Review Article

Revista Brasileira de Física Médica (2026) 20:908

The strategic role of the medical physicist and the production of radiopharmaceuticals: fundamentals, regulation, and pathways for the expansion of Brazilian Nuclear Medicine.

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Abstract

Nuclear Medicine (NM) has undergone a profound transformation driven by advances in radiopharmaceutical production, molecular imaging, theranostics, and personalized dosimetry. In Brazil, however, the sustainable expansion of NM remains constrained by structural challenges involving production capacity, regulatory complexity, logistics, technological incorporation, and unequal regional access. This narrative review critically analyzes the Brazilian radiopharmaceutical production chain, emphasizing the strategic role of the medical physicist in integrating scientific knowledge, technological innovation, regulatory compliance, and clinical practice. A qualitative review of scientific literature, textbooks, institutional reports, and national and international regulatory documents was conducted using major databases and official repositories. The analysis demonstrates that the expansion of NM requires a systemic approach combining resilient production infrastructure, risk-based regulation, decentralized production models, qualified logistics, and coordinated governance. Particular attention is given to advances in cyclotron technology, radionuclide generators, therapeutic radioisotopes, alpha-emitting radionuclides, predictive dosimetry, and conceptual operational models for decentralized radiopharmaceutical production. The review also discusses how the medical physicist has evolved beyond traditional responsibilities in radiation protection and quality control to become a strategic professional involved in production planning, process validation, dosimetry, regulatory implementation, innovation, and healthcare system development. The findings indicate that strengthening the integration of production, regulation, logistics, and clinical application is essential to improving equitable access to nuclear medicine in Brazil. The medical physicist is therefore positioned as a key stakeholder in building a safe, innovative, and sustainable national NM infrastructure capable of supporting future advances in precision medicine.

Keywords*: Nuclear Medicine; Medical Physics; Radiopharmaceuticals; Radiopharmacy; Precision Medicine; Theranostics.*

1. Introduction

Nuclear Medicine (NM) is one of the most sophisticated interfaces between physics, biology, and clinical practice. It is supported by the production and application of radioisotopes and radiopharmaceuticals capable of providing functional and molecular information with high sensitivity and specificity (1,2). The complexity of this chain spans fundamental phenomena in nuclear physics and the incorporation of radionuclides into biologically active molecules, ultimately enabling high-impact diagnostic and therapeutic applications (3,4).

International experience shows that these structural barriers can be overcome through coordinated infrastructure investment, regulatory modernization, and workforce development. Korea's first domestically developed cyclotron (KIRAMS-13), with isotope production achieved in 2005, was supplied to six universities and university hospitals, enabling the nationwide supply of PET radiopharmaceuticals (25). China developed a mature system for the production and management of radiopharmaceuticals that, by 2019, supported 1,148 nuclear medicine departments performing approximately 849,900 PET/CT examinations and

530,000 radionuclide therapy treatments annually (26). These examples illustrate that decentralized production, when accompanied by regulatory and workforce planning, can substantially expand national NM capacity (25,26).

In Brazil, despite the strategic relevance of the field, the production chain still faces important structural challenges. These challenges are particularly associated with centralized production, logistical constraints, dependence on suppliers, infrastructure limitations, slow technology adoption, and the need for regulatory evolution (5). These factors should not be understood in isolation. They compose an interdependent system in which economic, regulatory, production, and logistical failures directly impact the capacity for expanding NM and the population's access to diagnostic and therapeutic procedures. In this context, it is necessary to recognize that the expansion of NM in the country does not depend only on the acquisition of equipment or the introduction of new radiopharmaceuticals. It requires systemic planning, more resilient production models, institutional coordination, adequate regulatory infrastructure, and professionals capable of integrating science, technology, safety, production, and care (6). The medical physicist therefore plays a central role in this process. Their work is not limited to radiological protection, dosimetry, or quality control. In this context, the medical physicist serves as an integrating link between basic science, technological development, radioisotope production, radiopharmacy, regulation, logistics, and clinical practice, contributing directly to the sustainable expansion of NM (7).

2. Methodology

This study comprises a descriptive and critical narrative review of the nuclear medicine production chain, with emphasis on the production, regulation, logistics, and clinical application of radioisotopes and radiopharmaceuticals. The literature search included scientific databases, textbooks, institutional repositories, and regulatory sources, including SciELO, PubMed, Google Scholar, ScienceDirect, Anvisa, CNEN, ANSN, IAEA, NEA/OECD, PIC/S, FDA, and ICH.

The searches were conducted using descriptors in Portuguese and English, such as "nuclear medicine," "radiopharmaceuticals," "radioisotopes," "radiopharmacy," "radiopharmaceutical production," "radiopharmaceutical production chain," "medical physics," "PET," "SPECT," "nuclear medicine," "radiopharmaceuticals," "medical radioisotopes," "hospital radiopharmacy," "good radiopharmacy practice," and "medical physicist." The selection of references prioritized peer-reviewed articles, reference books, technical documents, regulatory standards, and international guidelines related to the topic.

No strict temporal cutoff was applied, given the need to include both classic works in the field and regulatory documents and recent publications. The analysis was conducted qualitatively, seeking to critically synthesize the main concepts, challenges, and perspectives related to the sustainable expansion of NM in Brazil.

3. Development

The review is organized into thematic sections addressing the main aspects of nuclear medicine expansion in Brazil. These include the structural challenges facing the field, the current production of radioisotopes and radiopharmaceuticals, therapeutic advances, cyclotron technology, the integration of nuclear physics with biology, regulatory frameworks, decentralized production models, predictive dosimetry, and the evolving role and training of the medical physicist in supporting the sustainable development of nuclear medicine in Brazil.

3.1. Structural problems of Brazilian NM and the need for a systemic response

The expansion of NM in Brazil requires addressing constraint that extend beyond purely technical considerations. The production and clinical use of radiopharmaceuticals depend on a supply chain that is highly sensitive to time, distance, infrastructure, regulation, and the availability of critical supplies. Thus, any instability in one of the links of the chain may compromise the predictability of care, technological incorporation, and the sustainability of the sector (3,8).

Table 1 below summarizes the main structural problems, their strategic axes, and the expected systemic results to support the expansion of NM in Brazil. An integrated assessment of this framework shows that nuclear medicine in Brazil does not face only a technological supply problem; rather, it faces systemic limitations, in which production, regulation, financing, logistics, market, public communication, and governance need to be addressed in a coordinated manner.

Table 1. Main problems identified and systemic approaches for NM in Brazil

Nº	Identified structural Limitation	Strategic axis	Expected systemic result
1	Economic lag in the SUS reimbursement	Economic	Financial sustainability and investment predictability
2	Low investment in infrastructure (Cyclotron and MN)	Economic and regionalization	Planned interiorization and technological modernization
3	Critical logistical limitation	Supply chain	Reduction of Improve in the operational predictability. Reduction in delivery failures.

4	Regulatory complexity (ANSN, ANVISA, MMA)	Regulation and governance	Reduction of technological lag
5	Delayed access to new technologies	Regulation and oncology	More agile therapeutic incorporation
6	Concentrated dependence on suppliers	Decentralization of production	Supply security and reduction of vulnerability
7	Supply unpredictability	Production redundancy and regional supply networks	Greater supply resilience and operational predictability
8	Fragmented and poorly coordinated market structure	Market planning and regional production strategies	Better coordination between production capacity and regional demand
9	Low strategic recognition of nuclear medicine	Health-system governance and strategic planning	Greater institutional priority and integration into healthcare planning
10	Absence of a structured national plan	Governance	Federative coordination and integrated political strength
11	Low institutional coordination	Governance	Federative coordination and integrated political strength
12	Excessive dependence on the political environment	Governance	Technical protection against political instability
13	Limited operational scale	Decentralization of production	Scale gains and reduction of inequality
14	Public misinformation about radiation	Access and communication	Reduction of cultural barriers
15	Overestimation of artificial intelligence as a substitute for structural solutions*	Strategic planning and technological innovation	Technological modernization aligned with structural priorities

Source: The author (2026). *Unlike the predominantly structural constraint listed above, the challenge related to artificial intelligence reflects a strategic and cultural perception. AI may support optimization, planning, imaging, dosimetry, and decision-making, but it does not replace the need for production infrastructure, qualified personnel, regulation, logistics, and coordinated governance

Without such an approach, the introduction of new technologies will not necessarily translate into sustained and equitable access for the population. This diagnosis reinforces the need for structuring models capable of connecting production, quality control, traceability, specialized logistics, and clinical use. It is in this context that the role of the medical physicist becomes strategic, as their training allows them to simultaneously understand the physical foundations, radiological risks, quality requirements, and clinical application of radiopharmaceuticals.

3.2. Current production base: radioisotopes, generators, and production systems

Nuclear medicine relies on radioisotopes produced in nuclear reactors, cyclotrons, and radionuclide generator systems, each with specific characteristics that determine its clinical applicability.

Nuclear reactors remain the primary source of several medically important radioisotopes. Among them, molybdenum-99, predominantly produced by uranium-235 fission, deserves particular attention as the parent radionuclide of technetium-99m, which remains the most widely used radionuclide in diagnostic nuclear medicine. Among therapeutic beta-emitting radionuclides, lutetium-177 remains one of the most established agents in theranostic applications. Although samarium-153 has played an important historical role, its clinical use has declined owing to the availability of radionuclides with more favorable physical and biological characteristics. In this context, terbium-161 has emerged as a promising alternative to lutetium-177 because it combines beta emission with Auger electron emission, potentially increasing energy deposition at the subcellular level and improving the treatment of micrometastatic disease.

In cyclotrons, production occurs through reactions induced by charged particles, with fluorine-18 being the main PET radioisotope. Other radionuclides, such as copper-64, zirconium-89, and gallium-68, significantly expand the diagnostic and therapeutic scope. Complementing these production routes, radionuclide generators play an essential role in the logistics and availability of radiopharmaceuticals, as highlighted in Table 2.

These systems enable the local production of short-lived radionuclides and are therefore fundamental to decentralized models and expanded access to nuclear medicine. The integrated understanding of this production base is essential for the strategic planning of the expansion of nuclear medicine, allowing technological capacity, availability of inputs, regional infrastructure, and clinical needs to be aligned (3,9).

Table 2. Main radionuclide generator systems for nuclear medicine

Generator system	Obtained radionuclide	Relevance to nuclear medicine
Mo-99/Tc-99m	Technetium-99m	Main diagnostic basis of conventional nuclear medicine
Ge-68/Ga-68	Gallium-68	Diagnostic PET applications,

		especially with peptides and PSMA
W-188/Re-188	Rhenium-188	Beta therapeutic potential with application in decentralized models
Ra-224/Pb-212	Lead-212	Emerging platform for alpha therapy
Sr-90/Y-90	Yttrium-90	Consolidated therapeutic applications.

Source: The author (2026).

3.3. Therapeutic advancement: beta, Auger, and alpha particle emitters

The evolution of therapeutic nuclear medicine has been closely associated with the increasing diversity of radionuclides and their emission characteristics.

Beta emitters, such as lutetium-177, have a range on the order of millimeters in a low-density medium, making them suitable for larger-volume tumors. Radionuclides such as terbium-161 add Auger electron emission, allowing highly localized energy deposition and enhancing DNA damage on a nanometric scale.

More recently, alpha therapy has expanded significantly, with emphasis on actinium-225, characterized by high LET and high capacity for localized cell destruction. Another radionuclide of growing interest is astatine-211, whose production presents relevant technical challenges, as it depends on nuclear reactions involving alpha beams in cyclotrons, in addition to chemical complexities associated with its handling. This scenario illustrates that innovation in nuclear medicine is directly linked to the production capacity, availability, and technological mastery of these radionuclides, directly impacting the expansion of clinical applications and the consolidation of new therapeutic paradigms.

However, therapeutic advances depend on more than the scientific development of a radionuclide or radiopharmaceutical. Translating these technologies into clinical access requires a production chain capable of ensuring reliable supply, quality control, validated transport, traceability, appropriate regulatory frameworks, and adequately trained professionals. Therefore, alpha therapy and new radiometals represent not only a new clinical frontier but also a requirement for production and regulatory reorganization (10,11,12).

3.4. Role of cyclotrons in modern production

Cyclotrons can be broadly classified according to their beam energy, as shown in Table 3.

Table 3. Conceptual classification of cyclotrons by energy range and their potential applications in radioisotope production.

Category	Approximate energy range	Main applications
Low energy	Up to approximately 10 MeV	Production of routine PET radionuclides, according to equipment configuration and regional applications.
Medium energy	10 to 20 MeV	Expanded PET production.
High energy	Above 20 MeV	Production of more complex radionuclides, translational research and advanced applications.

Source: The author (2026).

In Brazil, the currently authorized cyclotron infrastructure for radioisotope production is distributed across different regions of the country. Table 4 summarizes the facilities authorized by ANSN as of August 21, 2026 and highlights the energy range of the cyclotron infrastructure considered in this review.

Table 4. Cyclotron facilities authorized for radioisotope production in Brazil and energy range of the installed cyclotron infrastructure (position as of August 21, 2026).

Institution	City	State	Cyclotron energy range* (MeV)
CDTN – Unidade de Pesquisa e Produção de Radiofármacos (UPPR)	Belo Horizonte	MG	11–20
CMR Campinas Pharma Ltda	Campinas	SP	11–20
CMR Salvador Pharma Ltda	Lauro de Freitas	BA	11–20
Cyclopet Radiofármacos Ltda	Curitiba	PR	11–20
HC-FMUSP – Centro de Medicina Nuclear	São Paulo	SP	11–20
IBF – Indústria Brasileira de Farmoquímicos	Vitória de Santo Antão	PE	11–20
IBF – Indústria Brasileira de Farmoquímicos S.A.	São José do Rio Preto	SP	11–20

MJM Produtos Farmacêuticos e de Radioproteção Ltda	Itupeva	SP	11–20
R2 Soluções em Radiofarmácia	Rio de Janeiro	RJ	11–20
UBEA – Hospital São Lucas – Instituto do Cérebro	Porto Alegre	RS	11–20
Villas Boas Radiofármacos Brasil S/A	Brasília	DF	11–20
Villas Boas Radiofármacos Brasil S/A	Eusébio	CE	11–20

Source: Brazilian National Nuclear Safety Authority (ANSN), Authorized Facilities – Radioisotope Production (Cyclotron), position as of August 21, 2026. *The 11–20 MeV range refers to the technical characteristics of the currently installed cyclotron infrastructure considered in this review and is not provided in the ANSN authorized-facilities registry.

The classification presented in Table 3 helps determine the feasibility of producing different radionuclides. The operation of these systems requires in-depth knowledge of nuclear physics, particle–matter interactions, and target engineering, areas in which the medical physicist may contribute through expertise in process optimization, yield improvement, and quality assurance of the radioisotopes produced.. In addition to the physical operation of the equipment, the planning of a production structure based on a cyclotron requires assessment of regional demand, logistical feasibility, supply redundancy, quality control protocols, waste management, radiation protection, regulatory capacity and integration with the healthcare network. Thus, the cyclotron should be understood not only as a piece of equipment, but also as part of a strategic production infrastructure (13, 9, 14).

International experience shows that medical cyclotrons can also be adapted to produce novel radiometals beyond conventional PET radionuclides. The Paul Scherrer Institute of Research in Würenlingen (Switzerland), for example, has developed proof-of-concept production routes for scandium-44, scandium-43, copper-64, erbium-165, and terbium-161 using solid target designs and automated radiochemical separation, supporting preclinical and clinical translation (27). Brazil's cyclotron network could evaluate the feasibility of implementing comparable protocols to diversify the national radionuclide portfolio and reduce dependence on imported therapeutic isotopes.

From the perspective of nuclear medicine expansion, however, cyclotron energy should be analyzed together with the function of the accelerator within the production network. Compact low- and medium-energy cyclotrons, including so-called small cyclotrons, may play a strategic role in regionalized production models, particularly for short-lived radionuclides and production associated with local or microregional demand. Reducing the distance between production and clinical application decreases logistical dependence, limits losses related to radioactive decay, and may increase redundancy and resilience of the supply chain. Therefore, expansion of national production capacity should not be evaluated solely in terms of increasing the individual capacity of accelerators, but also according to their geographical distribution and the integration between production centers and clinical demand.

Conversely, some radionuclides require beam energies, currents, target systems, radiochemical infrastructure, and production scales that favor larger centralized facilities. High-energy cyclotrons — including facilities operating in the range of several tens of MeV and, for specific strategies, accelerators approaching 70 MeV — may expand the production of radionuclides that are not technically or economically suitable for local production. A national strategy should therefore not be understood as a choice between centralization and decentralization, but as a complementary architecture: centralized production for radionuclides requiring greater complexity or scale, combined with a decentralized network of compact cyclotrons and radionuclide generators for products whose physical half-life and clinical demand favor regional production. The definition of each facility should consider demand, physical half-life, production yield, required energy, CAPEX and OPEX, availability of qualified personnel, regulatory requirements, logistics, and operational sustainability. From this perspective, a pathway for expanding nuclear medicine in Brazil should combine regionalized production of short-lived radionuclides through appropriately distributed compact cyclotrons and generator systems with centralized facilities dedicated to radionuclides requiring higher energy, greater production scale, or more complex infrastructure. The medical physicist contributes to this planning by integrating physical production requirements with radiation protection, quality assurance, dosimetry, infrastructure assessment, clinical demand, and operational risk. This complementary production architecture provides the basis for discussing decentralization not as an isolated technological choice, but as a coordinated strategy for regional access, supply resilience, and sustainable expansion.

3.5. Decentralization and new production models

The decentralization of radiopharmaceutical production emerges as a strategic alternative to overcome structural barriers historically observed in nuclear medicine in Brazil. Models based on integrated regional centers can reduce logistical dependence, expand the availability of radiopharmaceuticals and foster local innovation, especially in a country of continental dimensions.

The presence of radionuclide generators, combined with the installation of low- and medium-energy cyclotrons, enables the creation of more resilient production networks adapted to regional demands. However, the effective implementation of

these models requires not only technological advances, but also a consistent evolution of the regulatory framework. In this context, the consideration of more flexible, risk-based regulatory models inspired by international best practices, becomes relevant, allowing the sanitary and operational classification of integrated units for the production and application of radiopharmaceuticals. Approaches such as the structuring of advanced centers, with different operational levels, activity categories, governance of critical inputs and robust traceability systems may provide a means of reconciling safety, quality, and expanded access. This regulatory evolution does not imply relaxing regulatory requirements, but rather adapting the regulatory framework to the specific characteristics of radiopharmaceuticals, thereby enabling greater operational efficiency without compromising radiation or sanitary safety (19, 20, 21, 22). To translate this decentralized strategy into an operational framework, different levels of integration and technical complexity can be conceptually defined according to the scope of production, preparation, distribution, and clinical application.

3.6. Operational levels and activity categories: a conceptual view for expansion

Without delving into a specific regulatory proposal, modern models for the expansion of nuclear medicine can be conceptually organized along two main axes: operational levels and activity categories. This structure makes it possible to differentiate the scope of healthcare provision from the technical complexity of the activities performed. An integrated healthcare and production unit, operating under unified technical governance, centralized sanitary responsibility, full traceability, and risk-proportional controls, could provide a framework for decentralized radiopharmaceutical production in the country.

Conceptually, the operational levels can be understood as follows (Table 5):

Table 5. Operational levels of radionuclides

Operational level	Main characteristic	Strategic purpose
Level 1	Institutional own use, with production, preparation, quality control and clinical application within the same institutional arrangement.	Structure safety, quality and traceability in integrated healthcare units.
Level 2	Microregional hub with a central unit and formally linked satellite clinics.	Expand regional access with validated logistics, assisted transfer and centralized governance.
Level 3	Integrated network of multiple units or hubs, with process harmonization and a unified quality system.	Organize regional or interregional expansion with standardization and systemic monitoring.

Source: The author (2026).

The activity categories, in turn, allow the degree of technical complexity to be modulated (Table 6):

Table 6. Degree of technical complexity

Category	Conceptual scope	Relative complexity
Category 1	Dispensing and fractionation of previously prepared radiopharmaceuticals, without critical alteration of the formulation.	Lower complexity
Category 2	Standardized preparation from kits, precursors or regulated critical inputs, following validated protocols.	Intermediate complexity
Category 3	Advanced preparation, justified adaptations, translational development or new technical arrangements.	Higher complexity

Source: The author (2026).

This conceptual matrix provides a framework for discussing expansion while maintaining appropriate safety requirements. It avoids treating all services as equivalent and prevents low-, medium-, and high-complexity activities from being automatically subjected to the same regulatory model. At the same time, it preserves the need for traceability, qualification of inputs, quality control, deviation management, pharmacovigilance, and radiation protection.

For the medical physicist, this approach is particularly relevant, as it brings medical physics closer to system governance. In this framework, the medical physicist contributes not only to technical activities but also to risk assessment, process validation, infrastructure assessment, production planning, logistics and the interface with sanitary and nuclear authorities (3, 20, 23, 22).

3.7 Structural challenges and regulatory milestones

The production chain in Brazil faces challenges related to centralization and supply logistics, especially due to the decay characteristics of radioisotopes. Unlike other pharmaceutical products, radiopharmaceuticals have a limited operational

window, require specialized transportation, time control, rigorous traceability and technical release compatible with their physical half-life. From a regulatory perspective, relevant standards include ANVISA RDC 738/2022 (10), which addresses aspects related to radiopharmaceuticals, and ANSN regulations, including standards applicable to facilities with cyclotrons (13), radiopharmacies (18), radiation protection (15) and the transportation of radioactive materials (8). These milestones establish rigorous requirements for safety, quality and traceability.

Other relevant standards in the regulatory and production context include RDC 658/2022 (16) and IN 128/2022 (11), related to good manufacturing practices, as well as RDC 488/2021 (17), associated with importation by health services under specific conditions. In the nuclear field, ANSN standards also play an indispensable role in radiation protection, facility safety, control of radioactive sources, occupational monitoring, waste management and transportation of radioactive material. These milestones are fundamental, but they also require high technical and organizational capacity for their implementation, demanding qualified professionals and well-structured systems to ensure compliance and operational efficiency (24).

International experience offers useful reference points for risk-based oversight. China's revised Drug Administration Law and its 2021–2035 Development Plan for Medical Isotopes promote independent domestic production, streamlined clinical trial pathways, and centralized radiopharmacies, coordinating production, distribution, and clinical oversight while maintaining quality and supply security (26). The EFOMP policy statement, in turn, recommends close collaboration between medical physicists and practitioners, investigator-led clinical trial support, and networking for the development of codes of practice (28). Regulatory complexity and the need for coordinated governance have also been repeatedly identified as constraints on the expansion of radiopharmaceutical therapy (29).

The current regulatory challenge is not to reduce safety requirements. On the contrary, it consists of structuring risk-proportional models capable of recognizing the particularities of radiopharmaceuticals, particularly short-lived radiopharmaceuticals, extemporaneous preparation, in-process control, release within a short time window and the need for post-release tests in technically justified situations.

Brazil's regulatory framework must therefore balance patient safety with the need to accelerate the clinical translation of novel radiopharmaceuticals. Risk-proportional oversight that differentiates requirements according to radionuclide complexity, production scale, and clinical application, together with streamlined approval pathways for well-characterized products, could reduce the administrative burden while maintaining safety standards (26). Coordinated governance among ANSN, ANVISA, state health secretariats, and academic institutions is also essential to align production, distribution, and clinical oversight. In addition, mechanisms supporting investigator-led clinical research on novel radiopharmaceuticals could facilitate academic and institutional development (28).

3.8. Physical foundations and integration with biological systems

The production of radioisotopes depends on parameters such as beam energy, cross section and target characteristics. However, their clinical efficacy depends on integration with biological systems through the production of radiopharmaceuticals. The choice of radionuclide is determined by the type of radioactive emission, half-life and energy deposited in the medium, directly influencing dose distribution and the therapeutic effect. This interface between physics and biology constitutes one of the pillars of modern medical physics and allows technological development to be guided by real clinical needs.

The integration of physical and biological considerations also guides decisions related to molecular selection, biodistribution, uptake kinetics, elimination, toxicity in critical organs and therapeutic potential. In therapies with radiopharmaceuticals, this integration becomes even more relevant, as clinical efficacy depends on the ability to deliver sufficient dose to the biological target while preserving healthy tissues within acceptable limits.

In this context, medical physics plays an essential role in the quantitative interpretation of activity distributions, dosimetric evaluation through absorbed-dose estimation, response modeling, and the definition of personalized therapeutic strategies. The expansion of modern nuclear medicine, therefore, depends on an increasingly integrated practice involving production, imaging, dosimetry, radiopharmacy and clinical practice.

3.9. Predictive dosimetry and integrated innovation

Advances in predictive dosimetry enable dose distributions to be estimated before treatment administration, potentially improving therapeutic precision and strengthening the integration between technological development and clinical application. This approach could not only optimize therapeutic protocols but also inform the development of new radioisotopes and radiopharmaceuticals, allowing production decisions to be guided by quantitative data and anticipated clinical evidence.

In addition, predictive dosimetry also strengthens the logic of personalized nuclear medicine. Prospective estimation of dose distribution in critical organs and target lesions may support individualized adjustment of administered activity, treatment intervals, radiopharmaceutical selection, and therapeutic strategy. This capacity transforms dosimetry into a decision-making tool, not only a retrospective one.

The integration between dosimetry, molecular imaging, radiopharmaceutical production and computational analysis represents one of the most relevant frontiers of modern nuclear medicine. This development may expand the participation of the medical physicist in therapeutic protocols, translational research, evaluation of new molecules and development of data-based models.

3.10. Training of the medical physicist and academic role

Practice in this scenario requires solid training in nuclear physics, radiation–matter interaction and production systems, combined with a strong academic foundation and capacity for innovation. The integration between universities, research centers and clinical practice is essential to train professionals capable of working in complex environments, especially at the interface between production and application. Familiarity with accelerators, physical systems and production processes represents a strategic advantage in the consolidation and expansion of nuclear medicine.

Despite this scientific proximity, the education of medical physicists has historically been structured primarily around the clinical applications of radiation, with emphasis on Radiation Oncology, Nuclear Medicine, and Diagnostic Imaging, whereas radioisotope and radiopharmaceutical production frequently remains at the interface with radiochemistry, radiopharmacy, engineering, and nuclear sciences. The current expansion of nuclear medicine makes this separation increasingly incompatible with contemporary professional practice. Cyclotrons, target systems, radionuclide generators, emerging radiometals, and therapeutic radiopharmaceuticals directly connect the foundations of nuclear physics with clinical application. Therefore, the education of medical physicists specializing in nuclear medicine should incorporate, at a level compatible with their professional responsibilities, fundamentals of radioisotope production, accelerator and target technology, principles of radiochemistry and radiopharmacy, quality control, production processes, radiation protection, radioactive waste management, regulation, and the logistics of short-lived radionuclides. The aim is not to train a single professional to perform every step of the production chain, but rather to prepare a medical physicist capable of understanding, integrating, and technically contributing to a chain that has become inseparable from modern nuclear medicine. Depending on the specific activity and level of responsibility, additional training and competency-based qualification may therefore be required, particularly in areas such as radioisotope production, radiochemistry, radiopharmacy, accelerator operation, and pharmaceutical quality systems. Such complementary training should be understood as an extension of the medical physicist's core competencies rather than as a replacement for the expertise of other professionals within the multidisciplinary team.

Medical physics training must evolve alongside the field. In a context characterized by therapeutic radiopharmaceuticals, radiometals, alpha therapy, personalized dosimetry, artificial intelligence, radionuclide generators, and decentralized models, traditional training must be broadened by incorporating aspects of radiopharmacy, regulation, quality, risk management, traceability and production planning. This broader scope does not alter the core identity of medical physics. On the contrary, it reinforces its interdisciplinary nature and its role as a field that integrates fundamental science with clinical application.

International workforce assessments reinforce this need. The rapid growth of radiopharmaceutical therapy has created a critical shortage of professionals across specialties, including physicians, technologists, radiochemists, physicists, and radiopharmacists; the Society of Nuclear Medicine and Molecular Imaging (SNMMI) position paper indicates that expansion will require hundreds of new centers and experts, supported by Centers of Excellence, facility accreditation, and global best-practice collaborations (32). Workforce development has also been identified as the paramount challenge for equitable access to theranostics across high-, middle-, and low-income countries, alongside infrastructure development, regulatory optimization, and coordinated training initiatives (29). Theranostic radiopharmaceuticals have been described as a "universal challenging educational paradigm" that demands new curricula and interdisciplinary competencies (33), and safe, effective radiopharmaceutical therapy depends on multidisciplinary collaboration among nuclear medicine physicians, oncologists, radiopharmacists, and medical physicists (30).

3.11. The medical physicist as a strategic link

The medical physicist acts as a link between science, technology and clinical practice, integrating production, quality control and application of radiopharmaceuticals. Their role extends beyond technical activities, encompassing strategic contributions to the expansion of nuclear medicine and to the development of solutions that broaden access, ensure quality, and promote innovation. This integrative capacity derives from the scientific and technical background of the medical physicist. Competencies in nuclear physics, radiation–matter interaction, instrumentation, quantification, dosimetry, radiation protection, quality control, uncertainty analysis, risk assessment, and process validation enable these professionals to simultaneously understand the origin of the radionuclide, the physical processes involved in its production, the associated safety and quality requirements, and the effects of its clinical application. Within the radiopharmaceutical chain, these competencies may be applied to the

assessment of accelerators and production systems, optimization of physical parameters, shielding design, radiation protection, process qualification, traceability, activity quantification, and clinical dosimetry. This does not imply replacing the specific competencies of radiopharmacists, radiochemists, nuclear medicine physicians, or engineers, but rather acting in a complementary and integrative role among these disciplines. This interdisciplinary position enables the medical physicist to contribute not only to the safe operation of services but also to planning the expansion of nuclear medicine.

In a system that depends on radioisotopes, complex equipment, dosimetry, radiation protection, quality control, logistics, and regulatory compliance, the medical physicist has a cross-disciplinary perspective on the radiopharmaceutical chain. This perspective helps integrate elements that are often treated separately: production, clinical care, safety, efficiency, and sustainability. Thus, the medical physicist must be recognized as an essential professional not only for the safe operation of services, but also for planning the expansion of nuclear medicine in the country. Their participation is particularly relevant to infrastructure assessment, protocol definition, process qualification, risk analysis, the implementation of new technologies, and coordination among academia, the production sector, healthcare services, and regulatory authorities.

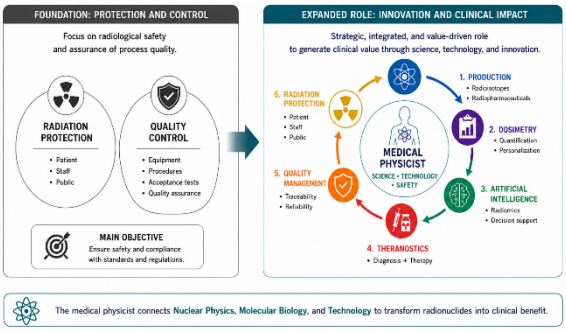


Figure 1. The evolution of the medical physicist's role from protection and control to innovation and clinical impact. Source: Generated with ChatGPT, May 2026.

4. Conclusion

The production of radioisotopes and radiopharmaceuticals constitutes one of the pillars of modern NM. Technological evolution, driven by the development of radiometals, the expansion of alpha therapy and the possibility of innovation and integration with predictive dosimetry models, points to a new paradigm in which production and clinical application evolve in an integrated manner.

In Brazil, overcoming structural challenges involves the adoption of more flexible and decentralized production models, supported by risk-based regulation, adequate technological infrastructure and governance capable of integrating production, logistics, quality and care. In this context, the pathway for expansion should be based on a complementary production architecture that combines centralized facilities for radionuclides requiring greater scale or technological complexity with regionalized production through compact cyclotrons and radionuclide generators when physical half-life, demand, and logistical conditions favor decentralization.

The framework of structural challenges presented in this article indicates that the expansion of NM cannot be achieved through a single isolated measure. Addressing these challenges requires a systemic approach involving funding, infrastructure, regulation, national production capacity, supplier networks, logistics, public communication, and institutional coordination. In this scenario, the medical physicist assumes a central role in building a more accessible, efficient and innovative NM, contributing directly to the improvement of care quality and to the consolidation of this field as an essential element of the healthcare system, always guided by patient benefit.

Rather than merely adapting to the transformation of NM, medical physicists should actively contribute to shaping its development. The safe, sustainable, and technically sound expansion of the field depends on the active involvement of medical physicists at the interface between science, production, regulation, and clinical care.

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