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POSITION PAPER

Radioligand Therapy in Canada

Regulatory Alignment, Specialty Competency,
and Institutional Accountability in the
Therapeutic Use of Radiopharmaceuticals

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EXECUTIVE SUMMARY

Executive Summary

The Canadian Association of Nuclear Medicine (CANM) is the national professional association representing Nuclear Medicine physicians and advancing the safe, effective, and sustainable delivery of Nuclear Medicine services across Canada. As Radioligand Therapy (RLT) expands nationally, CANM is issuing this Position Paper to clarify the governance principles, specialty accountability, and regulatory alignment required to support its responsible integration within the Canadian health system.

Radioligand Therapy involves the therapeutic administration of unsealed radioactive nuclear substances to patients and constitutes a licensed Nuclear Medicine therapeutic activity under Canada's federal nuclear regulatory framework. The rapid expansion of therapeutic radiopharmaceuticals, supported by recent regulatory approvals and theranostic oncology models, has accelerated the integration of targeted radionuclide therapy into cancer care.

As RLT programs expand across Canada, important questions have emerged regarding governance structures, medical supervision, institutional accountability, and the safe integration of therapeutic radiopharmaceuticals within multidisciplinary oncology systems. Structural clarity is increasingly necessary to support sustainable program development, regulatory compliance, and patient safety.

Institutions and provinces now decide which physicians direct Radioligand Therapy. Published models place this direction with Nuclear Medicine¹ or with Radiation Oncology². As these models differ in the training they require for the therapeutic use of unsealed sources, that training is the criterion on which the decision should rest. This Position Paper defines that criterion and the terms on which partner specialties contribute to Radioligand Therapy.

Radioligand Therapy operates within a dual federal regulatory framework. The possession and medical use of radioactive nuclear substances are governed under the Nuclear Safety and Control Act and its associated regulations, while therapeutic radiopharmaceuticals are also regulated as drugs under the Food and Drugs Act and Health Canada oversight. Together, these federal frameworks establish the licensing, radiation protection, infrastructure, and practitioner

accountability requirements necessary for therapeutic radiopharmaceutical delivery.

Canadian specialty training standards and international practice frameworks position Nuclear Medicine as the specialty most directly aligned with the therapeutic use of radioactive substances. Professional guidance from the Society of Nuclear Medicine and Molecular Imaging, the European Association of Nuclear Medicine, and international radiation protection authorities consistently situate Radioligand Therapy within Nuclear Medicine programs under physician leadership and defined radiation safety oversight.

This Position Paper sets out CANM's position on the governance alignment required between federal nuclear legislation, specialty-certified Nuclear Medicine practice, and institutional program design. While oncologic indication and systemic cancer management remain integral to multidisciplinary cancer care, the therapeutic direction of Radioligand Therapy must be exercised by physicians certified in Nuclear Medicine by the Royal College of Physicians and Surgeons of Canada, or holding an equivalent recognized Nuclear Medicine certification and authorized to practice within the applicable provincial jurisdiction, and who document training and supervised clinical experience in the therapeutic use of unsealed sources (Section 2.4). Accordingly, radiation protection oversight and nuclear licence accountability associated with Radioligand Therapy must remain structurally aligned within Nuclear Medicine services to ensure patient safety, regulatory compliance, and sustainable national program development.

SECTION 1

Purpose, Scope, and Interpretive Framework

The Canadian Association of Nuclear Medicine (CANM) issues this Position Paper to clarify the governance, clinical accountability, and institutional responsibilities associated with the delivery of Radioligand Therapy (RLT) in Canada. As therapeutic radiopharmaceuticals expand across oncology care and new treatment pathways emerge, questions regarding medical supervision, program governance, and regulatory accountability have become increasingly important for safe and sustainable implementation.

CANM is the national professional association representing Nuclear Medicine physicians in Canada and serves as the principal national voice for Nuclear Medicine practice, policy, and specialty advancement. In this role, CANM supports the safe integration of emerging Nuclear Medicine therapies, promotes specialty standards, and contributes to the development of coherent national frameworks that protect patients and sustain program quality across Canadian jurisdictions.

CANM affirms that while oncologic eligibility remains within multidisciplinary cancer care, the therapeutic administration and nuclear oversight of Radioligand Therapy constitute a distinct domain of professional and regulatory accountability under Canadian law. The principles articulated in this Position Paper apply uniformly across all Canadian jurisdictions. Federal nuclear obligations do not vary by province, funding model, or institutional designation. Accordingly, Radioligand Therapy must remain aligned with federal nuclear licence accountability, institutional privileging frameworks, and specialty-certified Nuclear Medicine practice in every setting where care is delivered.

Radioligand Therapy involves the therapeutic use of unsealed radioactive nuclear substances in human subjects and forms part of the evolving theranostic model of care, where diagnostic and therapeutic radiopharmaceuticals are integrated within a unified Nuclear Medicine framework. While delivered within multidisciplinary oncology systems, this integration reinforces coherent specialty governance across both diagnostic and therapeutic nuclear services.

The therapeutic use of unsealed sources began in 1941 with radioiodine treatment of thyroid disease³. Nuclear Medicine developed as a specialty from this practice. Radioiodine therapy is the origin of the theranostic principle on which current Radioligand Therapy rests.

The licensed use of radioactive nuclear substances gives rise to specific obligations related to radiation protection oversight, institutional licence accountability, infrastructure compliance, and therapeutic supervision under federal law. Clear governance alignment is therefore essential to preserve regulatory coherence, safeguard patient safety, support workforce sustainability, and guide equitable national program expansion as Radioligand Therapy capacity continues to grow.

This alignment directly supports the intent of the regulations and leverages established specialty expertise, eliminating potential ambiguity. This Position Paper is issued to preserve regulatory coherence, safeguard patient safety, and guide the responsible and sustainable expansion of Radioligand Therapy within Canada's health system.

Interpretive Statement

This document represents the formal position of the Canadian Association of Nuclear Medicine regarding the governance of Radioligand Therapy within Canada's existing legislative and regulatory framework.

It articulates CANM's position on the structural interpretation of governance responsibilities associated with the therapeutic use of radiopharmaceuticals in Canada. It does not amend, replace, or supersede statutory requirements, regulatory determinations, or license conditions issued by the Canadian Nuclear Safety Commission, Health Canada, provincial regulatory authorities, or other competent bodies.

In the event of inconsistency between institutional practice and applicable legislation, regulation, or license conditions, statutory and regulatory authority prevails.

This Position Paper does not constitute legal advice. Institutions remain responsible for ensuring compliance with all applicable federal and provincial requirements within their respective jurisdictions.

This Position Paper further elaborates the governance principles communicated by CANM regarding the delivery of therapeutic radiopharmaceuticals in Canada.

SECTION 2

Regulatory and Specialty Framework Governing Radioligand Therapy (RLT) in Canada

IN THIS SECTION

- 2.1 Radioligand Therapy as a Licensed Nuclear Medicine Therapeutic Activity
- 2.2 Radiopharmaceuticals as Schedule C Drugs Within a Dual Regulatory Framework
- 2.3 Alignment with Royal College Specialty Competency and Regulatory Intent
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Radioligand Therapy involves the therapeutic administration of unsealed radioactive nuclear substances and therefore operates within a dual regulatory framework in Canada. The practice is governed by federal nuclear legislation administered by the Canadian Nuclear Safety Commission, federal drug regulatory oversight administered by Health Canada, and specialty competency standards defined through Royal College certification in Nuclear Medicine.

2.1 Radioligand Therapy as a Licensed Nuclear Medicine Therapeutic Activity

Radioligand Therapy involves the therapeutic administration of unsealed radioactive substances to a person. It therefore falls within the scope of the Nuclear Safety and Control Act, which prohibits the possession, use, transfer, handling, or disposal of nuclear substances except in accordance with a license issued under federal authority⁴. For any institution or clinical facility intending to provide Radioligand Therapy, this means securing and maintaining the appropriate federal licence and adhering to all applicable regulatory controls governing safe handling, administration, and patient management.

The Radiation Protection Regulations require that licensees establish and maintain a radiation protection program that ensures exposures are kept as low as reasonably achievable. This includes obligations related to training, contamination control, monitoring of exposures, management of abnormal situations, and providing instructions to individuals who have been administered therapeutic nuclear substances in order to reduce exposure to others⁵. The Nuclear Substances and Radiation Devices Regulations further provide that a radioactive nuclear substance shall not be used on a person except under the direction of a qualified medical practitioner⁵.

Radioligand Therapy, therefore, constitutes a licensed radiological therapeutic activity governed by nuclear regulatory oversight and structured radiation protection requirements. Although Radioligand Therapy is administered systemically, it differs significantly from conventional systemic cancer treatment, including specialized infrastructure, radiation protection requirements, controlled environments, and personnel operating within federal and provincial nuclear regulatory frameworks to ensure the safety of patients, staff, and the public.

The Canadian Nuclear Safety Commission has issued REGDOC 2.5.6, which specifies design requirements for rooms where unsealed nuclear substances are used, including contamination control, ventilation, waste management, and access restrictions⁶. These infrastructure requirements differ from those in conventional infusion settings.

The Canadian Nuclear Safety Commission also provides best-practice guidance on the therapeutic use of nuclear substances, reinforcing that licensees remain responsible for program-level radiation safety compliance and oversight⁷.

Taken together, federal statutes, regulations, and regulatory guidance establish that Radioligand Therapy is a licensed Nuclear Medicine therapeutic activity that requires structured program governance.

2.2 Radiopharmaceuticals as Schedule C Drugs Within a Dual Regulatory Framework

Radiopharmaceuticals are regulated as drugs under the Food and Drugs Act and are explicitly identified under Schedule C⁸. The Food and Drug Regulations define radiopharmaceuticals as drugs that exhibit spontaneous disintegration of unstable nuclei with emission of particulate or electromagnetic radiation⁹.

Health Canada's regulatory roadmap for Schedule C drugs confirms that radiopharmaceuticals are subject to market authorization requirements based on evidence of safety, efficacy, and quality, with additional considerations related to radioactive properties¹⁰.

Radioligand Therapy, therefore, exists within a dual regulatory framework. It is both:

1. A regulated drug authorized for sale and use under federal drug legislation.
2. A licensed nuclear activity subject to radiation safety legislation.

This dual status reinforces the need for RLT governance to address both pharmaceutical and nuclear regulatory requirements simultaneously. Program leadership must be able to integrate drug authorization standards with nuclear safety compliance and radiation protection obligations.

2.3 Alignment with Royal College Specialty Competency and Regulatory Intent

The Royal College of Physicians and Surgeons of Canada defines Nuclear Medicine as the medical specialty concerned with the diagnostic and therapeutic use of unsealed radioactive sources. Specialty training requirements explicitly include molecular imaging interpretation for treatment eligibility and planning (e.g., PSMA and SSSTR-targeted imaging), the provision of therapy using unsealed sources of radiation, and competency in radiation safety and dosimetry¹¹.

Nuclear Medicine is the Royal College specialty in which the therapeutic use of unsealed radioactive sources is a defined core training requirement. Radiation Oncology training centres on external-beam radiation therapy and sealed-source brachytherapy. It includes radiobiology, medical physics and radiation safety, and it may include exposure to therapeutic radiopharmaceuticals. It does not include the interpretation of the diagnostic molecular imaging on which eligibility for Radioligand Therapy is decided. As the absorbed dose from an unsealed source is governed by the biodistribution and kinetics of the radiopharmaceutical, unsealed-source dosimetry differs from the dosimetry of sealed sources and external beams¹. A practitioner without specific training in unsealed sources may measure the administered activity inaccurately or miscalculate the absorbed dose to tumours and organs at risk¹.

Where the Nuclear Substances and Radiation Devices Regulations require that radioactive nuclear substances be used on a person only under the direction of a qualified medical practitioner¹², regulatory intent must be interpreted in alignment with established specialty competencies.

When federal regulation requires medical direction for therapeutic use of radioactive materials, and a Royal College specialty is specifically trained and certified in that practice, medical direction must reside within that specialty to ensure both patient safety and compliance.

Accordingly, CANM affirms that Radioligand Therapy constitutes a defined Nuclear Medicine specialty act under Royal College standards and that governance of therapeutic administration must align with that specialty competency. Pan-Canadian quality standards for Radiopharmaceutical Therapy programs require identified physician leadership and formalized radiation safety oversight¹³.

International doctrine similarly recognizes radiopharmaceutical therapy as a core Nuclear Medicine function requiring dedicated specialty oversight^{14,15}. Therefore, provincial ministries of health must explicitly embed these specialty oversight and governance requirements into hospital funding agreements and program

authorizations for Radioligand Therapy. Aligning policy with international best practice ensures regulatory coherence and supports safe, high-quality patient care.

2.4 Medical Direction and Therapeutic Episode Accountability

Medical direction under federal regulation encompasses the entire therapeutic episode. It includes clinical consultation, eligibility determination, informed consent specific to radiopharmaceutical therapy, determination of administered activity, supervision of administration within controlled radiation areas, provision of radiation protection instructions, and management of immediate therapy-related complications^{5,12}.

The obligation to provide post-therapy radiation protection instructions is a regulatory requirement, not merely a best practice⁵. The Canadian product monograph for lutetium 177 vipivotide tetraxetan specifies that therapy should be administered in facilities equipped to address radiation safety considerations and that healthcare professionals experienced in the use of radiopharmaceuticals should supervise therapy¹⁶. Thus, hospitals must ensure that oversight and therapeutic administration are led by appropriately credentialed professionals operating within an environment with institutional controls and specialized radiation safety programs, in line with monograph recommendations and regulatory expectations.

The therapeutic act, therefore, begins with prescription and extends beyond injection through radiation protection responsibility and follow-up monitoring. The therapeutic episode extends beyond the technical act of intravenous administration and includes clinical, radiation safety, and regulatory responsibilities that remain under Nuclear Medicine oversight.

Within Canadian hospitals, CANM affirms that medical direction for Radioligand Therapy must be assumed by a physician certified in Nuclear Medicine by the Royal College of Physicians and Surgeons of Canada, or holding an equivalent recognized Nuclear Medicine certification and authorized to practice within the applicable provincial jurisdiction, with appropriate institutional privileges in radiopharmaceutical therapy.

An equivalent certification documents training in the handling of unsealed radioactive sources, unsealed-source dosimetry and radiation protection, and supervised clinical experience spanning diagnostic molecular imaging and therapeutic patient management, to a standard comparable to Royal College certification in Nuclear Medicine. Internationally trained Nuclear Medicine physicians meet this definition when their training is documented to this standard

and they hold provincial authorization to practice. The directing physician documents a minimum number of supervised therapeutic administrations and maintains continuing professional development in Radioligand Therapy. The working group described in Section 6, item 9, defines this minimum number.

2.5 Administration and Controlled Acts

Intravenous administration of a radiopharmaceutical constitutes a controlled act under provincial legislation, such as the Regulated Health Professions Act¹⁷.

Execution of this act may be performed by authorized professionals pursuant to valid medical orders or delegation mechanisms consistent with provincial regulatory standards (College of Physicians and Surgeons of Ontario; College of Medical Radiation and Imaging Technologists of Ontario, 2025; College of Nurses of Ontario, 2025).

While specific technical acts may be performed by appropriately trained and authorized healthcare professionals, overall therapeutic direction, radiation safety oversight, and regulatory accountability remain within Nuclear Medicine governance.

Under federal nuclear regulation, direction and accountability for the use of a radioactive nuclear substance on a person remain with the physician directing the licensed nuclear medicine program⁵.

Delegation of execution does not transfer regulatory responsibility, radiation protection accountability, or therapeutic ownership. While specific technical acts may be delegated to appropriately trained and authorized healthcare professionals in accordance with institutional policies and provincial regulatory standards, accountability for therapeutic direction, radiation safety oversight, and regulatory compliance remains with the directing Nuclear Medicine physician.

2.6 Quality Governance and Radiation Safety Oversight

Pan-Canadian quality guidance for Radiopharmaceutical Therapy programs developed through the Pan-Canadian Quality Roundtable for Radiopharmaceutical Therapy (PCQRT) identifies the need for a physician clinical lead and a Radiation Safety Officer with defined reporting structures¹³.

National initiatives such as the Pan-Canadian Quality Roundtable for Radiopharmaceutical Therapy (PCQRT) have contributed to the development of quality assurance frameworks and technical guidance supporting the implementation of radiopharmaceutical therapy programs in Canada¹³. These

initiatives have largely emerged from academic and research-oriented centres with established theranostics infrastructure and multidisciplinary expertise.

As Radioligand Therapy expands into a broader range of clinical institutions, including non-academic hospitals to provide equitable patient access, clear program governance becomes increasingly important to ensure alignment with federal nuclear regulatory requirements, radiation safety obligations, and specialty competency frameworks. While PCQRT initiatives support the advancement of national quality practices, regulatory accountability and clinical governance for the medical use of radioactive nuclear substances remain defined by federal nuclear legislation and the regulatory framework administered by the Canadian Nuclear Safety Commission⁷.

The Radiation Safety Officer is responsible for ensuring compliance with radiation protection regulations, overseeing contamination control, and supporting audit and quality assurance mechanisms consistent with federal regulatory requirements⁷.

Governance of Radioligand Therapy must therefore include:

- Identified physician program leadership
- Defined Radiation Safety Officer oversight
- Structured multidisciplinary case review
- Documented quality assurance processes
- Formalized incident management pathways

In addition, program quality should be measured with clear indicators to support institutional self-assessment and continuous improvement. Examples of key performance indicators (KPIs) for Radioligand Therapy governance include the rate of contamination incidents per dose administered, adherence to post-therapy radiation safety instructions, timeliness of incident investigations, and completion rates for regular audits. Establishing and monitoring such concrete metrics reinforces accountability, enabling programs to benchmark performance, identify opportunities for improvement, and demonstrate compliance with national standards. These indicators operationalize compliance with federal radiation protection program requirements and structured quality governance obligations under the Nuclear Safety and Control Act and Radiation Protection Regulations^{4,12}.

Clinical indicators complete this set. Programs document for every treatment the indication, the eligibility imaging, the product and administered activity, toxicity, response, survival and patient-reported outcomes¹. CANM supports a national registry of these data that complies with provincial health information legislation. Outcome data allow programs to demonstrate the clinical value of Radioligand Therapy to provincial payers.

These governance elements are not optional enhancements. They are structural components required to satisfy federal nuclear regulatory obligations. Failure to meet these elements may trigger enforcement actions by the Canadian Nuclear Safety Commission under its statutory authority, including Administrative Monetary Penalties, licence amendment, suspension, or revocation pursuant to the Nuclear Safety and Control Act.

2.7 Access, Capacity, and Infrastructure Considerations

The reimbursement analysis of Canada's Drug Agency (CDA-AMC, formerly CADTH) for lutetium-177-based therapies highlights infrastructure and capacity considerations, including access to appropriate imaging modalities and system readiness to deliver therapy safely¹⁸. Ensuring equitable access also requires addressing the needs of rural and underserved populations, where geographic distance or limited specialized resources may otherwise restrict therapy availability. Scalable models such as hub-and-spoke arrangements or regional outreach programs can support broader, more equitable delivery of Radioligand Therapy across diverse settings. CANM defines two types of spoke site. A referral spoke performs selection imaging, laboratory monitoring and follow-up, and refers patients to the hub for therapy. A treatment spoke administers therapy under a nuclear substance licence, with therapeutic direction and accountability held by a Nuclear Medicine physician who meets the criteria of Section 2.4. Supervision at the spoke may be on site or remote. The working group described in Section 6, item 9, defines the conditions for remote supervision, including the availability of the directing physician, the training of local staff, the management of complications, and audit. The hub provides protocols, dosimetry support, case review and audit to both types of spoke. Ontario Health program descriptions similarly situate Radioligand Therapy within structured hospital-based programs requiring defined eligibility pathways and institutional authorization (Ontario Health, 2025). Expansion of access to Radioligand Therapy must therefore be aligned with infrastructure capacity, radiation protection readiness, and specialty oversight to ensure safety and equity.

Access and safety are interdependent. The need for accessibility and equitable delivery must remain aligned with regulatory compliance, radiation safety requirements, and the delivery of Radioligand Therapy within licensed facilities and specialized Nuclear Medicine programs.

2.8 Workforce Capacity and Specialty Training Pathways

The sustainable expansion of Radioligand Therapy in Canada depends on the availability of an appropriately trained Nuclear Medicine workforce capable of

meeting growing clinical demand while maintaining compliance with federal nuclear regulatory obligations. Royal College certification in Nuclear Medicine remains the principal pathway for the development of specialty competency in the therapeutic use of unsealed radioactive substances¹¹. Projected increases in therapeutic radiopharmaceutical volumes, driven by the introduction of additional PSMA-targeted, somatostatin receptor-targeted, and emerging radioligand agents, require coordinated workforce planning at the national level¹⁸.

Workforce shortages are already limiting the pace at which Radioligand Therapy programs can expand across several Canadian jurisdictions. Sustainable national implementation will require coordinated workforce planning to ensure that specialty capacity develops in parallel with infrastructure investment, radiopharmaceutical supply, and increasing clinical demand.

CANM affirms its commitment to supporting workforce expansion through structured fellowship programs in theranostics and Radioligand Therapy, continuing professional development modules addressing dosimetry and radiation safety, and engagement with Practice Eligibility Routes administered by provincial colleges to facilitate the integration of internationally trained Nuclear Medicine specialists into the Canadian workforce. Provincial ministries of health, in collaboration with academic health science centres, must support residency expansion, theranostics fellowship funding, and credentialing pathways that preserve specialty competency standards while addressing system capacity requirements. Where Nuclear Medicine capacity is limited, CANM supports expansion of the trained workforce through fellowships, hub-and-spoke networks and the recognition of internationally trained Nuclear Medicine specialists. The training standard for the therapeutic use of unsealed sources applies in every setting and does not change with local capacity.

2.9 Patient-Specific Dosimetry as a Regulatory and Quality Standard

Patient-specific dosimetry is increasingly recognized as a defining quality standard within Radioligand Therapy and reflects an evolving regulatory expectation aligned with international radiation protection doctrine. The European Association of Nuclear Medicine and the Society of Nuclear Medicine and Molecular Imaging have articulated dosimetry as a core component of therapeutic radiopharmaceutical practice, with structured guidance on activity prescription, absorbed dose calculation, and treatment optimization^{19,20}. The International Commission on Radiological Protection has further established that medical radiation exposure decisions require dose optimization by appropriately trained practitioners²¹. Beyond regulatory considerations, patient-specific dosimetry supports treatment

optimization by balancing therapeutic efficacy with radiation exposure to normal organs, thereby contributing to both patient safety and treatment quality.

Within the European regulatory framework, Council Directive 2013/59/Euratom requires that exposures of target volumes in radiotherapeutic procedures, including therapeutic nuclear medicine, be individually planned and verified²². Patient-specific dosimetry is a defined competency within Royal College Nuclear Medicine training. It is delivered by a team in which the medical physicist calculates the absorbed doses and the Nuclear Medicine physician integrates them into the prescription. Fixed-activity regimens remain appropriate for some agents. CANM supports the development of patient-specific absorbed-dose estimation for tumours and organs at risk, standardized post-therapy imaging, and research that defines when dosimetry changes management^{1,14}. As dosimetric results enter the prescription, dosimetric oversight is part of the therapeutic direction of the Nuclear Medicine physician.

2.10 Radiopharmacy, Supply Chain, and Compounding Compliance

Radioligand Therapy depends on a complex radiopharmaceutical supply chain encompassing isotope production, kit-based and on-site preparation, hot-cell compounding, and Good Manufacturing Practice or Good Radiopharmacy Practice compliance under Health Canada oversight^{8,10}. The therapeutic supply environment includes vulnerabilities related to global isotope availability, including molybdenum-99, lutetium-177, and emerging alpha-emitter precursors. Supply chain disruptions can directly affect patient access to Radioligand Therapy and may delay treatment delivery despite available clinical capacity, highlighting the importance of coordinated radiopharmacy planning and supply resilience. Programs must therefore maintain integrated radiopharmacy operations consistent with provincial compounding standards administered through the National Association of Pharmacy Regulatory Authorities and aligned with Health Canada drug establishment licensing requirements¹⁰.

The CNSC infrastructure design requirements for facilities handling unsealed nuclear substances, including ventilation, contamination control, and waste management, apply directly to radiopharmacy operations associated with Radioligand Therapy⁶. These structural and operational dependencies reinforce that Radioligand Therapy programs should be anchored in Nuclear Medicine governance, with integrated oversight of radiopharmacy operations, therapeutic administration, and regulatory compliance. Where institutions do not possess dedicated Nuclear Medicine services, implementation should require formal affiliation, referral, or shared-governance arrangements with a licensed Nuclear

Medicine program rather than being treated as an extension of general infusion or systemic therapy environments. Specialty-led radiopharmacy governance ensures regulatory coherence across drug compounding, nuclear licence accountability, and therapeutic administration.

2.11 Pediatric Radioligand Therapy

Pediatric applications of Radioligand Therapy, including iodine-131 metaiodobenzylguanidine for neuroblastoma, evolving DOTATATE-based therapy for pediatric neuroendocrine disease, and emerging alpha-emitter clinical trials, present distinct dosimetric, procedural, and radiation protection considerations. Pediatric administration introduces additional complexity related to weight-based activity determination, sedation requirements, family-centred radiation protection counselling, and exposure mitigation for caregivers and siblings^{21,23}.

Pediatric Radioligand Therapy represents a specialized and clinically important extension of theranostic practice. As novel radiopharmaceuticals and emerging alpha-emitter therapies advance, Canadian governance frameworks must be capable of addressing the specific needs of pediatric patients and their families.

CANM affirms that pediatric Radioligand Therapy requires the integrated leadership of Nuclear Medicine physicians working in coordination with pediatric oncology, pediatric anaesthesia, and child-life services within institutions equipped to meet CNSC infrastructure standards for unsealed nuclear substances⁶. The added clinical and regulatory complexity of pediatric administration reinforces, rather than diminishes, the structural requirement that therapeutic direction and radiation safety oversight remain within Nuclear Medicine specialty governance.

2.12 Next-Generation Radionuclides and Emerging Therapeutic Agents

The therapeutic radiopharmaceutical landscape is rapidly evolving beyond beta-emitter platforms to include alpha-emitting radionuclides such as actinium-225, lead-212, and astatine-211, as well as Auger-Meitner-electron emitters and combined emitters such as terbium-161. These agents present distinct considerations relating to shielding, contamination control, radioactive waste management, supply-chain stability, and patient-specific dosimetry that differ materially from those associated with lutetium-177¹⁵. As these agents progress from early-phase trials and indication-expansion studies toward expanded clinical deployment, Canadian institutions will require governance frameworks capable of supporting safe administration, individualized dosimetric optimization, radiopharmaceutical handling, and regulatory compliance.

Alpha-emitters in particular require enhanced radiation protection measures, specialized waste handling pathways, and refined dosimetric modelling consistent with their high linear energy transfer characteristics. Governance of these emerging therapies must therefore remain within a specialty trained in unsealed-source physics, dosimetry, and radiation protection. Nuclear Medicine certification under Royal College standards uniquely encompasses these competencies and ensures that Canadian programs can responsibly integrate next-generation radionuclides as they enter clinical practice¹¹.

2.13 Indigenous Health and Distinctions-Based Equity

Equitable expansion of Radioligand Therapy across Canada must be informed by the Truth and Reconciliation Commission Calls to Action and by distinctions-based health policy obligations toward First Nations, Inuit, and Métis peoples²⁴. Geographic dispersion, jurisdictional complexity in Indigenous health funding, and historical inequities in specialty access require deliberate program design rather than incidental accommodation.

The highly specialized infrastructure, workforce, and regulatory requirements associated with Radioligand Therapy often concentrate services within major urban and academic centres, creating additional access barriers for patients in remote, northern, and Indigenous communities.

CANM affirms that hub-and-spoke service models, regional outreach programs, and patient navigation pathways supporting access to Radioligand Therapy must be co-designed with First Nations, Inuit, and Métis health authorities and partner organizations. Specialty-led governance, when paired with culturally safe and distinctions-based program design, supports both regulatory compliance and meaningful equity in access to therapeutic radiopharmaceuticals across Canadian communities.

2.14 Clinical Trials and Research Infrastructure

Canada's continued participation and leadership in the international development of theranostic agents requires program structures capable of supporting investigator-initiated and industry-sponsored clinical trials within the joint regulatory frameworks administered by Health Canada and the Canadian Nuclear Safety Commission. Clinical Trial Applications under the Food and Drug Regulations must be coordinated with research licence amendments under the Nuclear Safety and Control Act, and with Research Ethics Board review at participating institutions^{4,8}.

As theranostic research increasingly depends on coordinated imaging, radiopharmaceutical handling, dosimetry, therapeutic administration, and

longitudinal safety monitoring, research governance must be integrated with the clinical and nuclear regulatory structures used for established Radioligand Therapy delivery.

Nuclear Medicine–led program governance enables this regulatory integration by maintaining unified accountability across drug, nuclear, and ethical oversight pathways. Programs structured outside Nuclear Medicine governance risk fragmentation across these regulatory streams, with corresponding implications for trial activation timelines, sponsor confidence, and Canadian competitiveness in theranostic research. Provincial ministries of health and academic health science centres should therefore align research infrastructure investment with the specialty governance framework articulated in this Position Paper.

2.15 Patient and Caregiver Safety Perspective

The governance principles articulated in this Position Paper directly serve patient and caregiver safety. Nuclear Medicine–led oversight ensures that patients receiving Radioligand Therapy receive consistent radiation protection counselling addressing household contact precautions, exposure mitigation for pregnant persons and children, travel documentation to support border and security screening, and management of bodily fluids during the post-therapy period^{12,16}. Radiation protection counselling extends beyond the patient to encompass household members, caregivers, and the public, making it a unique component of Radioligand Therapy that has no direct equivalent in most other therapeutic disciplines.

The counselling and communication of radiation protection requirements to patients, families, and household contacts is not an ancillary service. It is a core component of radiation safety practice and a defining element of the therapeutic episode under federal nuclear regulation^{5,12}. The Radiation Protection Regulations specifically require that licensees provide instructions to individuals who have been administered therapeutic nuclear substances in order to reduce exposure to others, establishing this counselling function as a regulatory obligation rather than a discretionary clinical activity¹².

The provision of post-therapy radiation safety counselling has been a central function of Nuclear Medicine practice for more than seven decades, originating with the introduction of radioiodine therapy for thyroid disease in the 1940s and 1950s and maturing through the subsequent expansion of radionuclide therapies for benign and malignant conditions. Across this seventy-year clinical tradition, Nuclear Medicine physicians have developed and refined the structured counselling frameworks now considered standard of care, including the assessment of household composition and occupational exposures, individualized restriction

periods, written instructions for patients and caregivers, and guidance on the management of bodily fluids and contaminated materials. This longitudinal experience encompasses the evolution of radioiodine therapy, peptide receptor radionuclide therapy, samarium-153 and radium-223 therapies, and contemporary PSMA-targeted radioligand therapy, and reflects an unbroken specialty continuity in the delivery of patient and family radiation protection counselling.

No other medical specialty possesses comparable depth of training, clinical experience, or institutional infrastructure for the provision of radiation protection counselling associated with the therapeutic use of unsealed radioactive substances. Royal College specialty training in Nuclear Medicine explicitly incorporates radiation safety, dosimetry, and patient and family counselling competencies as core requirements¹¹. International specialty doctrine consistently recognizes Nuclear Medicine physicians as the appropriately trained practitioners for the delivery of radiation protection instruction following therapeutic administration^{20,21}. Nuclear Medicine physicians are therefore uniquely prepared, experienced, and suited to perform this regulated counselling role, and the structural alignment of Radioligand Therapy under Nuclear Medicine governance ensures that this longstanding specialty competency continues to serve patients and families across the Canadian health system.

These obligations are not administrative formalities but regulatory requirements under the Radiation Protection Regulations and form part of the therapeutic episode for which the directing Nuclear Medicine physician retains accountability⁵. Specialty-led governance ensures that patient-facing radiation safety information is delivered consistently, accurately, and with the clinical context required for informed adherence.

2.16 Health Information, Cybersecurity, and Imaging Data Governance

Radioligand Therapy programs depend on integrated diagnostic and therapeutic imaging data, dose-tracking software platforms, and increasingly on artificial-intelligence-supported dosimetric and quantitative imaging tools. The integrity, security, and privacy of these data streams are integral to therapeutic decision-making and to compliance with provincial health information legislation, including the Personal Health Information Protection Act (Ontario), the Health Information Act (Alberta), and the federal Personal Information Protection and Electronic Documents Act²³.

Errors, loss of integrity, or unauthorized alteration of imaging, dosimetry, or dose-tracking data may affect patient selection, administered activity determination, treatment optimization, and post-therapy monitoring.

Program governance must therefore encompass cybersecurity oversight of dosimetry platforms, imaging archives, and quantitative analysis tools used in therapeutic decision-making. Nuclear Medicine specialty leadership, in coordination with institutional information security and privacy programs, ensures that the clinical integrity of therapeutic imaging and dosimetry data remains aligned with therapeutic accountability and federal nuclear licence obligations.

2.17 Environmental Stewardship and Radioactive Waste Management

Radioligand Therapy generates regulated radioactive waste streams that must be managed in accordance with CNSC licence conditions, including decay-in-storage protocols, sewage release limits, and the controlled disposal of contaminated materials^{6,7}. The introduction of alpha-emitter therapies further elevates environmental stewardship requirements, given the distinct radiotoxicity profiles and longer-lived daughter isotopes associated with these agents. As next-generation radionuclides enter clinical use, waste management planning will need to account for radionuclide-specific half-lives, decay chains, contamination risks, and institutional release pathways.

Program governance must integrate radioactive waste management within the broader radiation protection program, under the oversight of the Radiation Safety Officer and the directing Nuclear Medicine physician⁵. Environmental compliance is a regulatory obligation that cannot be separated from therapeutic delivery and reinforces the requirement that Radioligand Therapy programs remain anchored in Nuclear Medicine governance, with radioactive waste management integrated into institutional radiation protection programs.

SECTION 3

International Governance Frameworks for Radiopharmaceutical Therapy



Radiopharmaceutical Therapy, including Radioligand Therapy, is internationally recognized as a core therapeutic domain of Nuclear Medicine. Major professional organizations in Europe and North America have articulated governance and practice standards that situate the therapeutic use of unsealed radioactive substances under the leadership of Nuclear Medicine physicians and within licensed Nuclear Medicine programs.

The joint EANM SNMMI guideline on the use of ¹⁷⁷Lu-labeled PSMA-targeted radioligand therapy represents a clear expression of international specialty consensus¹⁴. Developed collaboratively by the European Association of Nuclear Medicine and the Society of Nuclear Medicine and Molecular Imaging, this guideline defines radioligand therapy as a Nuclear Medicine therapeutic procedure requiring physician expertise in internal dosimetry, radiation safety, activity prescription, and regulatory compliance. The guideline consistently situates therapeutic supervision within Nuclear Medicine services and identifies appropriately trained Nuclear Medicine physicians as responsible for the clinical and regulatory oversight of treatment.

EANM guidance further reinforces that radiopharmaceutical therapy requires defined responsibility by physicians trained in Nuclear Medicine, including accountability for treatment planning, dose optimization, radiation protection instruction, and compliance with national regulatory standards^{19,25}. These documents describe therapeutic administration not as a general infusion service, but as a specialty-led Nuclear Medicine intervention embedded within structured nuclear regulatory programs.

SNMMI procedural standards similarly characterize radiopharmaceutical therapy as a specialized Nuclear Medicine function that requires physician competency in radiation protection, dosimetry, and oversight of licensed radioactive materials²⁰.

Therapeutic supervision encompasses the full clinical episode under the direction of physicians trained in Nuclear Medicine, including patient evaluation, activity determination, radiation safety instruction, and post-therapy management.

International radiation protection doctrine aligns with this specialty framework. The International Atomic Energy Agency specifies that therapeutic use of radioactive substances must occur under defined clinical responsibility within formal radiation protection programs and licensed nuclear regulatory systems¹⁵. The International Commission on Radiological Protection further establishes that responsibility for medical radiation exposure decisions must rest with appropriately trained medical practitioners capable of dose optimization and risk assessment in accordance with radiation protection principles²¹. In practice, within therapeutic nuclear medicine, these responsibilities are exercised by physicians trained and certified in Nuclear Medicine.

In the United States, the Nuclear Regulatory Commission defines the qualification of the prescribing physician directly. Only an authorized user may prescribe unsealed byproduct material that requires a written directive. Eligibility is reached through documented training and supervised experience in the handling of unsealed sources, or through certification by a recognized specialty board¹. Nuclear medicine physicians, nuclear radiologists and radiation oncologists can each qualify as authorized users¹. Certificates issued by the American Board of Radiology after 31 December 2023 no longer provide the board route, a change made at the request of that board. The Society of Nuclear Medicine and Molecular Imaging has in addition established Radiopharmaceutical Therapy Centers of Excellence and an accreditation program for facilities that administer radiopharmaceutical therapy¹.

Canadian regulation requires direction by a qualified medical practitioner¹². CANM recommends that the Canadian Nuclear Safety Commission and the provincial colleges define this qualification by documented training and supervised experience in the therapeutic use of unsealed sources, consistent with Section 2.4.

Comparable national regulatory frameworks reinforce this specialty governance structure. In Germany, the medical use of radioactive substances is governed by national radiation protection legislation requiring that radionuclide therapies be performed within licensed facilities and under the supervision of physicians with appropriate nuclear medicine qualifications²⁶. Professional guidance issued by the German Society of Nuclear Medicine likewise describes radionuclide therapy as a nuclear medicine procedure performed within specialized nuclear medicine departments under physician supervision and radiation protection oversight²⁷.

In the United Kingdom, the administration of therapeutic radiopharmaceuticals is regulated under the Ionising Radiation (Medical Exposure) Regulations and the

licensing framework administered by the Administration of Radioactive Substances Advisory Committee (ARSAC). These regulations require that radioactive medicinal products be administered by authorized practitioners holding an ARSAC certificate and operating within licensed medical facilities. Nuclear medicine physicians commonly serve as ARSAC licence holders responsible for justification, administration, and radiation protection compliance associated with radionuclide therapy^{28,29}.

Similarly, in Australia and New Zealand, radiopharmaceutical therapy is delivered within licensed nuclear medicine facilities and administered by physicians trained in nuclear medicine. Guidance from the Australian and New Zealand Society of Nuclear Medicine describes theranostics as an extension of nuclear medicine practice integrating diagnostic imaging with targeted radionuclide therapy. National radiation protection frameworks likewise require the medical use of radioactive substances to be conducted under appropriately trained medical practitioners responsible for radiation safety oversight and clinical governance^{30,31}.

Across these international frameworks, governance of radiopharmaceutical therapy consistently incorporates three structural elements: leadership by Nuclear Medicine physicians, formal radiation safety oversight, and alignment with licensed nuclear regulatory programs. Radioligand therapy is therefore framed internationally as a regulated Nuclear Medicine therapeutic act requiring defined specialty competency and accountability.

The governance of Radioligand Therapy in Canada should remain consistent with these international frameworks. This consistency allows Canadian programs to adopt shared training standards, procedure guidelines, facility accreditation and quality indicators^{14,32}.

The governance principles articulated by the CANM in this Position Paper are consistent with this established international professional doctrine. Alignment between therapeutic direction, radiation safety oversight, and nuclear license accountability under the leadership of Nuclear Medicine physicians reflects global specialty standards and reinforces the structural interpretation advanced within the Canadian context.

SECTION 4

Institutional Governance and Program Authority for Radioligand Therapy

Radioligand Therapy is delivered within multidisciplinary cancer systems. Multidisciplinary collaboration strengthens patient care; however, it does not alter the regulatory architecture governing the therapeutic use of radioactive nuclear substances in Canada. Because Radioligand Therapy involves the licensed use of unsealed radioactive materials under the Nuclear Safety and Control Act⁴, its institutional structure must align with federal licence accountability, radiation protection obligations, and Royal College specialty competency requirements. Program design is therefore inseparable from regulatory compliance. Institutional governance must formally designate Nuclear Medicine as the program lead for Radioligand Therapy, with defined reporting structures that align nuclear licence accountability, medical direction, radiation safety oversight, and therapeutic supervision within a single accountable service.

Under the Nuclear Substances and Radiation Devices Regulations, a radioactive nuclear substance shall not be used on a person except under the direction of a qualified medical practitioner⁵. Royal College standards define Nuclear Medicine as the specialty responsible for the diagnostic and therapeutic use of unsealed radioactive sources and include therapeutic administration and radiation safety competency as core training requirements¹¹. When federal regulation requires medical direction and a single Royal College specialty is specifically trained in the therapeutic use of unsealed radioactive materials, alignment between regulatory intent and specialty competency is structurally required.

Radioligand Therapy programs must therefore be housed within Nuclear Medicine services. Structural ownership includes responsibility for therapeutic protocol selection, oversight of radiopharmaceutical preparation, compliance with radiation protection requirements, contamination control procedures, discharge authorization following radiation safety instruction, and the institutional

response to a CNSC audit. Licence conditions issued under the Nuclear Safety and Control Act attach to the licensed program. Where institutional structures separate Radioligand Therapy administration from Nuclear Medicine, while licence accountability remains within Nuclear Medicine, regulatory responsibility becomes fragmented. Fragmented accountability introduces material compliance risks under federal oversight and increases exposure to corrective measures under the CNSC's licence enforcement authority⁷. Under federal nuclear law, the licence holder bears direct legal accountability for compliance with licence conditions and radiation protection obligations. Institutional structures that fragment therapeutic supervision from licence accountability increase institutional liability exposure in the event of audit findings, reportable events, or enforcement review.

Medical Oncology and disease-site specialists remain essential partners in longitudinal cancer management, treatment sequencing, and multidisciplinary assessment of patient eligibility for Radioligand Therapy. However, the determination of oncologic indication does not constitute direction of a licensed nuclear therapeutic intervention. Radioligand Therapy differs fundamentally from chemotherapy because it involves federally regulated radioactive materials, radiation exposure monitoring obligations, mandatory post-therapy public exposure mitigation instructions under the Radiation Protection Regulations¹², and administration within environments compliant with CNSC design standards for unsealed nuclear substances⁶. The direction of these elements remains aligned with Nuclear Medicine competency and nuclear licence accountability.

Radiation Oncology is a partner in the care of many patients who receive Radioligand Therapy, including patients who need external-beam treatment of skeletal or oligometastatic disease. A consensus framework developed with equal representation from Radiation Oncology and Nuclear Medicine established that joint pathways of care for radiopharmaceutical therapy are feasible³³. This cooperation is most effective when each specialty contributes within its certified scope. Imaging-based selection, prescription of the radiopharmaceutical, dosimetry, administration, radiation safety and post-therapy assessment remain under Nuclear Medicine direction.

In many oncology models, the “most responsible physician” oversees systemic cancer care. That designation does not override federal nuclear regulatory requirements. Under Canadian law, responsibility for the use of a radioactive nuclear substance on a person remains tied to the directing medical practitioner under the applicable nuclear licence⁵. The existence of a primary oncology provider does not transfer regulatory direction of the radiopharmaceutical therapeutic act. Institutional policy must reflect this distinction to prevent ambiguity in accountability. Intravenous administration of a radiopharmaceutical constitutes a controlled act under

provincial legislation such as the Regulated Health Professions Act¹⁷. Technical administration may be performed by authorized professionals consistent with provincial regulatory standards (College of Physicians and Surgeons of Ontario; College of Medical Radiation and Imaging Technologists of Ontario, 2025; College of Nurses of Ontario, 2025). Technical execution, however, is distinct from therapeutic direction. Supervision in Radioligand Therapy encompasses verification of prescribed activity, oversight of radiopharmaceutical handling, monitoring of contamination control, enforcement of radiation protection measures during administration, and authorization of discharge following mandated radiation safety instruction. The Canadian product monograph for lutetium 177 vipivotide tetraxetan requires administration in facilities equipped for radiation safety and under the supervision of professionals experienced in radiopharmaceutical therapy¹⁶. Performance of specific technical acts by appropriately authorized healthcare professionals does not transfer nuclear licence accountability, radiation protection responsibility, or therapeutic oversight.

Pan-Canadian quality guidance requires identification of a physician clinical lead and a Radiation Safety Officer with defined reporting structures¹³. The Radiation Safety Officer supports compliance with the Radiation Protection Regulations and CNSC licence conditions⁷. Regulatory coherence requires that therapeutic direction, radiation safety oversight, and nuclear licence accountability remain structurally aligned within the same program. Administrative models that divide these functions create audit vulnerability and increase exposure to regulatory corrective measures.

Federal nuclear obligations do not vary by institutional designation^{4,12}. Academic centres, regional hospitals, and community institutions are equally bound by licence conditions and radiation protection program requirements. Structural housing of Radioligand Therapy within Nuclear Medicine services is therefore required across all Canadian settings to preserve alignment between specialty competency, medical direction, and federal regulatory accountability.

As Radioligand Therapy expands and additional radiopharmaceuticals enter clinical practice, structural clarity becomes increasingly important for sustainable implementation. CDA-AMC reimbursement analyses have identified infrastructure and system readiness as prerequisites for safe program expansion¹⁸. Expansion that occurs without structural alignment to nuclear regulatory governance risks compromising patient safety, creating inconsistent supervision models, increasing regulatory exposure, and contributing to inequitable access. Radioligand Therapy depends on preserving coherent alignment between funding, infrastructure, specialty oversight, and federal licence accountability.

This alignment extends beyond the immediate act of therapeutic administration. Program governance must also encompass patient-specific dosimetry, radiopharmaceutical preparation and supply-chain integrity, radioactive waste management, post-therapy household radiation protection counselling, health information and imaging-data governance, workforce planning, and clinical trial readiness. These domains are interdependent components of a licensed Nuclear Medicine therapeutic program and cannot be separated from the institutional structure responsible for nuclear licence accountability, radiation protection compliance, and therapeutic medical direction.

The expansion of Radioligand Therapy to pediatric indications, alpha-emitting and next-generation radionuclides, regional delivery models, and research-based therapeutic protocols further reinforces the need for unified Nuclear Medicine governance across Radioligand Therapy programs. Each of these developments introduces additional complexity in activity prescription, dosimetry, contamination control, family and caregiver instructions, radiopharmacy operations, environmental release management, and regulatory documentation. Fragmentation of these functions across disconnected administrative units would weaken the alignment required for safe, compliant, and sustainable program delivery.

Radioligand Therapy is a Nuclear Medicine therapeutic program delivered within oncology systems. Institutional clarity in program ownership, supervision, and reporting relationships, and operational accountability is both a patient safety requirement and a regulatory necessity under Canadian nuclear law. The structural alignment principles outlined in this section are consolidated in Annex A as a national governance and risk alignment matrix, Annex B as a role-based accountability matrix, and Annex C as an institutional implementation checklist for institutional hospital and policy reference.

SECTION 5

Health System Policy Implications for the Expansion of Radioligand Therapy (RLT)

The regulatory and specialty alignment principles articulated in Sections 2 to 4 have direct implications for provincial ministries of health, cancer agencies, hospital leadership, and health system planners. Radioligand Therapy is not solely an emerging oncology modality; it is a federally regulated Nuclear Medicine therapeutic activity governed by nuclear safety legislation, radiation protection regulations, and Royal College specialty certification standards^{4,5,11}. System-level authorization, funding, and expansion frameworks must therefore reflect this regulatory architecture.

Where provinces expand access to Radioligand Therapy, program approvals and funding mechanisms must formally require alignment between nuclear substance licence accountability and Nuclear Medicine program governance. Provincial authorization models should designate Nuclear Medicine services as the directing authority for Radioligand Therapy. Authorization structures that position Radioligand Therapy operationally outside Nuclear Medicine services while licence accountability remains anchored within Nuclear Medicine create structural inconsistency and regulatory exposure under federal nuclear oversight⁷.

Provincial cancer agencies and health authorities play a critical role in facilitating patient access. However, access expansion cannot occur independently of regulatory alignment. Radioligand Therapy involves federally controlled radioactive materials, mandated radiation protection programs, infrastructure standards specific to unsealed nuclear substances, and specialist competency requirements established through Royal College certification^{4,6,11}. System planning that does not explicitly preserve Nuclear Medicine governance within program authorization frameworks risks fragmenting these interdependent obligations.

Provincial ministries of health should condition Radioligand Therapy funding approvals on demonstrable alignment with federal nuclear licence accountability and Royal College-certified Nuclear Medicine oversight. Funding frameworks that do not incorporate this requirement risk creating structural misalignment between regulatory authority and operational governance. As additional radiopharmaceutical therapies enter clinical practice and theranostic approaches become more integrated across diagnostic and therapeutic pathways, the need for structural clarity increases.

Funding frameworks should reflect the full therapeutic episode. As the radiopharmaceutical is one component of this episode, funding the drug does not resource the program. Funding should cover molecular imaging for selection, multidisciplinary consultation, treatment delivery, radiation safety, medical physics and dosimetry, radiopharmacy, nursing, toxicity management and outcomes reporting^{1,32}.

International guidance recognizes radiopharmaceutical therapy as requiring coordinated oversight of radiation safety, infrastructure, dosimetry, and specialist supervision^{15,34}. Canadian implementation models must preserve, not dilute, the regulatory and specialty alignment required under federal nuclear law.

Equitable access across academic, regional, and community institutions further necessitates replicable governance models that remain compliant in all jurisdictions. Federal nuclear obligations apply uniformly across Canada^{4,5}. As programs expand beyond tertiary centres, provincial frameworks must ensure that new sites are established within Nuclear Medicine services, supported by appropriately credentialed physicians operating under valid nuclear substance licences, and integrated into established radiation protection programs.

The CDA-AMC reimbursement analyses have identified infrastructure readiness and system capacity as prerequisites for the responsible implementation of radiopharmaceutical therapies¹⁸. Infrastructure investment, workforce planning, and policy authorization must proceed in concert with governance alignment. Sustainable expansion of Radioligand Therapy depends on maintaining coherence between funding decisions, institutional program design, federal nuclear licence accountability, and Royal College specialty standards.

Radioligand Therapy represents a significant advancement in precision cancer treatment. Its continued expansion within Canada must occur within a governance framework that reflects federal nuclear law, specialty competency, and national quality standards. Provincial ministries of health, cancer agencies, and institutional leaders share responsibility for ensuring that policy, funding, and operational decisions preserve this alignment in order to protect patient safety, maintain

regulatory compliance, and safeguard the integrity of Nuclear Medicine practice within the Canadian health system.

SECTION 6

Formal Position of the Canadian Association of Nuclear Medicine

In consideration of the legislative framework, specialty certification standards, and governance principles outlined in this Position Paper, the Canadian Association of Nuclear Medicine affirms the following national position:

- 1** Radioligand Therapy is the therapeutic use of licensed nuclear substances and constitutes a regulated Nuclear Medicine activity under federal nuclear legislation and associated regulations.
- 2** Therapeutic direction of licensed radiopharmaceutical administration must be exercised by a physician certified in Nuclear Medicine by the Royal College of Physicians and Surgeons of Canada, or holding an equivalent recognized Nuclear Medicine certification as defined in Section 2.4, who operates under the conditions of an applicable federal nuclear substance licence. The physician holds documented training in the handling of unsealed radioactive sources, unsealed-source dosimetry and radiation protection, and supervised clinical experience spanning diagnostic molecular imaging and therapeutic patient management. Continuing professional development in Radioligand Therapy is expected.
- 3** Determination of oncologic indication and longitudinal systemic cancer management remain integral to multidisciplinary cancer care and are distinct from federally regulated nuclear therapeutic direction.
- 4** Delegation of technical acts, including intravenous administration, where authorized under provincial legislation, does not transfer medical direction, nuclear licence accountability, or radiation protection obligations established under federal law.

- 5 Institutional governance structures must preserve structural alignment among medical direction, radiation safety oversight, infrastructure compliance, and nuclear licence accountability within Nuclear Medicine services.
- 6 Provincial program authorization and funding frameworks for Radioligand Therapy must reflect the federal nuclear regulatory architecture and ensure governance alignment with Nuclear Medicine specialty standards recognized through Royal College certification or equivalent recognized Nuclear Medicine certification and applicable provincial authorization to practice in Canada.
- 7 Sustainable national expansion of Radioligand Therapy requires coherence among federal statutory obligations, Royal College specialty standards, institutional program design, and health system policy.
- 8 Radiation Oncology, Medical Oncology, Urology and Endocrinology contribute disease-site expertise to Radioligand Therapy within their certified scope. This collaboration complements the unsealed-source competency of Nuclear Medicine and leaves the medical direction of the therapeutic episode with the Nuclear Medicine physician.
- 9 CANM will convene a pan-Canadian working group of Nuclear Medicine physicians, medical physicists, radiopharmacists, technologists, nurses, radiation safety officers, partner oncology specialties and patient representatives. The working group will define minimum competencies, the minimum number of supervised administrations, institutional readiness criteria and clinical outcome indicators for Radioligand Therapy programs.

The Canadian Association of Nuclear Medicine (CANM) issues this Position Paper to promote national clarity, protect patient safety, uphold regulatory integrity, and support the responsible integration of Radioligand Therapy within Canada's health system.

SECTION 7

Conclusion

Radioligand Therapy represents a major advancement in precision oncology and a central component of the evolving theranostic model that integrates diagnostic imaging with targeted radionuclide therapy. The therapeutic administration of radiopharmaceuticals, however, involves the licensed medical use of unsealed, radioactive nuclear substances and therefore operates within a distinct federal regulatory framework governed by nuclear safety legislation, radiation protection regulations, and drug regulatory oversight.

Within this framework, the requirement for medical direction in the use of radioactive nuclear substances must be interpreted in alignment with established specialty competencies defined through Royal College certification. Nuclear Medicine is the only Royal College specialty formally trained in the therapeutic use of unsealed radioactive materials, including activity prescription, radiation safety, dosimetry, patient and household radiation protection counselling, radiopharmaceutical governance, and regulatory compliance. This alignment between statutory regulation and specialty competency establishes Nuclear Medicine as the specialty structurally responsible for the therapeutic use of radiopharmaceuticals in Canada.

The scope of Radioligand Therapy governance extends across the full therapeutic ecosystem. It includes clinical eligibility assessment within multidisciplinary cancer care, therapeutic imaging interpretation, prescription and activity determination, administration within controlled nuclear environments, patient-specific dosimetry, radiation safety instruction, radiopharmacy and supply-chain oversight, radioactive waste management, clinical trial readiness, data governance, workforce planning, and equitable access across Canadian jurisdictions. These functions are operationally linked and must remain aligned with federal nuclear licence accountability and Nuclear Medicine specialty leadership.

International practice standards reinforce this interpretation. Across Europe, North America, and other advanced nuclear medicine systems, radiopharmaceutical therapy is consistently governed within Nuclear Medicine programs under physician leadership with defined radiation safety oversight and regulatory accountability. Maintaining alignment with this established international

doctrine supports professional coherence, regulatory clarity, and safe clinical implementation.

As Radioligand Therapy expands across Canadian jurisdictions and additional theranostic agents enter clinical practice, including alpha-emitting and other next-generation radionuclides, clear governance structures will be essential to ensure sustainable program development. Provincial health authorities, cancer agencies, and hospital leadership must ensure that program authorization, infrastructure planning, workforce development, and funding frameworks remain aligned with federal nuclear licence accountability and Royal College-certified Nuclear Medicine oversight.

Radioligand Therapy is therefore not simply an emerging oncology modality, but a licensed Nuclear Medicine therapeutic activity governed by federal nuclear law. Institutional governance models that preserve alignment between therapeutic direction, radiation safety oversight, dosimetry, radiopharmacy, patient and caregiver safety, and nuclear licence accountability anchored in Nuclear Medicine governance are essential to protect patient safety, maintain regulatory compliance, and support equitable national access.

Through this Position Paper, the Canadian Association of Nuclear Medicine affirms its commitment to supporting the responsible integration and expansion of Radioligand Therapy in Canada through governance structures that respect federal nuclear regulatory architecture, reinforce specialty competency, and preserve patient safety and the integrity of Nuclear Medicine practice within the Canadian health system.

CANM presents these principles as a professional responsibility toward patients, their families and the public. They define the competencies that the safe therapeutic use of unsealed sources requires. CANM invites partner specialties, regulators and provincial health authorities to implement them jointly, and supports a joint statement with SNMMI, EANM, DGN and SGNM that applies the same standards across jurisdictions

ANNEX A

National Regulatory Architecture and Governance Risk Consolidation Matrix

Foundational Regulatory Principle	Governing Legal Authority	Specialty / Regulatory Standard	Structural Alignment Requirement	System-Level Exposure if Misaligned	Policy Alignment Expectation	Core Sources
Radioligand Therapy is the therapeutic use of unsealed radioactive nuclear substances and is therefore a licensed nuclear activity	Nuclear Safety and Control Act (federal statute)	CNSC licensing regime	Program must operate under a valid nuclear substance licence within Nuclear Medicine governance	Licence non-compliance; corrective measures; suspension or amendment of licence; reputational risk	Provincial authorization frameworks must require demonstrable nuclear licence alignment prior to program approval	(Government of Canada, 1997; Canadian Nuclear Safety Commission, 2024)
Therapeutic radioactive substances may only be used under direction of a qualified medical practitioner	Nuclear Substances and Radiation Devices Regulations	Royal College certification standards	Medical direction must reside with Royal College—certified Nuclear Medicine physician with appropriate privileges	Diffusion of accountability; regulatory ambiguity; enforcement exposure under licence authority	Program approvals must formally designate Nuclear Medicine as directing authority for RLT	(Government of Canada, 2000; Royal College of Physicians and Surgeons of Canada)
Nuclear Medicine is the only Royal College specialty formally certified in therapeutic use of unsealed radioactive materials	Royal College Objectives of Training	National specialty governance framework	Radioligand Therapy must be structurally housed within Nuclear Medicine services	Scope misalignment; conflict with national specialty standards; institutional governance inconsistency	Provincial cancer agencies must embed Nuclear Medicine governance within RLT funding models	(Royal College of Physicians and Surgeons of Canada)
Radiation protection programs, ALARA obligations, and post-therapy exposure mitigation are mandatory	Radiation Protection Regulations	CNSC compliance oversight	Radiation safety supervision, discharge authorization, and patient instruction must remain under licensed Nuclear Medicine program	Public exposure risk; audit findings; licence vulnerability; potential corrective action	Expansion planning must include validated radiation protection program integration	(Government of Canada, 2000; Canadian Nuclear Safety Commission, 2024)
Radiopharmaceuticals are Schedule C drugs subject to dual oversight	Food and Drugs Act; Health Canada authority	Health Canada market authorization framework	Governance must integrate drug regulatory compliance with nuclear safety oversight	Fragmentation between pharmaceutical and nuclear regulatory domains; compliance inconsistency	Institutional governance models must reflect dual regulatory accountability	(Government of Canada, 1985; Health Canada)
Infrastructure for unsealed radioactive substances requires controlled environments and contamination design standards	CNSC REGDOC 2.5.6	Product monograph requirements	Delivery within compliant Nuclear Medicine—controlled facilities	Infrastructure non-conformity; licence review vulnerability; program suspension risk	Capital planning and infrastructure investment must align with CNSC facility requirements	(Canadian Nuclear Safety Commission, 2023; Novartis Pharmaceuticals Canada Inc., 2025)

Foundational Regulatory Principle	Governing Legal Authority	Specialty / Regulatory Standard	Structural Alignment Requirement	System-Level Exposure if Misaligned	Policy Alignment Expectation	Core Sources
Delegation of injection does not transfer regulatory direction or licence accountability	Federal regulation; provincial controlled acts	Provincial regulatory college standards	Technical administration may be delegated; therapeutic and licence accountability remains with Nuclear Medicine physician	Misinterpretation of delegation; diffusion of responsibility; liability exposure	Institutional policies must clearly distinguish delegation from regulatory direction	(Government of Canada, 2000; Regulated Health Professions Act, 1991)
National quality frameworks require identified physician lead and Radiation Safety Officer alignment	Pan-Canadian QA standards	Structured QA governance	Unified governance linking clinical leadership and radiation safety oversight within same program	Audit vulnerability; quality governance deficiency; accreditation risk	Health authorities must require documented governance alignment in QA submissions	(Pan-Canadian Collaboration for Quality Assurance in Radiopharmaceutical Therapy, 2025)
Provincial program authorization and funding decisions must reflect federal nuclear regulatory architecture	Federal statutory supremacy; provincial health authority mandates	Provincial program approval mechanisms	RLT authorization must embed Nuclear Medicine governance and licence alignment	Structural inconsistency between funding authority and regulatory accountability; systemic compliance risk	Provincial ministries must condition RLT program expansion on Nuclear Medicine governance compliance	(Government of Canada, 1997; Canadian Agency for Drugs and Technologies in Health, 2023)
Expansion of theranostics requires integrated diagnostic and therapeutic nuclear governance	International nuclear safety doctrine	National implementation planning	Diagnostic and therapeutic radiopharmaceutical integration must remain within Nuclear Medicine services under unified licence accountability	Fragmentation of diagnostic and therapeutic oversight; erosion of specialty governance integrity; long-term regulatory instability	National theranostics strategy must preserve Nuclear Medicine structural leadership	(International Atomic Energy Agency; International Commission on Radiological Protection, 2004)

ANNEX B

Radioligand Therapy Governance and Accountability Matrix

Legend A Accountable under licence or governance authority · R Responsible for execution · C Consulted · I Informed

Clinical / Regulatory Process	Nuclear Medicine Physician	Medical Oncologist	Nuclear Medicine Technologist	Registered Nurse	Radiopharmacy	Medical Physicist	Radiation Safety Officer	Hospital Executive Governance
Oncologic Indication, Treatment Sequencing and Funding Eligibility	C	A/R	I	I	I	I	I	I
Theranostic Eligibility (target expression on PSMA or SSTR imaging, radiation-specific contraindications, renal and marrow reserve) and Decision to Treat	A/R	C	I	I	I	I	I	I
Therapeutic Imaging Interpretation (PSMA PET, SSTR PET)	A	C	R acquisition only	I	I	C	I	I
Radiopharmaceutical Therapy Prescription and Administered Activity Determination	A	C	I	I	C	C	I	I
Federal Medical Direction of Licensed Nuclear Substance Use (NSRDR s.16)	A	I	I	I	I	I	C	I
Radiopharmaceutical Preparation and Chain of Custody Compliance	C	I	C	I	A/R	C	C	I
Therapeutic Administration Within Controlled Nuclear Area	A	C	R if authorized	R if authorized	C	C	C	I
Verification of Prescribed Activity Prior to Administration	A	I	R	C	C	C	C	I
Mandatory Post-Therapy Radiation Protection Instruction	A	I	C	C	I	C	C	I
Discharge Authorization Under Radiation Protection Regulations	A	I	C	C	I	C	C	I
Contamination Event Management and Regulatory Reporting	A	I	R	R	C	C	A/R	I
Therapy-Specific Clinical Monitoring During Nuclear Episode	A	C	I	C	I	I	I	I
Longitudinal Systemic Oncology Management Outside Licensed Nuclear Episode	C	A	I	C	I	I	I	I
Program-Level Radiation Protection Compliance Framework	A clinical	I	R	C	C	R	A/R	A governance
Infrastructure Compliance With CNSC REGDOC 2.5.6	C	I	C	C	C	A/R	A/R	A
Institutional Nuclear Licence Accountability and Corrective Action Response	A	I	I	I	I	C	A/R	A

ANNEX C

Institutional Self-Assessment Checklist

Institutional self-assessment checklist mapping fifteen governance domains for Radioligand Therapy to their federal regulatory, Royal College specialty, and pan-Canadian quality bases, with status fields for documenting institutional compliance..

Governance Domain	Implementation Requirement	Regulatory or Standards Basis	Status (☐ Met / ☐ Partial / ☐ Not Met)
1 Program Structure	Radioligand Therapy program is structurally housed within Nuclear Medicine services with documented institutional designation.	Nuclear Safety and Control Act (Government of Canada, 1997); Royal College Nuclear Medicine standards	☐ Met ☐ Partial ☐ Not Met
2 Medical Direction	Medical direction is exercised by a physician certified in Nuclear Medicine by the Royal College, or holding equivalent recognized certification with provincial authorization to practice, with documented training and supervised experience as defined in Section 2.4.	Nuclear Substances and Radiation Devices Regulations (Government of Canada, 2000b); Royal College of Physicians and Surgeons of Canada	☐ Met ☐ Partial ☐ Not Met
3 Radiation Safety Oversight	A Radiation Safety Officer is formally appointed with defined reporting relationships to the Nuclear Medicine program lead and institutional leadership.	Radiation Protection Regulations (Government of Canada, 2000a); CNSC guidance (Canadian Nuclear Safety Commission, 2024)	☐ Met ☐ Partial ☐ Not Met
4 Facility Design	Facility design complies with CNSC REGDOC 2.5.6 requirements for rooms in which unsealed nuclear substances are used.	CNSC REGDOC 2.5.6 (Canadian Nuclear Safety Commission, 2023)	☐ Met ☐ Partial ☐ Not Met
5 Radiopharmacy Operations	Radiopharmacy operations comply with Health Canada drug establishment licensing and applicable compounding standards.	Food and Drugs Act (Government of Canada, 1985); Health Canada regulatory roadmap	☐ Met ☐ Partial ☐ Not Met
6 Dosimetry	Patient-specific dosimetry capability is available and integrated within therapeutic decision-making.	EANM Dosimetry Committee (2020); ICRP (2007); Kratochwil et al. (2023)	☐ Met ☐ Partial ☐ Not Met
7 Post-Therapy Counselling	Mandatory post-therapy radiation protection instructions are documented and provided to every patient prior to discharge.	Radiation Protection Regulations (Government of Canada, 2000a)	☐ Met ☐ Partial ☐ Not Met
8 Multidisciplinary Review	Multidisciplinary case review processes are formalized with documented terms of reference.	Pan-Canadian Collaboration for Quality Assurance in Radiopharmaceutical Therapy (2025)	☐ Met ☐ Partial ☐ Not Met
9 Quality Assurance	Quality assurance indicators are defined, monitored, and reviewed at regular intervals, including contamination incident rates and audit completion.	Radiation Protection Regulations (Government of Canada, 2000a); PCQRT (2025)	☐ Met ☐ Partial ☐ Not Met
10 Incident Management	Incident management and reportable event pathways are documented and aligned with CNSC reporting obligations.	Nuclear Safety and Control Act (Government of Canada, 1997); CNSC (2024)	☐ Met ☐ Partial ☐ Not Met
11 Clinical Trial Governance	Clinical trial governance integrates Health Canada Clinical Trial Application processes with CNSC research licence amendments and institutional Research Ethics Board oversight.	Food and Drug Regulations; Nuclear Safety and Control Act (Government of Canada, 1985; 1997)	☐ Met ☐ Partial ☐ Not Met
12 Equity and Access	Equity and access planning, including outreach to rural, remote, and Indigenous communities, is documented and implemented in partnership with relevant health authorities.	Truth and Reconciliation Commission of Canada (2015); CADTH (2023)	☐ Met ☐ Partial ☐ Not Met

	Governance Domain	Implementation Requirement	Regulatory or Standards Basis	Status (☐ Met / ☐ Partial / ☐ Not Met)
13	Health Information and Cybersecurity	Cybersecurity and health information governance for dosimetry and imaging data platforms are integrated within institutional privacy and information security programs.	Personal Information Protection and Electronic Documents Act (Government of Canada, 2000c); provincial health information legislation	☐ Met ☐ Partial ☐ Not Met
14	Radioactive Waste Management	Radioactive waste management is documented within the radiation protection program and complies with CNSC licence conditions.	CNSC REGDOC 2.5.6 (2023); CNSC (2024)	☐ Met ☐ Partial ☐ Not Met
15	Workforce Planning	Workforce planning, including specialty recruitment, fellowship support, and credentialing pathways, is documented at the institutional and regional level.	Royal College of Physicians and Surgeons of Canada; CADTH (2023)	☐ Met ☐ Partial ☐ Not Met

ANNEX D

Glossary of Abbreviations

ALARA	As Low As Reasonably Achievable	SNMMI	Society of Nuclear Medicine and Molecular Imaging
ARSAC	Administration of Radioactive Substances Advisory Committee (United Kingdom)	SSTR	Somatostatin Receptor
AU	Authorized user (United States, 10 CFR Part 35)	TRC	Truth and Reconciliation Commission
CADTH	Canadian Agency for Drugs and Technologies in Health		
CANM	Canadian Association of Nuclear Medicine		
CDA-AMC	Canada's Drug Agency (formerly CADTH)		
CNSC	Canadian Nuclear Safety Commission		
CPD	Continuing Professional Development		
EANM	European Association of Nuclear Medicine		
GMP	Good Manufacturing Practice		
GRPP	Good Radiopharmacy Practice		
IAEA	International Atomic Energy Agency		
ICRP	International Commission on Radiological Protection		
IRMER	Ionising Radiation (Medical Exposure) Regulations (United Kingdom)		
KPI	Key Performance Indicator		
MIBG	Metaiodobenzylguanidine		
NAPRA	National Association of Pharmacy Regulatory Authorities		
PCQRT	Pan-Canadian Quality Roundtable for Radiopharmaceutical Therapy		
PIPEDA	Personal Information Protection and Electronic Documents Act		
PRRT	Peptide Receptor Radionuclide Therapy		
PSMA	Prostate-Specific Membrane Antigen		
REB	Research Ethics Board		
REGDOC	Regulatory Document (CNSC)		
RLT	Radioligand Therapy		
RSO	Radiation Safety Officer		

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ABOUT THIS PAPER

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Radioligand Therapy in Canada



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