning of work inside PEC. To prevent hand contamination, multiple gloves may be required. |
| 461-462 | Personnel must also routinely inspect the gloves that they are wearing for holes, punctures, radioactivity contamination, or tears. | More emphasis must be made on periodic monitoring of gloves for radioactive glove contamination as insufficient monitoring and exchange of gloves results in both spread of contamination and contamination of hands. This is especially important when handling therapeutic radionuclides where the consequences of even minor contamination may be extremely serious. | ADD: Additionally, gloves must be periodically monitored for radioactive contamination |
| 469 | | Add provisions for remediation after line 469 | If touch contamination occurs the critical site should be re disinfected if possible and or the needle or syringe should be changed if contaminated. |
| 481 | rooms must be continuously maintained at a temperature of 25 °C or cooler | ADD °C | Rooms must be continuously maintained at a temperature of 25 °C or cooler |
| 482 | and should be continuously maintained at a relative humidity below 60% to | Add RH | and should be continuously maintained at a relative humidity below 60% RH to |
| 524-525 | An SRPA must not be located adjacent to environmental control challenges (e.g., restrooms, | Too prescriptive. Risk is adequately can be addressed by lines 526-527. Open to misinterpretation by regulators. Common accepted | Remove "An SRPA must not be located adjacent to environmental control challenges (e.g., |

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| | warehouses, or food preparation areas). | configurations of Nuclear Medicine Departments would site SRPA within "Hot Lab/ restricted area" configurations that include areas contiguous to the SRPA that are utilized for Non-Sterile Oral (MEAL) dose preparation.<br>This prescriptive exclusion likely will be interpreted to exclude Non-Sterile Oral meal preparation, and will impose unreasonable burdens on existing facilities to create separate facilities.<br>Risk is adequately can be addressed by lines 526-527. | restrooms, warehouses, or food preparation areas)." |
| 564-566 | In situ air pattern analysis via smoke studies must be 565 conducted at the critical area to demonstrate unidirectional airflow and 566 sweeping action over and away from the site under dynamic conditions | It is unclear whether a separate smoke visualization study is needed for the same PEC if multiple operations are carried out inside the same PEC at various times (e.g. dispensing one day and preparation on another), or is performing a single smoke study under "worst case" conditions sufficient. | Add: Smoke visualization studies should evaluate worst case operations upon initial use, significant reconfiguration, or repair. |
| 756 | | Acknowledge priority & primacy of Radioactive Material License conditions. | Add: RAM license conditions may supersede the following requirements for environmental controls described in this section. |
| 778 - 784 | 3. Restricted area must be negative pressure compared to the unrestricted area<br>4. SRPA must be negative pressure compared to unrestricted areas in the presence of volatile or airborne radiopharmaceuticals. | Confusing and misleading text, intent to maintain negative pressure environment specific to risk of volatile or airborne radiopharmaceuticals could be misinterpreted to be applicable to all restricted areas irrespective of volatile or airborne RAM risk. | Remove line 778-781. Remove 3 & 4<br>Add to line 778:<br>3. Restricted areas and SRPA's must be negative pressure compared to unrestricted areas when there is a potential to exceed license condition limits for volatile or airborne radiopharmaceuticals. |
| Line 786 | Table 2<br>Limits for number of particles ≤0.5 µm measured under dynamic operating conditions. | Typo on particle size: should be ≥0.5µm | Limits for number of particles ≥0.5 µm size measured under dynamic operating conditions. |
| 794-795 | All pressure monitoring devices must be tested for accuracy and required performance at least every 6 months. | Unreasonable burden, bring in line with annual certifications: room DP/particulate/HEPA filter testing | All pressure monitoring devices must be tested for accuracy and required performance at least annually or as recommended by manufacturer. |
| 796 | AMBIENT ATMOSPHERE FOR IMMEDIATE USE PREPERARATIONS | Spelling error = PREPERARATIONS | AMBIENT ATMOSPHERE FOR IMMEDIATE USE PREPARATIONS |
| 799-801 | Non-patient care space, functionally separate (not another room) from | Remove - Conflicts with standard of care for administration as defied under CDC guidelines | Remove |

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| | 800 the patient care area, such as a radiopharmaceutical handling space, or hot lab, in a hospital, clinic, or mobile coach | | |
| 1212 | Apply a cleaning agent | Clarification should be provided whether the cleaning agent needs to be sterile or not | Apply a sterile cleaning agent |
| 1214 | Disinfect with a sterile disinfectant (e.g., sterile 70% IPA) | Clarification should be provided about whether the use of sterile IPA is still needed when using the EPA registered, one-step disinfectant cleaner. If the former disinfects already, why use the IPA? | When using the sterile, non-residualizing EPA registered, one-step disinfectant cleaners, subsequent disinfection with IPA is not required. |
| 1232-1235 | In this case, the syringes may be opened and appropriately labeled outside of the ISO Class 5 environment and placed in disinfected shielding, immediately prior to the forthcoming dispensing cycle. | In addition to syringes, luer-lock caps are very often used during the dispensing process. | In this case, sterile syringe or sterile pathway device outer wrappers may be opened and appropriately labeled outside of the ISO Class 5 environment and placed in disinfected shielding immediately prior to the forthcoming dispensing cycle. |
| 1248-1249 | Syringes that have been used in a patient care area must not be brought back into the classified room (e.g., buffer or ante-room) or SRPA for re-assaying or disposal. | Standard radiopharmaceutical administration practice includes assay of used syringe to determine actual administered dose. Many departments have only one dose calibrator, mandating second dose calibrator would be burdensome.<br>Change must to should and add provision that used dose should be sealed into a non- permeable container to allow for post-administration dose assay for residual activity. | Syringes that have been used in a patient care area should not be brought back into the classified room (e.g., buffer or ante-room) or SRPA for re-assaying or disposal unless sealed in non-permeable barrier container (such as a polyethylene sample bag) and assayed using a dedicated dose calibrator dipper to prevent cross contamination of dispensing dose calibrator.<br>If a separate dose calibrator is not available (use verbiage for tagging RBCs) |
| 1267 | Radionuclide Generator | Need to specify ISO Air quality vs ISO classification | Remove Ga-68 from tables (generator does not have to be in ISO 8 or 5 environment)<br>Air quality equivalent to ISO 8 particle count |
| 1306 | that the radionuclidic impurity Mo-99 not exceed 0.15 mCi Mo-99 per | Typo – mCi should be µCi | that the radionuclidic impurity Mo-99 not exceed 0.15 µCi Mo-99 per |
| 1393 | Records of compounded radiopharmaceuticals | Remove: covered in line 1388 MFR<br>Add: | Record of distributed doses and final disposition of radiopharmaceutical including disposal and/or decay waste stream information. |
| 1431 | Name of the person who prepared and name of the supervising personnel (e.g., ANP or AU physician) who verified the final drug product | Inappropriate requirement for AU /ANP review for minor deviation. Would pose unreasonable requirement for healthcare facility services.<br>FDA definition of preparation with minor deviations is “a change that does not affect the | Change to :<br>Name of the person who prepared or compounded the product and name of the supervising personnel (e.g., ANP or AU physician) who verified the final drug product if |

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| | | quality of the product" thereby alleviating documentation other than an assigned MFR following documented facility procedures and protocols,. | compounded under either direct or indirect supervision as established by approved institutional work place policy and procedures. |
| 1562 | A dedicated space for blood handling must be designated. This area must be free from clutter and not used for any other radiopharmaceutical preparation or handling | Too restrictive – unreasonable burden on practice of medicine sites. Dedicated space may be used for other preparations following disinfection. | A dedicated space for blood handling must be designated. This area must be free from clutter and may only be used for other radiopharmaceutical preparation or handling following disinfection according to CDC guidelines or institutional guidelines for handling blood products. |
| 1567 | Dedicated equipment must be used for blood handling (e.g., l-block, | Typo –Should be L-Block | Dedicated equipment must be used for blood handling (e.g., L-block, |
| 1617-1620 | ingredients must be 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 must detail the selection of a material that is suitable for the intended use | Add USP/NSF as component supply | Ingredients must be 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, USP or NSF grade material may be used. The MFR must detail the selection of a material that is suitable for the intended use |
| 1621-22 | The MFR must establish the identity, strength, purity, and quality of the ingredients by validated means (e.g., CoA). | Inappropriate for Oral meals,<br>Add following after line1622 | Requirements for non-sterile oral meal components are limited to common food grade description and are not required to establish identity by validated means. |
| 1639 | In some cases, this may require systematic quality control | Initial quality control is required to validate when altering kit formulation or chemistry | Systemic quality control testing is required over time. |
| 1643 | should be restricted to times of shortage to stretch existing inventory to | Change "should" to "must". | must be restricted to times of shortage to stretch existing inventory to |
| 1644 | ADD after meet patient need | Kit splitting is equivalent to a copy of a currently manufactured drug and as such requires consultation and authorization from the prescribing physician as to the patient specific benefit ( i.e. availability during drug shortage) | Meet patient need. Before dispensing of a fractionated kit can occur the prescriber's determination of patient need in face of drug shortages must be documented in writing on the prescription or order by either (1) the prescribing practitioner or (2) the compounder reflecting a conversation with the prescribing practitioner as to the potential for changes in the clinical image produced with use of a fractionated kit. |

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| | | | The individual responsible for kit splitting is required to establish the BUD by performing quality control on the radiolabeled aliquot at two times: 1) at the end of labeling and 2) at the time determined to be the BUD. Additionally this testing should be performed on 3 separate aliquots to assure a consistent response. |
| 1651 | In some cases, systematic quality control testing is | Systemic quality control is required for validation of fractionated kits. Once validated, the product can be verified for routine production. | systematic quality control testing is |
| 1672 | substance includes a radioisotope, a ligand, or other substance, such as a | Change radioisotope to radionuclide | substance includes a radionuclide, a ligand, or other substance, such as a |
| 1700 | Except for an unopened manufacturer container, the final patient dose or | NUREG 1556 vol 9 8.18 allows for radiopharmacy or PET doses to be used without re-assay.<br>Add provision for NUREG opt out for final pt. dose | Except for an unopened manufacturer container, or a dose provided from a provider following 10 CFR 32.72 or 10CFR 30.32(j) the final patient dose or |
| 1766-1769 | If there are problems with the infusion device, no sterile container associated with the system can be repunctured or transferred to a PEC for further manipulations and the container, with contents, must be discarded | Presents an unreasonable burden for equipment failure.<br>Add provision following line 1799 | Reuse of a punctured infusion device container may occur if reuse according to manufacturer guidelines and is able to show risk for microorganism ingrowth or contamination of the device is highly unlikely. |
| 1796 | 131 sodium iodide oral capsules) and for nonsterile radiopharmaceuticals | Tl-201 should be Sterile | 131 sodium iodide oral capsules) and for sterile radiopharmaceuticals |
| 2008 | systems (e.g., manipulator arms) of various designs. Numerous air quality | Include other modalities | systems (e.g., manipulator arms, automated dispensing systems, automated synthesis systems) of various designs. Numerous air quality |
| 2019-2021 | Hot lab: Nonclassified radiopharmaceutical processing area without a PEC located within a hospital or clinical site that is only appropriate for immediate use radiopharmaceuticals. | Inappropriate restrictive classification of areas that serve as the main processing area for medical license users. Include SRPA as allowable in a Hot Lab | Hot lab: Non-classified radiopharmaceutical processing area commonly located within a hospital or clinical site that is appropriate for immediate use radiopharmaceuticals.<br>Is appropriate for preparation and preparation with minor deviations of radiopharmaceuticals with establishment of a designated SRPA within the Hot Lab space that incorporates an ISO-5 PEC. |
| 2028 | Immediate Use | Clarify and establish dispensing allowed under immediate use if pt. dose is administered within one hour. Covers radiological dose adjustment by needle change or dilution. | Includes dispensing. |

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| 2040-2041 | Ligand: An ion or molecule that binds to a metal atom to form a coordination complex. | Binding definition can be misleading | Ligand: An ion or molecule that binds to a metal atom to form a coordination covalent bond or coordination covalent complex. |