Pan-Canadian Collaboration for Quality Assurance in Radiopharmaceutical Therapy (PCQRT)

Quality Assurance Guidelines for Canadian Radiopharmaceutical Therapy Programs

(April 1, 2025)

Preface

Radiopharmaceutical Therapy (RPT) is experiencing growth, marking a significant development in oncological practices both in Canada and globally. This method of therapy targets cancer cells, whether systemically or locally, and is noted for its ability to deliver targeted radiotherapy.

The development and implementation of RPT programs are characterized by their complexity and the need for a multidisciplinary approach, incorporating diverse expertise. Presently, RPT is being increasingly explored for various indications and malignancies, a trend bolstered by the approval of new RPT agents targeting different types of cancer. This underscores its expanding role as a vital component within the spectrum of oncological treatments.

Establishing quality guidelines for radiopharmaceutical therapy is crucial to ensure the safety of patients and the efficacy of treatments. As RPT technology advances, implementing specialized safeguards becomes essential to maintain the quality and safety of treatments and to mitigate potential risks.

Education and training are fundamental in ensuring the effective provision of radiopharmaceutical therapy. The expertise of medically trained professionals in preparing, handling, and administering radiopharmaceutical therapies is critical in clinical settings, emphasizing the need for comprehensive guidelines and standards.

The Pan-Canadian Collaboration for Quality Radiopharmaceutical Therapy (PCQRT) has brought together subject matter experts from across Canada, to ensure nationwide access to high-quality and safe RPT. Its mission includes enhancing system-wide performance, developing consensus-driven guidelines, and supporting the establishment and evaluation of Radiopharmaceutical Therapy programs. These initiatives are essential for patient safety, effective treatment outcomes, and the progression of cancer care in Canada.

As the field of RPT evolves, the guidelines and performance metrics formulated by the PCQRT are intended to be adaptable and regularly updated, reflecting the dynamic nature of healthcare and radiopharmaceutical therapy. This cooperative and forward-looking approach positions Canada as an active participant in the field of cancer treatment innovation, utilizing RPT to improve patient care.

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1. Expert Panel and Project Team

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2. Introduction

The Pan-Canadian Collaboration for Quality Radiopharmaceutical Therapy (PCQRT) underscore crucial elements of radiopharmaceutical therapy quality assurance that should be consistent across all Radiopharmaceutical Therapy programs in Canada. They do not aim to supplant detailed specifications, standard operational procedures, or institution-specific policies. Instead, their purpose is to support the formation and preservation of a national approach to radiopharmaceutical therapy quality assurance. The paramount goal is to ensure that Canadians receive radiopharmaceutical therapy of the highest caliber, seamlessly integrated into the broader landscape of cancer care, while actively mitigating the risks associated with medical errors and undesired clinical results. Implementation and ongoing monitoring of quality assurance measures should be embraced by all organizations and agencies devoted to radiopharmaceutical cancer treatment within the country.

The World Health Organization (WHO) has framed quality assurance in therapies like radiopharmaceutical therapy as all procedures that guarantee consistent medical prescription and its safe execution, ensuring optimal dose delivery to the target volume with minimal exposure to surrounding tissues, limited personnel exposure, and thorough patient monitoring to ascertain the treatment's final outcome. Consequently, an effective quality assurance program should encompass all dimensions of radiopharmaceutical therapy delivery – from overarching program structure, qualification of professionals engaged in therapy, to the formulation of policies, procedures, incident tracking, and uniform reporting of outcomes.

3. Development Process

To ensure a wide-ranging and authoritative perspective, a Pan-Canadian expert panel was assembled. This panel, brought together through collaborative efforts with the Canadian Association of Provincial Cancer Agencies (CAPCA) and the provincial health authorities, comprised a diverse group of professionals with expertise in radiopharmaceutical therapy. Their collective knowledge spanned across various aspects of RPT and geography across Canada, ensuring a holistic approach to the guideline development.

The process was structured to foster collaboration and consensus. The expert panel followed a project plan that defined their deliverables, meeting schedules, and accountability. The guideline development involved multiple stages, including the formulation of key themes and sub-themes through a consensus process. This was complemented by a series of scoring rounds and virtual workshops, allowing for comprehensive input and review from panel members and other stakeholders.

The surveys and virtual workshops were instrumental in gathering wider feedback and perspectives, ensuring the guidelines were grounded in practical insights and real-world applicability. The draft consensus document was also subjected to extensive consultation, involving additional subject-matter experts, and professional colleges. This collaborative approach was pivotal in refining the guidelines to align with the highest standards of quality and safety.

The culmination of this process was the finalization and distribution of the consensus-based Radiopharmaceutical Therapy programmatic quality guideline document, which was endorsed and disseminated by CAPCA. However, the process does not end with the publication of the guidelines. Recognizing the dynamic nature of healthcare and RPT, the document is slated for regular reviews, to ensure its continued relevance and effectiveness in the evolving landscape of Canadian healthcare and radiopharmaceutical therapy.

This comprehensive and iterative process underscores PCQRT's commitment to developing guidelines that are not only evidence-based and consensus-driven but also adaptive and responsive to the changing needs of the healthcare community and patients in Canada.

Summary of Key Quality Indicators: Programmatic Organization

KQI	Description	Indicator Measure	Section
1	The Radiopharmaceutical Therapy program aligns with the broader cancer care processes, ensuring that patients receive comparable support, safety, and resources as they would within a dedicated cancer program.	None (0) Some (0.25) Most (0.75) All (1)	2.1
2	The Radiopharmaceutical Therapy program ensures adequate staffing levels for personnel that are required to safely deliver Radiopharmaceutical treatment according to best evidence and practice guidelines.	None (0) Some (0.25) Most (0.75) All (1)	2.1
3	The Radiopharmaceutical Therapy program has explicit, documented accountabilities detailing the responsibilities of all involved personnel in maintaining and enhancing the quality of patient care delivered.	None (0) Some (0.25) Most (0.75) All (1)	2.1
4	The Radiopharmaceutical Therapy program has clearly defined its reporting structure, and the responsibilities of all personnel and committees, to ensure accountability for the quality of care it provides.	None (0) Some (0.25) Most (0.75) All (1)	2.1
5	The Radiopharmaceutical Therapy program has a clearly defined administrative and physician leader who are accountable for all aspects for the program.	0 or 1	2.1
6	The Radiopharmaceutical Therapy program establishes a solid foundation for patient care through its quality assurance committee, which may involve a dedicated RTQAC or be part of an existing committee.	0 or 1	2.2
7	The Radiopharmaceutical Therapy program's quality assurance initiative is grounded on detailed, written policies and procedures encompassing all its quality assurance activities.	None (0) Some (0.25) Most (0.75) All (1)	2.2
8	The Radiopharmaceutical Therapy program has a process in place for retaining all documents pertinent to quality assurance activities from the Radiopharmaceutical therapy quality assurance committee (or equivalent).	None (0) Some (0.25) Most (0.75) All (1)	2.2
9	The Radiopharmaceutical Therapy program's RTQAC, or its equivalent in an existing committee, is well-structured and has documented terms of reference that meet all the requirements for composition, and accountabilities as outlined above.	None (0) Some (0.25) Most (0.75) All (1)	2.3
10	The Radiopharmaceutical Therapy Quality Assurance Committee (or equivalent) has a “blame-free” process for	0 or 1	2.4

	personnel to access the committee and to report concerns about radiation treatment quality or safety.		
11	There is a radiation safety program that has written policies and procedures to address the safe use of ionizing radiation according to the pertinent laws and regulations specified in this section	0 or 1	2.5
12	The Radiopharmaceutical Therapy program has written policies and procedures that address the reporting, investigation, action, documentation, and monitoring of Radiopharmaceutical therapy incidents.	0 or 1	2.6
13	The Radiopharmaceutical Therapy program identifies and reports critical incidents as defined by this section.	0 or 1	2.6

Summary of Key Quality Indicators: Personnel

KQI	Description	Indicator Measure	Section
14	The Radiopharmaceutical Therapy program/ organization demonstrates a commitment to ensuring all personnel are adequately educated and trained.	0 or 1	3.1
15	In addition to continuous education required through professional associations/ colleges, there is a continuing education program with internal seminars, rounds, and/or conferences to ensure that personnel are exposed to new developments in Radiopharmaceutical therapy and quality assurance.	0 or 1	3.1
16	Percentage of physicians who practice within the Radiopharmaceutical Therapy program with specialized training,	Score Range: 0-1 [0-100% / 100]	3.2
17	Percentage of preparators involved in on-site preparation of Radiopharmaceutical therapy products with specialized training in Radiopharmaceutical therapy.	Score Range: 0-1 [0-100% / 100]	3.3
18	Percentage of Medical Physicists certified by the Canadian College of Physicists in Medicine (CCPM) or equivalent with a sub-specialty in nuclear medicine.	Score Range: 0-1 [0-100% / 100]	3.4
19	Percentage of Nuclear Medicine Technologists licensed by the provincial regulatory body, or where such a body does not exist, who are members of the Canadian Association of Medical Radiation Technologists (CAMRT).	Score Range: 0-1 [0-100% / 100]	3.5
20	The organization has an identified physician leader tasked with overseeing the essential clinical components of the Radiopharmaceutical Therapy program.	0 or 1	3.6

21	There is an identified Radiation Safety Officer who reports directly to the organization's applicant authority.	0 or 1	3.7
22	The Radiation Safety Officer (RSO) possesses current RSO certification or registration.	0 or 1	3.7
23	There is a radiation safety training program for all personnel associated with the Radiopharmaceutical Therapy program at a level appropriate to their job function, according to national regulatory guidelines.	None (0) Some (0.25) Most (0.75) All (1)	3.8

Summary of Key Quality Indicators: Facility

KQI	Description	Indicator Measure	Section
24	The Radiopharmaceutical Therapy program maintains proper equipment and shielding to handle a Radiopharmaceutical therapy dose from the moment of receiving to the administration of the dose.	None (0) Some (0.25) Most (0.75) All (1)	4.1
25	The Radiopharmaceutical Therapy program has adequately shielded therapy rooms that utilize As Low As Reasonably Achievable (ALARA) principles.	0 or 1	4.1
26	The Radiopharmaceutical therapy rooms have washrooms dedicated to Radiopharmaceutical therapy patients.	0 or 1	4.1
27	The Radiopharmaceutical Therapy program has access to adequately shielded inpatient rooms with 24/7 care support. Staff in this area are trained in caring for patients treated with a Radiopharmaceutical therapy.	0 or 1	4.2
28	The Radiopharmaceutical Therapy program possesses secured space for radioactive waste management, complemented by shielding and staff training.	0 or 1	4.3
29	The Radiopharmaceutical Therapy program utilizes a waste management system designed for efficient tracking and auditing of radioactive waste.	0 or 1	4.3

Summary of Key Quality Indicators: Equipment and Instrumentation

KQI	Description	Indicator Measure	Section
30	The Radiopharmaceutical Therapy program consistently follows detailed quality control procedures for all imaging, treatment, and major accessories, ensuring optimal performance and safety standards.	None (0) Some (0.25) Most (0.75) All (1)	5.1
31	The Radiopharmaceutical Therapy program has a dedicated committee that actively supervises equipment quality control activities, endorsing both quality and safety standards.	0 or 1	5.2
32	For the introduction of new equipment (hardware and/or software), the implementation of a quality control procedure/process is ensured prior to the commencement of clinical usage.	None (0) Some (0.25) Most (0.75) All (1)	5.3
33	When introducing new equipment (hardware and/or software), it's mandatory for all involved personnel to receive appropriate and comprehensive training.	None (0) Some (0.25) Most (0.75) All (1)	5.3
34	Percentage of major pieces of equipment (SPECT/CT, PET/CT, and Gamma Cameras) that are less than 10 years old.	Score Range: 0-1 [0-100% / 100]	5.4
35	The Radiopharmaceutical Therapy program commits to conducting an independent calibration and dosimetry audit every year, ensuring the continuous accuracy and safety of its equipment.	0 or 1	5.5

Summary of Key Quality Indicators: Policy and Procedures

KQI	Description	Indicator Measure	Section
36	Policies and procedures have a planned review date, with a regular planned review cycle, ideally this occurs annually.	0 or 1	6.1.1
37	The Radiopharmaceutical Therapy program collaboratively establishes processes for the selection, consistent implementation, and regular reassessment of clinical practice guidelines.	0 or 1	6.1.2
38	Proportion of complex radiopharmaceutical therapy cases are reviewed in multidisciplinary rounds.	None (0) Some (0.25) Most (0.75) All (1)	6.1.3
39	Attendance rate of Radiopharmaceutical therapy specialists at applicable disease site rounds	None (0) Some (0.25) Most (0.75) All (1)	6.1.4

40	The organization employs a well-defined method, be it internally devised or externally adopted (ex. provincial), to ascertain and adhere to wait-time targets in the delivery of Radiopharmaceutical therapy and PET/CT services.	0 or 1	6.2
41	Percentage of PET/CT performed within target.	Score Range: 0-1 [0-100% / 100]	6.2
42	The healthcare institution utilizes at least two person-specific identifiers, to ascertain the accurate identity of patients and ensure they receive the intended medical services or procedures.	0 or 1	6.3.1
43	The Radiopharmaceutical Therapy program implements an authorization process for Radiopharmaceutical therapies, which mandates a physician-signed order, explicitly specifying the dose, before commencing any treatment or course.	0 or 1	6.3.2
44	The Radiopharmaceutical Therapy program has a thorough screening processes for pregnancy in patients of reproductive age prior to Radiopharmaceutical therapy.	0 or 1	6.3.3
45	There is documentation of informed consent for Radiopharmaceutical therapy prior to the delivery of treatment.	0 or 1	6.4.1
46	The Radiopharmaceutical Therapy program provides written or online educational materials about Radiopharmaceutical therapy planning, treatment delivery, side effects, and follow-up to patients and their families.	0 or 1	6.4.2
47	The Radiopharmaceutical Therapy program has a process for peer review of complex therapy cases, particularly where individual dosimetry assessment or dose adjustment is required, to confirm dosing accuracy and therapeutic appropriateness.	0 or 1	6.5
48	The Radiopharmaceutical Therapy program has a systematic approach for the random or targeted selection of Radiopharmaceutical therapy cases for peer review, ensuring a comprehensive quality check across varying case complexities.	0 or 1	6.5
49	The Radiopharmaceutical Therapy program has a process to record the analysis of peer review outcomes, such as recommendations for changes in Radiopharmaceutical therapy plans. Results from this process feed in to programmatic continuous improvement where applicable.	0 or 1	6.5
50	A verification process by a second registered health care professional is in place, covering all critical aspects of Radiopharmaceutical therapy	0 or 1	6.6
51	Appropriate staff are present at the Radiopharmaceutical therapy facility or are capable of responding within a time limit set by the program.	0 or 1	6.7.1

52	The Radiopharmaceutical Therapy program incorporates a definitive emergency protocol for patients that may require emergency/urgent care or admission post therapy.	0 or 1	6.7.2
53	The Radiopharmaceutical Therapy program has record-keeping protocols, capturing patient journey from consent to post-treatment follow-up, while adhering to privacy standards.	None (0) Some (0.25) Most (0.75) All (1)	6.8.1
54	The proportion of Radiopharmaceutical therapy patients who undergo a complete set of evaluations — including but not limited to bloodwork, imaging studies, and symptom tracking — before and after treatment, as well as having access to medical reviews by specialists where required.	None (0) Some (0.25) Most (0.75) All (1)	6.8.2
55	The Radiopharmaceutical Therapy program has a process to conduct comprehensive audits to assess key clinical outcomes.	0 or 1	6.8.3
56	The Radiopharmaceutical Therapy program's adherence level to ICRU Report 96 guidelines and reporting measures to enhance the accuracy and safety of radiopharmaceutical therapies.	None (0) Some (0.25) Most (0.75) All (1)	6.8.4
57	The Radiopharmaceutical Therapy program is committed to maintaining the highest quality of care and safety standards by actively pursuing and upholding accreditation through respected and recognized radiopharmaceutical therapy accreditation programs.	0 or 1	6.9
58	Conformity to Established Technical Standards	None (0) Some (0.25) Most (0.75) All (1)	6.10
59	Engagement in Research Activities in Radiopharmaceutical Therapy	0 or 1	6.11

2. Programmatic Organization

2.1 Organization Integration, Resources and Accountability

The Radiopharmaceutical Therapy program collaborates with or is embedded in an inter-professional cancer program. Organizational leadership ensure the provision of adequate human, structural, and informational resources. This collaboration is key for the safe delivery of radiopharmaceutical therapy in line with evidence-based guidelines and best practices.

To maintain safety and quality in treatment delivery, the program adheres to applicable provincial, national, and professional staffing guidelines to ensure appropriate staffing levels across all required disciplines.

Key Quality Indicator #1,2	Indicator Measure
The Radiopharmaceutical Therapy program aligns with the broader cancer care processes, ensuring that patients receive comparable support, safety, and resources as they would within a dedicated cancer program.	None (0) Some (0.25) Most (0.75) All (1)
The Radiopharmaceutical Therapy program ensures adequate staffing levels for personnel that are required to safely deliver radiopharmaceutical treatment according to best evidence and practice guidelines.	None (0) Some (0.25) Most (0.75) All (1)

The Radiopharmaceutical Therapy program recognizes the critical importance of transparency and accountability in ensuring the highest standards of patient care. To this end, the program has well-documented accountabilities that are embedded into its reporting structure. Every role within the program, from leadership to the frontline personnel, has clearly outlined duties and responsibilities to ensure that the quality of patient care is never compromised and that there are established protocols and pathways for reporting, feedback, and improvement.

Key Quality Indicator #3,4,5	Indicator Measure
The Radiopharmaceutical Therapy program has explicit, documented accountabilities detailing the responsibilities of all involved personnel in maintaining and enhancing the quality of patient care delivered.	None (0) Some (0.25) Most (0.75) All (1)
The Radiopharmaceutical Therapy program has clearly defined its reporting structure, and the responsibilities of all personnel and committees, to ensure accountability for the quality of care it provides.	None (0) Some (0.25) Most (0.75) All (1)
The Radiopharmaceutical Therapy program has a clearly defined administrative and physician leader who are accountable for all aspects for the program.	0 or 1.

2.2 Radiopharmaceutical Therapy Quality Assurance Program

The Radiopharmaceutical Therapy program emphasizes a quality assurance system. This ensures optimal radiopharmaceutical therapy planning and delivery, impacting patient care outcomes. A cornerstone of this system is the presence of either a dedicated Radiopharmaceutical Therapy Quality Assurance Committee (RTQAC) or as an integrated segment within an existing committee. The program also adheres to well-defined policies guiding all quality assurance activities and ensures consistent retention of all related documents.

Key Quality Indicator #6,7	Indicator Measure
The Radiopharmaceutical Therapy program establishes a solid foundation for patient care through its quality assurance committee, which may involve a dedicated RTQAC or be part of an existing committee.	0 or 1
The Radiopharmaceutical Therapy program's quality assurance initiative is grounded on detailed, written policies and procedures encompassing all its quality assurance activities.	None (0) Some (0.25) Most (0.75) All (1)

For a Radiopharmaceutical Therapy program to be effective and accountable, retaining crucial documentation related to quality assurance activities is crucial. This ensures transparency, traceability, and an opportunity for periodic reviews and improvements.

Key Quality Indicator #8	Indicator Measure
The Radiopharmaceutical Therapy program has a process in place for retaining all documents pertinent to quality assurance activities from the radiopharmaceutical therapy quality assurance committee (or equivalent).	None (0) Some (0.25) Most (0.75) All (1)

2.3 Radiopharmaceutical Therapy Quality Assurance Committee

The Radiopharmaceutical Therapy program upholds a high standard for quality assurance through its Radiopharmaceutical Therapy Quality Assurance Committee (RTQAC) or a dedicated segment of an existing committee. The terms of reference for this committee are thorough and well-defined, ensuring every aspect of radiopharmaceutical therapy receives due oversight.

Composition and Organization: The RTQAC (or similar) integrates a diverse set of expertise. It includes, at a minimum, a physician with expertise in radiopharmaceutical therapy, a medical physicist with a sub-specialty in nuclear medicine, a radiation safety specialist, and a nuclear medicine technologist responsible for quality assurance. The committee's activities and findings are transparently communicated, reporting to the Radiopharmaceutical Therapy program leadership (both clinician and admirative) and potentially other committees or groups responsible for quality in the broader cancer program or organization.

Duties and Responsibilities:

1. The committee ensures adherence to all equipment quality control procedures and maintains the requisite documentation.
2. The committee confirms the strict compliance of radiopharmaceutical therapy policies and procedures and delves into instances of non-compliance.
3. It undertakes reviews of radiopharmaceutical therapy incidents, ensuring they are managed as per the program and organizational guidelines. The committee is also proactive, taking preventive steps against recurring incidents, especially critical ones or emerging patterns of lesser incidents.
4. The committee is responsible for reporting incident data to local, provincial, national, or international entities, where applicable.
5. The committee actively defines and monitors quality indicators for the Radiopharmaceutical Therapy program, promptly reporting trends to the organization if required.
6. The committee uses the information discussed to formulate and implement continuous improvement initiatives.

Key Quality Indicator #9	Indicator Measure
The Radiopharmaceutical Therapy program's RTQAC, or its equivalent in an existing committee, is well-structured and has documented terms of reference that meet all the requirements for composition, and accountabilities as outlined above.	None (0) Some (0.25) Most (0.75) All (1)

2.4 Access to Radiopharmaceutical Treatment Quality Assurance Committee

There is a mechanism for personnel to access the radiopharmaceutical therapy quality assurance committee (or equivalent) to report concerns about radiopharmaceutical treatment quality.

Key Quality Indicator #10	Indicator Measure
The Radiopharmaceutical Therapy Quality Assurance Committee (or equivalent) has a “blame-free” process for personnel to access the committee and to report concerns about radiation treatment quality or safety.	0 or 1

2.5 Radiation Safety Program

The Radiopharmaceutical Therapy program has a radiation safety program to oversee the safe use of radioactive devices and materials in compliance with applicable federal and provincial legislation.

Key Quality Indicator #11	Indicator Measure
There is a Radiation Safety program that has written policies and procedures to address the safe use of ionizing radiation according to the pertinent laws and regulations.	0 or 1

2.6 Radiopharmaceutical Therapy Incident Management

The Radiopharmaceutical Therapy program should possess an incident management system, which might leverage the existing hospital framework. This system would be utilized to investigate treatment incidents that transpire during the entire treatment journey. Not only does it document and report these occurrences, but it also takes decisive action in response. Special attention is paid to the identification of critical incidents, notably hardware or software anomalies that might culminate in detrimental outcomes for patients or potential hazards for the staff or the general public. Furthermore, such incidents are reported to pertinent organizations with an emphasis on enacting measures to prevent recurrence.

Key Quality Indicator #12,13	Indicator Measure
The Radiopharmaceutical Therapy program has written policies and procedures that address the reporting, investigation, action, documentation, and monitoring of Radiopharmaceutical therapy incidents.	0 or 1
The Radiopharmaceutical Therapy program identifies and reports critical incidents as defined by this section.	0 or 1

3. Personnel

3.1 Competence, Credentials, Certifications, and Licensing

Every individual, whether directly or indirectly involved in the provision of radiopharmaceutical therapy, must be thoroughly educated, trained, qualified, and competent according to the standards set out for physicians and allied health care professionals by national organizations including the Royal College of Physicians and Surgeons of Canada, the Canadian Association of Medical Radiation Technologists (CAMRT), the Canadian Nurses Association (CNA), the Canadian Organization of Medical Physicists (COMP), the Canadian Radiation Protection Association (CRPA), and Provincial Licensing Bodies. Furthermore, the Radiopharmaceutical Therapy program is dedicated to ensuring continuous professional development through continuous improvement. This includes internal seminars, rounds, and conferences that keep personnel informed of the latest advancements in radiopharmaceutical therapy and quality assurance. Compliance with continuing education standards set by licensing organizations or professional associations is of paramount importance. Additionally, engagement in continuing education activities is tracked, often serving as a pivotal aspect of employee performance assessments and/or the competency maintenance program where applicable. To ensure utmost credibility and adherence to high standards, the Radiopharmaceutical Therapy program, either through the quality assurance committee or another appropriate channel, establishes a method to validate that personnel possess the requisite credentials from pertinent professional colleges, associations, or licensing entities. It also emphasizes the necessity of these credentials being current.

Key Quality Indicator #14,15	Indicator Measure
The Radiopharmaceutical Therapy program/ organization demonstrates a commitment to ensuring all personnel are adequately educated and trained.	0 or 1

In addition to continuous education required through professional associations/ colleges, there is a continuing education program with internal seminars, rounds, and/or conferences to ensure that personnel are exposed to new developments in radiopharmaceutical therapy and quality assurance.	0 or 1

3.2 Radiopharmaceutical Therapy Specialist Training

Given the unique skill set and knowledge demanded by radiopharmaceutical therapy, there arises a pressing need for tailored training, especially for specialists whose primary expertise does not lie within nuclear medicine. The complexity and specificity of radiopharmaceutical therapy warrant that professionals, including nuclear medicine physicians without formal radiopharmaceutical training through an accredited residency program, undergo specialized fellowship or additional training. This training should, at a minimum, meet the professional college guidelines for competency in the provision of radiopharmaceutical therapy. Such a program equips them with the necessary competencies to deliver radiopharmaceutical therapy with the highest standards of care and safety. The continuous evolution in the field further underscores the importance of this dedicated training to ensure optimal patient outcomes and to uphold the integrity of the practice.

Key Quality Indicator #16	**Indicator Measure**
Percentage of physicians who practice within the Radiopharmaceutical Therapy program with specialized training.	Score Range: 0-1 [0-100% / 100]

3.3 Radiopharmaceutical Therapy Preparators

In the Radiopharmaceutical Therapy program, the role of preparators including, radiopharmacists, radiochemists, technologists and pharmacists with specialized training in Radiopharmaceutical therapy, is pivotal, especially for sites that label Radiopharmaceutical therapy products on-site. These professionals are expected to operate with a deep understanding of and compliance with relevant federal and provincial regulations. Their expertise ensures not only the safe, effective, documented preparation and handling of radiopharmaceuticals but also aligns the practice with the highest standards of patient care and safety, adhering to all applicable legal and professional requirements.

Key Quality Indicator #17	**Indicator Measure**
Percentage of preparators involved in on-site preparation of radiopharmaceutical therapy products with specialized training in radiopharmaceutical therapy.	Score Range: 0-1 [0-100% / 100]

3.4 Medical Physicists

Medical Physicists who independently perform clinical physics activities relating to radiopharmaceutical therapy are certified by the Canadian College of Physicists in Medicine (CCPM) or equivalent with a

nuclear medicine specialty, or are in the process of collecting sufficient work experience to meet certification requirements.

Key Quality Indicator #18	Indicator Measure
Percentage of Medical Physicists certified by the Canadian College of Physicists in Medicine (CCPM) or equivalent with a specialty in nuclear medicine.	Score Range: 0-1 [0-100% / 100]

3.5 Nuclear Medicine Technologists

Nuclear Medicine Technologists meet provincial licensing requirements. Where such a provincial regulatory body does not exist, membership to the CAMRT is another measure of qualification.

Key Quality Indicator #19	Indicator Measure
Percentage of Nuclear Medicine Technologists licensed by the provincial regulatory body, or where such a body does not exist, who are members of the Canadian Association of Medical Radiation Technologists (CAMRT).	Score Range: 0-1 [0-100% / 100]

3.6 Radiopharmaceutical Therapy Division Physician Leadership

Within the organization, a designated physician, irrespective of the specific department they originate from, is identified as responsible for leading the Radiopharmaceutical Therapy program. This physician carries clear responsibilities for the clinical aspects of the Radiopharmaceutical Therapy program and boasts the clinical and administrative experience necessary to meet those responsibilities.

Key Quality Indicator #20	Indicator Measure
The organization has an identified physician leader tasked with overseeing the essential clinical components of the Radiopharmaceutical Therapy program.	0 or 1

3.7 Radiation Safety Officer

A qualified individual is designated as having primary responsibility for all aspects of radiation safety in the Radiopharmaceutical Therapy program. With respect to matters of radiation safety, the Radiation Safety Officer reports directly to the organization's applicant authority. The Radiation Safety Officer reports as necessary, and at least annually, to the organization quality committee or equivalent, on matters relating to radiation safety.

Key Quality Indicator #21,22	Indicator Measure
There is an identified Radiation Safety Officer who reports directly to the organization's applicant authority.	0 or 1

The Radiation Safety Officer (RSO) possesses current RSO certification or registration.	0 or 1

3.8 Radiation Safety Training

All personnel associated with the Radiopharmaceutical Therapy program in the facility regularly receive radiation safety training at a level appropriate to their job function. The training follows accepted recommendations published by regulators, such as the Canadian Nuclear Safety Commission. Participation in radiation safety training activity is monitored as part of an employee performance evaluation and/or competency maintenance program where applicable.

Key Quality Indicator #23	Indicator Measure
There is a radiation safety training program for all personnel associated with the Radiopharmaceutical Therapy program at a level appropriate to their job function, according to national regulatory guidelines.	None (0) Some (0.25) Most (0.75) All (1)

4. Facility

4.1 Radiopharmaceutical Therapy Area

Investing in and maintaining dedicated infrastructure for radiopharmaceutical therapy is critically important. Proper infrastructure not only safeguards the delivery and efficacy of the therapy but also promotes the welfare, privacy, and dignity of patients and staff. Crucial components encompass areas for precise dose handling and shielding prior to dose administration, appropriately shielded therapy rooms, and therapy rooms with dedicated washrooms.

Key Quality Indicator #24,25,26	Indicator Measure
The Radiopharmaceutical Therapy program maintains proper equipment and shielding to handle a radiopharmaceutical therapy dose from the moment of receiving to the administration of the dose.	None (0) Some (0.25) Most (0.75) All (1)
The Radiopharmaceutical Therapy program has adequately shielded therapy rooms that deploy As Low As Reasonably Achievable (ALARA) principles.	0 or 1
The radiopharmaceutical therapy rooms have washrooms dedicated to radiopharmaceutical therapy patients during treatment.	0 or 1

4.2 Radiopharmaceutical Therapy Infrastructure for Inpatients

Given the potential medical necessity to admit patients undergoing radiopharmaceutical therapy due to unforeseen events, the organization should possess adequately shielded inpatient areas. This ensures

that patients who have received or require a radiopharmaceutical treatment can be observed with minimized exposure risks to the public and staff. Furthermore, proper designation of these spaces, comprehensive shielding, clear signage, staff education and protective measures are essential components to safeguard both patients and staff.

Key Quality Indicator #27	Indicator Measure
The Radiopharmaceutical Therapy program has access to adequately shielded inpatient rooms with 24/7 care support. Staff in this area are trained in caring for patients treated with a Radiopharmaceutical therapy.	0 or 1

4.3 Radioactive Waste Management

The proper management of radioactive waste is crucial within an organization that utilizes open source radioactivity. This involves an area for the strict segregation, security, and shielding of radioactive materials and waste. The space should be dedicated solely to this purpose, ensuring that these materials are kept distinctly apart from regular trash. In addition to this, locking mechanisms for these exclusive storage areas are essential, along with precise shielding tailored to the type and volume of radioisotopes in use. To maintain safety, regular audits, staff training, and adherence to safety guidelines are of utmost importance.

Key Quality Indicator #28,29	Indicator Measure
The organization that performs radiopharmaceutical therapy possesses secured space for radioactive waste management, complemented by shielding and staff training.	0 or 1
The organization that performs radiopharmaceutical therapy utilizes a waste management system designed for efficient tracking and auditing of radioactive waste.	0 or 1

5. Equipment and Instrumentation

Radiopharmaceutical therapy equipment includes molecular imaging equipment, radiation safety equipment, radiopharmacy, radiotherapy suites and all major accessories used in the Radiopharmaceutical Therapy program. Specifically, this includes all SPECT/CT, PET/CT, dose calibrators, computer systems, electronic information systems that are integrated with the above equipment, and other calibration and quality assurance devices used in relation to the above equipment.

5.1 Equipment and Quality Control Procedures

Effective and safe radiopharmaceutical therapy requires meticulous attention to equipment and its associated quality control. This encompasses specific testing protocols, regular monitoring, and maintenance routines for imaging, treatment instrumentation, and major accessories. Comprehensive procedures should elucidate the test types, their frequency, individual qualifications for those conducting tests, allowed tolerances, and responsive strategies if tests reveal deviations. Notably, this includes calibration methods to ensure quality in molecular imaging devices.

Key Quality Indicator #30	Indicator Measure
The Radiopharmaceutical Therapy program consistently follows detailed quality control procedures for all imaging, treatment, and major accessories, ensuring optimal performance and safety standards.	None (0) Some (0.25) Most (0.75) All (1)

5.2 Oversight of Equipment Quality Control

The holistic integrity of radiopharmaceutical therapy equipment is underpinned by vigilant oversight. A dedicated committee, which could be a Radiopharmaceutical Therapy Quality Assurance Committee (RTQAC), or radiation safety committee (or similar), plays a pivotal role in this context. This entity is tasked with monitoring a variety of equipment performance indicators, ensuring commitment to all established quality control procedures, and validating that comprehensive documentation is consistently maintained. The overarching objective is to safeguard the high caliber and safety of the equipment, which directly influences patient outcomes. Although not required, this would ideally be achieved through a quality control dashboard for quick review and easy trend analysis.

Key Quality Indicator #31	Indicator Measure
The Radiopharmaceutical Therapy program has a dedicated committee (or segment within an existing committee) that actively supervises equipment quality control activities, endorsing both quality and safety standards.	0 or 1

5.3 Introduction of New Equipment and Procedures

Introducing new equipment, whether hardware or software, into clinical service necessitates a well-defined approach. Before the commencement of clinical use, quality control measures are established, and acceptance tests are performed where required. Crucially, personnel who engage in the calibration, operation, or maintenance of the device undergo specialized training. This encompasses understanding radiation safety implications related to the equipment and responding aptly to emergencies stemming from equipment failures or complications with major accessories.

Key Quality Indicator #32, 33	Indicator Measure
For the introduction of new equipment (hardware and/or software), the implementation of a quality control procedure/process is ensured prior to the commencement of clinical usage.	None (0) Some (0.25) Most (0.75) All (1)
When introducing new equipment (hardware and/or software), it's mandatory for all involved personnel to receive appropriate and comprehensive training.	None (0) Some (0.25) Most (0.75) All (1)

5.4 Equipment Obsolescence

It is crucial that equipment and software utilized in the field of nuclear medicine are current and meet the requisite standards of patient care. When equipment or software becomes obsolete, meaning it no longer aligns with the contemporary demands and standard-of-care practices, it is promptly earmarked for either an upgrade or a full replacement. Reports such as the Nuclear Medicine Equipment Life Expectancy Study (June 2014) from the Canadian Association of Nuclear Medicine (CANM) or similar documents from other recognized organizations should be used as a guide where appropriate.

Key Quality Indicator #34	Indicator Measure
Percentage of major pieces of equipment (SPECT/CT, PET/CT, and Gamma Cameras) that are less than 10 years old.	Score Range: 0-1 [0-100% / 100]

5.5 External Calibration or Dosimetry Audit

Within the realm of radiopharmaceutical therapy, ensuring the precision and safety of equipment is crucial. A tool in this pursuit is the conduct of independent calibration and dosimetry audits on an annual basis. These audits are crafted to verify the accuracy of the equipment and guarantee that they are functioning within the desired parameters. Moreover, by subjecting the equipment to an independent assessment, any discrepancies, no matter how minor, can be identified and rectified promptly. Such a practice not only bolsters the trust in the equipment's capabilities but also upholds the safety and well-being of patients. The results of this audit are reviewed with the Radiopharmaceutical Therapy program's leadership, along with the committee responsible for quality assurance.

Key Quality Indicator #35	Indicator Measure
The Radiopharmaceutical Therapy program commits to conducting an independent calibration and dosimetry audit every year, ensuring the continuous accuracy and safety of its equipment.	0 or 1

6. Policies and Procedures

6.1 Practice Guidelines and Manuals

6.1.1 Policy and Procedure Manual

The cornerstone of a proficient Radiopharmaceutical Therapy program lies in its comprehensive and well-maintained policy and procedure manual. This document serves as the definitive guide for the clinical care aspects, operational management, and procedural protocols of the program. It underscores the importance of systematic updates, incorporating a regular review cycle to reflect the evolving landscape of radiopharmaceutical therapy, including advancements in clinical practice and regulatory compliance. The manual ensures that all staff members are equipped with current, clear, and standardized instructions for delivering high-quality patient care.

Key Quality Indicator #36	Indicator Measure
Policies and procedures have a planned review date, with a regular planned review cycle, ideally this occurs annually.	0 or 1

6.1.2 Clinical Practice Guidelines

For a Radiopharmaceutical Therapy program to be truly effective, its actions, procedures, and principles must be guided by the best available evidence. A collaboration with multidisciplinary disease teams and the interprofessional cancer program ensures this by promoting adherence to evidence-based clinical practice guidelines. Beyond mere adoption, it's imperative that the program possesses mechanisms for the selection, consistent implementation, and periodic review of these guidelines to ensure they reflect the latest research and are aligned with best practices. Additionally, an essential aspect of this alignment is the capability to navigate and resolve potential conflicts or discrepancies stemming from different recommendations.

Key Quality Indicator #37	Indicator Measure
The Radiopharmaceutical Therapy program collaboratively establishes processes for the selection, consistent implementation, and regular reassessment of clinical practice guidelines, ensuring that they remain updated and aligned with the most recent findings and best practices.	0 or 1

6.1.3 Multidisciplinary Cancer Rounds for Radiopharmaceutical Therapy

The integration of multidisciplinary cancer rounds in the radiopharmaceutical therapy process is pivotal for validating and enhancing the treatment pathway. These rounds bring together diverse medical professionals from various specializations to collectively review and confirm the proposed radiopharmaceutical therapy plans. Such collaborative meetings foster a holistic approach to patient care, encourage the sharing of knowledge and expertise, and help ensure that every aspect of the patient's condition and treatment options is thoroughly considered. The presence of oncologists, nuclear medicine physicians, physicians with expertise in radiopharmaceutical therapy, radiologists, pathologists, and other specialists in these discussions underscores the program's dedication to delivering care that is both comprehensive and consensus-driven.

Key Quality Indicator #38	Indicator Measure
Proportion of complex radiopharmaceutical therapy cases are reviewed in multidisciplinary rounds.	None (0) Some (0.25) Most (0.75) All (1)

6.1.4 Expert Physician Presence at Disease Site Rounds

In the context of radiopharmaceutical therapy, the presence of physicians with specialized expertise in radionuclide therapy and molecular imaging during disease site rounds is essential. These experts contribute significant value by providing insights specific to radiopharmaceutical therapy and associated

imaging, ensuring that this treatment modality is considered appropriately in the patient's care plan. Their participation ensures that all relevant clinical aspects of radiopharmaceutical therapy and imaging are integrated into the broader treatment discussion, fostering a comprehensive approach to disease management that leverages the full spectrum of available therapeutic options.

Key Quality Indicator #39	Indicator Measure
Attendance rate of radiopharmaceutical therapy specialists at applicable disease site rounds	None (0) Some (0.25) Most (0.75) All (1)

6.2 Wait-Time Monitoring for Radiopharmaceutical Therapy and Molecular Imaging

To deliver top-tier care in the domain of radiopharmaceutical therapy and molecular imaging, a commitment to timeliness is crucial. Patients, based on the urgency and clinical necessities of their condition, should not be kept waiting. Thus, it becomes important for programs to not only be cognizant of wait-times but to track and monitor them systematically. This proactive approach ensures that service delivery remains prompt and reflects the immediate needs of the patient, maintaining the integrity of the care pathway and patient trust.

Key Quality Indicator #40, 41	Indicator Measure
The organization employs a well-defined method, be it internally devised or externally adopted (ex. provincial), to ascertain and adhere to wait-time targets in the delivery of radiopharmaceutical therapy and molecular imaging services.	0 or 1
Percentage of PET/CT performed within target.	Score Range: 0-1 [0-100% / 100]

6.3 Individual Safety Policies and Procedures

6.3.1 Patient Identification

In the intricate world of medical services, even the smallest errors in patient identification can lead to detrimental outcomes. To mitigate these risks, it's vital that institutions have stringent protocols in place to verify the identities of their patients. This involves the consistent use of at least two person-specific identifiers. By employing these dual checks, healthcare providers can significantly bolster the accuracy and safety of their services, ensuring that each patient receives the specific care intended for them.

Key Quality Indicator #42	Indicator Measure
The healthcare institution utilizes at least two person-specific identifiers, to ascertain the accurate identity of patients and ensure they receive the intended medical services or procedures.	0 or 1

6.3.2 Authorization of Radiopharmaceutical Therapy Procedures

A robust framework of checks and balances is required when delivering radiopharmaceutical therapy. Ensuring that every therapy, modification to a previously approved treatment plan, or any change in course is diligently authorized guarantees optimal patient safety and treatment efficacy. This systematic approach not only serves as a protective measure for patients but also solidifies the integrity and accountability of the care provider. Central to this framework is the inclusion of processes like physician-signed orders that must explicitly mention the activity, thereby reinforcing the sanctity of the authorization protocol.

Key Quality Indicator #43	Indicator Measure
The Radiopharmaceutical Therapy program implements an authorization process for therapies, which mandates a physician-signed order, explicitly specifying the activity or absorbed dose (if applicable), before commencing any treatment or course.	0 or 1

6.3.3 Pregnancy Status and Breastfeeding Guidelines Prior and Post Radiopharmaceutical Treatment

Radiopharmaceutical therapy, while offering therapeutic benefits, comes with specific risks, particularly for patients of reproductive age. It is vital to have procedures ensuring that pregnancy status is known for patients within this age group prior to initiating therapy. Additionally, it's imperative that these patients receive comprehensive guidance about the requisite precautions, especially when it pertains to breastfeeding following therapy. Such steps ensure that potential risks are minimized, and patients are well-informed to make appropriate decisions regarding their health and that of their potential offspring, and young children.

Key Quality Indicator #44	Indicator Measure
The Radiopharmaceutical Therapy program has a thorough screening processes for pregnancy in patients of reproductive age prior to Radiopharmaceutical therapy.	0 or 1

6.4 Patient Engagement and Education

6.4.1 Informed Consent

The process of informed consent for radiopharmaceutical therapy is a cornerstone of ethical patient care, upholding patient autonomy and ensuring clear understanding of the treatment. It is a comprehensive practice that necessitates conveying information about the proposed therapy, available alternatives, expected outcomes, and potential adverse effects in a manner that is readily understandable. This practice honors patient individuality by considering cultural beliefs and values, allowing ample time for reflection, thoroughly addressing any patient queries, and ensuring that the consent is documented meticulously in the patient's medical records.

Key Quality Indicator #45	Indicator Measure
There is documentation of informed consent for Radiopharmaceutical therapy prior to the delivery of treatment.	0 or 1

6.4.2 Patient Education

Ensuring patients and their families are well-informed about all aspects of radiopharmaceutical therapy is an integral part of patient-centered care. This involves a multifaceted approach to education, spanning from the initial planning stages through to the treatment delivery, management of side effects, and the follow-up care. Utilizing a combination of written or digital resources and direct verbal communication ensures that the information is accessible. The approach is personalized, respectful of cultural beliefs, mindful of literacy levels, language preferences, and the diverse functional abilities of patients and their families.

Key Quality Indicator #46	Indicator Measure
The Radiopharmaceutical Therapy program provides written or online educational materials about radiopharmaceutical therapy planning, treatment delivery, side effects, and follow-up to patients and their families.	0 or 1

6.5 Radiopharmaceutical Therapy Physician Peer Review

In radiopharmaceutical therapy, the incorporation of a thorough peer review process is deemed important for safeguarding patient safety and treatment efficacy. This process involves evaluation by a team of physicians and medical physicists, all with specialized expertise in radiopharmaceutical therapy, focusing primarily on therapy plans with substantial therapeutic potential. The central goal is to ensure the judicious selection of radiopharmaceutical doses, with a keen eye on the ramifications of any dose-related inaccuracies. Conducting these reviews before the commencement of the treatment is ideal to preempt any issues. Furthermore, the program should embrace a flexible policy to periodically review treatments oriented towards symptom relief or conservative therapeutic goals, which are crafted according to the unique needs of the practice.

Key Quality Indicator #47, 48, 49	Indicator Measure
The Radiopharmaceutical Therapy program has a process for peer review of complex therapy cases, particularly where individual dosimetry assessment or dose adjustment is required, to confirm dosing accuracy and therapeutic appropriateness.	0 or 1
The Radiopharmaceutical Therapy program has a systematic approach for the random or targeted selection of radiopharmaceutical therapy cases for peer review, ensuring a comprehensive quality check across varying case complexities.	0 or 1
The Radiopharmaceutical Therapy program has a process to record the analysis of peer review outcomes, such as recommendations for changes in radiopharmaceutical therapy plans. Results from this process feed in to programmatic continuous improvement where applicable.	0 or 1

6.6 Review of Treatment

The sphere of radiopharmaceutical therapy demands thorough and meticulous validation of treatment plans and dose calculations. To uphold this standard, stringent verification measures require an independent assessment by an alternate registered professional before any treatment is administered. This verification encompasses detailed examinations to affirm that the patient is the correct candidate for the treatment, verifying patient identity, ensuring dose accuracy, cross-checking associated medications where required, and confirming patient preparedness. A formalized procedure must clearly specify all essential verification actions to minimize errors and guarantee superior patient treatment quality.

Key Quality Indicator #50	Indicator Measure
A verification process by a second registered health care professional is in place, covering all critical aspects of radiopharmaceutical therapy administration, with the procedure being well-documented and executed before the commencement of the treatment.	0 or 1

6.7 Radiopharmaceutical Treatment Emergencies and Personnel Availability

6.7.1 Physician and Radiation Safety Availability

A physician with expertise in radiopharmaceutical therapy and a radiation safety specialist are present at the radiopharmaceutical therapy facility, or are readily available and capable of responding within an appropriate time limit set by the Radiopharmaceutical Therapy program, whenever any radiopharmaceutical therapy treatment is delivered. A medical physicist, though not required on-site, should be available to respond within the program's specified time frame, ensuring immediate expert support during radiopharmaceutical therapy treatments.

Key Quality Indicator #51	Indicator Measure
A physician specialized in Radiopharmaceutical therapy and radiation safety specialist are on-site, and the medical physicist is available to respond within the program's set time limit.	0 or 1

6.7.2 Emergency Protocols for Post-Radiopharmaceutical Therapy Care

For a Radiopharmaceutical Therapy program, the implementation of a comprehensive emergency care response is required even though it may not be frequently used. This extends beyond immediate response actions to include effective patient identification systems that flag individuals who have received radiopharmaceutical therapy. A multilayered approach should be established, integrating patient education to ensure self-identification, alongside robust electronic medical records that clearly mark the administration of radiopharmaceutical treatments. This dual approach ensures rapid recognition and appropriate management of post-therapeutic emergencies, facilitating prompt isolation procedures and deployment of trained personnel. The program must also maintain designated, equipped spaces for the secure treatment of patients in need of urgent care that reduce radiation exposure risk to others.

Key Quality Indicator #52	Indicator Measure
The Radiopharmaceutical Therapy program incorporates a definitive emergency protocol for patients that may require emergency/urgent care or admission post therapy.	0 or 1

6.8 Outcomes

6.8.1 Radiopharmaceutical Therapy Records

The effectiveness, safety, and continuity of radiopharmaceutical therapies rely heavily on record management. This includes the maintenance of detailed records that capture patient care, ranging from medical history and diagnostic findings to education, consent, treatment specifics, in-treatment assessments, and follow-up outcomes. Adherence to prescribed archival durations in compliance with regional and national directives, as well as the safeguarding of patient privacy and record confidentiality, forms the backbone of a robust Radiopharmaceutical Therapy program's operational integrity.

Key Quality Indicator #53	Indicator Measure
The Radiopharmaceutical Therapy program has record-keeping protocols, capturing patient journey from consent to post-treatment follow-up, while adhering to privacy standards.	None (0) Some (0.25) Most (0.75) All (1)

6.8.2 Medical Review of Patients Receiving Radiopharmaceutical Therapy

The Radiopharmaceutical Therapy program ensures patient oversight through efficient medical reviews and checks, which include pre- and post-therapy evaluations like bloodwork, imaging, and symptom assessments. A streamlined system enables quick access to medical professionals for both scheduled oversight and unforeseen concerns, fostering a comprehensive and responsive care environment.

Key Quality Indicator #54	Indicator Measure
The proportion of radiopharmaceutical therapy patients who undergo a complete set of evaluations — including but not limited to bloodwork, imaging studies, and symptom tracking — before and after treatment, as well as having access to medical reviews by specialists where required.	None (0) Some (0.25) Most (0.75) All (1)

6.8.3 Analysis of Clinical Outcomes

The Radiopharmaceutical Therapy program is dedicated to outcome analysis, equipped with expert personnel, information systems, and necessary infrastructure to conduct regular audits. This framework is pivotal for assessing clinical outcomes such as treatment side effects, efficacy, patient survival, and quality of life, ensuring alignment with treatment objectives.

Key Quality Indicator #55	Indicator Measure
The Radiopharmaceutical Therapy program has a process to conduct comprehensive audits to assess key clinical outcomes.	0 or 1

6.8.4 Standardization in Radiopharmaceutical Therapy Dosimetry

With diverse radiopharmaceutical types, including beta-particle, alpha-particle, and Auger-electron emitters, radiopharmaceutical therapy has seen significant advances. However, clinical optimization and comparisons are challenged by the lack of standardized dosimetric practices. Adhering to guidelines, such as those in ICRU Report 96, ensures harmonization in the prescription, documentation, and reporting of radiopharmaceutical therapy dosimetry, crucial for effective therapy alone or in combination with other modalities. This adherence includes employing standardized definitions and procedures for activity quantification, applying bioeffect models, and understanding the radiobiological implications to enhance treatment precision and inter-center comparability while mitigating normal tissue toxicity.

Key Quality Indicator #56	Indicator Measure
The Radiopharmaceutical Therapy program's adherence level to ICRU Report 96 guidelines and reporting measures to enhance the accuracy and safety of radiopharmaceutical therapies.	None (0) Some (0.25) Most (0.75) All (1)

6.9 Accreditation

A Radiopharmaceutical Therapy program is characterized by its adherence to stringent quality and safety standards as defined by leading accreditation bodies. This involves a dual-layered commitment to both national and specialized accreditation standards that dictate best practices in patient care. By securing accreditation through esteemed bodies such as Accreditation Canada and the SNMMI Radiopharmaceutical Therapy Accreditation program, the program demonstrates a pledge to excellence in therapy delivery, patient safety, and continuous quality improvement. Such accreditations serve as benchmarks of excellence and assure patients and stakeholders of the program’s adherence to high standards of clinical care and operational management.

Key Quality Indicator #57	Indicator Measure
The Radiopharmaceutical Therapy program is committed to maintaining the highest quality of care and safety standards by actively pursuing and upholding accreditation through respected and recognized radiopharmaceutical therapy accreditation programs.	0 or 1

6.10 Importance of Technical Consistency

The Radiopharmaceutical Therapy program places a strong emphasis on adherence to established technical standards, ensuring a consistent and high-quality level of patient care across the institution. By following rigorously defined protocols and guidelines, the program demonstrates a commitment to maintaining a standard of excellence and uniformity in treatment delivery. The proactive alignment with these standards underscores the program's dedication to best practices and patient safety within the scope of existing frameworks.

Key Quality Indicator #58	Indicator Measure
Conformity to Established Technical Standards	None (0) Some (0.25) Most (0.75) All (1)

6.11 Commitment to Continuous Improvement Through Research

The Radiopharmaceutical Therapy program recognizes the value of engaging in diverse types of research, each contributing uniquely to the advancement of the field. Whether it's through clinical trials, operational research, academic collaborations, or exploring new treatment methodologies, the program participates in research initiatives that align with its capabilities and goals.

Key Quality Indicator #59	Indicator Measure
Engagement in Research Activities in Radiopharmaceutical Therapy	0 or 1

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