

Radiopharmaceutical Therapy: Rapid Growth, Rising Challenges, and the Critical Need for Expertise

Heather A. Jacene¹, Jean-Luc Urbain², Jason S. Lewis³, Helen Nadel⁴, Julie D. Bolin⁵, and Cathy S. Cutler⁶

¹Brigham and Women's Hospital/Dana-Farber Cancer Institute, Boston, Massachusetts; ²Theranostic Solution, Winston-Salem, North Carolina; ³Molecular Pharmacology Program and Department of Radiology, Memorial Sloan Kettering Cancer Center, New York, New York; ⁴Department of Radiology, Lucile Packard Children's Hospital at Stanford, Stanford University School of Medicine, Stanford, California; ⁵GateWay Community College, Phoenix, Arizona; and ⁶Isotope Research and Production Department, Brookhaven National Laboratory, Upton, New York

The field of theranostics dates back over 80 y, when Hertz and Roberts first used radioactive iodine to treat thyroid disease. Recent theranostic approvals for neuroendocrine tumors and prostate cancer have expanded the use of radiopharmaceutical therapy (RPT), and there is significant near-term potential for further expansion across multiple tumor types. This Society of Nuclear Medicine and Molecular Imaging (SNMMI) position paper emphasizes the leadership role of nuclear medicine and nuclear medicine professionals in the high-quality and safe delivery of RPT through specific training, education, regulatory guidance, and collaborations. The rapidly increasing demand for access to and delivery of radiopharmaceuticals has the potential to spur hundreds of thousands of cycles of RPT, with the resultant need for hundreds of new centers and more experts to deliver these therapies. Such an expansion would involve the entire SNMMI membership, including physicians, technologists, radiochemists, physicists, radiopharmacists, scientists, and allied health professionals. All nuclear medicine team members are accredited by specific training programs covering the selection and use of radiopharmaceuticals for theranostics to minimize risks and tailor procedures to the needs of individual patients. The administration of RPT without appropriate training and experience poses significant risks in terms of patient outcomes, impacting safety, efficacy, and overall quality of care. For over 70 y, SNMMI has set comprehensive standards and clinical guidelines for the entire field of nuclear medicine, including RPT, which undergo continual review and updating. Recently, SNMMI established RPT Centers of Excellence and, in collaboration with the International Accreditation Commission (IAC), an accreditation program for facilities administering RPT. Through the Clinical Trials Network (CTN) and Therapy Clinical Trials Network (TCTN), the SNMMI also supports research and quality assurance for imaging cameras used to evaluate patients receiving RPT in clinical trials. Furthermore, collaborations with other international nuclear medicine societies ensure the continual promotion of best practices and knowledge sharing to advance the field of nuclear medicine globally.

Key Words: radiopharmaceuticals; theranostics; nuclear medicine therapy

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BACKGROUND

By all measures, interest in RPTs is growing rapidly. Pharmaceutical companies are investing billions of dollars in their development, and an increasing number of clinical trials involve new theranostic agents and combination treatments, building on the success of ¹⁷⁷Lu-DOTATATE (Lutathera; Novartis) and ¹⁷⁷Lu-vipivotide tetraxetan (formerly ¹⁷⁷Lu-PSMA-617, Pluvicto; Novartis). While RPT is not new—nuclear medicine practitioners have been providing it for nearly a century—the recent surge in growth and expansion has drawn interest from those outside of nuclear medicine. Nuclear medicine professionals have undergone intensive and specialized training for the safe and high-quality administration of RPT. High-quality and safe practices must be maintained as RPT expands. There are concerns regarding the risks posed by practitioners, advanced practice practitioners (APPs), technologists, and support staff who may not have the necessary training and credentials to administer these therapies.

Additionally, limited patient access to RPT and a shortage of nuclear medicine professionals specifically trained in emerging theranostic therapies raise further issues. SNMMI, recognizing the importance of patient access to these promising therapies and the field's significant growth, has been preparing for this expansion by offering training, establishing centers of excellence, providing accreditation, developing treatment protocols, and offering guidance to companies through the CTN and TCTN.

Given these developments, SNMMI leadership felt it was necessary and appropriate to issue a position paper outlining the current situation. This paper aims to emphasize the critical and central role of nuclear medicine in RPTs and the need to maintain high standards of safety and quality in the field through proper education, training, and expertise.

HISTORICAL OVERVIEW

Theranostics—the combination of diagnostic and therapeutic radiopharmaceuticals to visualize and precisely treat disease—defines the medical specialty of nuclear medicine; its history dates back over 80 y. Between 1890 and 1925, the groundwork was laid for the medical use of radioactive isotopes through several seminal discoveries: the revelation of disease-specific biology, the discovery of radioactivity, the description of the “tracer principle,” and the generation of artificial radioactivity (1). In the 1930s, Saul Hertz, chief of the Thyroid Unit at Massachusetts General Hospital, conceived the idea of treating thyroid disease with radioactive iodine. His work with Arthur Roberts, a medical physicist in the Massachusetts Institute of Technology Radiation Laboratory, led

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For correspondence, contact Cathy S. Cutler (ccutler@bnl.gov).
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to the first radioiodine treatment in a patient in 1941 (2–4). In the late 1930s and early 1940s, John Lawrence and his team began treating patients with leukemia and polycythemia vera with ^{32}P (5–7), and Charles Pecher demonstrated accumulation of ^{89}Sr in osteoblastic bone for the treatment of bone sarcoma and bone pain palliation (8).

Nuclear medicine subsequently developed as a medical specialty—formally so in 1971, with the publication of specific education and training for physicians, radiochemists, physicists, and nuclear medicine technologists in the principles and practice of applying unsealed sources for diagnosis and therapy (9). Aspects of this education and training unique to these different groups within nuclear medicine are discussed below.

Over the 80 y since the birth of theranostics, other RPTs have emerged (Table 1) (10–30). Early excitement for some, such as radiolabeled anti-CD20 antibodies for lymphoma (11,31) and ^{131}I -MIBG for paraganglioma and pheochromocytoma (12), fizzled into commercial failure, despite their efficacy. Nuclear medicine gained extensive experience with these agents, including multidisciplinary work with physicists specializing in dosimetry of radiopharmaceuticals to develop simplified methods to integrate personalized dosing into clinical practice (32).

Over the past decade, ^{223}Ra , ^{177}Lu -DOTATATE, and ^{177}Lu -vipivotide tetraxetan have brought theranostics back to the forefront of cancer research and clinical practice. Phase 2/3 randomized controlled trials of these new RPT agents demonstrated survival benefits compared with current standards of care, garnering attention from the broader medical community and accelerating adoption (13,14,33,34).

The resurgence of theranostics has changed the landscape of nuclear medicine, rapidly increasing the demand for, access to, and delivery of approved radiopharmaceuticals. In 2022, it was estimated that approximately 41,500 patients with neuroendocrine tumors and prostate cancer would be eligible for approximately 1,50,000 cycles of RPT, and that between 70–280 centers would be needed to deliver such treatments (35). The Lancet Oncology Commission Report on Radiotherapy and Theranostics (36) published informative and interesting estimates on the global potential of RPT. Making several assumptions, which are well-described in the report, the Commission estimated that more than half a million doses of PSMA RPT per year would be needed to treat more than 158,000 patients with stage 4 metastatic castration-resistant prostate cancer. Pharmaceutical companies have reported significant increases in radiopharmaceutical sales, and market estimates suggest that the total sales of radiopharmaceuticals could grow from about \$750 M in 2022 to \$5.5B in 2028 (37). Pharmaceutical and smaller biotechnology companies are investing heavily in radiopharmaceutical research and development, with more than 80 new radiopharmaceutical assets in clinical development (37). Additionally, ^{177}Lu -vipivotide tetraxetan is now approved for the treatment of metastatic castration-resistant prostate cancer before taxane chemotherapy, significantly increasing the number of patients eligible for PSMA RPT. Both ^{177}Lu -vipivotide tetraxetan and ^{177}Lu -DOTATATE are also being investigated for additional indications, which could further increase the number of patients eligible to receive RPT (NCT04720157, NCT04689828, NCT04647526, NCT05204927, and NCT03972488). Meeting such a demand will require a parallel increase in the capacity of centers and workforces dedicated to delivering high-quality care with RPTs.

The field of nuclear medicine is poised to drive the clinical implementation and global expansion of theranostics. However, we must proactively strategize on how to effectively prepare and

operationalize around this impending “tsunami”—a surge that could be argued is already here, as emphasized by the recent label expansion for ^{177}Lu -vipivotide tetraxetan. Strategies include actively participating in multidisciplinary tumor boards, engaging with and expanding into the community, and championing RPT within our institutions. Through these efforts, we will demonstrate our critical role in patient management teams.

QUALITY AND SAFETY

High-quality, safe, patient-centered care must be prioritized in the delivery of RPTs. High-quality, safe administration depends on the expertise of the professionals involved in patient care. The rapid growth and increasing demand for RPT have led to concerns that the administration of these agents by professionals without specific training in unsealed sources could compromise patient safety and quality of care.

Before ordering a dose of the therapeutic radiopharmaceutical, patients receiving RPT should be evaluated holistically. Patient-centered care pathways must involve multidisciplinary teams throughout the RPT course, and details of such pathways and approaches have been previously published (38,39). Patient evaluation for and selection of RPT includes consulting with the authorized user to review relevant oncologic and medical histories, as well as laboratory and imaging evaluations, discussion of the risks and benefits of RPT in the context of available therapeutic options, and shared decision-making. The patient should receive education about what to expect on the days of and after therapy, along with radiation safety instructions. Several members of the RPT team may provide this education, depending on institutional workflows and practices. These discussions must be held before consent for RPT is obtained. A detailed discussion of all the steps required for high-quality and safe RPT selection, administration, and follow-up is beyond the scope of this paper and has been previously published (38,39). A few additional key points are highlighted below.

RPTs should adhere to each nuclear medicine program’s quality management program. As required by the Nuclear Regulatory Commission (NRC), appropriate quality control procedures should be performed for all radiopharmaceutical equipment and scanners. Many departments have developed a quality management program form for therapeutic radiopharmaceutical administration, which may be included with the written directive. Some include a checklist to ensure that each necessary element is addressed. A standard system with multiple time points and at least 2 qualified independent verifiers is strongly advised. Furthermore, there are chemotherapy standards that have been proven to increase patient safety (40). While some of these standards overlap with radiation safety programs, by comparing best practices from both radiation safety programs and chemotherapy standards and adapting these to suit local practice, centers administering therapeutic radiopharmaceuticals can improve quality of care and obviate common errors before they arise.

Like all drugs, radiopharmaceuticals must be manufactured and dispensed after standards of administration. In radiopharmaceutical manufacturing, the production of radiopharmaceuticals must meet the specifications of regulatory bodies, such as the Food and Drug Administration (FDA) and the European Medicines Agency, following Current Good Manufacturing Practice regulations to ensure stringent standards for patient safety. FDA-approved theranostic agents may be delivered directly to a medical facility for patient administration or to centralized nuclear pharmacies for patient-specific unit-dose dispensing.

TABLE 1
Therapeutic Radiopharmaceuticals with Approved Marketing Authorization for Indications in Oncology

Therapeutic radiopharmaceutical	Year of initial approval (FDA; EMA)	Approved PET/SPECT diagnostic companion(s)	Therapeutic radiopharmaceutical indication(s)	Data
¹³¹ I-sodium iodide	Before 1982; 1971*	¹³¹ I-sodium iodide; ¹²³ I-sodium iodide	Treatment of selected cases of differentiated thyroid carcinoma	Low-risk thyroid cancer (15); metastatic thyroid cancer (16,17)
⁸⁹ Sr-chloride	1993; 1993*	^{99m} Tc-bisphosphonates (e.g., ^{99m} Tc-medronate, ^{99m} Tc-oxidronate, ^{99m} Tc-pyrophosphate)	Relieve bone pain in patients with painful osteoblastic skeletal metastases	Pain response rates higher in ⁸⁹ Sr vs. placebo groups; myelosuppression occurs, with delayed nadirs between 12 and 16 wk
¹⁵³ Sm-EDTMP†	1997; 1998	^{99m} Tc-bisphosphonates (e.g., ^{99m} Tc-medronate, ^{99m} Tc-oxidronate, ^{99m} Tc-pyrophosphate)	Relieve bone pain in patients with multiple painful osteoblastic skeletal metastases	Patients who respond generally experience onset of pain relief within 1 wk after treatment; relief of pain may persist for 4 wk up to 4 mo (18); by 4 wk, improvement in pain score and opioid use vs. control group (19)
⁹⁰ Y-ibritumomab tiuxetan†	2002; 2004	¹¹¹ In-ibritumomab tiuxetan	Relapsed or refractory, low-grade, or follicular B-cell NHL; previously untreated patients with follicular NHL who achieve PR or CR to first-line chemotherapy	ORR, 80% vs. 56% for rituximab alone (CR in 30% vs. 16%); median duration of response, 14.2 mo vs. 12.1 mo; durable response ≥ 6 mo in 64% vs. 47% (11); clinical benefit seen in various combination settings (20–24)
¹³¹ I-tositumomab‡	2003; 2003	¹³¹ I-tositumomab	CD20-positive relapsed or refractory, low-grade, follicular, or transformed NHL after progression during or after rituximab therapy	ORR, 49%–64%; median duration of response, 13–16 mo (25,26)
¹³¹ I-ibenguanine (or MIBG) [§]	1994; 2018* (27)	¹²³ I-ibenguanine	Treatment of adults and adolescents age 12 y or older with rare tumors of adrenal gland (pheochromocytoma or paraganglioma) who are positive for norepinephrine transporter	22% of patients treated achieved PR; 53% of responders experienced durable tumor response ≥ 6 mo; median OS, 36.7 mo (12)
²²³ Ra-dichloride	2013; 2013		Adults with CRPC, symptomatic bone metastases, and no known visceral metastases	Median OS, 14.9 mo vs. 11.3 mo; increased time to first SSE; increase in pain control and QoL (14,28,29)
¹⁷⁷ Lu-DOTATATE (¹⁷⁷ Lu-[DOTA ⁰ ,Tyr ³] octreotate)	2018; 2017	⁶⁸ Ga-DOTATATE (United States); ⁶⁴ Cu-DOTATATE (United States); ⁶⁸ Ga-DOTATOC (European Union)	Treatment of somatostatin receptor positive gastroenteropancreatic neuroendocrine tumors	Median OS, 48.0 vs. 36.3 mo; increase in QoL; true difference in OS likely underestimated because 36% crossed over from control group (30)
¹⁷⁷ Lu-vipivotide tetraxetan (PSMA-617)	2022; 2022	¹⁸ F-piflufolastat (DCFPLY); ⁶⁸ Ga-gozetotide (PSMA-11); ¹⁸ F-flotufolastat	Treatment of metastatic CRPC who have been treated with androgen receptor pathway inhibition and taxane-based chemotherapy	ORR, 29.8 vs. 1.7%; increased time to first SRE; high-grade adverse effect rate, 52.7% vs. 38.0% (32)

*European Medicines Agency nationally authorized medicinal product.

†Discontinued in United States in 2021.

‡Discontinued in 2014.

§Discontinued in United States in 2023 and only available as a compounded medication.

EDTMP = ethylenediaminetetramethylenephosphonic acid; NHL = non-Hodgkin lymphoma; PR = partial response; CR = complete response; ORR = overall response rate; MIBG = metaiodobenzylguanidine; OS = overall survival; SSE = symptomatic skeletal event; CRPC = castration-resistant prostate cancer; QoL = quality of life; SRE: skeletal-related event.

Adapted from Table 2 in (10).

For clinical trials, radiopharmaceuticals are frequently manufactured at contracted organizations that handle the research, development, and manufacturing of smaller quantities for patient-specific clinical trials. As with large-scale manufacturing organizations, strict regulatory requirements must be followed, but these radiopharmaceuticals will not have undergone final FDA regulatory approval. In any manufacturing setting, a qualified user who has met facility-specific training requirements must verify the release of the final radiopharmaceutical product.

There are some additional unique aspects of RPT. Specific calibrated nuclear medicine instrumentation is crucial for accurate measurement of the radioactivity to be administered. Although the role of dosimetry is evolving for RPT, dosimetry for unsealed sources differs from that performed for sealed sources. In both instances, practitioners without proper training may inaccurately measure the amount of radioactivity to be administered or miscalculate doses for tumors or normal organs. Authorized users must

be supported by other well-trained nuclear medicine professionals and adhere to established protocols and participate in ongoing education to maintaining the safety and effectiveness of RPT.

NUCLEAR MEDICINE PROFESSIONALS: ROLE, EDUCATION, AND TRAINING

Like other patient-centered oncology care models, theranostics is multidisciplinary by nature (41,42). At the center of the theranostics team are nuclear medicine professionals who span a variety of roles. Some provide direct patient care, whereas others ensure the quality and safety of care, including compliance with all local and national regulations around medical use of radioactivity.

Each set of nuclear medicine professionals within the RPT team must undergo intensive and specialized training for the safe and high-quality administration of RPTs (Table 2). Different training programs' accreditation and certification boards are categorized below.

TABLE 2
Overview of Roles of Nuclear Medicine Professionals in the Delivery of RPT

Professional	Primary Roles
Attending physician or authorized user (nuclear medicine physician, nuclear radiologist, and radiation oncologist)	• Ensure overall regulatory compliance of RPT program. • Evaluate patients' appropriateness for RPT. • Provide patient education on radiation safety, procedure, and side effects. • Prescribe RPT. • Monitor toxicity, manage side effects, and assess response of RPT. • Collaborate with other specialists caring for patients during RPT.
Nuclear medicine technologist	• Calibrate nuclear medicine instruments and equipment. • Conduct quality control checks. • Ensure proper receipt, storage, and disposal of all radiopharmaceuticals. • Prepare and administer RPT, per the written directive. • Administer adjunctive medications per local policy. • Prepare and monitor therapy rooms. • Acquire nuclear medicine images. • Provide patient education and communication, including information about radiation safety. • precautions, protocols, potential side effects in conjunction with authorized user.
Radiochemist	• Identify and develop new radiopharmaceuticals, including optimizing production methods and quality control. • Manage and perform experimental studies, including investigational new drug-enabling studies. • Collaborate with physicians, biologists, and physicists to identify new targets for RPT.
Radiopharmacist	• Manufacture, prepare, dispense, and perform quality assurance on radiopharmaceuticals. • Has increased involvement in dispensing single patient unit doses.
Nuclear medicine physicist	• Calibration and quality assurance of all nuclear medicine equipment, including dose calibrators, imaging scanners, well counters, and probes. • Optimize imaging scanner acquisition protocols. • Perform dosimetry calculations.
RSO	• Oversee safe medical use of radioactivity for patients, health care workers, and the public. • Oversee implementation and management of radiation protection programs, including compliance with regulations.
Nurses and nurse coordinator	• Coordinate overall care. • Provide patient education before RPT. • Assess patients before, during, and after RPT. • Administer adjunctive medications. • Monitor patients for adverse events.
APP	• Coordinate overall patient care. • Evaluate patients' appropriateness for RPT. • Provide patient education on radiation safety, procedure, and side effects. • Monitor toxicity, manage side effects, and assess RPT response. • Collaborate with other specialists caring for patients during RPT.

Nuclear Medicine Physicians and Other Authorized Users of Therapeutic Radiopharmaceuticals

Only physicians who are authorized users under 10 CFR 35.390 can prescribe and deliver unsealed byproduct material for which a written directive is required (i.e., performed with administered RPT). There are several training pathways to become an authorized user.

Nuclear medicine physicians and nuclear radiologists specialize in using radiopharmaceuticals for the diagnosis and treatment of disease.

Training and education for nuclear medicine physicians and nuclear radiologists in the United States encompasses several pathways and differs from training outside the United States. Nikpanah et al. recently provided a comprehensive overview of the pathways in nuclear medicine, describing strengths and opportunities (43). The Accreditation Council for Graduate Medical Education provides standards and accredits U.S. residency and fellowship programs. Common to all pathways is the completion of one year of a clinical internship after medical school. Nuclear medicine residency training duration varies, with 3 y for those entering directly after internship, 2 y for those who have completed a nonradiology residency (e.g., internal medicine, neurology), and 1 y for those who have completed a diagnostic radiology residency. Most who complete a nuclear medicine residency pursue board certification through the American Board of Nuclear Medicine and become authorized user-eligible by way of this certification. Additionally, diagnostic radiology residents may enter nuclear medicine through a yearlong nuclear radiology fellowship or 16-mo pathway within their residency. Board certification may be pursued through the American Board of Nuclear Medicine or the American Board of Radiology (ABR).

All pathways mentioned above cover the main features of nuclear medicine, such as diagnostic imaging, basic radiopharmacy with a radiopharmacy rotation, medical physics, radiobiology, radiation safety and regulations, and RPTs.

Radiation oncologists specialize in using targeted radiation therapy to treat cancer and other conditions. Radiation oncology residencies are accredited by the Accreditation Council for Graduate Medical Education and require a yearlong clinical internship after medical school. The training includes experience with therapeutic radiopharmaceuticals, medical physics, radiobiology, radiation safety, and regulations. Diagnostic image interpretation is not included, but programs must provide training on current imaging techniques, nuclear medicine, and a few other services. Board certification is through the ABR.

In 2021, NRC ceased recognizing new ABR certifications for authorized user eligibility; ABR-certificate holders must document training and experience through an alternate pathway outlined in 10 CFR part 35, obtaining the necessary training through a residency or continuing education.

All authorized users are responsible for ensuring overall regulatory compliance, evaluating and selecting patients for RPT, monitoring toxicity between treatments, and collaborating with specialists to care for patients during RPT. Authorized users must be supported by other well-trained nuclear medicine professionals. Given the various education pathways, there may be future opportunities for collaboration on curricula for RPT.

Nuclear Medicine Technologists

Nuclear medicine technologists play a critical role in ensuring the safe and effective delivery of RPT, monitoring and minimizing radiation exposure to protect both patients and health care staff. They calibrate instruments, conduct quality control checks, and are

responsible for the proper receipt, storage, and disposal of radiopharmaceuticals, including therapeutic radiopharmaceuticals (44,45).

Nuclear medicine technologists prepare radiopharmaceuticals for administration, measuring doses and handling them in accordance with safety protocols. They prepare therapy rooms, including surveying them for radiation contamination risks. Additionally, they operate advanced imaging equipment, such as SPECT/CT and PET/CT, imaging patients before and after therapy to inform therapeutic planning and dosimetry calculations (45).

Patient management, accurate documentation, and effective communication are fundamental to the nuclear medicine technologist's responsibilities. Technologists maintain detailed records of administered doses, patient responses, and imaging results, ensuring all information is up-to-date and readily available for clinical review. Before therapy, technologists provide patients with thorough radiation safety instructions, communicating relevant protocols and potential side effects. They review written directives to verify doses and administration routes prescribed by the nuclear medicine physician or authorized user (44,45). Technologists establish and maintain intravenous access to facilitate the safe and effective administration of therapies before administering the radiopharmaceutical under the supervision of a nuclear medicine physician or authorized user. Technologists can administer adjunctive medications as part of the therapy process, but this practice may vary by institution (44,45). They carefully review physician orders to ensure the appropriateness of medications, such as amino acids and antiemetics, preparing and administering these drugs while following aseptic techniques and institutional protocols. After therapy, they educate patients on necessary precautions, including providing guidance for family members and caregivers to minimize radiation exposure in the home setting (44,45).

Nuclear medicine technologists undergo rigorous academic and clinical training in nuclear medicine procedures, instrumentation, radiation biology, radiation protection and regulations, radiation physics, patient care and management, and advanced imaging technology (44–46). Nuclear medicine technologists typically hold an associate's or bachelor's degree. Professional certification is available through the Nuclear Medicine Technology Certification Board or the American Registry of Radiologic Technologists.

Radiochemists

Radiochemists provide specialized expertise in target identification, identify lead compounds, manage experimental studies (both in vivo and in vitro, including investigational new drug-enabling studies), and optimize production methods and quality control procedures. They often collaborate closely with biologists and physicists to identify the appropriate nuclide for a given targeting platform isotope. They work with nuclear medicine physicians and radiopharmacists to optimize radiolabeling methods for both efficacy and safety, refining these processes to improve therapeutic outcomes and minimize potential risks.

Radiochemists typically hold a PhD degree in chemistry, radiochemistry, or a related field. Some professionals may hold master's degrees in isotope chemistry and nuclear processes. Training for radiochemists often focuses on radiochemistry, isotope production, and radiolabeling; it could also include radiolabeling of drugs for clinical trials and the quality control of radiopharmaceuticals.

Radiopharmacists

Radiopharmacists are licensed pharmacists who hold either a Bachelor of Science or Doctor of Pharmacy degree from an

accredited pharmacy school and have undergone specialized training to meet the NRC training requirements and achieve Authorized Nuclear Pharmacist status. Nuclear pharmacists can also obtain board certification in nuclear pharmacy through the Board of Pharmacy Specialties.

Radiopharmacists are responsible for the manufacturing, preparation, dispensing, and quality assurance of various diagnostic SPECT and PET radiopharmaceuticals. In the United States, a radiopharmacist is typically required for dispensing FDA-approved radiopharmaceuticals. In the context of therapy, the role of the radiopharmacist has expanded to include dispensing single, patient-specific unit doses from manufacturer-supplied radiopharmaceutical material. Radiopharmacists prepare patient-specific doses on the basis of written directives or prescriptions from nuclear medicine physicians or authorized users. This preparation involves calculating the correct amount of radioactivity, aseptically withdrawing and dispensing the final patient-specific dose with a unit-dose syringe, and ensuring safe transport to the end user. Unit-dose-dispensing nuclear pharmacies are licensed by state boards of pharmacy and are required to follow standards set forth by the United States Pharmacopeia for sterile product preparation, compounding, dispensing, and repackaging of radiopharmaceutical products.

Nuclear Medicine Physicists

As critical members of “best practices” theranostics teams and comprehensive quality assurance programs, nuclear medicine physicists ensure that all equipment necessary for the administration and monitoring of RPT (e.g., dose calibrators, well counters, probes, imaging equipment) are properly calibrated and functioning. Physicists also help ensure compliance with applicable regulations and accreditation requirements. They apply their expertise to oversee nuclear medicine imaging devices, such as γ -cameras, SPECT, PET, and CT, including optimizing qualitative and quantitative aspects of these devices. In addition, physicists support other aspects of a theranostic program, including patient dosimetry analysis, optimization of administered activity, imaging protocols, PACS archiving and management, and radiation safety. Many nuclear medicine physicists also serve as radiation safety officers (RSOs), a role mandated by NRC for any facility licensed to handle radioactive materials; in smaller facilities, a physician-authorized user often assumes this responsibility.

Radiopharmaceutical dosimetry represents a specialization within nuclear medicine; physicists specializing in dosimetry have extensive knowledge of radiobiology, radionuclide decay properties, radiopharmaceutical pharmacokinetics and pharmacodynamics, and dosimetry calculation methods for unsealed sources. By analyzing advanced imaging data in conjunction with mathematic models, nuclear medicine physicists estimate the distribution and kinetics of radiopharmaceuticals within the body, helping to calculate the precise radiation dose delivered to target and at-risk normal tissues and organs. These skills are applied not only in the research domain for drug development but also in clinical practice. In addition, physicists’ involvement in multidisciplinary teams supports the continuous improvement and innovation of RPTs, particularly in the growing areas of personalized medicine and the integration of artificial intelligence. Medical physicists generally require a master’s degree or PhD in their field, followed by a clinical residency. Board certification in medical physics (through the American Board of Radiology or the American Board of Science in Nuclear Medicine) with a specialization in nuclear medicine physics is also required.

RSOs and Health Physicists

RSOs and health physicists ensure that the medical use of radioactivity is safe for patients, health care workers, and the public. They also oversee the implementation and management of radiation protection programs, ensuring compliance with local, national, and international regulations. It is the responsibility of RSOs and health physicists to safeguard everyone involved in the handling, administration, and management of radiopharmaceuticals. In private practices and elsewhere, radiologists or nuclear medicine physicians often also serve as RSOs.

RSOs generally hold a bachelor’s or master’s degree in health physics, medical physics, or nuclear engineering. Some RSOs may also have degrees in radiologic or nuclear medicine technology, with additional training in radiation safety. They receive extensive training in radiation protection, regulatory compliance, and the management of radioactive materials. Many RSOs are certified by the American Board of Health Physics or the National Registry of Radiation Protection Technologists.

Health physicists have in-depth knowledge of radiation protection principles, their application in medical settings, and the regulatory requirements for radiation safety programs. They often work under the guidance of an RSO. The American Board of Health Physics can certify health physicists, who generally hold a bachelor’s or master’s degree in health physics or nuclear engineering or have a scientific degree and extensive work experience under an RSO.

Nurses

Nurses and nurse coordinators play critical roles in nuclear medicine, which are only expanding with the growth of theranostics. Nurses coordinate overall care; educate patients before procedures; assess patients, including their medical history, allergies, current medications, and laboratory values; administer concomitant nonradioactive medications (e.g., amino acids, premedications); and monitor patients for adverse reactions. Nurses often lead care after radiopharmaceutical administration, including care related to hydration, radiation safety, and adverse reactions. Presently, specific training for nurses and nurse coordinators is typically provided at the institutional level through nuclear medicine and radiation safety programs.

APPs

The growth of theranostics has expanded the nuclear medicine workforce to include other allied professionals such as nurse practitioners (NPs), physician assistants (PAs), or nuclear medicine advanced associates (NMAAs) (47). NPs and PAs play a vital role in oncology and interventional radiology practices, facilitating safe, high-quality, efficient patient care (48–50). Many theranostic centers have added NP and PAs to their team, and the role of the NMAA is expected to grow. APPs help bridge the gap between physicians and patients, enhancing the efficiency and quality of care. They perform the same tasks as nuclear medicine physicians but, in addition, act as key coordinators in patients’ care journeys, ensuring that all health care professionals involved in the therapy (e.g., nuclear medicine physicians, primary oncology team) are aligned and prepared for treatment administration. They monitor patient recovery, manage side effects, and provide guidance on lifestyle modifications to minimize radiation exposure. They conduct follow-up visits to assess and manage side effects and toxicity, assess treatment effectiveness, and adjust care plans, if necessary, in consultation with physicians.

APPs have different pathways of education and training depending on their degree. NPs typically hold a Master of Science in Nursing or Doctor of Nursing Practice, whereas PAs hold a master's degree from a PA program. Both NPs and PAs receive training in clinical medicine, pharmacology, and patient management. NMAAs are advanced practice nuclear medicine technologists who work as physician extenders under the supervision of licensed physicians to enhance patient care in diagnostic imaging, theranostics, and radiotherapy. While the NMAA program incorporates nuclear medicine technologist training, including diagnostic and therapeutic nuclear medicine, some NP and PA programs currently do not. As in other subspecialties, training is gained on the job. As the APP workforce within nuclear medicine expands, the need for additional education and training for APPs will increase.

SNMMI: ROLE AND INITIATIVES

Procedure Standards and Guidelines

Since its inception in 1954, SNMMI has set comprehensive standards and clinical guidelines for diagnostic and therapeutic nuclear medicine, providing detailed protocols for the safe and effective use of radiopharmaceuticals and helping practitioners deliver optimal care. The organization also sets safety standards for the handling, administration, and disposal of radiopharmaceuticals, which are essential for protecting patients and health care providers.

The SNMMI Committee on Procedure Standards reviews and updates standards routinely and works to identify new topics, particularly as the FDA increasingly processes novel theranostic pairs for approval. Guideline committees are multidisciplinary. SNMMI collaborates with other organizations to facilitate national and international standardization, such as the European Association of Nuclear Medicine (51–63). Appropriate use criteria have also been developed to help practitioners in the clinical use of theranostic agents. These efforts are part of the SNMMI Value Initiative Quality of Practice domain, which focuses on expanding the integration of best practices in all aspects of nuclear medicine and molecular imaging to optimize patient care and access.

RPT Centers of Excellence and SNMMI IAC Accreditation

SNMMI established the Radiopharmaceutical Centers of Excellence Program in 2022. This initiative recognizes institutions with the training, personnel, equipment, and experience required for high-quality RPT administration. Centers may apply for 2 levels of Centers of Excellence recognition: comprehensive RPT or Clinical RPT. The primary difference between the 2 levels is the center's level of engagement in research. The network of RPT Centers of Excellence now includes both national and international sites and represents a growing commitment to advancing standards in RPT. The RPT Centers of Excellence network helps guide patients to institutions that have demonstrated a focus on quality, safety, and expertise in delivering radiopharmaceutical treatments.

In 2023, SNMMI partnered with the IAC to create the RPT Accreditation Program. Through this collaboration, SNMMI and IAC built on the RPT Centers of Excellence and IAC nuclear medicine accreditation programs to develop quality and safety standards for RPT. Accredited sites must demonstrate adherence to rigorous standards, including appropriate professional and support staff, experience, facilities, equipment, and policies and procedures. Since the program's launch in Fall 2024, 5 centers have been accredited.

Education and Training

SNMMI provides a comprehensive array of educational resources in multiple formats to support the skills and knowledge of all professionals involved in RPT. The SNMMI Annual Meeting and Mid-Winter Meeting are live, in-person events with dedicated continuing education and scientific sessions on theranostics. A hybrid option is available for the Annual Meeting. An annual 2.5-d-long Therapeutics Conference was initiated in 2018 to focus exclusively on RPT. In collaboration with the American College of Nuclear Medicine, webinars on clinical topics in diagnostic and therapeutic nuclear medicine, dosimetry, safety protocols, and operational aspects are offered throughout the year. Additional educational offerings include the SNMMI Technologist Section's "Therapy Thursday" Therapy Tumor Boards series. A recent initiative in development is a tiered certification course in dosimetry, with classes tailored for physicists, physicians, and technologists.

SNMMI is committed to the growth and development of a diverse, qualified workforce trained to provide equitable care in diagnostic and therapeutic nuclear medicine. The Value Initiative's Workforce Pipeline and Life-Long Learning domain focuses on developing resources to introduce nuclear medicine as a career choice earlier in the decision pathway for students, from high school to medical school levels.

Research Support and Outreach Programs

CTN offers a PET/CT scanner validation program that is isotope-specific to support accurate quantitation for clinical trials. More than 700 scanners have been validated worldwide. CTN provides quantitation services for the entire radiopharmaceutical pathway, from the drug product manufacturer through to the site dose calibrator, scanners, and well counters for accurate RPT development. Through the Research and Discovery domain's Dosimetry Task Force, dosimetry training for RPT has been integrated into national meetings. Data generated from the ^{177}Lu Dosimetry Challenge has helped identify the areas of variability in current dosimetry practice, leading to recommendations for best practices for each step of the dosimetry process. The Artificial Intelligence Task Force has also published recommendations for best practices in developing, training, testing, and implementing artificial intelligence in nuclear medicine.

CTN collaborates with the National Institutes of Health and FDA on emerging topics, including the development and registration of RPTs. In anticipation of the increased need for clinical sites for RPT, SNMMI established the TCTN. TCTN sites have shared detailed information on their equipment, personnel, and key contacts and have created standard budget templates to streamline trial feasibility assessments and start-ups. Sites have validated SPECT scanners and radionuclide dose calibrators for ^{177}Lu , with other isotopes in process. As it expands, TCTN aims to help sites with the infrastructure needed to participate in industry-sponsored clinical (phase 1–3) trials.

Through its outreach programs, SNMMI provides information about the benefits and safety of RPTs, educating patients, the public, and health care professionals. This includes a nationwide public relations campaign, presentations at relevant medical society meetings, educational road show events, and, in collaboration with the Society's Patient Advocacy Advisory Board, the development of patient-friendly online resources as well as Patient Education Day at the SNMMI Annual Meeting.

SNMMI advocates for policies and regulations that support the safe and effective use of RPTs, including working with regulatory agencies to shape guidelines and standards that impact clinical practice.

INTERNATIONAL PERSPECTIVES AND COLLABORATION

SNMMI works to harmonize guidelines and standards for RPT across different regions, with the goal of promoting the consistency of nuclear medicine practices, reducing variability in treatment quality, and improving patient outcomes worldwide.

Collaboration remains central to this work. SNMMI engages with international regional organizations, such as the International Atomic Energy Agency, World Federation of Nuclear Medicine and Molecular Biology, European Association of Nuclear Medicine, Nuclear Medicine Global Initiative, American Latin Association of Societies of Biology and Nuclear Medicine, Asian Oceania Association of Nuclear Medicine and Biology, Arab Society of Nuclear Medicine, Australia–New Zealand Society of Nuclear Medicine, and other national societies and associations. These partnerships promote best practices, support knowledge exchange, and contribute to advancing nuclear medicine globally.

The rapid clinical expansion of RPT and the growth in drug development underscores the need for collaborations beyond the global nuclear medicine community. Strengthening established collaborations, such as with the American Association of Physicians in Medicine and other radiologic societies, and building new ones, such as with the American Society of Therapeutic Radiation Oncology, will be critical for ensuring sustainable access to safe, high-quality RPT. There are successful models of how nuclear medicine and radiation oncology can work together to treat patients and move the field of RPT collaboratively. Increasing collaborations with medical and surgical oncology societies should also be a key priority.

Looking ahead, SNMMI will work with partners across disciplines to meet these evolving challenges, advance the field of RPT, and improve outcomes for patients around the world.

CONCLUSION

As RPTs rapidly transform patient care, particularly in oncology, the highest standards of excellence, safety, and quality must be maintained as interest, investment, and the number of clinical trials in the field increase.

Beginning with a historical overview of the essential contributions of nuclear medicine professionals to the field over its 8 decades of existence, this SNMMI position statement on RPT highlights the education, training, experience, and expertise required for the safe and efficient delivery of RPTs. It emphasizes strict adherence to safety protocols, including the handling of radiopharmaceuticals, accurate dosimetry, and robust radiation safety measures, which are crucial for protecting patients and ensuring the safe and effective administration of therapies. Continuous professional development is also advocated to keep nuclear medicine practitioners up-to-date on technical advancements in the field, ensuring the highest standards of practice.

This position paper promotes the use of evidence-based best practices, grounding the administration of RPT in the latest research and clinical data. SNMMI supports continuous quality improvement through the regular evaluation of therapeutic results and quality assurance measures, monitoring treatments against their intended goals. Furthermore, this paper highlights SNMMI's leadership in establishing internationally recognized guidelines and standards, with the establishment of RPT Centers of Excellence and an accreditation program through a collaboration with IAC, whose high standards and stringent criteria ensure the excellence of care.

Finally, this paper underscores SNMMI's commitment to excellence through numerous educational, clinical, and research initiatives

aimed at enhancing the expertise of professionals involved in RPT. SNMMI fosters collaborations with other disease-specific specialty associations and promotes international partnerships across the global nuclear medicine community. By harmonizing guidelines and standards across regions and specialties, SNMMI aims to promote safety, efficiency, and consistency in the delivery of RPTs. Through interdisciplinary and multidisciplinary collaboration, nuclear medicine professionals can advance the field, innovate productively, and share and implement best practices worldwide.

DISCLOSURE

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