



THE  
COLLEGE  
OF  
PHYSICIANS  
AND  
SURGEONS  
OF  
ONTARIO

# INDEPENDENT HEALTH FACILITIES

## Clinical Practice Parameters and Facility Standards



**Nuclear Medicine – November 2018**

(including PET/CT procedures)

## **College of Physicians and Surgeons of Ontario Mandate**

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The College of Physicians and Surgeons of Ontario (CPSO) regulates the practice of medicine in Ontario. Physicians are required to be members to practice medicine in Ontario. The role of the CPSO and its authority and powers are set out in the *Regulated Health Professions Act (RHPA)*, the *Health Professions Procedural Code* under the *RHPA* and the *Medicine Act*.

### **What we do:**

**Registration** – Physicians are required to be members of the College to practise medicine in Ontario. The College’s Registration Department handles all inquiries regarding the registration process.

**Quality** - CPSO has a legislated mandate to continuously improve the quality of care provided by physicians. We monitor and maintain standards of practice through peer assessment and remediation

**Investigations & Discipline** - A central responsibility of the CPSO is to respond to concerns and to investigate complaints from members of the public about doctors in Ontario. If necessary, cases are referred to the Discipline Committee .

**Guiding Professional Conduct** - Develop policies to provide guidance to physicians about legislative/regulatory requirements and the expectations of the medical profession.

### **Our Mission**

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***Serving the people of Ontario through effective regulation of medical doctors***

### **Our Regulatory Principles**

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We commit to being accountable, respectful and responsive.

We will demonstrate professionalism and excellence.

We will value communication and compassion.





# **Independent Health Facilities**

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## **Clinical Practice Parameters and Facility Standards**

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*Nuclear Medicine – November 2018*

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## Preface

The Independent Health Facilities Act (IHFA), proclaimed in April 1990, last amended in 2011, gives the College of Physicians and Surgeons of Ontario (CPSO) the primary responsibility for carrying out quality assessments in Independent Health Facilities. These non-hospital facilities may provide some of the following insured services:

- in diagnostic facilities: radiology, ultrasound, magnetic resonance imaging (MRI), computed tomography (CT), nuclear medicine, positron emission tomography (PET), pulmonary function, and sleep studies
- in treatment or surgical facilities: one or more of a variety of procedures in peripheral vascular disease, plastic surgery, obstetrics and gynaecology, dermatology, nephrology, ophthalmology, and their related anaesthetic services and perhaps other specialties.

The College of Physicians and Surgeons of Ontario has a legislative mandate under the Act to perform quality assessment and inspection functions. This responsibility, and others set out by agreement with the Ministry of Health (MOH), contribute to the College achieving its goals as stated in the College's Mission Statement. An important goal of the College is to promote activities which will improve the level of quality of care by the majority of physicians. The Independent Health Facilities (IHF) program helps reach this goal by developing and implementing explicit clinical practice parameters and facility standards for the delivery of medical services in Ontario, assessing the quality of care provided to patients, and as a result, promotes continuous quality improvement.

## Purpose of Clinical Practice Parameters

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The Independent Health Facilities Clinical Practice Parameters and Facility Standards are designed to assist physicians in their clinical decision-making by providing a framework for assessing and treating clinical conditions commonly cared for by a variety of specialties. The primary purpose of this document is to assist physicians in developing their own quality management program and act as a guide for assessing the quality of patient care provided in the facilities.

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***Note: The parameters and standards are not intended to either replace a physician's clinical judgment or to establish a protocol for all patients with a particular condition. It is understood that some patients will not fit the clinical conditions contemplated by certain parameters and that a particular parameter will rarely be the only appropriate approach to a patient's condition.***

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In developing these Clinical Practice Parameters, the objective is to create a range of appropriate options for given clinical situations, based on the available research data and the best professional consensus. The product, therefore, should not be thought of as being "cast in stone", but rather subject to individual, clinically significant patient differences.

The IHF Clinical Practice Parameters and Facility Standards, including any referenced guidelines, protocols, standards, and Acts, e.g. *Healing Arts Radiation Protection (HARP) Act*, Provincial Infectious Diseases Advisory Committee (PIDAC), are used by the CPSO to inform its assessments processes, as well as decisions by the CPSO Facility Review Panels.

## **Role of the College of Physicians and Surgeons of Ontario**

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The College adopted the role of a facilitator for the development of these Clinical Practice Parameters and Facility Standards. Representatives of national specialty societies and sections of the Ontario Medical Association, and individuals with acknowledged skill, experience and expertise formed specialty-specific Task Forces.

All Clinical Practice Parameters and Facility Standards undergo an external review process.

**External Reviewers include:** Registrars of other regulatory colleges, department heads at relevant academic institutions, relevant national and provincial organizations, independent health facilities, IHF assessors and other stakeholders as determined by the relevant Task Force.

Task Force members ensure that:

- clinical practice parameters are based on the appropriate mix of current, scientifically-reliable information from research literature, clinical experience and professional consensus
- any parameter-setting exercises are done exclusively from the quality perspective. That may well mean that some of the conclusions reached could add to medical care costs
- parameters are flexible enough to allow for a range of appropriate options and need to take into account the variations in practice realities from urban to rural areas
- parameters are developed by consensus and consultation with the profession at large
- parameters provide support and assistance to physicians without boxing them in with “cookbook formulas”
- parameters are regularly updated based on appropriate research studies
- parameters help to reduce uncertainty for physicians and improve their clinical decision-making
- information on practice parameters is widely distributed to ensure that all physicians benefit from this knowledge

## **Responsibilities of the College**

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Responsibilities of the College include:

- assessing the quality of care when requested by the Ministry. The College will maintain a roster of physicians, nurses, technologists and others to serve as inspectors and assessors as required
- inspecting the illegal charging of facility fees by unlicensed facilities when requested by the Ministry
- monitoring service results in facilities. The College’s information system will monitor individual and facility outcome performance. This is a unique feature of the IHFA, which for the first time in North America, requires facility operators to establish and

maintain a system to ensure the monitoring of the results of the service or services provided in a facility

- providing education and assisting facilities so that they may continually improve the services they provide to patients. The College will work with and assist physicians in these facilities so that they can develop their own Quality Management Programs based on the parameters and standards, monitor facility performance by conducting quality assessments, work with facilities to continually improve patient services, assist in resolving issues and conducting reassessments as necessary

## Updating this Document

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These parameters and standards are subject to periodic review, and amendments may be issued from time to time. Notifications of such updates will be mailed automatically to all relevant Independent Health Facilities. A comprehensive review and update of the parameters and standards will be undertaken at intervals not greater than five years. The external review process will be repeated to validate the new parameters as they are developed.

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***Note: Facilities must remain up-to-date with all information contained in this document, including externally-sourced material, such as content from outside organizations, as well as information made available via hyperlinks. In addition, while the CPSO reviews and updates externally sourced materials and hyperlinks in this document at regular intervals, it is possible that links may become broken or invalid over time. If that occurs, facilities are encouraged to source the updated links on their own.***

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# **Independent Health Facilities: Clinical Practice Parameters and Facility Standards**

## ***Nuclear Medicine***

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### **VOLUME 1 FACILITY STANDARDS**

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# Chapter 1 Staffing a Facility

## 1.1 Overview

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Each licensee in consultation with the Quality Advisor (QA) ensures the following:

- There is a current written plan describing the organization of the facility and its services.
- There are sufficient numbers of qualified physicians, medical radiation technologists (MRTs), and other clinical or clerical personnel available to meet the stated goals and objectives.
- Facility staff (i.e. regulated health professionals (RHPs)) have the appropriate education and experience including any certifications, examinations, courses and/or other training to perform their specific services and procedures, taking into account the requirements of the Canadian Nuclear Safety Commission (CNSC). This includes an annual review of each RHP's continuing professional development (CPD) to ensure each RHP's CPD meets their regulatory body's CPD requirements. Documentation that confirms the aforementioned must be kept up-to-date and on site.
- Physicians must be licensed to practice in Ontario by the CPSO in order to refer to themselves as physicians or doctors in any setting, including an IHF. In order to practise in Ontario, MRTs must be registered with the College of Medical Radiation and Imaging Technologists of Ontario (CMRITO).
- The duties and responsibilities of all nuclear medicine imaging staff are specified in job descriptions. They are kept up to date and on site.
- Quality Advisors, physicians, MRTs, and licensees review their legal obligations to obtain professional liability insurance, and if it is legally required, it must be documented and maintained on site. If it is not a legal requirement, obtaining professional liability insurance may be considered, as there is potential for liability issues in IHFs.
- The Licensee, Quality Advisor and staff working in the IHF are up-to-date on the standards for infection prevention and control, and have an ongoing process to ensure current infection and prevention control practices are reflected in staff orientation/training ([3.3.2](#)), infection prevention and control policies and procedures ([3.3.8](#)), as well quality management ([5.1](#)). To meet this requirement, facilities must, at a minimum, review the following:
  - Public Health Ontario's newsletter, which informs subscribers about updates to Provincial Infectious Diseases Advisory Committee (PIDAC) documents. To sign up for newsletters, use the following link: <https://www.publichealthontario.ca/en/EUM/Pages/Register.aspx>
  - Public Health Ontario's Infection Prevention and Control online training courses: [IPAC Core Competencies Course](#) and [Reprocessing in Community Health Care Settings Course](#).
- Staff responsible for cleaning, disinfecting, sterilizing, and/or reprocessing of medical equipment must complete adequate education and training, including

manufacturer's training. To determine appropriate training, the Quality Advisor must complete the [Infection Prevention and Control's Checklist for Infection Prevention and Control \(IPAC\) CORE Elements in Clinical Office Practice](#) and if applicable, also complete the [Checklist for Reprocessing of Medical Equipment/Devices in Clinical Office Practice](#).

- Staff obtains education/training (which is documented and maintained on site) in areas mandated by the Ontario Government, such as the following:
  - Workplace Hazardous Materials Information System 2015 (WHMIS 2015);
  - Health and safety awareness;
  - Workplace violence and sexual harassment, and;
  - Accessibility for Ontarians with Disabilities
- There is a Joint Health and Safety Committee (based on number of workers). Refer to the [Guide for Health and Safety Committees and representatives](#).
- Staff are familiar with and understand radiation safety, privacy and confidentiality legislation and applicable site policies.
- At least one staff member with current Basic Life Support (BLS) certification is on site at all times during hours of operation. Documentation regarding BLS certification is maintained on site. It is expected that the training includes being certified in both theory and hands-on components.

## 1.2 Qualifications of Interpreting Physicians

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Physicians must have a current, valid and active certificate of registration with the College of Physicians.

Nuclear medicine services are provided by physician(s):

- certified by the Royal College of Physicians of Canada (FRCPC) in Nuclear Medicine
- or**
- approved by the Registration Committee of the College of Physicians and Surgeons of Ontario to practice independently in Nuclear Medicine (Refer to the [CPSO Specialist Recognition Criteria in Ontario policy](#) for more information).
- or**
- approved or in the process of being supervised through the College of Physicians and Surgeons of Ontario for a change in scope of practice to report nuclear medicine studies in an IHF setting – specifically, [Radiologists Intending to Interpret and Supervise Nuclear Medicine Studies in Independent Health Facilities](#), and [Cardiologists Intending to Interpret Nuclear Cardiology Studies in Independent Health Facilities](#). Physicians who have been approved by the College, or are in the process of undergoing a change in scope must keep CPSO documentation on site attesting to their status.

### **1.2.1 Responsibilities of the Interpreting Physician**

Interpreting Physicians are responsible for:

- maintaining a level of competence for the range of studies being offered. This is accomplished by attending nuclear medicine review courses or conferences, reviewing current nuclear medicine literature, etc.
- contacting the Quality Advisor for advice regarding quality of care matters.
- managing any complications or problems that arise, either clinically or from the standpoint of radiation safety, and informing the Quality Advisor.
- ensuring a physician is present in the facility during studies in which the patient may require immediate medical attention or intervention, such as, but not limited to pharmacological intervention (e.g Lasix, Captopril, and CCK ) or cardiac stress testing.

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***Note: Physicians whose role is restricted to supervising stress studies or administering pharmaceuticals for enhancement procedures are not required to be certified in nuclear medicine.***

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## **1.3 Quality Advisor**

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The Quality Advisor (QA) must be a physician licensed to practice in Ontario by the College of Physicians and Surgeons of Ontario and must be:

- certified by the Royal College of Physicians of Canada (FRCPC) in Nuclear Medicine
- or**
- approved by the Registration Committee of the College of Physicians and Surgeons of Ontario to practice independently in Nuclear Medicine (Refer to the CPSO [Specialist Recognition Criteria in Ontario](#) policy for more information).

The Quality Advisor must submit the *Notice of Appointment of Quality Advisor* and *Quality Advisor Acknowledgement* forms to the Director, IHF. These forms are available at <http://www.health.gov.on.ca/en/public/programs/ihf/forms.aspx>.

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***NOTE: In instances where a facility provides more than one type of service and the Quality Advisor does not possess the appropriate specialty background associated with a particular service, then he or she must appoint a Medical Lead for each additional service (refer to 1.4).***

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### **1.3.1 Role of the Quality Advisor**

The role of the Quality Advisor is an important one. Quality Advisors play a vital role in the overall operation of the IHF to ensure that the services provided to patients are being conducted appropriately and safely.

Each IHF licensee is responsible for operating the facility and providing services in accordance with the requirements of the IHFA. Pursuant to Ontario Regulation 57/92 under the

*Independent Health Facilities Act (see [Appendix I](#))*, “every licensee is required to appoint a Quality Advisor to advise the licensee with respect to the quality and standards of services provided in the IHF. The Quality Advisor must be a **physician** who ordinarily provides insured services in or in connection with the facility and whose training enables him or her to advise the licensee with respect to the quality and standards of services provided in the facility”.

### **1.3.2 Duties and Responsibilities of a Quality Advisor**

The Quality Advisor is responsible for advising the licensee with respect to the quality and standards of services provided. To fulfill this duty the Quality Advisor:

- Shall personally attend the facility at least twice each year, and may attend more frequently, where in the opinion of the Quality Advisor it is necessary based on the volume and types of services provided in the facility. The visits may be coordinated as part of the Quality Advisory Committee (QA Committee) meetings.
- Shall document all visits to the facility made in connection with the Quality Advisor’s role.
- Shall ensure that a qualified physician be available for consultation during the facility’s hours of operation.
- Shall seek advice from other health professionals where in the opinion of the Quality Advisor it is necessary to ensure that all aspects of the services provided in the facility are provided in accordance with generally accepted professional standards and provide such advice to the licensee.
- Shall chair the QA Committee. The QA Committee shall meet at least twice a year, or more often, as needed. Regular agenda items should include: review of cases; policies and procedures; quality control matters on equipment; incidents, medical and technical issues.
- Shall ensure all QA Committee meetings are documented.
- Obtain copies of assessment reports from the licensee/owner/operator. If deficiencies were identified in the assessment, the Quality Advisor shall review same with the QA Committee and document such review. The Quality Advisor’s signature is required on any written plan submitted by the licensee to the College.

The Quality Advisor shall advise the licensee on the implementation of an ongoing Quality Management (QM) Program, which should include, but not be limited to, the following:

- Ensuring ongoing and preventive equipment maintenance.
- Follow-up of interesting cases.
- Follow-up of patient and/or medical and technical staff incidents.
- Continuing education for medical and technical staff.
- Ensuring certificates of registration, BLS, etc. are current.
- Regular medical and technical staff performance appraisals.
- Patient and referring physician satisfaction surveys.

The Quality Advisor will advise the licensee, and document the provision of such advice, in connection with the following:

- **Health professional staff hiring decisions**, in order to ensure that potential candidates have the appropriate knowledge, skill and competency required to provide the types of services provided in the facility.
- **Continuing education** for all health professional staff members employed in the facility, as may be required by their respective regulatory Colleges or associations.
- **Appropriate certification** for all health professional staff members employed in the facility with the respective regulatory Colleges or associations.
- **Leadership** as may be required to address and resolve any care-related disputes that may arise between patients and health professional staff.
- **Appropriate resources** for health professional staff members employed in the facility.
- **Formal performance appraisals** for all health professional staff.
- **Technology** used in the facility, in order to ensure it meets the current standard(s) and is maintained through a service program to deliver optimal performance.
- **Establishment and/or updating of medical policies and procedures** for the facility, e.g., consultation requests, performance protocols, infection control, and standardized reports, and other issues as may be appropriate.
- **Equipment and other purchases** as may be related to patient care.
- **Issues or concerns** identified by any staff member, if related to conditions within the facility, that may affect the quality of any aspect of patient care.
- **Establishing and/or updating system(s)** for monitoring the results of the service(s) provided in the facility.

#### **1.3.2.1 Quality Advisor Duty to Report to Director IHF**

If the Quality Advisor has reasonable grounds to believe the licensee is not complying with the licensee's obligation to ensure that services are being provided in accordance with the generally accepted standards and to ensure that the persons who provide services in the facility are qualified to provide those services, the Quality Advisor must inform the Director of Independent Health Facilities forthwith in accordance with the provisions and Regulations under the *Independent Health Facilities Act*.

The Quality Advisor should acknowledge, in writing, his/her role in connection with Quality Assurance.

#### **1.3.2.2 Quality Advisor Duty for Infection Prevention and Control**

In order to determine appropriate infection prevention and control training of staff, the Quality Advisor must annually complete the [Checklist for Infection Prevention and Control \(IPAC\) Core Elements in Clinical Office Practice](#), and if applicable, also complete annually the [Checklist for Reprocessing of Medical Equipment/Devices in Clinical Office Practice](#), and must verify

completion of relevant training by all staff. Evidence of completion of the Checklists must be maintained on file at the facility.

## 1.4 Medical Lead(s) for IHFs licensed by the MOH for more than one service

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According to the *Independent Health Facilities Act*, facilities are required to have one Quality Advisor noted on the IHF license. For IHFs that have been licensed for more than one service such as Diagnostic Imaging/Pulmonary Function Studies/Nuclear Medicine/Sleep Medicine, where the Quality Advisor is not a specialist in the field associated with the particular service(s), then he or she must appoint Medical Lead(s) for each additional applicable service. The Medical Lead must be a physician and either be certified by the Royal College of Physicians of Canada (FRCPC) in the specialty associated with the service, or be approved by the Registration Committee of the College of Physicians and Surgeons of Ontario to practice independently in that specialty.

The Medical Lead's role is to **assist** with IHF staff compliance with policies and procedures set out by the Quality Advisor, especially as it relates to monitoring and reporting on the quality of services.

## 1.5 Radiation Safety Officer

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The facility must have a designated radiation safety officer as required by the Canadian Nuclear Safety Commission. If the radiation safety officer is a professional other than the physician in medical charge of the facility, the physician in medical charge is available to the radiation safety officer to receive regular reports and for consultation on an emergency basis.

The RSO must be:

- A Fellow of the Royal College of Physicians and Surgeons of Canada (Nuclear Medicine Specialty), or
- A Member of the Professional Corporation of Physicians of Quebec certified as a specialist in nuclear medicine, or
- A Member or Fellow of the Canadian College of Physicists in Medicine, or
- A registered technologist certified in nuclear medicine by the Canadian Association of Medical Radiation Technologists (CAMRT) or CMRITO or by the Ordre des Techniciens en Radiologie du Quebec, or
- A person approved in writing by the CNSC. [Submission of Request to Appoint a New Radiation Safety Officer Nuclear Substances and Radiation Devices Licence](#) is required acknowledging his/her willingness to be designated as the applicant's RSO and acceptance of the responsibilities described in the submitted job description.

For additional information, please access the following sites:

- [Canadian Nuclear Safety Commission \(CNSC\)](#)
- [CNSC Nuclear Substances and Radiation Devices Licence Application Guide: Nuclear Substances and Radiation Devices](#)

### **1.5.1 Duties and Responsibilities of the RSO**

The person occupying the position of RSO has several responsibilities, including mainly ensuring that all CNSC requirements are followed whenever the activities authorized under the facility's licence are performed. RSO's responsibilities will include those duties listed in the facility's Radiation Safety Manual (RSM) and must also satisfy the [CNSC's regulatory requirements](#). Duties may include, but are not necessarily limited, to the following:

- ensuring the health and safety of personnel, the public and the environment
- managing the daily aspects of the Radiation Safety Program
- acting as the primary contact with the CNSC for licensing and compliance matters
- identifying radiation safety problems
- implementing corrective actions for identified concerns
- ensuring compliance with the CNSC regulatory requirements
- reporting regulatory non-compliances to the CNSC
- holding the authority to stop any activity that might result in a regulatory non-compliance
- developing procedures and policies related to radiation safety and training
- acting as the signing authority for CNSC licences.

## **1.6 Radiation Protection Officer**

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According to the [HARP Act](#), a Radiation Protection Officer (RPO) must be designated for the facility. This role may be assumed or designated by the Quality Advisor, with the overall responsibility on the RPO.

### **1.6.1 Duties and Responsibilities of the RPO**

The minimum roles and responsibilities of the RPO are indicated in [O. Reg. 543 the X-ray Safety Code under the Healing Arts Radiation Protection \(HARP\) Act](#). According to Section 8 of the *HARP Act*, the RPO's responsibilities include, but are not limited to:

- ensuring that every person who operates an x-ray machine in the facility is qualified to operate the machine;
- establishing and maintaining procedures and tests for the x-ray machine (s) and x-ray equipment to ensure compliance with the Regulation;
- ensuring that protective accessories of prescribed parameters are available for use by persons who may be exposed to x-rays;
- providing the Director of X-ray Safety with written results of certain tests conducted on the x-ray machine (s) and maintaining records of such tests;
- ensuring that certain procedures and tests as prescribed in the Regulation are conducted on a periodic basis; and
- ensuring that the entrance exposure of certain parts of the patient do not exceed the prescribed exposure limits; and
- notifying the Director of the occurrence of an accident involving an x-ray machine or an overexposure to radiation involving one or more patients.

The RPO plays an important role in ensuring that the safe operation of x-ray equipment in the facility, and ensuring that patients who receive x-rays are adequately protected and are not subject to unnecessary risk of overexposure to radiation.

The American College of Radiology-American Association of Physicists in Medicine (ACR-AAPM) also has a document "[ACR-AAPM Radiation Safety Officer Resources](#)" which contains numerous x-ray safety activities that the RPO may choose to implement. These activities, which are outlined below, coincide with some of the requirements under the *HARP Act*:

#### 1. Radiation Protection (ALARA) Program

- To the extent practical, the RPO should assure that the facility uses procedures and engineering controls based on sound radiation protection principles to achieve occupational doses and doses to members of the public that are in line with ALARA.

#### 2. Radiation Dose Limits

- Radiation dose limits are specified by the [X-ray Safety Code](#)

#### 3. Personal Radiation Monitors

##### a. Who must be monitored?

- Adults likely to receive greater than 5 mSv/year
- Minors (less than 18-year-old) likely to receive greater than 1 mSv/year or a lens dose equivalent in excess of 1.5 mSv
- Declared pregnant women. The fetus must not receive more than 5 mSv during the entire pregnancy
- Individuals working with medical fluoroscopic equipment.

##### b. Where must monitors be worn?

- For the dose to an embryo/fetus of a declared pregnant woman, under the protective apron at the waist.
- For the lens dose, at the neck (collar) or an unshielded location closer to the eye, outside the protective apron.
- When only one individual monitoring device is used to determine the effective dose equivalent, at the neck (collar) outside the protective apron.
- If a second individual monitoring device is used for the same purpose, under the protective apron at the waist.
- The second individual monitoring device is required for a declared pregnant woman.

#### 4. Occupational Dose Limits

##### a. Adults

##### ○ i. Annual limit of adults

- 50 mSv, however 20 mSv is recommended averaged over 5 years, with no single year exceeding 50 mSv.

##### ○ ii. Annual limits to tissues/organs include the following:

- Lens: 150 mSv;
- Skin or extremities: 500 mSv

b. Dose limits for individual members of the public

- Whole-body effective dose of 5 mSv/year. However, a maximum of 1 mSv per year is recommended.

5. General X-ray Safety Policies

Policies and procedures are required for protection of staff, as well as patients and other visitors/persons, including monitoring of X-ray utilization as it relates to BMD, SPECT CT and PET/CT.

6. Registration of Radiation Machine Facilities

Initial: New X-ray equipment must be registered with the X-ray Inspection Service (XRIS).

Changes: Changes made to equipment (such as replacement of a non-OEM (original equipment manufacturer) X-ray tube, CR to DR upgrade) require a new submission and approval to the XRIS.

7. Equipment Surveys

The RPO must have certain tests of equipment performed according to the X-ray Safety Code requirements. It is the responsibility of the RPO to ensure that competent and qualified individuals are utilized.

8. X-ray Room Shielding

New or remodeled facilities or facilities whose use changes in a way that may change radiation exposure levels must have a shielding plan developed by a qualified expert (e.g., qualified medical physicist) and, approved by the XRIS.

Records related to shielding should be maintained for inspection, including lead equivalent-thickness of shielding, machine characteristics, and measurements of radiation behind shielding materials. It is important to keep these records to verify current shielding in case a future shielding plan indicates a need to change the shielding.

Signage: As per the X-ray Safety Code, where doors are accessible to the public, a warning sign sufficient to alert persons to the presence of the x-ray equipment must be posted.

Radiation Protection Surveys may be performed and should adhere to the standards in NCRP 147 (i.e. shielding integrity and shielding adequacy evaluations).

9. X-ray Equipment Servicing and Services

Ensure the individuals who install, repair, or test X-ray equipment are qualified to perform these tasks.

10. Records

The RPO is responsible for maintaining all records required by the XRIS. Records of personnel exposure and records verifying exposure levels to the general public must be kept indefinitely. Records of surveys, calibrations, maintenance, and modifications performed on the x-ray systems are required to be kept for six years.

11. Quality Assurance Program

A quality management (QM) program typically includes the following:

- Written standard operating procedures on radiation protection and the practice of radiologic technology reviewed and updated annually by management;
- Employee review and written acknowledgement of standard operating procedures and policies on radiation protection and the practice of radiologic technology;
- Credentialing of practitioners, medical physicists, and x-ray equipment operators;
- Record retention in accordance with the HARP Act requirements.

## 12. Research Involving Radiation

Any research that uses radiation machines on humans must be approved by the Quality Advisor, and if appropriate, by an institutional review board.

## **1.7 Medical Radiation Technologists**

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In Ontario, Medical Radiation Technologists (MRTs) are self-regulated registered professionals with the College of Medical Radiation and Imaging Technologists of Ontario (CMRITO). The practice of medical radiation technology is the use of ionizing radiation, electromagnetism and other prescribed forms of energy for the purposes of diagnostic and therapeutic procedures, the evaluation of images and data related to the procedures and the assessment of the condition of the patient before, during and after the procedure.

MRTs must have a current and valid certificate of registration with the CMRITO, and should only perform the services and procedures for which they have the necessary knowledge, skills and judgement. This means that MRTs must not perform any service or procedure unless they are competent to do so, and they must maintain their competence in their practice area.

### **Medical Radiation Technologists in the specialties of Nuclear Medicine and Radiography – MRT(N) and MRT(R)**

Medical radiation technologists registered in nuclear medicine (MRT(N)) and radiography (MRT(R)) may perform bone mineral densitometry (BMD), computed tomography (CT), as well as other services or procedures which fall within the scope of practice of the profession for which they have the necessary knowledge, skills and judgement to perform the services or procedures safely and effectively.

#### ***1.7.1 Duties and Responsibilities of MRTs***

As self-regulated professionals and under the CMRITO's Standards of Practice, MRTs can practice only in those areas in which they have the education and experience, and only perform procedures for which they have the necessary knowledge, skills and judgement to perform effectively, safely and ethically. MRTs should comply with the CMRITO Standards of Practice (as described below) as well as facility policies/protocols.

MRTs are responsible for the day-to-day operation of the facility. These responsibilities include, but are not limited to the following:

1. Adhere to all relevant provincial and federal legislation and guidelines governing the practice of the profession including:
  - [CMRITO Standards of Practice](#)
  - [CMRITO Code of Ethics](#)
  - [CMRITO By-laws](#)
  - [CMRITO's sexual abuse prevention program](#)
  - *Personal Health Information Protection Act*
  - *Health Care Consent Act*
  - [Canadian Nuclear Safety Commission regulatory documents](#)
2. Adhere to the facility policies, procedure and protocols, including:
  - Quality Control assessments (e.g. nuclear medicine equipment, bone mineral densitometers, generator eluate and radiopharmaceuticals and manufacturers' product monograph. Cleaning of all equipment including ancillary equipment (e.g. resuscitation devices, gamma cameras, thyroid probes, bone mineral densitometers and stress testing equipment, computer keyboards)
  - Maintain full records of incidents, unusual occurrences, reactions
  - Record and report any equipment faults or problems to appropriate personnel
  - Ensure that equipment which comes in direct contact with the patient, such as, resuscitation devices, gamma cameras, thyroid probes, bone mineral densitometers and stress testing equipment is mechanically and electrically sound
  - Use appropriate aseptic techniques and infection prevention and control practices in the course of the diagnostic procedure as per PIDAC/IPAC best practices (refer to [3.3.8 Infection Prevention and Control policies and procedures](#)).

**Patient Examination:**

- Ensure appropriate delegations, and appropriate knowledge, skills and judgement are in place for all examinations
- Follow facility policy regarding situations where the use of chaperones may be appropriate
- Ensure the room is prepared for the procedure specified in the order
- Select and set up the equipment and materials needed for the procedure specified in the order
- Ensure correct patient identification (e.g., confirmation of patient name, date of birth, examination to be performed, and physician/authorized health professional authorization is present)
- Confirm that the order is appropriate based on the patient history
- Inquire about and record any contraindications (e.g. pregnancy/breastfeeding, anaphylaxis) before starting the exam, as well as obtain and record the direction of

the physician/authorized health professional to proceed, modify, or halt the exam as per facility policy

- Ensure that the worklist contains the correct patient information (if applicable)
- Obtain informed consent (oral or written as per facility policy) before each examination (after explaining the procedure and answering any questions)
- Ensure pertinent clinical history is available and supplement as necessary
- Follow the facility examination protocols
- Follow facility protocols when unexpected findings are found that would require immediate attention (e.g. pneumothorax)

**Throughout the Examination:**

- Assess the patient's condition before, during and after the procedure or course of treatment and make modifications to procedures or treatment based on the patient's physical, medical and/or emotional status and needs
- Instruct the patient to remove only the clothing and items that will interfere with the procedure, providing the patient with a gown or sheet to cover areas where clothing was removed and explaining to the patient when and where the MRT may touch them and why
- Maintain patient comfort, privacy and dignity at all times
- Stop procedure if at any time the patient withdraws consent and record withdrawal of consent and reason
- Use personal protection equipment (masks, gloves) and devices (e.g. lead shields) as required for the procedure and as indicated by personal risk assessment
- Ensure that the orientation of the body and other pertinent parameters are marked correctly on the image and data
- Ensure that patient examination images and data contains patient name, ID#, date of examination and type of examination
- Ensure that each patient record has the MRT identified (name in full) to verify who performed the examination
- Comply with privacy and confidentiality legislation such as the *Personal Health Information Protection Act* (Ontario).

# Chapter 2 Facilities, Equipment and Supplies

## 2.1 Overview

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The facility must have adequate space, equipment, and supplies for the safe and efficient performance of nuclear medicine services.

## 2.2 Facilities, Equipment and Supplies

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Facilities must have sufficient space to meet workload requirements and ensure the effective care and privacy of patients.

Appropriate safety precautions are maintained and documented against electrical, mechanical, and radiation hazards, as well as against fire and explosion, so that personnel and patients are not endangered. Facilities that are not latex-free must have latex-free alternative products.

There is appropriate emergency facilities/equipment for the types of services provided. The following must be available:

- Fire extinguisher
- Safety Data Sheets (SDS) information
- First Aid Kit
- Appropriate emergency cart and resuscitation equipment

Pregnancy warning signs are posted in the waiting area, change rooms and examination rooms.

### 2.2.1 Infection Prevention and Control

Basic supplies and personal protective equipment (PPE) (e.g. alcohol-based hand rub (ABHR), gloves, gowns, mask, eye protection) for infection prevention and control are readily available at point of use and used appropriately as per IPAC best practice documents. Resources are available through [the Provincial Infectious Diseases Advisory Committee of Public Health Ontario](#).

### 2.2.2 Eye Wash Stations

An eyewash station must be located in the reprocessing area. For more information about eye wash stations, refer to the [Canadian Centre for Occupational Health and Safety](#).

### 2.2.3 Radiopharmaceuticals

Radiopharmaceutical policies as outlined in the Chapter 3 on Policies and Procedures as well as Chapter 22 on Radiopharmacy Best Practices are implemented.

The quality management program meets the regulatory requirements of the Canadian Nuclear Safety Commission.

Data which result from the application of the radiopharmaceutical quality control protocols and dispensing records are retained and logged on the appropriate forms. The forms are easily understood and quickly accessible to facilitate recognition of problems as they occur. These conform to the

[Guidelines for Radiopharmaceutical Quality Assurance in Nuclear Medicine](#) published by the Health Protection Branch of Health Canada.

### **2.2.4 Instrumentation**

Instrumentation policies, as outlined in Chapter 3 *Developing Policies and Procedures*, are implemented.

## **2.3 Equipment Quality Control**

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Diagnostic equipment should be digital and meet the standard of practice.

When equipment is installed, it must undergo acceptance testing. Performance parameters are recorded for future comparisons. When equipment performance diverges from the expected results, maintenance or replacement is carried out.

### **2.3.1 Gamma Cameras**

Routine gamma camera quality control procedures must be performed, and results logged for future reference. These include, but are not limited to:

- Flood field uniformity
- Isotope energy peaking, or pulse height analysis
- SPECT centre of rotation
- Gamma camera safety systems.

These should be performed at a frequency necessary to maintain required specifications.

### **2.3.2 Well Counter, Dose Calibrator, and Survey Meters**

The well counter, dose calibrator, and survey meters are:

- compared against known reference sources at regular intervals to monitor stability and accuracy.
- checked daily against background contamination.

### **2.3.3 Dual Energy X-ray Absorptiometers (bone densitometers)**

#### **Bone Mineral Densitometry**

Facilities are encouraged to obtain facility accreditation through the [Ontario Association of Radiologists' \(OAR's\) Canadian Bone Mineral Densitometry \(CBMD\) Accreditation Program](#).

Should a facility not obtain CBMD accreditation, then the minimum required activities must include: Shewhart testing on each clinical day of operation and an up-to-date precision study for each MRT and machine. Up-to-date refers to a precision study that has met the following criteria:

- a) Precision study data is no older than 5 years
- b) New MRT is performing DXA exams on patients (at least 5% of the weekly volume)

A new precision study is to be performed if an additional unit is installed in the facility. If the additional unit is of the same make and model, then all models must be tested to allow for interchangeability between machines of the same make and model should this be desired.

[Shewhart and Precision calculators](#) are available through the Ontario Association of Radiologists website.

## 2.4 Nuclear Medicine Reporting Stations

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Please refer to Volume 4 Teleradiology (PACS).

## 2.5 Aging Equipment

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Facilities must ensure that equipment (e.g. gamma cameras) meets all quality control parameters available through the [National Electrical Manufacturers Association](#), or through the manufacturer's standards; otherwise, it may need to be replaced. Equipment used for analysis is highly computerized with continuous technical modifications that enhance patient care. It is therefore expected that equipment be kept up to date.

Equipment age should conform to the [CAR guidelines for lifecycle guidance](#) (see CAR chart) which provides a range for high-mid-low utilization for each type of equipment. The CAR guidelines also indicate that the maximum life expectancy and clinical relevance should be no longer than 15 years for any technology.

**BMD:** If a facility chooses to extend the lifecycle of its BMD machines past the [CAR Lifecycle Guidance for Medical Imaging Equipment in Canada](#) for low utilization (for BMD, it is 12 years), then the facility must obtain the services of a Qualified Medical Physicist to evaluate and determine if the units are still appropriate for routine clinical use. Evaluations must be done once every three (3) years by a Qualified Medical Physicist. The Qualified Medical Physicist may choose to delegate this work, but the final report must be signed off by the Qualified Medical Physicist.

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### **Notes:**

***(i) Refurbishing equipment does not change the age of equipment. Age of the equipment is based on the date of manufacture.***

***(ii) Facilities which have been accredited through Ontario Association of Radiologists' (OAR's) Canadian Bone Mineral Densitometry (CBMD) Facility Accreditation program will be deemed acceptable through to the end of its accreditation period. However, once the accreditation period ends, equipment must meet the CAR guidelines for lifecycle guidance based on low utilization, and is subject to the need for testing and re-certifying (if it exceeds the lifecycle for low utilization).***

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A Qualified Medical Physicist is an individual who is competent to practice independently in one or more of the subfields in medical physics. The Qualified Medical Physicist must be certified in Medical Nuclear Physics or Radiological Physics by the American Board of Radiology; in Nuclear Medicine Physics by the American Board of Medical Physics; in Nuclear Medicine Physics by the Canadian College of Physicists in Medicine; or in Nuclear Medicine Physics and Instrumentation by the American Board of Science in Nuclear Medicine.

Qualified Medical Physicists meeting this definition may be found by using the [National QMP Registry on the CRCPD \(Conference of Radiation Control Program Directors\) website](#).

**TABLE I: MI EQUIPMENT LIFE EXPECTANCY GUIDANCE (UTILIZATION AND AGE RELATED)**

Device type (analogue or digital)	Device life expectancy based on utilization:  HIGH - MID - LOW (see columns to the right)	Utilization based on exams / year		
		HIGH, e.g., 24 hours 5 days / week or 750 8-hour shifts/ year	MID, e.g., 16 hours 5 days / week or 500 8-hour shifts/ year	LOW, e.g., 8 hours 5 days / week or 250 8-hour shifts/ year
Radiography, general	10 - 12 - 14	> 20,000	10,000 - 20,000	< 10,000
Radiography, mobile	10 - 12 - 14	> 6,000	3,000 - 6,000	< 3,000
R/F fluoroscopy (conventional/remote)	8 - 10 - 12	> 4,000	2,000 - 4,000	< 2,000
R/F interventional integrated c-arm	8 - 10 - 12	> 4,000	2,000 - 4,000	< 2,000
R/F urology	8 - 10 - 12	> 1,500	750 - 1,500	< 750
Mobile C-arm (all types including O-Arms)	8 - 10 - 12	> 2,000	1,000 - 2,000	< 1,000
Angiography (1/2 plane)/ interventional	8 - 10 - 12	> 4,000	2,000 - 4,000	< 2,000
Cardiac suite (single/biplane)	8 - 10 - 12	> 3,000	1,500 - 3,000	< 1,500
CT scanner	8 - 10 - 12	> 15,000	7,500 - 15,000	< 7,500
MRI scanner	8 - 10 - 12	> 8,000	4,000 - 8,000	< 4,000
Ultrasound	7 - 8 - 9 <sup>10</sup>	> 4,000	2,000 - 4,000	< 2,000
SPECT/gamma	8 - 10 - 12	> 6,000	3,000 - 6,000	< 3,000
SPECT/CT	8 - 10 - 12	> 4,000	2,000 - 4,000	< 2,000
PET (likely replace with a different technology such as PET/CT)	8 - 10 - 12	> 6,000	3,000 - 6,000	< 3,000
PET/CT	8 - 10 - 12	> 4,000	2,000 - 4,000	< 2,000
Bone densitometry	8 - 10 - 12	> 10,000	5,000 - 10,000	< 5,000
Mammography	8 - 9 - 10 <sup>11</sup>	> 7,000	3,500 - 7,000	< 3,500
Lithotripter	8 - 10 - 12	> 3,000	2,000 - 3,000	< 2,000

**NOTES:**

- Maximum life expectancy and clinical relevance should be no longer than 15 years for any technology
- New and emerging technologies should be integrated into equipment and financial plans within the organization.

10 Some ultrasound scanners may be subject to a faster rate of obsolescence. Ultrasound requires a high level of diagnostic capability and optimum technology is considered essential.

11 Mammography units require a high level of diagnostic capability and optimum technology is considered essential.

# Chapter 3 Policies and Procedures

## 3.1 Overview

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Current written policies and procedures are required to provide staff with clear direction on the scope and limitations of their functions and responsibilities for patient care.

## 3.2 Radiation Safety and Dose Reduction (ALARA Principles)

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The facility adheres to the requirements of the Canadian Nuclear Safety Commission (CNSC).

The ALARA principle (As Low As Reasonably Achievable) must be considered for all examinations using ionizing radiation. Adequate dose management strategies must be adhered to in order to ensure the necessary clinical information is present on images, while ensuring patient doses are reasonable. Particularly for ultrasound, the goal is to minimize acoustic power output to the patients.

Policies and procedures should be developed under the direction of the Radiation Safety Officer (RSO).

For further details, please refer to the RSO section in Chapter 1.

## 3.3 Developing Policies and Procedures

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The procedure manual is available for consultation by all facility staff. The manual is reviewed and signed off by all staff, licensee, and Quality Advisor annually, revised as necessary, and dated to indicate the time of the last review or revision.

There is documentation to indicate who makes the policies, sets the standards, and who supervises physicians, medical radiation technologists, and other staff. In addition, it should also include a copy of the MOH form outlining the name of the Quality Advisor.

The procedure manual contains all policies and procedures, including those described below.

### 3.3.1 Facility

Policies and procedures include, but are not limited to, the following:

- a description of the scope and limitations of imaging services provided by the facility
- patient-booking systems
- patient requests for a chaperone for intimate examinations, or any other common patient requests related to examinations/procedures; facilities must provide options where possible;
  - procedures must include specific chaperone signage posted in the facility; for example:
    - Chaperone Policy: Are you being examined? If you wish, we can provide another member of staff to be present; or a friend or family member can accompany you. PLEASE ASK THE TECHNOLOGIST, DOCTOR OR NURSE. In the

event that we are unable to provide you with a chaperone, you will be given the option of rebooking for a new date.

- documentation of and method for receiving written and telephone referrals for consultation

### **3.3.2 Facility Staff**

Policies and procedures include, but are not limited to, the following:

- professional guidelines, such as:
  - [CAMRT Best Practice Guidelines](#)
  - [CMRITO Standards of Practice](#)
  - [CMRITO Code of Ethics](#)
- delegated acts and medical directives. Refer to [CPSO policy on Delegation of Controlled Acts](#).
- review of all regulated health professionals' (RHP) education and experience including any certifications, examinations, courses and/or other training in order to ensure that all RHPs have the necessary knowledge, skills, and judgement to perform their specific services or procedures. Documentation that confirms the aforementioned must be kept up-to-date and on site.
- supervision of staff who may be working at an IHF while in the process of pursuing specialized training in a particular area specific to the type of patients seen in the facility. Supervision will continue until staff acquires the knowledge, skill and judgement through the training and if applicable, the certification, examination, and/or course.
- staff roles for emergency procedures, which are appropriate to the role they would assume in an emergency (e.g. fire, power failure, other emergency evacuation)
- The Licensee, Quality Advisor and staff working in the IHF are always up-to-date on the standards for infection prevention and control, and have an ongoing process to ensure current infection and prevention control practices are reflected in staff training, policies and procedures (3.3.8), as well quality management (5.1). To meet this requirement, facilities must, at a minimum, review the following:
  - Public Health Ontario's newsletter, which informs subscribers about updates to Provincial Infectious Diseases Advisory Committee (PIDAC) documents. To sign up for newsletters, use the following link:  
<https://www.publichealthontario.ca/en/EUM/Pages/Register.aspx>
  - Public Health Ontario's Infection Prevention and Control online training courses: [IPAC Core Competencies Course](#) and [Reprocessing in Community Health Care Settings Course](#).
- Staff responsible for cleaning, disinfecting, sterilizing, and/or reprocessing of medical equipment must complete appropriate training, including manufacturer's training. To determine appropriate training, the Quality Advisor must annually complete the [Infection Prevention and Control's Checklist for Infection Prevention and Control \(IPAC\) CORE Elements](#)

[in Clinical Office Practice](#), and if applicable, also complete the [Checklist for Reprocessing of Medical Equipment/Devices in Clinical Office Practice](#). Refer to [3.3.8 Infection Prevention and Control policies and procedures for links to PIDAC/IPAC best practices](#).

- Safety education/training for medical and non-medical staff (which is documented and maintained on site) that addresses areas mandated by the Ontario Government, such as the following:
  - Workplace Hazardous Materials Information System 2015 (WHMIS 2015);
  - Health and safety awareness;
  - Workplace violence and sexual harassment, and;
  - Accessibility for Ontarians with Disabilities

For more information, please refer to the [Guide to the Occupational Health and Safety Act](#).

- There is a Joint Health and Safety Committee (based on number of workers). Refer to the [Guide for Health and Safety Committees and representatives](#).
- orientation for all new staff to ensure adequate training. This must include a review of policy and procedure manuals, modality specific protocols, infection prevention and control practices and all safety training. The employee must sign off indicating that they have successfully completed all of the above training.
- Written performance evaluations for all staff at completion of probationary period, and thereafter as defined by the facility, preferably annually.
- Annual review of continuing professional development (CPD) of all regulated health professionals (RHPs) to ensure that each RHP's CPD meets with their regulatory body's CPD requirements. Documentation that confirms the aforementioned must be kept up-to-date and on site.

### **3.3.3 Diagnostic Services**

Policies and procedures include, but are not limited to, the following:

- specific protocols for the techniques performed at the facility, including appropriate patient preparation, radiopharmaceutical dose, and specific patient instructions following the procedure. Refer to the following guidelines:

[Society of Nuclear Medicine and Molecular Imaging](#)

[European Association of Nuclear Medicine](#) and

[British Nuclear Medicine Society](#)

- Every exam must have the MRT name recorded
- Process for staff to deal with any contraindications to the procedure; this includes notifying the physician/authorized health professional of the contraindication, and obtaining direction to proceed, modify or halt the procedure

- MRTs do not give preliminary interpretation

### **3.3.4 Records and Communication/ Reporting & Privacy Principles**

Policies and procedures include, but are not limited to, the following:

- Integrity of reportable results: a written process to ensure the accuracy of patient data and testing information from input of patient data to delivery of procedure, i.e. MRTs must place a check mark on the label confirming accuracy of patient name, date of birth, exam ordered, and referring physician. This should include a process to deal with errors should they occur
- Verbal reports: a written policy and procedure must be in place to ensure verbal reports are communicated to the referring physician/health care provider by the nuclear medicine physician or his/her designate
- Urgent findings: a written policy and procedure be in place to ensure that all positive findings are relayed to the referring physician/health care provider by the nuclear medicine physician or designate
- Confidentiality of patients and staff, including a policy indicating that the use of cameras to take pictures and videos are not permitted in the clinical setting unless mutually agreeable to the parties involved
- Patient consent, written or verbal, based on the scope of practice in the facility and in accordance with the *Health Care Consent Act*
- Maintenance of requisitions, imaging media and interpretation reports (see [Appendix I, Independent Health Facilities Act- Ontario Regulation 57/92](#))
- Privacy and release of health record information, including Bill 31 the Personal Health Information Protection Act 2004. (PHIPA). Information available at [www.ipc.on.ca](http://www.ipc.on.ca)

### **3.3.5 Pharmaceutical Safety**

Policies and procedures include, but are not limited to, the following:

- radiation safety and radiopharmaceuticals quality control including:
  - emergency procedures for minor and major spills.
  - acquisition, storage, security, preparation, administration, and disposal of radiopharmaceuticals.
  - optimum dosage of radiopharmaceutical for patients of different ages.
  - methods for reducing organ doses in various procedures.
  - precautions to be followed in women of reproductive age.
  - protocols to be followed in case radiopharmaceuticals are administered incorrectly, e.g. incorrect radiopharmaceutical or over-dosage.
  - Radiopharmaceutical substitution may be permitted provided equivalency.

- establishing and maintaining a program to evaluate the technical performance of the instruments used for imaging, and radiation monitoring. This includes procedures for testing instruments according to manufacturers' guidelines and any applicable regulations.

For more information on radiopharmaceutical safety, please refer to Chapter 22 on Radiopharmacy Best Practice Standards.

### ***3.3.6 Equipment Maintenance***

Policies and procedures include, but are not limited, to the following:

- routine maintenance, calibration, and evaluation of image quality of all diagnostic equipment. The activities should be performed as a minimum on an annual basis. This should include frequency of testing, responsibility for following up on recommendations, documentation and maintenance of records for all of the above. Please refer to Chapter 2 on Facilities, Equipment and Supplies for more details.

### ***3.3.7 Emergency Procedures and Safety Policies***

Policies and procedures include, but are not limited to, the following:

- Specific first aid measures to be followed in an adverse health event, including a description of the arrangements for transferring patients to an acute care facility when required
- Protocol to be followed to deal with emergencies, e.g. fire, evacuation, disaster, violent/behavioural situation, cardiac arrest, bomb threats, missing patient, hazardous spill, hostage situation
- At least one staff member with current Basic Life Support (BLS) certification is on site at all times during hours of operation.
- 70-90% alcohol-based hand rub be available for staff and patients at all points of care
- A hands-free eyewash station be installed in the facility (as per WHMIS).
- Anaphylaxis (if facility is not latex free)
- Safety Data Sheets (SDS) for all chemicals maintained in the facility
- Workplace safety and harassment

### ***3.3.8 Quality Management (See Chapter 5)***

### ***3.3.9 Infection Prevention and Control***

Policies and procedures are up-to-date with PIDAC documents, and include, but are not limited to, the following:

- Routine practices and additional precautions to prevent infection transmission are in keeping with current infection prevention and control best practices. Resources are

available through the [Provincial Infectious Diseases Advisory Committee's \(PIDAC's\) Infection Prevention and Control for Clinical Office Practice](#) document

- Hand hygiene – see [PIDAC Best Practices for Hand Hygiene in Health Care Setting](#)
- Environmental Cleaning – see [PIDAC Best Practices for Environmental Cleaning in Health Care Settings](#)
- Cleaning, Disinfection, Sterilization and Reprocessing of reusable medical devices and equipment - see [PIDAC Best Practices for Cleaning, Disinfection and Sterilization in Health Care Settings](#) and [PIDAC Infection Prevention and Control for Clinical Office Practice Settings](#)
- Adequate education and training of staff responsible for the sterilization and reprocessing of medical equipment. Please visit the [CPSO website for an approved list of courses specific to sterilization and reprocessing](#).
- For information about infection control within the context of radiopharmacy, please refer to [Chapter 22 on Radiopharmacy Best Practice Standards](#).

#### **3.3.9.1 Infection Prevention and Control related to Equipment**

There must be written policies and procedures relating to equipment cleaning/ disinfection/ sterilization and storage (e.g. tables) that require sterilization.

Staff performing High Level Disinfection (HLD) or sterilization must have documented annual training specific to the type of equipment being used.

Facilities should use [Public Health Ontario's Checklist for Reprocessing tool](#) to confirm their reprocessing/sterilization compliance.

Auxiliary equipment must be cleaned between patients with a Low Level Disinfectant (LLD) (for guidance on LLD, please refer to [PIDAC Best Practices for Environmental Cleaning for Prevention and Control of Infections in All Health Care Settings, 3<sup>rd</sup> Edition, April 2018](#)). Paper sheets and pillow cases on exam tables must be changed between patients, and tables must be cleaned and disinfected between patients and/or when visibly soiled.

#### **3.3.9.1 Infection Prevention and Control related to Hand Hygiene**

Policies and procedures include, but are not limited to, the following:

- Education of staff and patients about Public Health Ontario's "Hand Hygiene Methods", which can be found in [PIDAC Infection Prevention and Control for Clinical Office Practice Settings](#). This includes posting of the document for IHF staff and patients in designated areas
- Documentation attesting to annual staff compliance. Refer to [PIDAC Best Practices for Hand Hygiene in Health Care Setting](#), 4<sup>th</sup> edition

### **3.3.9.2 Infection Prevention and Control related to Infectious Patients**

Policies and procedures include, but are not limited to the following:

- Handling of infectious patients, for example, those who have any possibility of transmitting infection, at the initial contact with the patient. Refer to Additional Precautions in [PIDAC Infection Prevention and Control for Clinical Practice Settings](#).

### **3.3.10 Personal Protective Equipment (PPE)**

Policies and procedures include, but are not limited to the following:

- Indications for and use of PPE (gloves, masks, gowns and eye-protection) based on personal risk assessment
- Proper disposal of PPE
- Documentation attesting to annual staff compliance

### **3.3.11 Disposal of Sharps**

Policies and procedures include, but are not limited to the following:

- Appropriate precautions to prevent injuries from sharps
- Disposal guidelines and requirements for dedicated sharps containers

# Chapter 4 Requesting and Reporting Mechanisms

The content of this chapter is largely derived from the [Canadian Association of Radiologists Practice Guidelines for Communication of Diagnostic Imaging Findings \(2010\)](#) with modifications to reflect the practice of nuclear medicine. Last accessed: February, 2018

## 4.1 Overview

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Communication is a critical component of the art and science of medicine and is especially important in Diagnostic Services. It is incumbent upon nuclear medicine physicians and the facilities in which they work to ensure that the results of diagnostic services are communicated promptly and accurately in order to optimize patient care.

The final product of any consultation is the submission of a report on the results of the consultation. In addition, the nuclear medicine physician and the ordering physician have many opportunities to communicate directly with each other during the course of a patient's case management. Such communication is encouraged because it leads to more effective and appropriate utilization of diagnostic services and it can enhance the diagnostic yield of the study in question. From a utilization standpoint, discussions with the referring team will help to focus attention on such concerns as radiation exposure, appropriate studies, clinical efficacy, and cost-effective examinations. The provision of a well-defined clinical question and the overall clinical context can improve interpretation of complex cases and may enable the nuclear medicine physician to streamline the diagnostic impression into a few likely and relevant differential considerations rather than providing a textbook list of possible differential diagnoses that may be of less utility and of less impact.

These principles apply to all nuclear medicine consultations irrespective of the technology used, including teleradiology, Picture Archival Communication System (PACS) or an equivalent electronic workstation with an archival system (refer to Volume 4: Teleradiology (PACS)).

In order to afford optimal care to the patient and enhance the cost-effectiveness of each diagnostic examination, nuclear medicine consultations should be provided and images interpreted within a known clinical setting.

The Canadian Association of Radiologists supports radiologists who insist on clinical data with each consultation request and the IHF Nuclear Medicine Task Force supports this same principle.

All communication should be performed in a manner that respects patient confidentiality. Medical images and reports constitute confidential patient information and must be treated accordingly. It is incumbent upon IHF staff and all imaging personnel including nuclear medicine physicians to ensure patient privacy. This includes institution of appropriate privacy procedures, and appropriate policies and procedures for release of images or reports to third parties.

Policies and practice must be consistent with [privacy legislation](#).

## 4.2 Requesting Procedures

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Written requisitions are completed for all nuclear medicine procedures. Requests sent electronically to the facility must be transmitted using a secure system or tool, and must include the name (in digital format) of the referring physician/health care provider who requested the procedure.

The requisition must be clear, understandable, easy to use and provide enough space for documentation of clinical history and include the disclaimer: “This requisition form can be taken to any licensed facility providing health care services including hospitals and IHFs , such as those listed on the [IHF Program website](#)”.

The relationship between the referring physician and the physician practising nuclear medicine is consultative.

Although the ultimate responsibility for the appropriateness of requested procedures is that of the referring physician, the physician practising nuclear medicine communicates to the referring physician his or her concerns about the potential risk to the patient, the complexity of the procedure, or the cost of the procedure.

With reason, the physician practising nuclear medicine may alter the study requested, if in his/her judgment the appropriate test was not requested. Similarly, if the physician practising nuclear medicine believes that it is in the patient's best interest not to perform a procedure, it is at the discretion of this physician to cancel the request, and inform the referring physician as to reasons for cancelling or substituting the test.

An appropriate request specifies:

- the basic demographic information of the patient such as name, health number, date of birth, and sex
- the name of the referring physician and the names of any other regulated health professional who are to receive copies of the report

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**Note:** *When an order for a procedure is dictated by telephone, the person to whom the order was dictated transcribes the procedure(s) requested, the working diagnosis, the name of the requisitioning physician, the date and time of the order, and signs the record of the order.*

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- the service requested
  - a concise statement of the reason for the examination
  - any additional relevant history, physical findings
- **or**
- other information useful for interpreting or modifying the test procedure.

### 4.3 MRT Documentation

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MRTs must include their name on any documentation at the time of the examination in order for the interpreting physician to identify the MRT performing the examination.

### 4.4 The Nuclear Medicine Final Written Report

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The final report is considered to be the definitive means of communicating to the ordering physician the results of an imaging examination or procedure. Additional methods of communication of results are necessary in certain situations.

The final report should be transmitted to the ordering physician who is responsible for the clinical follow-up. The ordering physician also shares in the responsibility of obtaining the results of imaging studies he or she has ordered.

The timelines of reporting any imaging examination varies with the nature and urgency of the clinical problem. Best efforts should be made in order to ensure the final report is made available within two business days to the ordering physician who is responsible for the clinical follow-up.

The final report should be proofread carefully to avoid typographical errors, accidentally deleted words, and confusing or conflicting statements, and verified by the reporting nuclear medicine physician.

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***Note: If this is not possible, a disclaimer statement is stated on the report that the report has not been proofread.***

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Electronic and rubber-stamp signature devices, instead of a written signature, are acceptable if access to them is secure. In any case, the name of the dictating nuclear medicine physician must appear as such on the report.

A copy of the nuclear medicine study is retained as the permanent record for the appropriate length of time as prescribed by regulations.

If there was a significant discrepancy between the preliminary report and the final report, this should be documented and the referring physician notified of the change in cases where the change may alter immediate patient management.

Voice recognition systems are widely employed to facilitate timely reporting. These systems are not foolproof and methods should be in place to allow detection and correction of program generated errors.

Final reports may be transmitted by paper, fax, and electronically, provided appropriate security measures are in place. Facilities should seriously consider instituting “read receipt” mechanisms to identify any report that has not been picked up by the ordering physician/health care provider.

A copy of the final report should be archived by the imaging facility as part of the patient’s medical record (paper or electronic) and be retrievable for future reference. It is of sufficient quality to record permanent findings, to be used for comparison with subsequent examinations, and enable third party nuclear medicine physicians to confirm the diagnosis.

The IHF must have the ability to retrieve and/or produce a copy of the image(s) stored within one working day of the request as required.

The imaging media and reports are filed using an accepted coding system which allows images and reports to be retrieved by patient identification information.

Unusual and interesting examinations are maintained for educational purposes in accordance with the IHF Regulations.

Previous stored imaging studies are available for the interpreting physician.

Ideally, reports and imaging should be available on regional electronic medical record and PACS systems.

#### **4.4.1 Report Attributes**

Reports of the interpretation of imaging procedures include the following:

- name of patient and another identifier, such as gender, birth date, pertinent identification number or office identification number.

- the facility or location where the study was conducted.

- name of the ordering physician or health care provider.

- name of most responsible physician/health care provider for patients cared for by multiple clinical services.

- rationale: To provide more accurate routing of the report to one or more locations specified by the ordering physician/health care provider. Each facility has a policy to ensure proper distribution of the written report to the most responsible physician and/or other physicians/health care providers.

- name or type of examination.

- date of examination.

- whenever possible, the month should be spelled rather than risking the ambiguity of US and international formats (e.g., 03 July 2010 rather than 03/07/10 or 07/03/10).

- dates of dictation.

- rationale: quality control.

- date transcribed.

#### **4.4.2 Body of the Report**

The effective transmission of imaging information from the nuclear medicine physician to the ordering physician/health care provider constitutes the main purpose of the report.

The report should be clear and concise. Normal or unequivocally positive reports can be short and precise. Whenever indicated the report includes the following items:

#### **4.4.2.1 Procedures and Materials**

A description of the examinations and/or additional procedures performed, including rationale and any administered substances, medications, catheters, or devices if not reported elsewhere. Any known significant patient reaction or complication should be recorded.

Rationale: To ensure accurate communication and availability of the information for future reference.

#### **4.4.2.2 Findings**

Use precise anatomical, radiological and pathological terminology to describe the findings accurately. Abbreviations should be avoided to avoid ambiguity and risk of miscommunication, unless initially spelled out.

#### **4.4.2.3 Limitations**

Where appropriate, identify factors that can limit the sensitivity and specificity of the examination. Such factors might include technical factors, patient anatomy (e.g., patient body habitus), and limitations of the technique (e.g., the low sensitivity of a bone scan for strictly lytic lesions).

#### **4.4.2.4 Clinical Issues**

The clinical history, indication or clinical question may be inserted at the beginning of the report. While not mandatory this practice is encouraged.

The report should address or answer any pertinent clinical issues raised in the request for the imaging examination. If there are factors that prevent answering the clinical question, these should be stated.

#### **4.4.2.5 Comparative Data**

Comparisons with previous examinations and reports, when possible, are part of an imaging consultation and report, and should be included in the body of the report and/or conclusion section when appropriate.

#### **4.4.2.6 Assessment and Recommendations**

The report should conclude with an interpretive commentary on the data described. The proper terminology for ending the report may include the following terms: conclusion, impression, interpretation, opinion, diagnosis or reading.

Each examination should contain such an interpretive commentary. Exceptions can be made when the study is being compared with other recent studies and no changes have occurred during the interval or the body of the report is very brief and a separate conclusion would be a redundant repetition of the body of the report.

Give a precise diagnosis whenever possible.

Give a differential diagnosis when appropriate.

Recommend follow-up and/or additional imaging studies to clarify or confirm the conclusion, only when appropriate.

Any significant patient reaction should be reported.

#### **4.5 Standardized Computer-Generated Template Reports**

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Standardized computer-generated template reports (or other structured report formats) that satisfy the above criteria are considered acceptable. Facilities are encouraged to use standardized reports and terminology amongst their reporting physicians.

#### **4.6 Preliminary Reports**

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A preliminary report may precede the final report in certain circumstances and contains limited information relevant to immediate patient management. It may be time sensitive and should not be expected to contain all the imaging findings. It should be generated when a timely communication is necessary in unexpected elective cases where clinical urgency mandates immediate communication of the results.

A preliminary report may not have the benefit of prior imaging studies and/or reports and may be based upon incomplete information due to evolving clinical circumstances which may compromise its accuracy. Preliminary reports may be communicated verbally, in writing or electronically and this communication should be documented. Preliminary communications should be reproduced into a permanent format as soon as practical.

#### **4.7 Retention of Patient Records**

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Facilities are required to comply with *Ontario Regulation 57/92 s. 11* which specifies duration of retention of patient records.

#### **4.8 MOH Independent Health Facilities Program Information and Fact Sheets related to Patient Charges for Records**

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When the patient attends an IHF to obtain a copy of their images and reports for their ongoing care/treatment the acceptable turnaround time for requests that are received by the IHF for the images and reports to be made available for courier or pick-up is within three (3) working days of receiving the request. For additional information, refer to the [MOH's Independent Health Facilities program information and fact sheets](#).

#### **4.9 Retrieval of Images and Patient Information from another IHF/Institution**

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When previous images and reports are required from another IHF in order to make a comparison, the acceptable turnaround time for requests that are received by the IHF would be for the images and reports to be made available for courier or pickup within three (3) working days of receiving the request. Based on the above turnaround time couriered images and reports must be received

by the requesting party within a maximum of 5 working days of the IHF receiving the original request.

# Chapter 5                      Quality Management

## 5.1 Overview

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The Quality Management Program is intended to monitor the work of the facility to continuously improve all aspects of the services provided.

Each facility must have a Quality Management Program supervised by a Quality Advisory Committee (QAC) as set out in the IHFA regulations (see [Appendix I](#))

The requirements for, and responsibilities of, the Quality Advisor (QA) are as detailed in Chapter 1 Staffing a Facility.

The Quality Advisory Committee must consist of the Quality Advisor, licensee, the PACS administrator and site-specific health professionals (e.g. physician, MRT) who provide health services (representing each modality) at the IHF.

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***Note: An exception to this is where the physician is the sole provider of the services, is owner/operator and Quality Advisor, and the services provided are part of his/her office practice.***

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The QA Committee shall meet at least twice a year (or more often, as needed).

[QAC meeting agendas](#) must, at a minimum, include:

- Approval of minutes from previous meetings
- Business arising from Minutes (confirmation of completed items, and discussion of outstanding actions)
- Recommendations from Assessment/Accreditation Visit/Ministry of Health X-ray Inspection Services and HARP (if applicable). Such issues are to remain on the agenda until they are clearly finalized
- Goals and objectives:
  - i. Staff changes/New staff
  - ii. Staff under supervision - progress on examinations/courses/accreditation
  - iii. Expansion/relocation plans
  - iv. General practice goals
- Policies and procedures (including but not limited to):
  - i. Policy and Procedures Manual – general updates, staff sign-off
  - ii. Technical – general practice guidelines for facility
  - iii. Infection Prevention and Control
  - iv. SDS
  - v. Other
- Review of IPAC requirements and staff orientation/training
- Equipment – problems, upgrades, training or facility configuration issues
- Incidents or complaints, adverse drug reactions, complications
- Review of the results of the Facility’s quality review process
- Review of current statistics on the time between referral and subsequent diagnostic examinations

- Review of difficult or inconclusive cases and how they were dealt with
- Patient/referring physician survey results (see samples in [Appendix II](#) and [Appendix III](#))
- Any staff or staffing issues
- Staff performance appraisals & training – when, who, how often

## 5.2 Quality Management Program Goals

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The goals of the program include, but are not limited to, ensuring that:

The services planned and provided are consistent with the patient needs and assure diagnostic reliability and patient safety.

Services conducted in the facility are safe.

Services conducted are appropriate to the problem(s) being investigated.

The facility is to have a system to deal with incomplete or inappropriate requests for services.

## 5.3 Providing Quality Care

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A nuclear medicine physician must be available for consultation with the MRT on a case-by-case basis.

Nuclear medicine procedures are carried out in a manner in which patient privacy is respected.

## 5.4 Components of a Quality Management Program

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The facility establishes and maintains a system to regularly monitor the results of the services provided.

The facility establishes a Quality Management Program appropriate for its size, volume and types of services provided. It is recognized that Quality Management Programs will vary depending on the facility size, scope of practice, and geographical considerations.

Quality Management Program activities are documented and maintained on-site.

To ensure that the goals of the Quality Management Program are met the Committee's tasks include but are not limited to:

1. Review quality management goals and objectives annually.
2. Supervise and document a systematic ongoing review of the facility policy and procedures manual.
3. Review safety data on any equipment new to the facility since the last meeting, and ensure that all equipment in the facility meets safety standards.
4. Review any incident or accident report since the last meeting and document any such actions to prevent similar incidents or accidents. Provide a report of all such proceedings to the facility's Quality Advisor.

5. Review and implement recommendations from other assessing bodies such as the Ministry of Health, and Ministry of Labour.

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***Review and implement recommendations from the Canadian Nuclear Safety Commission as well as HARP and Preventative Maintenance (PM) reports as it relates to BMD, SPECT CT and PET CT.***

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6. Supervise and document a program of annual performance reviews for all staff who have patient contact, including documentation of action taken to correct any significant deficiencies in performance.
7. Ensure all registration certificates, BLS certificates, etc., are valid and current for all staff.
8. Ensure that the CPD activities of the technical and medical staff meet the relevant College or Society requirements. For example, all specialist physicians have fulfilled their annual RCPSC Maintenance of Certification (MOC) requirements.
9. The QAC arranges regular discussions of interesting/challenging cases ascertained at the facility at least annually, and ensures any teaching points are disseminated to the staff.
10. The QAC reviews the results from regular surveys of patient, referring physician and staff satisfaction surveys at least annually, and shall document actions to address any suggestions, problems or issues raised.
11. Implements and documents a quality review process that evaluates the quality of care provided by all regulated health professionals involved in patient care, and one that follows the basic principles of the [CAR peer review program](#) toward achieving the following program goals:
  - Enhances the consistency and accuracy of nuclear medicine services to improve quality of care for patients
  - Supports ongoing improvements to image interpretation skills through peer to peer learning in a non-punitive environment
  - Enables informed decisions about patient treatment, enhancement of quality programming, physician training and continuing medical education
  - Supports maintenance of ongoing learning, education and contribution to a culture of quality improvement, transparency and accountability

## **5.5 Monitoring the Program**

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The Quality Advisor is responsible for all aspects of the program including any aspect delegated to any other staff member.

Minutes of each QAC meeting shall be circulated to all members of the QAC for comment and revision, and once finalized by the QA they shall be circulated to all staff.

Recommendations from the QA Committee shall be circulated to all staff once they are finalized. These recommendations shall be reviewed at a general staff meeting including all health care professionals who provide services in or in connection with the IHF. Quorum for such staff meetings shall be two (2) or 50% of the staff whichever is greater. Staff may attend by secure

conference call. Staff members who cannot attend are to review and sign off on the minutes of that meeting.

Records are to be maintained at the facility in a form that is clear and easily accessible to a reviewer, and shall include:

- Minutes of the Quality Advisory Committee
- Minutes of General Staff meetings
- All the reviews and surveys noted above and any subsequent commentary, suggestions, recommendations, or follow-up.

# **Independent Health Facilities: Clinical Practice Parameters and Facility Standards**

## ***Nuclear Medicine***

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**VOLUME 2 CLINICAL PRACTICE PARAMETERS**

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## Chapter 6

# First Transit with or without Blood Pool Images

### 6.1 Overview

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Dynamic imaging is performed following the intravenous administration of a radionuclide bolus. After recording the first transit (blood flow), a static (blood pool) image of the same region of interest is obtained, usually immediately or soon after completing the injection. However, for first transit without blood pool images, the immediate or blood pool image are not performed when the information to be gained does not contribute to the diagnostic process.

### 6.2 Prerequisites for First Transit with and without Blood Pool Images

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Radionuclide blood flow studies may be added for their inherent diagnostic value in specific clinical situations. They are performed as the initial component of other nuclear imaging procedures made mostly at the discretion of the practising nuclear medicine physician. In such situations, the decision to perform or not to perform the flow study must be made before administering the radionuclide to the patient.

### [6.3 Reporting Guidelines \(see Chapter 4\)](#)

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## Chapter 7

# Infection and Inflammation Scintigraphy

### 7.1 Overview

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There are several radiopharmaceuticals which are useful in the detection and assessment of infection and inflammation, including Ga-67 and Tc-99m or In-111 labelled white blood cells (WBCs). The choice of the radiopharmaceutical used is primarily dependent on its availability and knowledge of its localization properties, as it pertains to the clinical question.

Inflammatory and infection scintigraphy may be complemented by other nuclear medicine studies such as Tc-99m sulfur colloid and Tc-99m MDP bone scan as well as conventional diagnostic imaging to increase the test's specificity.

### 7.2 Common Clinical Indications

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Common clinical indications for performing inflammation and infection scintigraphy may include:

Sepsis or inflammation detection. Most commonly:

- Skeletal infection/inflammation:
  - osteomyelitis
  - joint space infection/neuropathic joint
  - discitis
  - prosthetic aseptic loosening and infection.
  
- Soft tissue infection/inflammation including:
  - abscess localization
  - assessment of inflammatory bowel disease
  - renal parenchymal and peri-renal infections

### [7.3 Reporting Guidelines \(see Chapter 4\)](#)

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## Chapter 8

# Myocardial Perfusion Scintigraphy

### 8.1 Overview

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Myocardial perfusion scintigraphy and/or metabolism is a non-invasive procedure used to detect and evaluate coronary artery disease as manifested through ischemic burden or changes in cellular metabolism.

Diffusible radiolabelled compounds such as Thallium-201 chloride or Tc-99m labeled products distribute in myocardial tissue proportional to regional blood flow. Consequently, those regions with relatively higher blood flow at the time of injection appear more intense on scintigraphy compared to regions with a relatively lower blood flow.

The current minimum standard of practice for perfusion scintigraphy requires SPECT for optimal localization as well as increased sensitivity and specificity of diagnosis. Cardiac imaging may be performed with SPECT/CT or cardiac specific gamma camera. If the facility does not have the capability of SPECT, the perfusion study should not be performed.

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**Note:** *Guidelines for various stress procedures are not addressed by these Clinical Practice Parameters. If exercise or pharmacological stress tests are performed, this should be done under the supervision of a physician, and with appropriate resuscitation equipment immediately available.*

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### 8.2 Common Clinical Indications

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Common clinical indications for performing myocardial perfusion scintigraphy may include the need to:

- evaluate coronary artery disease and ischemic burden.
- assess coronary revascularization, i.e. post-CABG, post-PTCA, post-anticoagulation.
- detect myocardial infarction.
- perform post-myocardial infarction risk assessment and stratification.
- evaluate cardiac status prior to cardiac or non-cardiac surgery.
- myocardial viability using Thallium-201 chloride.

### [8.3 Reporting Guidelines \(see Chapter 4\)](#)

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## Chapter 9

# Myocardial Wall Motion Studies with Ejection Fraction

### 9.1 Overview

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This may be performed with  $Tc^{99m}$  labelled red blood cells, or by gated SPECT myocardial perfusion images, at rest or during exercise. Subsequent analysis allows the assessment of cardiac chamber volumes, myocardial contractility and global or segmented ventricular function.

Gated blood pool studies may be performed as an independent test. Gated SPECT is generally performed in conjunction with myocardial perfusion scans.

### 9.2 Common Clinical Indications

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Common clinical indications for performing myocardial wall motion studies include the need to assess:

- coronary artery disease (ischemia or infarction)
- intrinsic myocardial disease
- cardiac valvular disease
- evaluation for Implantable Cardiac Defibrillator (ICD)
- response to therapy (drug, angioplasty, bypass)
- complications of chemotherapy

### [9.3 Reporting Guidelines \(see Chapter 4\)](#)

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# Chapter 10

# Thyroid Uptake and Repeat Uptake

## 10.1 Overview

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Thyroid function is measured by labeling the extrathyroidal iodine pool with orally or IV administered  $I^{131}$  or  $I^{123}$ . An estimate of thyroid gland activity is generated by determining the fraction of administered radionuclide retained in the thyroid gland following a specific interval of time (i.e., 10 minutes, 1, 2, 4, or 24 hours etc.).

## 10.2 Prerequisites

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Inquiry should be made to determine if the patient is taking any medications or has undergone recent radiologic examinations involving iodine contrast that may interfere with the test and this information should be recorded and taken into account.

[http://snmmi.files.cms-plus.com/docs/Thyroid\\_Scintigraphy\\_1382732120053\\_10.pdf](http://snmmi.files.cms-plus.com/docs/Thyroid_Scintigraphy_1382732120053_10.pdf)

## 10.3 Common Clinical Indications

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Common clinical indications for performing a thyroid uptake include the need to assess:

- thyroid function in hyperthyroidism.

## [10.4 Reporting Guidelines \(see Chapter 4\)](#)

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# Chapter 11      Thyroid Scintigraphy

## 11.1 Overview

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After administration of  $I^{131}$ ,  $I^{123}$ , or  $Tc^{99m}$  pertechnetate, the acquired images provide a map of the distribution of functioning thyroid tissue either within the thyroid gland or extra-thyroidal locations.

Thyroid trapping may be quantified following the intravenous administration of  $Tc^{99m}$  pertechnetate.

## 11.2 Prerequisites

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Inquiry should be made to determine if the patient is taking any medications or has had recent radiologic examinations involving iodine contrast that may interfere with the test and this information should be recorded and taken into account.

[http://snmmi.files.cms-plus.com/docs/Thyroid\\_Scintigraphy\\_1382732120053\\_10.pdf](http://snmmi.files.cms-plus.com/docs/Thyroid_Scintigraphy_1382732120053_10.pdf)

## 11.3 Common Clinical Indications

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Common clinical indications for performing thyroid scintigraphy include the need to assess:

- hyperthyroidism (including nodules associated with hyperthyroidism)
- Congenital hypothyroidism
- Masses in the neck or mediastinum suspected to be thyroid in origin.
- Assessment of multinodular glands to guide tissue sampling
- Assessment nodules with equivocal Fine Needle Aspiration findings.

Nuclear thyroid assessment is not generally indicated for the investigation of *adult* hypothyroidism.

Thyroid nodules less than 1 cm in size may not be accurately assessed by thyroid scintigraphy.

## [11.4 Reporting Guidelines \(see Chapter 4\)](#)

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# Chapter 12                      Parathyroid Scintigraphy

## 12.1 Overview

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Primary hyperparathyroidism is a disorder characterized by excess synthesis and secretion of parathyroid hormone which results in elevated levels of serum calcium. Radionuclide imaging can be performed using either dual-phase or dual-isotope protocols to localize hyperfunctioning parathyroid tissue.

### **12.1.1 Radiopharmaceuticals Used**

Dual-phase:    Tc-99m sestamibi/tetrofosmin

                    Tc-99m sestamibi/Tc-99m pertechnetate

Dual-isotope: Tc-99m sestamibi/I-123

## 12.2 Prerequisites

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- Documented elevated level of serum calcium and parathyroid hormone.

## 12.3 Common Clinical Indications

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- Localize parathyroid adenomas in patients with hyperparathyroidism prior to surgery.

## [12.4 Reporting Guidelines \(see Chapter 4\)](#)

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# Chapter 13

# Hepatobiliary Scintigraphy

## 13.1 Overview

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Hepatobiliary scintigraphy has proved to be a useful imaging technique in diagnosing a wide variety of disorders of the liver and biliary tract.

The Tc-99m iminodiacetic acid analogues are handled in the liver by the same carrier mediated anionic clearance mechanism as bilirubin. The images generated reflect the distribution of bilirubin and consequently the state of hepatobiliary function. It is necessary to correlate scintigraphic findings with clinical information and findings on other relevant modalities in order to establish a diagnosis.

When appropriate, adjunctive pharmacological or physiological intervention further increases the clinical utility of the test.

## 13.2 Prerequisites

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The patient must fast for a minimum of 2 hours and preferably 4-6 hours before the radiotracer is administered. Fasting for longer than 24 hours may result in normal gallbladders not filling. When pharmaceutical intervention is given it must be administered under the supervision of a physician in the facility.

## 13.3 Common Clinical Indications

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Common clinical indications for performing hepatobiliary scintigraphy include the need to:

- Evaluate functional pain syndromes and right-upper-quadrant pain variants
- Evaluate for acute cholecystitis
- Evaluate biliary system patency.
- Calculate a gallbladder ejection fraction in assessing for chronic cholecystitis and biliary dyskinesia.
- Detect bile leakage.

## [13.4 Reporting Guidelines \(see Chapter 4\)](#)

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## Chapter 14

## Liver and Spleen Scintigraphy

### 14.1 Overview

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The liver and spleen are both principle organs of the reticuloendothelial system (RES). The function of this system can be assessed by recording the distribution of intravenously administered microcolloids labelled with a radionuclide. Tc<sup>99m</sup> Sulfur Colloid is the most common agent used. For detecting a haemangioma, liver imaging with Tc<sup>99m</sup> labelled red cells is used. SPECT imaging is a requisite. It is necessary to correlate scintigraphic findings with clinical information and findings on other relevant modalities in order to establish a diagnosis.

### 14.2 Common Clinical Indications

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Common clinical indications for performing a liver and spleen scintigraphy may include the need to:

- Differentiate hepatic hemangiomas and focal nodular hyperplasia from other liver lesions.
- Identify functional splenic tissue.

ACR-SNM-SPR Practice Guideline for the Performance of Liver and Spleen Scintigraphy, 2010

### [14.3 Reporting Guidelines \(see Chapter 4\)](#)

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# Chapter 15

# Renal Scintigraphy

## 15.1 Overview

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Renal scintigraphy provides important functional data to assist in the diagnosis and management of a variety of genitourinary problems. There are several Tc-99m-based radiotracers used in renal scintigraphy which include MAG3, DTPA, DMSA and glucoheptonate. The choice of radiopharmaceutical used for renal imaging will depend on proposed clinical question and the availability of the appropriate radiotracer.

In cases of dynamic renal scintigraphy, typically Tc-99m MAG3 or DTPA are used. These agents assess renal blood flow and function. The radionuclide is given as an intravenous bolus and data is dynamically collected by computer for about 30 minutes. In some patients, delayed static renal imaging may be required, usually at 1-3 hours after the radionuclide is administered.

If the clinical question is obstruction uropathy, the test can be augmented with furosemide (Lasix). Edicrine may be substituted for Furosemide in patients with an allergy.

In cases of suspected renal artery stenosis causing renovascular hypertension, ACE-inhibitor (ACEI) renography can be performed with oral captopril and IV enalaprilat. Before the test, a detailed history of the drugs medications should be performed as certain anti-hypertensives can influence the sensitivity of the test. Anti-hypertensives can be withheld prior to the study but usually at the discretion of the referring physician.

Medications used in renal scintigraphy should be administered and monitored in a fashion, which is consistent with the policies outlined in this document.

Renal cortical imaging can be performed in combination with dynamic imaging with Tc-99m glucoheptonate or with static imaging in cases when Tc-99m DMSA is used. These tests are utilized in the diagnosis of renal cortical scarring, renal infection/pyelonephritis and the assessment of renal hypertrophy. Static images with the addition of SPECT imaging are preferred for the assessment of renal morphology.

## 15.2 Common Clinical Indications

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Common clinical indications for performing a renal scintigraphy may include the need to:

- Assessment of renal split function
- Obstructive uropathy
- Renal scarring

## [15.3 Reporting Guidelines \(see Chapter 4\)](#)

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# Chapter 16

# Bone Scintigraphy

## 16.1 Overview

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Images of the skeleton are obtained after administering intravenous radiopharmaceuticals which localize in the mineral compartment of the skeleton and reflect the distribution of bone metabolism. As bone scans show physiological processes and radiographs demonstrate anatomical detail, these techniques are complimentary.

## 16.2 Common Clinical Indications

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Common clinical indications for performing a bone scan include the need to:

- detect skeletal metastatic disease.
- detect skeletal lesions in symptomatic patients.
- evaluate the activity of abnormalities seen on correlative imaging
- assess for bony infection or complications of surgery.

## [16.3 Reporting Guidelines \(see Chapter 4\)](#)

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# Chapter 17      Tumour Scintigraphy

## 17.1 Overview

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Radiotracers used for the detection of tumours, typically are commonly limited to thyroid cancers and neuroendocrine tumours. Radiotracers used in the detection of these tumors may include I-123/I-131, In-111 Octreotide, and I-123/I-131-MIBG.

Tumour scintigraphy utilizing traditional SPECT radiotracers can be helpful to discriminate benign versus malignant lesions, particularly in cases of equivocal anatomical imaging. Moreover, given that whole-body imaging is typically performed with SPECT tracers, detection of occult lesions can also be facilitated.

In the case of diagnostic I-123/I-131 scintigraphy for thyroid cancer, one should consider the diagnostic appropriateness of the test. (See the [American Thyroid Association Management Guidelines Adult Patients with Thyroid Nodules and Differentiated Thyroid Cancer: The American Thyroid Association Guidelines Task Force on Thyroid Nodules and Differentiated Thyroid Cancer](#)).

Please see dedicated PET section for other types of tumour scintigraphy. Depending on the clinical circumstances, bowel preparation may be used.

## 17.2 Common Clinical Indications

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Common clinical indications for performing tumour scintigraphy include:

- Neuroendocrine tumours
- Thyroid malignancies

## [17.3 Reporting Guidelines \(see Chapter 4\)](#)

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## Chapter 18

# Brain Scintigraphy with Single Photon Emission Computed Tomography

### 18.1 Overview

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Brain scintigraphy utilizes radiotracers (Tc-99m HMPAO or Tc-99m ECD) which parallel cerebral perfusion. In a number of conditions, subtle changes in cerebral perfusion will often predate anatomical changes on CT or MRI. As such, these radiotracers can be helpful to localize or characterize a number of neurologic conditions.

In most cases, it is preferable that the interpretation of cerebral SPECT studies be performed with the aid of quantification analysis software.

### 18.2 Common Clinical Indications

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Common clinical indications for performing this test include:

- Dementia

### [18.3 Reporting Guidelines \(see Chapter 4\)](#)

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## Chapter 19

# Perfusion and Ventilation Scintigraphy

### 19.1 Overview

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A radionuclide ventilation scan demonstrates the patency of airways and the distribution of aerated lung tissue. The patient inhales radio tracers in gaseous, aerosol, or particulate form. Multiple images in various projections are obtained with a gamma camera.

A radionuclide perfusion lung scan demonstrates the distribution of the pulmonary blood flow following the intravenous injection of radioactive labeled particles which temporarily embolize the pulmonary capillary bed. Multiple images in various projections are obtained using a gamma camera.

Commonly these two procedures are performed consecutively on the same day.

To demonstrate normal and occluded pulmonary artery anatomy, a ventilation/perfusion scan (ideally with SPECT) or a CT pulmonary angiogram can be done, based on the appropriate clinical situation.

### 19.2 Common Clinical Indications

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Clinical indications for performing ventilation and perfusion lung scans include the need to:

- diagnose suspected pulmonary embolism.

### [19.3 Reporting Guidelines \(see Chapter 4\)](#)

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## Chapter 20

## Scintimammography

### 20.1 Overview

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Scintimammography has high sensitivity for detecting palpable breast lesions (> 1cm). It is very helpful in further characterizing breast lesions which are equivocal, non-diagnostic or difficult to interpret on mammography. Due to the relatively low sensitivity in detecting non-palpable lesions (< 1cm), scintimammography should not be used as a screening test for breast carcinoma. Sometimes, scintimammography is also able to demonstrate axillary metastasis. The minimum standard for scintimammography is a SPECT gamma camera. Imaging should be performed on a breast specific gamma camera if available.

### 20.2 Common Clinical Indications

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Scintimammography should be used as a second line diagnostic tool in patients whose mammogram is equivocal, non-diagnostic or difficult to interpret. These include:

- the patient has a dense breast(s) and one or both of the following risk factors:
  - a first degree relative with breast cancer diagnosed prior to age 50; or
  - a first degree relative with breast cancer diagnosed over age 50 and patient is within 5 years of the age when the relative was diagnosed with breast cancer.
- architectural distortion of the breasts due to prior breast surgery, radiotherapy, chemotherapy or the presence of breast prosthesis rendering mammography interpretation difficult
- malignant breast lesion when mammography is unable to exclude multifocal disease
- solitary lesion identified on mammography of greater than 1 cm.

### [20.3 Reporting Guidelines \(see Chapter 4\)](#)

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# Chapter 21            Solid Gastric Emptying

## 21.1 Overview

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A radionuclide study for solid gastric emptying is a comprehensive procedure for quantitative assessment of gastric emptying functioning using a physiologic meal.

The standard meal and standard imaging protocol has established by the Society of Nuclear Medicine and American Neurogastroenterological and Motility Society should be used to ensure validity and reproducibility of the results as reference values have been obtained through a large multicenter trial. Please refer to:

[http://interactive.snm.org/docs/GES\\_Consensus\\_Manuscript\\_4-23a-2007.pdf](http://interactive.snm.org/docs/GES_Consensus_Manuscript_4-23a-2007.pdf)

### 21.1.1 Radiopharmaceuticals Used

- Technetium labelled sulfur colloid.

## 21.2 Common Clinical Indications

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Common clinical indications include:

- Symptoms of gastroparesis (early satiety/postprandial fullness, abdominal bloating/discomfort and nausea/vomiting)
- Symptoms of rapid gastric emptying including those related to dumping syndrome

## [21.3 Reporting Guidelines \(see Chapter 4\)](#)

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# Chapter 22 Radiopharmacy Best Practice Standards

## 22.1 Overview

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The preparation, compounding, dispensing and repackaging of high quality, safe and efficacious radiopharmaceuticals is critical to providing patient-centered clinical services in nuclear medicine. The transport and delivery of radiopharmaceuticals also pose additional important considerations. Facilities involved in any of these activities must comply with the product monograph, and must follow the expected standards for practice.

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**NOTE: All records and documentation related to the preparation, compounding, dispensing, repackaging, as well as transport and delivery of radiopharmaceuticals must be made available on site.**

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## 22.2 Regulatory Oversight for Radiopharmaceutical Preparation

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- The National Association of Pharmacy Regulatory Authorities (NAPRA) has developed [Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations](#), which while geared at pharmacists and pharmacy technicians, also serve as best practice guidelines for other health care practitioners. NAPRA has also published [Model Standards for Pharmacy Compounding of Non-Sterile Preparations](#) that provide important information.
- Individuals must have the knowledge, training, and expertise, as well as the facilities, including equipment required to compound sterile products. Furthermore, [NAPRA's Model Standards](#) state that individuals who do not meet these requirements must refer patients to a colleague who does have the competencies and facilities required to do so or, where permitted by provincial/territorial legislation, ask another pharmacy to compound the product for them.
- Facilities compounding radiopharmaceuticals must adhere to both [NAPRA's Model Standards](#) in order to ensure patient safety and nuclear medicine image quality. These standards outline best practices with regard to core requirements for a sterile compounding service, product and preparation requirements, and quality assurance program.
- Facilities should also obtain additional guidance through the [Canadian Society of Hospital Pharmacists publication "Compounding: Guidelines for Pharmacies"](#), which is a comprehensive set of guidelines that apply to the preparation of radiopharmaceuticals and other hazardous pharmaceuticals.
- Additionally, facilities should seek out information on radiopharmaceuticals from the following [United States Pharmacopeia \(USP\) Standards](#):
  - USP<795> on Pharmaceutical Compounding—Nonsterile Preparations;
  - USP<797> on Pharmaceutical Compounding – Sterilize Preparations;
  - USP<800> on Hazardous Drugs – Handling in Healthcare Settings, and;

- USP<823> on Radiopharmaceuticals for Positron Emission Tomography (PET) - Compounding
- USP<825> on Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging.
- Facilities are also required to comply with relevant requirements set by the [Canadian Nuclear Safety Commission](#).

## 22.3 Core Requirements for a Sterile Compounding Service

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Facilities must comply with the [Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations](#) with regard to Core Requirements for a Sterile Compounding Service (personnel, policies and procedures, facilities and equipment, and general maintenance log).

Additional detailed guidance is also available in the following:

- Canadian Society of Hospital Pharmacists publication “Compounding: Guidelines for Pharmacies;
- SP<795> on Pharmaceutical Compounding—Nonsterile Preparations, USP<797> on Pharmaceutical Compounding – Sterilize Preparations, USP<800> on Hazardous Drugs – Handling in Healthcare Settings, USP<823> on Radiopharmaceuticals for Positron Emission Tomography (PET) – Compounding, and USP<825> on Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging.

## 22.4 Product and Preparation Requirements

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Facilities that compound radiopharmaceuticals must comply with the product monograph.

***Note: While the NAPRA Model Standards provide guidance on deviations from product monograph (e.g. beyond-use shelf life extensions; cold-kit radioactivity load and associated preparation parameters), IHFs are NOT permitted to deviate from the product monograph.***

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Facilities must comply with the [Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations](#) with regard to product and preparation requirements (including, but not limited to: compounded sterile preparation protocols, aseptic compounding of hazardous sterile preparations, receipt and storage of hazardous products, transport and delivery).

With regard to transport and delivery, facilities should also obtain guidance through the Government of Canada’s [Packaging and Transport of Nuclear Substances Regulations, 2015](#).

Additional detailed guidance is also available in Canadian Society of Hospital Pharmacists publication “Compounding: Guidelines for Pharmacies, as well as USP<795> on Pharmaceutical Compounding—Nonsterile Preparations, USP<797> on Pharmaceutical Compounding – Sterilize Preparations, USP<800> on Hazardous Drugs – Handling in Healthcare Settings, USP<823> on

Radiopharmaceuticals for Positron Emission Tomography (PET) – Compounding, and USP<825> on Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging.

## 22.5 Quality Assurance Program

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Facilities must comply with the [Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations](#) with regard a quality assurance program (including, but not limited to, program content, verification of equipment and facilities, quality assurance of personnel involved in aseptic compounding, quality assurance of hazardous compounded sterile preparations, documentation of quality control activities).

Additional detailed guidance is also available in Canadian Society of Hospital Pharmacists publication “Compounding: Guidelines for Pharmacies, as well as USP<795> on Pharmaceutical Compounding—Nonsterile Preparations, USP<797> on Pharmaceutical Compounding – Sterilize Preparations, USP<800> on Hazardous Drugs – Handling in Healthcare Settings, USP<823> on Radiopharmaceuticals for Positron Emission Tomography (PET) – Compounding, and USP<825> on Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging.

## References

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1. National Association of Pharmacy Regulatory Authorities (NAPRA) Model Standards  
[https://napra.ca/sites/default/files/2017-09/Mdl\\_Stnds\\_Pharmacy\\_Compounding\\_Hazardous\\_Sterile\\_Preparations\\_Nov2016\\_Revised\\_b.pdf](https://napra.ca/sites/default/files/2017-09/Mdl_Stnds_Pharmacy_Compounding_Hazardous_Sterile_Preparations_Nov2016_Revised_b.pdf)  
[https://napra.ca/sites/default/files/documents/Mdl\\_Stnds\\_Pharmacy\\_Compounding\\_Nonsterile\\_Preparations\\_March2018\\_FINAL.pdf](https://napra.ca/sites/default/files/documents/Mdl_Stnds_Pharmacy_Compounding_Nonsterile_Preparations_March2018_FINAL.pdf)
2. **United States Pharmacopeia Reference Standards**  
<http://www.usp.org/reference-standards>
3. **USP Public Standards for Compounded Sterile Radiopharmaceuticals: Recommendations from SNMMI**  
[http://snmmi.files.cms-plus.com/SNMMI-USP-Recommendations-Final\\_2016.pdf](http://snmmi.files.cms-plus.com/SNMMI-USP-Recommendations-Final_2016.pdf)
4. **CARS: Report of the Canadian Association of Radiopharmaceutical Scientists (CARS) Task Force on USP<797 Standards in Canada:**  
<http://radiopharmacycanada.com/pdfs/USP797%20CARS%20Final%20Nov%202013%20W%20BIBLIO%20Apr%202016.pdf>
5. **Canadian Society of Hospital Pharmacists publication “Compounding: Guidelines for Pharmacies**  
<https://www.cshp.ca/compounding-guidelines-pharmacies>
6. **Government of Canada Packaging and transport of nuclear substances regulations**  
<http://nuclearsafety.gc.ca/eng/nuclear-substances/packaging-and-transport-of-nuclear-substances/index.cfm>



# **Independent Health Facilities: Clinical Practice Parameters and Facility Standards**

## ***Nuclear Medicine***

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**VOLUME 3      POSITRON EMISSION TOMOGRAPHY  
– COMPUTED TOMOGRAPHY (PET-  
CT)**

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## Chapter 23

## FACILITY STANDARDS FOR PET-CT

**If a facility is providing PET-CT services, then the following Facility Standards apply in addition to those listed in Volume 1: Facility Standards**

### 23.1 Staffing a Facility

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#### ***23.1.1 Interpreting Physician Qualifications***

Nuclear medicine (PET-CT) services are provided by a Nuclear Medicine physician who has had formal training in PET-CT and/or has been actively interpreting PET-CT, and is registered to practice in Ontario by the College of Physicians and Surgeons of Ontario and is:

- a specialist certified in nuclear medicine by the Royal College of Physicians and Surgeons of Canada after 2014, or
- approved by the Registration Committee of the College of Physicians and Surgeons of Ontario to practice independently in nuclear medicine services, including PET-CT, or
- a physician who does not meet either of the above criteria, must contact the CPSO to clarify suitability to include PET-CT as part of their practice in accordance with the CPSO Changing Scope of Practice policy.

#### ***23.1.2 Medical Radiation Technologists***

Medical Radiation Technologists performing PET-CT procedures must have a current and valid certificate of registration with the College of Medical Radiation and Imaging Technologists of Ontario (CMRITO), and should only perform the services and procedures that fall within the [scope of the profession](#).

In addition, MRTs are responsible for performing quality control procedures on all nuclear medicine equipment, including PET-CT according to facility policies and manufacturers' product monograph.

### 23.2 Facilities, Equipment and Supplies

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#### ***23.2.1 Equipment Quality Control***

PET/CT scanners should be full ring PET/CT scanners with the CT having a minimum of four (4) multi-slice capability operating for the purpose of anatomic localization and attenuation correction.

#### ***23.2.2 Equipment Testing***

**PET/CT Scanners**

Daily and routine PET/CT scanner quality control procedures, including preventative maintenance, as specified by the manufacturer must be performed and results logged for future comparisons.

## Chapter 24

# CLINICAL PRACTICE PARAMETERS FOR PET-CT

**If a facility is providing PET-CT services, then the following Clinical Practice Parameters apply in addition to those listed in Volume 2: Clinical Practice Parameters**

### 24.1 Cancer Imaging with PET/CT

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The modern standard for molecular imaging of malignancy is 18F-FDG-PET/CT with additional tracers to become available in the near future.

#### **24.1.1 Common Clinical Indications**

The evidence to support the clinical use of PET/CT changes rapidly. Therefore, the indications listed below represent the current state. Updated indications can be found at the following CCO website: <https://www.petscansontario.ca/>

#### **[24.1.2 Reporting Guidelines \(see Chapter 4\)](#)**

### 24.2 Cardiac Imaging with PET/CT

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PET tracers, such as Rb-82, exist for the evaluation of myocardial perfusion to assess for coronary artery disease and the assessment of scar and ischemic burden. Images reflecting regional perfusion are acquired at rest and compared to those acquired during stress.

F-18FDG is another tracer used to assess myocardial glucose metabolism. Depending on patient preparation glucose metabolism can reflect viable or hibernating myocardium, or underlying inflammatory conditions affecting the myocardium, most commonly sarcoidosis.

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**Note:** *Guidelines for various stress procedures are not addressed by these Clinical Practice Parameters. If exercise or pharmacological stress tests are performed, this should be done under the supervision of a physician, and with appropriate resuscitation equipment immediately available.*

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#### **24.2.1 Common Clinical Indications**

The evidence to support the clinical use of PET/CT changes rapidly. Therefore, the indications listed below represent the current state. Updated indications can be found at the following CCO website: <https://www.petscansontario.ca/>

#### **[24.2.2 Reporting Guidelines \(see Chapter 4\)](#)**

# **Independent Health Facilities: Clinical Practice Parameters and Facility Standards**

## ***Nuclear Medicine***

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**VOLUME 4**

**TELERADIOLOGY (PACS)**

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# Teleradiology Standards

Facilities must comply with the Ontario Association of Radiologists (OAR) Teleradiology Practice Standard (on next page), as well as the CPSO Telemedicine Policy, which are provided for reference.

## **CPSO Telemedicine Policy**

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<https://www.cpso.on.ca/Physicians/Policies-Guidance/Policies/Telemedicine>

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*Note: As per the Health Insurance Act, the reporting Nuclear Medicine specialist must be physically in Ontario at the time of reviewing and reporting.*

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For information about technical standards, facilities should also refer to:

## **ACR–AAPM–SIIM Technical Standard for Electronic Practice of Medical Imaging**

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<https://www.acr.org/-/media/ACR/Files/Practice-Parameters/Elec-Practice-MedImag.pdf>

## **CAR Teleradiology Standards**

<https://car.ca/patient-care/practice-guidelines/>

# OAR Teleradiology Practice Standard

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Ontario Association of Radiologists

May 2015

## **OAR TELERADIOLOGY PRACTICE STANDARD Amended May 2013**

### **Originally Approved June 2007 Definition**

Teleradiology in Ontario is the electronic transmission of radiographic images from one geographical location to another for the purposes of interpretation and consultation by diagnostic imaging physicians accredited by the Royal College of Physicians and Surgeons of Canada (or recognized equivalent) and licensed by the College of Physicians and Surgeons of Ontario.

*These guidelines and standards have been developed to protect patients and ensure their data is kept confidential. Teleradiology services are to facilitate patient care and are not intended to be a cost-cutting measure, which may jeopardize patient safety and the standards of health care.*

### **Preface**

The transmission of images between centres has been going on for a number of years and has proved to be valuable for centres seeking expert opinions on emergency and problem cases. The most common such connections have been with radiologists who work at a site and are now able to offer image interpretations online from other sites within an institution, from their offices, home or elsewhere. More recently radiological images have been transmitted to main centres from smaller community hospitals in areas of low population density where small radiology departments have proven unsustainable. The vastly improved capacity of the internet and the speed of transmission have permitted a much wider use of teleradiology.

Teleradiology has advantages but it must be done properly to ensure that a high quality of care is provided to patients and to maintain the radiologist interaction with their clinical colleagues. It is also important that those radiologists providing the service are properly trained, are registered with the appropriate authorities, and undergo continuing update through Continuing Medical Education (CME). The services provided must be open to audit and the ability to discuss cases with those reporting the studies must be available. This standard has been developed to provide guidance to radiologists, managers of health care facilities, patient's representatives and governments on

appropriate standards for teleradiology services.

Teleradiology has undergone a number of health-technology assessments in different countries with regard to the context of its use, but a great deal of thought and study is still required. Teleradiology clearly has a number of advantages, but it also has the potential to create considerable difficulties for the delivery of a high-quality radiological service to patients, unless its role and the legal responsibilities involved are clearly defined.

### **Role of a Diagnostic Radiologist**

The role of a radiologist providing medical services in a diagnostic imaging service is considerably wider than simply issuing a diagnostic interpretation and report. It includes:

Evaluating the clinical information produced by referring physician clinicians

Deciding which test is appropriate

Establishing and assuming responsibility for the imaging protocols, quality parameters and a host of other technical factors that are integral to the creation of the diagnostic image and report

Being responsible for the technical staff/standards involved in the diagnostic imaging facility

Optimizing the study and assisting the referring physician colleague

Evaluating the study and relating it to the clinical findings

Having knowledge of the practice of referring physicians

Reviewing previous examinations and their interpretations to compare them with the current study

Identifying further appropriate management including diagnostic investigations essential to obtain a comprehensive diagnosis and treatment, and reviewing those recommendations with referring physicians

Reviewing all *clinical data* in a multi-disciplinary environment

Performing interventional therapeutic and diagnostic procedures

Assuming responsibility for the appropriate management of the patient during the diagnostic imaging procedure

Contributing radiological expertise to the management of the diagnostic imaging service to ensure the highest possible quality assurance and quality control

Being responsible for patient safety by ensuring minimal exposure to radiation dose and other matters that could compromise patient care

Adhering to all provincial and federal regulations, statutes relating to the delivery of medical services generally and diagnostic imaging services provincially; meeting and

exceeding the standard of care in the delivery of diagnostic imaging services in the province; maintaining membership in all of the licensing bodies and fulfilling the requirements of that licensure regime

Ensuring the selection and use of appropriate and modern equipment, properly trained staff and other elements in the high-quality delivery of diagnostic imaging

Where relevant, teaching radiology residents and fellows according to national training program requirements

Where relevant, participating in radiology research

Auditing the delivery of radiology services in the sites where the radiologist works

Ensuring timely communication of urgent findings

Maintaining appropriate records/confidentiality as mandated by legislation

In essence, appropriate teleradiology in this era is the same as the whole practice of radiology. The fact that patient data can be moved over a broadband connection does not alter the role or responsibilities of the supervising and interpreting radiologist.

The importance of interaction between the referring clinicians and the radiologist cannot be over-emphasized. There are considerable quality patient care and medical-legal implications when teleradiology services are provided by a radiologist outside the patient's jurisdiction. Regulatory bodies, licensing and credentialing (including the College of Physicians and Surgeons of Ontario, the Royal College of Physicians and Surgeons of Canada, Health Protection Branch, the Ministry of Health's Independent Health Facility branch, OHIP, X-ray Inspection branch, and other provincial and federal bodies), are unable to enforce regulations outside their jurisdiction yet have a responsibility to patients with respect to the enforcement of a wide spectrum of regulations and statutes inter-linked to the high quality delivery of radiologists' services in the province. The requirements of these and other related bodies are constantly subject to change requiring the radiologist to comply with a new and more stringent degree of responsibility with respect to the delivery of patient care.

## **Key Principles**

Diagnostic radiology is an integrated medical service required in every modern health care system.

Referring physicians are dependent upon the local availability of diagnostic imaging physicians to assist them to manage the health of their patients.

Only fully qualified diagnostic radiologists should provide the teleradiology service. They must be properly accredited, registered, and licenced in Ontario. The radiologist

should be subject to licensing and quality assurance requirements of the provincial health authority; legislative and professional requirements of the facility providing the service; the provincial College of Physicians and Surgeons, accreditation and be in good standing with the Royal College of Physicians and Surgeons of Canada.

A definitive report is mandatory with the signature of the reporting radiologist. Electronic signatures are acceptable as long as they can be authenticated.

In a public hospital the members of the radiology department must be credentialed and be part of the recognized medical staff.

The department head via the Medical Advisory Committee (MAC) and Board is responsible for the medical service.

In an Independent Health Facility (IHF), the off-site radiologist must be approved by the radiologist Quality Advisor who is legislatively responsible for Quality Control/Quality Assurance (QC/QA) at the IHF.

All radiologists providing teleradiology services must be covered by the Canadian Medical Protective Association (CMPA) for medical liability issues and ensure they are compliant with current CMPA guidelines and policies covering diagnostic imaging physicians to safeguard patient interests.

Ensure that all radiologists and their staff involved in the delivery of teleradiology services are in full compliance with relevant privacy legislation and facility policies to protect patient confidentiality.

Ensure that the information received for a primary read is the full data set and that the reading radiologist should have all of the functionality of the PACS at his/her disposal to do an interpretation.

### **Key Management Issues**

***Teleradiology services must be organized between the source radiologists and the off-site radiologist provider to guarantee the proper management of the patient.***

This will ensure that:

The clinical evaluation and data are provided with the request for the examination.

The requirements of the Healing Arts Radiation Protection Act (HARP) (including justification, appropriate techniques, optimization, and good procedure) are fulfilled.

The report of the teleradiology service can be reviewed with clinicians and where applicable, in multi-disciplinary meetings and integrated with patients' notes and previous studies.

The reporting radiologist of the teleradiology service is able to communicate directly with the referring radiology department and clinicians in order to discuss the clinical background and unexpected diagnosis, which may be relevant to the timely management of the patient.

Teleradiology services that are developed to meet the needs of rural, remote and small community areas must be linked to the nearest substantive radiology department and the service is managed by that department. The radiologists involved in providing the service must have a close connection and knowledge of referring clinicians, and technologists, and should understand any particular local disease and cultural factors.

***Equipment used for teleradiology should provide a similar level of resolution and functionality as is available in the radiology department/facility.***

The American College of Radiology's (ACR) Technical Standard for Teleradiology for equipment and other supporting technologies used in the delivery of teleradiology is the acknowledged current technical standard. Radiologists delivering teleradiology standards are expected to comply or exceed the ACR Technical Standard for Teleradiology.

## **Real and Potential Problems**

### ***Clinico-Radiological Communication***

If reporting of radiographs is taken away from close proximity with the patient, the clinical contact between the referring clinicians and radiologists is substantially reduced. It is imperative that teleradiology facilities have phone links with the hospitals and/or clinics from which images are obtained and have the ability for direct discussion between a referring clinician and the reporting radiologist on individual cases. Without this, the bond between the patient and the radiologist becomes unclear. If urgent or significant unexpected features are found, the teleradiology service must transmit them directly to the referring clinician. This will be impossible unless there is a clear point of contact for the teleradiology service.

### ***Team Working***

The ability to hold multi-disciplinary meetings is much more difficult with teleradiology, even with teleconference links. It is now widely accepted that multi-disciplinary meetings, which are often led by the radiology department, are essential in the management of problematic cases, i.e., cancer care. They maximize the understanding of the clinical problems by radiologists.

External reviews of health care disasters have emphasized the importance of teamwork especially in medicine and the need for enhanced teamwork, involving radiology has been highlighted. Interaction between different members of the hospital team with radiology may be impaired, if radiology is undertaken at the long distance by a teleradiology link.

### ***Communication***

***It is necessary that there be good communication between referring physicians, radiologists and technologists***

### ***Wording of Report and Clinical Impact***

Even if radiologists and referring clinicians have a common first language, it has to be recognized that radiological reporting may be subject to regional variation. Radiological reports often rely on verbal expressions of probability and may contain some regionally-used expressions.

Modern imaging commonly demonstrates an abundance of reportable findings, some of which are clinically relevant and some of which are incidental findings/pseudo-disease. Multiple pathologies can exist in the same patient. The clarity and certainty conveyed in the text is particularly important in converting a report that is merely 'diagnostically accurate' into one that has a diagnostic outcome and potentially a therapeutic outcome for the patient. Clinicians are more likely to act on the nuances intended in a report generated by a radiologist with whom they regularly liaise compared with a report generated by a third party teleradiology service from someone they never met. Specific wording of reports for general family doctors may be necessary, which is different from the reports to specialists within their sphere of interest. Familiarity with the referring doctors can make specific reports more appropriate and useful. Health care delivery varies between different jurisdictions. Recommendations for further imaging/specialist referral, which might be appropriate in the locale where a teleradiology service is provided, may be inappropriate in the area where the patient is located.

### ***Access to Previous Examinations/Interpretations***

The failure to review previous examinations and interpretations has been shown to be a significant cause of errors in both perception and cognition. It is therefore important that previous studies and reports are available to the reporting radiologist where these are relevant. This should be possible if the teleradiology service has access to the referrer's PACS system. There also has to be access to the hospital information system, so relevant lab data and clinical notes can be reviewed.

### ***Downstream Costs***

Teleradiology may generate significant downstream costs. There is potentially increased cost from recommendations by the teleradiology service (which may actually be unnecessary) are required due to the inexperience or insecurity of the reader of the initial study or from clinicians responding to reports describing clinically insignificant radiological findings. There may be variations in the style of practice in different jurisdictions that impact the kind or volume of studies ordered. This problem will be compounded by a potential lack of background clinical knowledge of the case and the clinical expectations of the referring clinician by the teleradiology service. Clinicians who are not confident in a report from a teleradiology service may ask radiologists with whom they work to re-report the images and to advise on case management, thus leading to duplication and poor use of financial resources. For all of these reasons, the importance of close communication between the radiologist and the clinician to minimize inappropriate clinical referrals for imaging cannot be over emphasized.

### ***Quality Control and Quality Assurance***

Quality control is paramount with teleradiology in order to prevent errors in radiology. Learning from mistakes through participation in radiological discrepancy/error meetings is established practice. Much informal feedback occurs at clinico-radiological meetings and corridor encounters. Audit is another potent form of radiological quality assurance. All these activities are much more difficult for a teleradiology service which would need a very close link between the radiologists and clinicians at the source hospital/facility. It is difficult for teleradiology services to have a proper feedback of the outcome and undertake satisfactory audit of their reports.

Radiologists providing services may provide advice relating to radiation exposure, image quality, patient positioning, and several other quality assurance and quality control (QA/QC) issues based on images they have received for interpretation. They must communicate directly with technologists, often real time, so as to be able to intervene directly to ensure optimal QA and QC. The Radiation Protection Officer, an on-site radiologist, remains responsible for the overall QA and QC and ensuring safe operation of a facility.

## ***Legal Issues***

There are a number of potential legal issues.

The registration of the reporting doctors must be accredited by the regulatory body of the local jurisdiction of a hospital/facility or the health authority purchasing the service. This is an essential requirement in order to maintain proper standards of practice. The reporting radiologists must demonstrate that they undergo appropriate CME and are properly trained in the tasks to be undertaken.

The providers of the service must abide by the jurisdiction's health and safety legislation.

The use of radiology also creates difficulties in terms of the medico-legal issues and the medico-legal responsibilities of the referring hospital/facility and that of the reporting teleradiology services must be identified. Any radiologist that reviews images has a responsibility. Liability may also reside with the purchasers of the radiology service and/or the employers of the "radiologist". It must be clear who maintains responsibility for the patient. It is clear that the "radiologist" has a direct responsibility for the patients whose study they interpret. Teleradiology providers would have to comply with any statutory duty of candor to inform the hospital/facility and patient(s) when they become aware of a negligent act or omission. At present, the legal status of teleradiology remains to be clearly established.

**Consent.** It is not clear whether the patients will be required to give explicit consent for their images to be transferred to another country or different provincial jurisdiction for reporting.

**Jurisdiction.** An individual has the right to sue a company providing electronic services within another country and the suit would be heard in the patient's own country or provincial jurisdiction.

**Patient confidentiality.** The teleradiology service must ensure patient confidentiality and be of adequate technical specification. It must comply with the data protection legislation in the transmitting and receiving provincial jurisdiction.

There is increasing awareness of the need to reduce the radiation dose that many patients receive, particularly CT scanning. When creating teleradiology contracts, it must be made clear who has responsibility for defining the protocol of an individual imaging

study, e.g. high or low dose depending on clinical indication. Teleradiology providers need to comply with pertinent directives mandated in the provincial jurisdiction.

### ***OHIP Billing Rule Affecting Teleradiology in Ontario***

OHIP added the following rule interpretation commentary to the October 2010 Schedule of Benefits (refer to page D1 of the Diagnostic Radiology section of the Schedule) where the additional note was added and remains in effect:

***Commentary: As described in Regulation 552 of the Health Insurance Act, for a service to be insured, the interpreting physician must physically be present in Ontario when the interpretation service is rendered.***

### **Legal Interpretation**

The specific legal reference is found in Subsection 37.1(1) of R.R.O. 1990, Regulation 552 made under the Health Insurance Act, R.S.O., c. H. 6. Section 37.1(1) of the Regulation provides:

*A service rendered by a physician in Ontario is an insured service if it is referred to in the schedule of benefits and rendered in such circumstances or under such conditions as may be specified in the Schedule of Benefits. [emphasis added]*

### **Guidelines for the Development and Appropriate Use of Teleradiology**

The principle that the patient is best served by a close liaison between the patient, the clinicians and the clinical radiology department should be paramount.

The radiologist's expected duty of care to the patient must not be compromised, lowered, or altered in any way by the use of teleradiology.

Teleradiology referrals should, be in the majority of cases, organized between clinical radiologists and the teleradiology provider. It is important that the radiologists act as practitioners under the statutes, regulations, directives, policies, bulletins, bylaws issued by provincial and local hospital/clinic authorities in order to ensure that appropriate investigations are performed and to justify any further investigations suggested by the reporting radiologist.

The full agreement of radiologists should be obtained in order for the development of teleradiology services to be implemented.

Teleradiology services developed for rural, remote and/or under-serviced areas should be linked to other facilities in the province of Ontario and the service

should be managed by the receiving department/clinic unless there is a radiologist at the originating centre who may elect to assume that responsibility or share it with the receiving centre radiologist. The radiologists involved in providing the service should have close communication with the referring clinicians and patients and should understand any particular local disease and cultural factors.

The radiologists providing the service must be properly accredited and registered within the provincial jurisdiction where the patient receives the service. They should also be registered and subject to quality and revalidation requirements, where applicable.

Under no circumstances should teleradiology reports be made by radiologists in training without supervision and the implementation of teleradiology should not be to the detriment of the training in the originating centre.

The use of subspecialty services should be for the benefit of a second opinion or for the immediate transfer of patients to specialist centres and not for the centralization of subspecialty reporting away from general hospitals/clinics.

The reporting radiologist of the teleradiology service must be able to communicate directly with the referring radiology department and clinicians in order to discuss the clinical background and unexpected diagnosis which may be relevant to the timely management of the patient. The equipment used to undertake the whole process of teleradiology must be of a quality and standard that provides diagnostic quality images at all times.

Proper audit procedures should be in place in order to check the quality of the teleradiology service, the accuracy of the radiological reports and the overall therapeutic and clinical impact of the service. This must include user/clinician feedback.

The teleradiology service must comply with all national and provincial data protection standards. Transfer of images outside the province could pose significant problems of data protection. It is essential that the privacy and the integrity of patient information must be preserved at all times.

There needs to be clearly defined agreement with the teleradiology service with regard to confidentiality of the images which should allow retention for comparison, proper defense against litigation or other clinically appropriate reason.

The legal arrangements must be clearly defined between the user and the provider so that proper restitution may be made to patients, if errors are made. If the service is less

than optimal, patients should not be required to litigate in the foreign country in the event of a complaint unless they have consented formally to the transfer of their rights for local litigation in addition to initial image transfer.

At all times the provision of teleradiology must be primarily developed in the best interest of the patient care and not as a cost cutting measure which may jeopardize patient safety and standards of health care.

# **Independent Health Facilities: Clinical Practice Parameters and Facility Standards**

## ***Nuclear Medicine***

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### **APPENDICES**

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# **Appendix I      Independent Health Facilities Act – Ontario Regulation 57/92**

<https://www.ontario.ca/laws/regulation/920057>

# Appendix II Sample Referring Physician Satisfaction Survey

Physician Initials (optional): \_\_\_\_\_

DATE: \_\_\_\_\_

Address, xx, city, ON postal code  
 Tel: (XXX) XXX-XXXX Fax: (XXX) XXX-XXXX

## REFERRING PHYSICIAN SATISFACTION SURVEY

Your satisfaction with our service is very important to us. To assist us in monitoring the quality of our service, please take a few minutes to complete this questionnaire and FAX it back to **XXXXX** the attention of **XXXXX**. Please indicate which of our facilities your comments most apply to:

Facility Name	Street Address	City / Town	Private Tel #

QUESTION (place check mark in the appropriate column)	YES	NO
1. Are you satisfied with the way the appointments are arranged?		
2. Are your phone calls attended to promptly and courteously?		
3. Is the requisition easy to follow?		
4. Do you receive verbal reports in appropriate circumstances or when requested?		
5. Are the reports concise and comprehensive?		
6. Are reports received in a timely manner?		
7. Do you find our locations and office hours to be convenient?		

GENERAL COMMENTS / SUGGESTIONS FOR IMPROVEMENT:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

DO YOU REQUIRE MORE REQUISITION PADS Y  N  PDF REQ?

Which EMR do you work with: \_\_\_\_\_

Please provide your Email address: \_\_\_\_\_

Physician emergency contact number - after hours/weekend use only: \_\_\_\_\_

# Appendix III

# Sample Patient Satisfaction Survey

Gender:  Male  Female

Age:  Less than 18       19 – 45  
 46 – 65       66 – 75  
 76 and over

This questionnaire is being completed by:  
 Self( patient)       Caregiver/parent

Clinic: \_\_\_\_\_ Date of Visit \_\_\_\_\_

EMAIL ADDRESS: \_\_\_\_\_

**Marking Instructions**  
 Please indicate your answer by filling in the bubbles like this  not like  or .  
 Thank you!

**Interpretation of the Rating:** This form is used by a variety of patients, therefore, not all of the following items may be relevant to you. If any of these are **NOT** relevant to you, mark these "Unable to Assess/Not Applicable".

Indicate how much you agree with the statements on the left side of the page using the following scale. |

Clinic Specific Feedback	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Unable to Assess/ Not Applicable UA/NA
	1	2	3	4	5	
<b>Based on my MOST RECENT VISIT:</b>						
1. My appointment time was convenient for my lifestyle	<input type="radio"/>					
2. The clinic was easy to find	<input type="radio"/>					
3. The clinic was clean and comfortable	<input type="radio"/>					
4. I was taken care of in a timely fashion upon arrival	<input type="radio"/>					
5. Explanations and instructions were given clearly	<input type="radio"/>					
6. The clinic staff were helpful, pleasant and knowledgeable	<input type="radio"/>					
7. The examination was explained clearly before it started	<input type="radio"/>					
<b>GENERAL:</b>						
A. I am interested in booking appointments online	<input type="radio"/>					
B. I am interested in using check-in kiosk at the clinic	<input type="radio"/>					
C. I would be interested in getting a copy of my report via online access	<input type="radio"/>					
D. Which mode of transportation did you use today to get to the clinic?						

**COMMENTS:**

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

