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# Nuclear Medicine Safety

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## Introduction

Nuclear medicine uses radioactive materials known as radiopharmaceuticals to diagnose and treat many disease processes. Acknowledging the risks inherent to radiopharmaceuticals and underscoring the significance of strict adherence to safety protocols is imperative. Regulatory authorities such as the Nuclear Regulatory Commission (NRC) and the International Commission on Radiological Protection (ICRP) have established comprehensive standards governing radiopharmaceutical handling, administration, and disposal.

To ensure compliance with these standards, physicians must attain authorized user (AU) status, which grants the authority to prescribe and oversee procedures involving radiopharmaceuticals. Achieving AU status requires specific qualifications, including board certification in radiology, nuclear medicine, or radiation oncology. Board certification demonstrates completion of postgraduate residency or fellowship programs and competence in dose calculations, radiobiology, decontamination procedures, practical experience in handling radioisotopes, patient release calculations, written directives, and clinical supervision.

This activity aims to consolidate critical safety policies encompassing the proper utilization of protective equipment when handling radiopharmaceuticals, adherence to exposure thresholds for personnel, and adherence to maximum exposure limits for patients and staff. The overarching objective is to reinforce and promote best practices within an evolving medical subspecialty where advanced techniques necessitate optimizing safety protocols to harness nuclear medicine's diagnostic and therapeutic benefits. This activity will focus on NRC regulations; the ICRP and the International Atomic Energy Agency (IAEA) have similar, albeit slightly varied regulations. The dynamic nature of regulatory guidelines for radiopharmaceuticals cannot be understated. Regulations also demonstrate geographic variance; a comprehensive understanding of and adherence to specific local regulations is required.

## Function

### Regulatory Framework and Personnel Responsibilities

#### Authorized users and radiation safety officers

The NRC imposes specific qualifications and responsibilities for individuals authorized to prescribe or handle radioactive materials within the field of nuclear medicine. Attending physicians attain AU status by completing specialized training supported by documentation of supervised clinical experience. The extent of AU prescription privileges is contingent upon the scope of training. For instance, the American Board of Nuclear Medicine certification typically qualifies individuals for diagnostic and therapeutic procedures. Other medical boards may offer certification more focused on diagnostic or limited therapeutic procedures. A common credentialing requirement is the completion of 5 to 10 mentored therapeutic procedures, such as

the oral administration of sodium iodine I 131 or parenteral administration of any beta emitter.[1] [2] AUs must approve prescribing radiopharmaceutical procedures, oversee safe radioactive material handling, ensure compliance with regulations, and help maintain personnel certification and laboratory accreditation.

The appointed radiation safety officer (RSO) has undergone comprehensive training encompassing equipment operation, contamination surveys, and incident response. The RSO assumes responsibility for managing radiation protection, regulatory compliance, and adapting safety measures to new technologies.[3] In academic medical centers, acquiring a broad-scope license necessitates formally establishing a radiation safety committee (RSC). This committee provides additional oversight, conducts reviews of adverse events, and ensures rigorous adherence to established standards.[4]

**Nuclear Regulatory Commission regulations, licenses, and dose limits**

Part 35 of the Nuclear Regulatory Commission (NRC) Regulations Title 10, Code of Federal Regulations establishes comprehensive requirements governing the medical application of byproduct materials; these regulations are continually updated after feedback from stakeholders.[5] Part 35 addresses various practice areas, including but not limited to fundamental radionuclide handling, personnel training, and therapeutic interventions requiring written directives specifying prescribed dosages. Compliance with regulations requires adherence to prescribed dose limits for occupational workers, the general public, and radiation-sensitive populations. For instance, all radiation workers are subject to stringent exposure restrictions defined as an annual effective dose limit of 5 rem (50 mSv). However, pregnant workers are afforded greater protection; the annual effective dose limit for pregnant workers is 0.5 rem (5 mSv) to minimize fetal radiation exposure.

**Nuclear Regulatory Commission technical requirements for safety**

The NRC imposes strict equipment accuracy standards within the domain of nuclear medicine. These standards include the calibration of dose calibrators used in preparing radiopharmaceuticals and the precision of survey meters employed in contamination analysis. NRC regulations underscore the importance of proper labeling, meticulous documentation of administered dosages, and comprehensive assessments of area exposure. Adherence to these standards requires that medical facilities conduct regular area surveys to confirm that radiation doses remain below specified thresholds within designated restricted work zones. Despite the intricacies and challenges inherent in navigating the regulatory landscape, adherence to these standards is essential for ensuring the safe and responsible utilization of nuclear imaging and therapeutic modalities.

**Regulatory Compliance for the Handling and Administration of Radiopharmaceuticals**

**Instruments used and administered dosages**

The NRC mandates that facilities possess and routinely calibrate instruments for directly measuring patient radiopharmaceutical dosages. Dose calibrators must conform to national standards and maintain an accuracy of ± 10% to determine the precise quantity of radioactivity in millicuries or becquerels. Clinical sites receiving unit doses from radiopharmacies can utilize direct readings or decay adjustments based on the labeled calibrated activity provided by the originating lab. Administered dosages must not deviate from the prescribed dosage by more than 20% without authorization from an AU. Maintaining clear and comprehensive documentation,

encompassing dosage, patient information, radiopharmaceutical details, route of administration, date, and administrator identity, is instrumental in upholding these standards.

**Labeling and surveys for safety**

Compliance also extends to labeling and surveys, aiming to enhance safety measures. Any vial, syringe, or shielding container utilized for storing or transporting radiopharmaceuticals must be accompanied by appropriate identification tags specifying the isotope and volume or dose. Additionally, written directives necessitate regular area exposure surveys to confirm that radiation doses remain below 5 millirems (0.05 mSv) per hour within controlled work zones. Facilities must also conduct periodic wipe tests on surfaces, vial shields, and equipment to detect and address potential contamination. The meticulous maintenance of measuring equipment, thorough documentation of checks, and prompt resolution of identified issues all contribute to optimizing low-exposure conditions.

**Safe handling procedures and administration protocols**

Strict protocols are implemented to ensure the safety of staff members when directly handling unshielded nuclear materials. Vital protective measures include using syringe shields, vial shields, and lead containers. Personal dosimetry badges are employed to monitor cumulative radiation exposure over time. The handling of radioactive materials necessitates vigilant oversight by authorized users, encompassing verification of the identity, dosage, and route of the administered radiopharmaceutical before patient administration. Facilities also designate appropriately labeled spaces exclusively for the handling and storing of radioactive materials. By seamlessly integrating regulatory safety compliance into their daily workflows, nuclear medicine departments uphold the crucial aspects of instrumentation calibration, contamination prevention, and the responsible administration of radioactive agents, all essential for maintaining ethical and responsible practice.

## Issues of Concern

**Training Requirements, Uses of Radioactive Materials, and Personnel Safety**

**Training requirements**

AUs tasked with prescribing or handling unsealed byproduct materials must complete specialized training as mandated by their regulatory authority. Eligibility pathways for authorization in diagnostic administration include participating in accredited residency programs such as nuclear medicine; such programs require 620 hours of direct training in radiation safety and radionuclide handling. Alternatively, after completing a diagnostic radiology residency training program, radiologists can pursue a 1-year nuclear medicine fellowship providing 700 supervised hours of training in radiation safety and radionuclide handling. Both pathways offer clinical experience and specific training in the fundamental topics of radiation physics, radiopharmacy, radiation biology, mathematics, chemistry, and radiation safety practices. Although specialty training or fellowship is recommended, any individual who meets NRC requirements can become an AU, including general radiologists, cardiologists, oncologists, and other specialists.

Authorization eligibility for therapeutic administrations, such as radioiodine, necessitates further advanced, hands-on training comprising a minimum of 80 hours of classroom and laboratory work combined with supervised clinical experience focused on therapeutic radionuclides. This comprehensive training encompasses preparation, dosage calculations, radiopharmaceutical administration, decontamination procedures, written directives, and clinical practicums. The

number of procedures and cases performed during training should be documented to facilitate credentialing. Once certified, maintenance of certification (MOC) for diagnostic and therapeutic specialties requires ongoing education.

The RSO undergoes focused classroom and hands-on training in equipment operations, contamination monitoring, emergency response preparations, access control, waste handling, record keeping, and regulatory policies. This training ensures the optimized oversight of radiation safety protocols.

Certification processes for physicians, technologists, nurses, physicists, and pharmacists ensure adequate training and specialized expertise. Facilities can complete accreditation protocols to ensure this training meets certification standards. Accreditation requirements for nuclear medicine departments are critical in ensuring high-quality care delivery.[6] These standards include evaluations of equipment quality, staff qualifications, and procedural protocols, all contributing to the safe and effective provision of services. Additionally, regular internal and external audits play a significant role in maintaining compliance with these stringent standards, promoting a culture of continuous improvement within nuclear medicine departments. Not all regions mandate nuclear medicine clinic accreditation, and clinics applying for accreditation often show suboptimal adherence to guidelines.[7][8]

**Distinction between unsealed materials with and without a written directive**

The requirement for a written directive is a significant determinant in the categorization of procedures. Specifically, parenteral administration of any radionuclide formulation exceeding 30 μCi of Iodine 131 or designed for relatively localized tissue or organ irradiation necessitates the issuance of a written directive by an AU. This written directive customizes radioactivity doses and administration routes to suit the needs of each patient. However, diagnostic administrations falling below this radioactivity threshold do not require written directives but still demand precise dosage calibration and approval by an AU, accompanied by appropriate clinical indications.

**Personnel safety measures and dosimetry**

To minimize the risk of radiation exposure, all personnel handling unsealed radioactive materials must utilize protective equipment, including syringe shields, gloves, and radiopharmacy safety cabinets. Additional specific safeguards are in place for more vulnerable individuals, including pregnant patients subject to lower maximum exposure thresholds. To monitor occupational exposure, devices such as personal dosimetry film badges are worn by all staff members at risk of exceeding 10% of the annual exposure limits. Dosimeters assess total radiation exposure over months to years for dose comparison against established reference thresholds. The RSO rigorously scrutinizes these results to ensure timely intervention for upward trends. Cultivating a safety-focused culture and a strong sense of responsibility plays a pivotal role in mitigating inherent occupational hazards associated with harnessing the diagnostic and therapeutic potential of radioactivity. Personnel exposures in well-run nuclear medicine clinics typically have exposures well below established limits.[9][10]

Ensuring patients are fully informed regarding the scheduled procedures, potential adverse effects, and alternative therapeutic interventions is paramount. This is crucial given the invasive nature of some nuclear medicine procedures and the use of radioactive materials. An ethical imperative is to minimize radiation exposure to patients and healthcare staff, guided by the As Low As Reasonably Achievable (ALARA) principle. The ethical practice also demands

constantly updating protocols based on the latest scientific evidence and regulatory guidelines, ensuring the highest patient care and safety standards.

**Safety Policies, Procedures, and Radiation Safety Committees**

**Medical events and reporting protocols**

In nuclear medicine, unintended radiation exposures may occur despite the implementation of rigorous preventative protocols. These rare events necessitate the implementation of and adherence to strict reporting procedures. Examples of events that may result in unintended radiation exposure include the incorrect administration of radiopharmaceuticals, dosage errors, incorrect routes of administration, errors in patient identification, or cases where absorbed doses significantly deviate from prescribed values or result in permanent functional damage following interventions. Such medical events require immediate notification of the RSO to initiate coordinated institutional reporting and response efforts. Facilities must promptly inform federal and state regulatory bodies and the referring physician within 1 day of such an event, and a comprehensive written report detailing contributory factors and corrective actions must be submitted within 15 days.

Thorough and timely reporting is essential for all stakeholders to promptly and effectively address adverse events. Reportable medical events typically entail a whole-body dose greater than 5 rem or a single-organ dose greater than 50 rem.

**Release of patients and criteria based on administered activity and dose rate**

After radiopharmaceutical therapy, patients undergo thorough screening to confirm a low likelihood of exposing the public to radiation levels exceeding defined limits before discharge, following NRC rules. Activities involving less than 33 mCi of Iodine 131 or dose rates under 7 millirems (0.07 mSv) per hour at 1 meter require no additional calculations. However, calculations are necessary for higher administered activities. These calculations specify required precautions and provide written instructions to limit radiation doses to a maximum of 5 mSv for close contacts, such as young children and pregnant persons. The stringent application of patient release criteria is instrumental in minimizing radiation levels within the community.

**Roles and responsibilities of radiation safety committees**

Institutions, particularly academic medical centers and other facilities operating under broad-scope NRC licenses are mandated to establish radiation safety committees (RSCs). These committees comprise facility leadership, AUs, the RSO, and nursing and technical staff representatives. RSCs conduct semiannual reviews of occupational radiation records, standard operating procedures, facility inspection findings, and records of medical and other events to ensure compliance with safety policies. RSCs must annually evaluate the overall functionality of the radiation protection program. RSCs play a pivotal role in sustaining robust oversight and refining processes essential for the responsible utilization of complex technologies like nuclear imaging, ultimately benefiting patient care.

## Clinical Significance

**Latest Advancements in Nuclear Medicine Safety**

Technological innovation has largely driven the recent significant advancements in nuclear medicine safety protocols. Enhanced imaging technologies, like advanced positron emission tomography/magnetic resonance imaging (PET/MRI), have been instrumental in reducing patient

radiation exposure.[11] Concurrently, developing more precisely targeted radiopharmaceuticals has minimized radiation to healthy tissues, ensuring safer and more effective treatments. Moreover, integrating artificial intelligence and machine learning in diagnostic processes has improved accuracy and reduced errors, bolstering safety standards.[12][13] The advent of more accurate radiation monitoring equipment and the incorporation of robotics for radiopharmaceutical handling are pivotal in minimizing occupational hazards. These developments and the increasing use of telemedicine for remote consultations are reshaping the landscape of nuclear medicine, prioritizing patient safety and occupational health.

## Other Issues

**Waste Disposal, Environmental Protection, and Biological Effects of Radiation**

**Procedures for radioactive waste disposal and environmental protection**

Proper handling and disposal of nuclear medicine waste are paramount, both for staff safety and to prevent environmental contamination. Radioactive waste encompasses a range of materials, including but not limited to used syringes, vials, flood sources, and liquids. The exposure thresholds defined for patient release also apply to releasing radioactive waste. The specific procedures depend on factors such as the physical half-life and the radiation emitted. Common techniques include selecting appropriate isolation periods before releasing waste into sewer systems and utilizing shielding drums to store waste until it decays to background radiation levels. The transportation of waste to specialized facilities adheres to strict regulations governing authorized containment, labeling, documentation, and other requirements, as mandated by the Department of Transportation.

**Major and minor spills**

Spills of radiopharmaceuticals are not uncommon, and certain dose thresholds can determine how spills are managed. For technetium Tc 99m and thallous chloride Tl 201, the major spill threshold is 100 mCi. For indium In 111, iodine I 123, and gallium Ga 67, a spill threshold of 10 mCi constitutes a major spill. For iodine I 131, a spill threshold of 1 mCi constitutes a major spill.

The management of major and minor spills is similar. In a minor spill, the spill should be confined and cleaned, and the area and those cleaning the spill should be surveyed. In the setting of a major spill, the area is cleared, and the RSO is notified immediately. Shielding the spill is often required. It is important to indicate the boundaries of a spill area and limit patient and worker movement within the contaminated area.

**Understanding radiation quantities, units, and sources of exposure**

A fundamental understanding of units such as absorbed radiation dose (gray; Gy), equivalent dose (sievert; Sv), effective dose (Sv), and activity (becquerel; Bq) is essential for assessing the biological effects of radiation (see **Table 1**). On average, the typical American annually absorbs approximately 6 mSv of radiation from various sources. Approximately 50% of this exposure originates from natural background sources, including radon, while 40% can be attributed to medical radiation from diagnostic imaging and nuclear medicine procedures. The remaining 10% is due to factors such as occupational exposure, air travel, or nuclear industries. Consequently, nuclear imaging significantly contributes to public radiation levels, underscoring the importance of meticulous adherence to dose optimization policies.

**Table**

Table 1. Measurement Units for Radiation, With Definitions and Conversion Factors.

**Radiation Effects and Their Implications**

The biological risks associated with radiation exposure encompass deterministic effects, such as tissue burns and acute radiation poisoning, which occur when high doses lead to substantial cellular damage. At lower doses, an increase in stochastic risks is apparent, including cancer and genetic effects, where the probability of harm linearly correlates with exposure without a strict threshold. This linear no-threshold (LNT) hypothesis postulates that even a tiny amount of radiation is harmful. The LNT hypothesis should be applied in radiation safety programs. However, some evidence suggests that small amounts of radiation are benign and possibly associated with improved health.[14] Nevertheless, these intricate dose-response dynamics and variability within and between individuals highlight the critical need for vigilant adherence to fundamental radiation safety practices and ALARA in nuclear medicine.[15] Such practices are essential to maximize benefits while minimizing preventable harm conscientiously.

## Enhancing Healthcare Team Outcomes

The ethical imperative of safe handling of radioactive materials within nuclear medicine is paramount to ensure the well-being of patients and staff. This summary consolidates major policies, encompassing worker protection programs, waste disposal procedures, mandatory personnel training, and associated responsibilities. The purpose is to reinforce best practices in nuclear medicine safety for emerging clinicians and seasoned professionals. As advanced molecular imaging continually unlocks new diagnostic and therapeutic capabilities, the centrality of radiation safety is increasingly vital.

The future landscape of nuclear medicine safety is expected to witness the growing integration of newer modalities and the continued expansion of theranostic agents, which combine diagnostic imaging with therapeutic delivery. These developments emphasize the necessity for enhanced training and safety protocols. Emerging technologies like augmented reality are promising for optimizing real-time radiation monitoring. Ultimately, by upholding rigorous safety standards and cultivating a culture of education, accountability, and universal precaution, the nuclear medicine community can responsibly harness the remarkable tools based on radioactivity to benefit patients.

While this activity covers fundamental principles, the regulatory guidelines undergo frequent changes. Regulations vary significantly by location, so adhering to local regulations is essential.

## Review Questions

- Access free multiple choice questions on this topic.
- Comment on this article.

## References

1. Delbeke D, Graham M, Royal H, Segall G, Shulkin BL, Ziessman HA., Accreditation Council of Graduate Medical Education. American College of Nuclear Medicine. American Board of Nuclear Medicine. Conjoint Statement of the SNM, ACNM, and ABNM on

credentialing and delineation of privileges for therapeutic procedures using radiopharmaceuticals. J Nucl Med. 2011 Feb;52(2):323-6. [PubMed: 21270458]
2. Spratt DE, Zaki BI, Franc BL, Hartford AC, Osborne JR. ACR Practice Parameter for the Performance of Therapy With Unsealed Radiopharmaceutical Sources. Clin Nucl Med. 2016 Feb;41(2):106-17. [PubMed: 26646993]
3. Berry K, Elder D, Kroger L. The Evolving Role of the Medical Radiation Safety Officer. Health Phys. 2018 Nov;115(5):628-636. [PubMed: 30260854]
4. Baldwin JA, Bag AK, White SL, Palot-Manzil FF, O'Malley JP. All You Need to Know as an Authorized User. AJR Am J Roentgenol. 2015 Aug;205(2):251-8. [PubMed: 26204272]
5. Wallner PE, Lieto RP, Dillehay GL, Ghesani MV, Rosenthal SA, Rosenzweig KE, Steinberg ML, Yoo DC, Small W. Potential Significant Changes in Nuclear Regulatory Commission Policies Regarding Training and Experience Requirements for the Use of Radiopharmaceuticals. J Am Coll Radiol. 2021 Feb;18(2):312-317. [PubMed: 32860755]
6. MacFarlane CR., American College of Radiologists. ACR accreditation of nuclear medicine and PET imaging departments. J Nucl Med Technol. 2006 Mar;34(1):18-24. [PubMed: 16517965]
7. Tafti D, Farrell MB, Dearborn MC, Banks KP. Reexamining Compliance with Gastric Emptying Scintigraphy Guidelines: An Updated Analysis of the Intersocietal Accreditation Commission Database. J Nucl Med Technol. 2024 Mar 05;52(1):26-31. [PMC free article: PMC10924152] [PubMed: 37316303]
8. Maddux PT, Farrell MB, Ewing JA, Tilkemeier PL. Improving compliance with Intersocietal Accreditation Commission (IAC) reporting standards: A serial comparison of 523 labs over seven years. J Nucl Cardiol. 2018 Dec;25(6):2044-2052. [PubMed: 28474194]
9. Jha AK, Singh AM, Shetye B, Shah S, Agrawal A, Purandare NC, Monteiro P, Rangarajan V. Radiation safety audit of a high volume Nuclear Medicine Department. Indian J Nucl Med. 2014 Oct;29(4):227-34. [PMC free article: PMC4228585] [PubMed: 25400361]
10. Piwowarska-Bilska H, Birkenfeld B, Gwardyś A, Supińska A, Listewnik MH, Elbl B, Cichoń-Bańkowska K. Occupational exposure at the Department of Nuclear Medicine as a work environment: A 19-year follow-up. Pol J Radiol. 2011 Apr;76(2):18-21. [PMC free article: PMC3389918] [PubMed: 22802825]
11. Martin O, Schaarschmidt BM, Kirchner J, Suntharalingam S, Grueneisen J, Demircioglu A, Heusch P, Quick HH, Forsting M, Antoch G, Herrmann K, Umutlu L. PET/MRI Versus PET/CT for Whole-Body Staging: Results from a Single-Center Observational Study on 1,003 Sequential Examinations. J Nucl Med. 2020 Aug;61(8):1131-1136. [PubMed: 31806777]
12. Bradshaw TJ, Boellaard R, Dutta J, Jha AK, Jacobs P, Li Q, Liu C, Sitek A, Saboury B, Scott PJH, Slomka PJ, Sunderland JJ, Wahl RL, Yousefirizi F, Zuehlsdorff S, Rahmim A, Buvat I. Nuclear Medicine and Artificial Intelligence: Best Practices for Algorithm Development. J Nucl Med. 2022 Apr;63(4):500-510. [PMC free article: PMC10949110] [PubMed: 34740952]
13. Decuyper M, Maebe J, Van Holen R, Vandenberghe S. Artificial intelligence with deep learning in nuclear medicine and radiology. EJNMMI Phys. 2021 Dec 11;8(1):81. [PMC free article: PMC8665861] [PubMed: 34897550]
14. Oakley PA, Harrison DE. Death of the ALARA Radiation Protection Principle as Used in the Medical Sector. Dose Response. 2020 Apr-Jun;18(2):1559325820921641. [PMC free article: PMC7218317] [PubMed: 32425724]
15. Bondy SC. The Hormesis Concept: Strengths and Shortcomings. Biomolecules. 2023 Oct 12;13(10) [PMC free article: PMC10604602] [PubMed: 37892194]

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