Independent Health Facilities

Clinical Practice Parameters and Facility Standards

(Updated to incorporate PET/CT procedures currently insured under the OHIP Fee Schedule)
First Edition, August 1993:
Members of the Nuclear Medicine Task Force:
Dr. David Greyson (Chair) Toronto, Ontario
Dr. Earl Brown Kitchener, Ontario
Dr. Cameron Hunter North Bay, Ontario
Dr. Adel Mattar London, Ontario
Dr. Shawn Ripley Tecumseh, Ontario
Dr. Fabiano Taucer Ottawa, Ontario

Second Edition, December 2001:
Members of the Nuclear Medicine Task Force:
Dr. David Greyson (Chair) Toronto, Ontario
Dr. Cameron Hunter North Bay, Ontario
Dr. Adel Mattar London, Ontario
Dr. Shawn Ripley Tecumseh, Ontario
Dr. Fabiano Taucer Ottawa, Ontario

Third Edition, March 2008:
Members of the Nuclear Medicine Task Force:
Dr. David Greyson (Chair) Toronto, Ontario
Dr. Judith Ash Toronto, Ontario
Dr. Richard Dubeau Kitchener, Ontario
Dr. David Gilday Toronto, Ontario
Dr. David Webster Sudbury, Ontario
Ms. Janet Wilmot St. Catharines, Ontario
Dr. Kathy Yip Mississauga, Ontario

Member of the PACS Working Group
Dr. David Gilday (Chair) Toronto, Ontario
Ms. Zany Dhalla Markham, Ontario
Dr. Alex Hartman Richmond Hill, Ontario
Ms. Marlene McCarthy Collingwood, Ontario
Dr. Mark Prieditis Scarborough, Ontario
Dr. Tim Richardson Creemore, Ontario

Fourth Edition, August 2011
Members of the PET Task Force
Dr. Christopher O’Brien Brantford
Dr. Judith Ash Toronto
Dr. Marc Freeman Toronto
Dr. Francois Raymond Ottawa
Dr. William Pavlosky London
Dr. Kathy Yip Mississauga
Mr. Douglass Vines Toronto
Published and distributed by the College of Physicians and Surgeons of Ontario. For more information about the Independent Health Facilities program, contact:

Wade Hillier
Associate Director
Practice Assessment and Enhancement
Quality Management Division
The College of Physicians and Surgeons of Ontario
80 College Street
Toronto, Ontario M5G 2E2
Toll free (800) 268-7096
(416) 967-2636
email: whillier@cpso.on.ca
The College of Physicians and Surgeons of Ontario

Our Strategic Plan
The Council of the College of Physicians and Surgeons of Ontario developed a strategic plan to establish College priorities for the next several years. The priorities articulated in the strategic plan serve as a guide to action and focus our energies toward attaining our new vision – Quality Professionals, Healthy System, Public Trust.

Our Mandate
Build and maintain an effective system of self-governance. The profession, through and with the College, has a duty to serve and protect the public interest by regulating the practice of the profession and governing in accordance with the Regulated Health Professions Act.

Our Vision Defined
Quality Professionals, Healthy System, Public Trust
Our new vision is the framework by which we organize ourselves. It guides our thinking and actions into the future. It defines not only who we are, but what we stand for, the role we see for ourselves, our critical relationships, in what system we work, and the outcomes we seek. Each component of our vision is defined below:

Quality Professionals – as a profession and as professionals, we recognize and acknowledge our role and responsibility in attaining at a personal, professional, and at a system-level, the best possible patient outcomes. We are committed to developing and maintaining professional competencies, taking a leadership position on critical issues that impact the performance of the system, and actively partner to provide tools, resources, measurement, to ensure the optimal performance at all levels of the system.

Healthy System – the trust and confidence of the public and our effectiveness as professionals is influenced by the system within which we operate. Therefore, we, as caring professionals, are actively involved in the design and function of an effective system including:
- accessibility
- the interdependence of all involved
- measurements and outcomes
- continued sustainability

Public Trust – as individual doctors garner the trust of their patients, as a profession we must aim to have the trust of the public by:
- building positive relationships with individuals
- acting in the interests of patients and communities
- advocating for our patients and a quality system

Our Guiding Principles
Integrity, accountability, leadership and cooperation
The public, through legislation, has empowered the profession to regulate itself through the College. Central to the practice of medicine is the physician-patient relationship and the support of healthy communities. As the physician has responsibility to the patient, the profession has the responsibility to serve the public through the health-care system. To fulfill our vision of quality professionals, healthy system, public trust we will work to enhance the health of the public guided by professional competence and the following principles:

Integrity – in what we do and how we go about fulfilling our core mandate:
- Coherent alignment of goals, behaviours and outcomes;
- Steadfast adherence to a high ethical standard.

Accountability to the public and profession – we will achieve this through:
- An attitude of service;
- Accepting responsibility;
- Transparency of process;
- Dedicated to improvement.

Leadership – leading by proactively regulating our profession, managing risk and serving the public.
Cooperation – seeking out and working with our partners – other health-care institutions, associations and medical schools, etc. – to ensure collaborative commitment, focus and shared resources for the common good of the profession and public.
TABLE OF CONTENTS

Preface ................................................................................................................................. i

Purpose of Clinical Practice Parameters ................................................................. 1
Role of the College of Physicians and Surgeons ...................................................... II
Responsibilities of the College .................................................................................... III
Updating this Document ............................................................................................ III

Volume 1 .......................................................................................................................... 1

Facility Standards ........................................................................................................... 1

Chapter 1 - Staffing a Facility ...................................................................................... 1

Overview ....................................................................................................................... 1
Qualifications of Physician in Medical Charge of a Nuclear Medicine Service ............... 1
Responsibilities ............................................................................................................ 2
Quality Advisor ........................................................................................................... 2
Qualifications ............................................................................................................. 4
Radiation Safety Officer ............................................................................................. 5
Interpreting Physician Qualifications ........................................................................ 5

Nuclear Medicine Services ........................................................................................ 5
PET/CT Procedures ..................................................................................................... 6
Responsibilities ......................................................................................................... 6

Technologists ............................................................................................................. 7
Qualifications ............................................................................................................. 7
Responsibilities ......................................................................................................... 7

Technologists Performing BMD Studies .................................................................... 9

Chapter 2 - Facilities, Equipment and Supplies ....................................................... 11

Overview ....................................................................................................................... 11
Facilities, Equipment and Supplies .......................................................................... 11

Chapter 3 - Developing Policies and Procedures ................................................... 13

Overview ....................................................................................................................... 13
Developing Policies and Procedures .......................................................................... 13
Infection Control ......................................................................................................... 14

Chapter 4 - Requesting and Reporting Mechanisms ............................................ 15

Overview ....................................................................................................................... 15
Requesting and Reporting Mechanisms .................................................................... 15

Chapter 5 - Providing Quality Care ......................................................................... 17

Overview ....................................................................................................................... 17
Providing Quality Care .............................................................................................. 17
Radiation Safety ......................................................................................................... 17
Radiopharmaceuticals ................................................................................................. 18
Instrumentation .......................................................................................................... 18
Equipment Testing ....................................................................................................... 18

Gamma Cameras .......................................................................................................... 18
PET/CT Scanners ...................................................................................................... 18
Well Counter, Dose Calibrator, and Survey Meters .................................................... 18
Film Processor ............................................................................................................ 19
Dual Energy X-ray Absorptiometers (bone densitometers) ........................................ 19
<table>
<thead>
<tr>
<th>Chapter</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chapter 6 -</td>
<td>Clinical Practice Parameters</td>
<td>23</td>
</tr>
<tr>
<td>Chapter 7 -</td>
<td>First Transit without Blood Pool Images</td>
<td>25</td>
</tr>
<tr>
<td>Chapter 8 -</td>
<td>First Transit with Blood Pool Images</td>
<td>27</td>
</tr>
<tr>
<td>Chapter 9 -</td>
<td>Myocardial Perfusion Scintigraphy</td>
<td>29</td>
</tr>
<tr>
<td>Chapter 10 -</td>
<td>Myocardial Wall Motion Studies with Ejection Fraction</td>
<td>31</td>
</tr>
<tr>
<td>Chapter 11 -</td>
<td>Thyroid Uptake and Repeat Uptake</td>
<td>33</td>
</tr>
<tr>
<td>Chapter 12 -</td>
<td>Thyroid Scintigraphy with Tc 99m, I-131, I-123, or FDG</td>
<td>35</td>
</tr>
<tr>
<td>Chapter 13 -</td>
<td>Biliary Scintigraphy</td>
<td>37</td>
</tr>
<tr>
<td>Chapter 14 -</td>
<td>Liver and Spleen Scintigraphy</td>
<td>39</td>
</tr>
</tbody>
</table>

**ADDITIONAL COMPONENTS OF QUALITY MANAGEMENT** ........................................................................................................ 19

**Volume 2** ........................................................................................................................................................................ 21

Clinical Practice Parameters .................................................................................................................................................. 21

**Chapter 6 - Clinical Practice Parameters** .................................................................................................................... 23

Overview ................................................................................................................................................................................. 23

Performing Appropriate Tests ................................................................................................................................................ 23

**Chapter 7 - First Transit without Blood Pool Images** .................................................................................................. 25

Overview ................................................................................................................................................................................. 25

Clinical Indications .............................................................................................................................................................. 25

Reporting Guidelines ............................................................................................................................................................ 25

**Chapter 8 - First Transit with Blood Pool Images** ..................................................................................................... 27

Overview ................................................................................................................................................................................. 27

Prerequisites ........................................................................................................................................................................ 27

Clinical Indications ............................................................................................................................................................. 27

Reporting Guidelines ........................................................................................................................................................... 27

**Chapter 9 - Myocardial Perfusion Scintigraphy** .......................................................................................................... 29

Overview ................................................................................................................................................................................. 29

Clinical Indications .............................................................................................................................................................. 29

Reporting Guidelines ............................................................................................................................................................ 30

**Chapter 10 - Myocardial Wall Motion Studies with Ejection Fraction** ........................................................................ 31

Overview ................................................................................................................................................................................. 31

Clinical Indications .............................................................................................................................................................. 31

Reporting Guidelines ............................................................................................................................................................ 31

**Chapter 11 - Thyroid Uptake and Repeat Uptake** ........................................................................................................ 33

Overview ................................................................................................................................................................................. 33

Prerequisites ........................................................................................................................................................................ 33

Clinical Indications ............................................................................................................................................................. 33

Reporting Guidelines ............................................................................................................................................................ 33

**Chapter 12 - Thyroid Scintigraphy with Tc 99m, I-131, I-123, or FDG** ........................................................................ 35

Overview ................................................................................................................................................................................. 35

Prerequisites ........................................................................................................................................................................ 35

Clinical Indications ............................................................................................................................................................. 35

Reporting Guidelines ............................................................................................................................................................ 36

**Chapter 13 - Biliary Scintigraphy** ................................................................................................................................. 37

Overview ................................................................................................................................................................................. 37

Prerequisites ........................................................................................................................................................................ 37

Clinical Indications ............................................................................................................................................................. 37

Reporting Guidelines ............................................................................................................................................................ 38

**Chapter 14 - Liver and Spleen Scintigraphy** .................................................................................................................. 39

Overview ................................................................................................................................................................................. 39

Clinical Indications ............................................................................................................................................................. 39

Reporting Guidelines ............................................................................................................................................................ 39
Chapter 15 - Dynamic Renal Scintigraphy ................................................................. 41
  OVERVIEW........................................................................................................ 41
  CLINICAL INDICATIONS ............................................................................... 41
  REPORTING GUIDELINES ............................................................................ 41

Chapter 16 - Computer Assessed Renal Function (includes first transit) ....... 43
  OVERVIEW........................................................................................................ 43
  RADIOPHARMACEUTICALS USED ................................................................. 43
  PREREQUISITES............................................................................................ 43
  CLINICAL INDICATIONS ............................................................................... 43
  REPORTING GUIDELINES ............................................................................ 43

Chapter 17 - Repeat Computer Assessed Renal Function after Pharmacological Intervention ................................................................. 45
  OVERVIEW........................................................................................................ 45
  PREREQUISITES............................................................................................ 45
  Intervention with furosemide ........................................................................ 45
  Intervention with ACE inhibitors ................................................................. 45
  CLINICAL INDICATIONS ............................................................................... 46
  CONTRAINDICATIONS AND PRECAUTIONS ............................................ 46
  Drug Allergy .................................................................................................. 46
  REPORTING GUIDELINES ............................................................................ 46

Chapter 18 - Static Renal Scintigraphy ................................................................. 47
  OVERVIEW........................................................................................................ 47
  CLINICAL INDICATIONS ............................................................................... 47
  REPORTING GUIDELINES ............................................................................ 47

Chapter 19 - Bone Scintigraphy ........................................................................ 49
  OVERVIEW........................................................................................................ 49
  CLINICAL INDICATIONS ............................................................................... 49
  REPORTING GUIDELINES ............................................................................ 49

Chapter 20 - Sepsis, Inflammation and/or Tumour Scintigraphy ...................... 51
  OVERVIEW........................................................................................................ 51
  CLINICAL INDICATIONS ............................................................................... 51
  PET/CT Clinical Indications: ......................................................................... 52
  REPORTING GUIDELINES ............................................................................ 53

Chapter 21 - Bone Mineral Content by Dual Energy Absorptiometry (DEXA) . 55
  OVERVIEW........................................................................................................ 55
  BONE DENSITOMETRY .................................................................................. 55
  PREREQUISITES............................................................................................ 56
  CLINICAL INDICATIONS ............................................................................... 56
  REPORTING GUIDELINES ............................................................................ 57

Chapter 22 - Brain Scintigraphy with Single Photon Emission Computed Tomography ................................................................. 59
  OVERVIEW........................................................................................................ 59
  CLINICAL INDICATIONS ............................................................................... 59
  REPORTING GUIDELINES ............................................................................ 59

Chapter 23 - Perfusion and Ventilation Scintigraphy ......................................... 61
Preface


- 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 and Long-Term Care, 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 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

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 specialities. 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.

Note: The parameters and standards are not intended to either replace a physician's clinical judgement 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.

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.

Role of the College of Physicians and Surgeons

At the beginning of this process, the College adopted the role of a facilitator for the development of 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.

The Task Force members’ initial work, distributed in March 1991, was sent to the following organizations for their review and comments:

- all relevant specialty physicians in Ontario, national specialty societies and specialty sections of the Ontario Medical Association
- Ontario Chapter of the College of Family Physicians of Canada
- Canadian Medical Association
- American Medical Association
- Canadian Council on Health Facilities Accreditation (now the Canadian Council on Health Services Accreditation)
- College of Nurses of Ontario

The Task Forces continue to adhere to the following principles:

- clinical practice parameters must be based on the appropriate mix of current, scientifically-reliable information from research literature, clinical experience and professional consensus.
- any parameter-setting exercise must be done exclusively from the quality perspective. That may well mean that some of the conclusions reached could add to medical care costs.
- parameters have to be 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 need to be developed by consensus and consultation with the profession at large.
- parameters should provide support and assistance to physicians without boxing them in with “cookbook formulas.”
- parameters will need to be regularly updated based on appropriate research studies.
- parameters should reduce uncertainty for physicians and improve their clinical decision-making.
• information on practice parameters must be widely distributed to ensure that all physicians benefit from this knowledge.

Responsibilities of the College

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 legislation, 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

These parameters and standards, updated in the year 2011 are subject to periodic review, and amendments in the form of replacement pages may be issued from time to time. Such pages will be mailed automatically to all relevant independent health facilities.

The Chapters included in this text represent the service most often considered by nuclear medicine physicians. These procedures, and any other procedure in the OHIP fee schedule, that are not included in this document may still be performed.

It is planned to issue new editions of the parameters and standards at intervals not greater than five years. The external review process will be repeated to validate the new parameters as they are developed.
Chapter 1- Staffing a Facility

Overview

Nuclear medicine services are provided to patients by appropriately qualified medical, technical and clerical personnel taking into account the requirements of the Ontario Tripartite Nuclear Medicine Advisory Committee, Canadian Nuclear Safety Commission (CNSC) and the Independent Health Facilities Act.

Qualifications of Physician in Medical Charge of a nuclear medicine service

The physician in medical charge of a nuclear medicine service is a member licensed 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, or
- previously approved by the Tripartite Committee on the basis of its requirements. (Please see Appendix 1.), or
- formally recognized as a specialist in nuclear medicine by the College of Physicians and Surgeons of Ontario, based on the “Recognition of Non-Family Medicine Specialists” policy. Documentation must be available to demonstrate full compliance with any terms, condition or limitations of their registration with the CPSO, including any supervision requirement or scope of practice definition, or

If Positron Emission Tomography (PET/CT) is being performed in the IHF, the physician in medical charge of a nuclear medicine service must meet one of the criteria noted above and have

- a minimum of an additional 6 months of didactic and observational training with a minimum of 250 cases(CANM) and evidence of continuing practice in PET/CT within the previous 5 years, or
- was/is in medical charge of a PET/CT service in an IHF or accredited hospital in Ontario prior to January 1, 2011.

Note: These qualifications reflect the current indications for PET/CT in Ontario. As the indications for PET/CT change, the Task Force will address any required changes at that time.
Responsibilities
Please see Ontario Tripartite Nuclear Medicine Advisory Committee, Information Sheet (Appendix I)

Quality Advisor
The role of the Quality Advisor is an important one. Quality Advisors play a vital role in the overall operation of the Independent Health Facility 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 O.Reg. 57/92 under the Independent Health Facilities Act, 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 independent health facility. The Quality Advisor must be a health professional 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.

The Quality Advisor is responsible for advising the licensee with respect to the quality and standards of services provided. In order 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 co-ordinated as part of the Quality Advisory Committee (QA Committee) meetings.
- The Quality Advisor shall document all visits to the facility made in connection with the Quality Advisor’s role.
- The Quality Advisor shall ensure that a qualified physician be available for consultation during the facility’s hours of operation.
- The Quality Advisor 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.
- The Quality Advisor shall chair the QA Committee. The QA Committee shall meet at least twice a year if the facility employs more than six full-time staff equivalents including the Quality Advisor; otherwise the QA Committee shall meet at least once a year. Regular agenda items should include: review of cases; policies and procedures; quality control matters on equipment; incidents, medical and technical staff issues.
- All QA Committee meetings shall be documented.
The Quality Advisor shall 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, BCLS 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 staffing hiring decisions**, in order to ensure that potential candidates have the appropriate knowledge, skills 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, eg., 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.

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 forwhith 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.

Qualifications

The Quality Advisor is a physician licensed 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, or
- previously approved by the Tripartite Committee on the basis of its requirements. (Please see Appendix 1), or
- formally recognized as a specialist in nuclear medicine by the College of Physicians and Surgeons of Ontario, based on the “Recognition of Non-Family Medicine Specialists” policy. Documentation must be available to demonstrate full compliance with any terms, condition or limitations of their registration with the CPSO, including any supervision requirement or scope of practice definition or

If PET/CT procedures are being performed in the IHF, the physician in medical charge of a nuclear medicine service must meet one of the criteria noted above and have

- a minimum of an additional 6 months of didactic and observational training with a minimum of 250 cases(CANM) and evidence of continuing practice in PET/CT within the previous 5 years, or
- was/is in medical charge of a PET/CT service in an IHF or accredited hospital in Ontario prior to January 1, 2011.

Note: These qualifications reflect the current indications for PET/CT in Ontario. As the indications for PET/CT change, the Task Force will address any required changes at that time.
Radiation Safety Officer
The facility has 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.

Radiation Protection Officer
If the facility has one or more x-ray tubes (for example computed tomography, and/or DEXA) it must have a radiation protection officer (RPO) in accordance with the provisions set out under the Healing Arts Radiation Protection Act (HARP Act).

Interpreting Physician Qualifications

Nuclear Medicine Services
Nuclear medicine services are provided by a physician who is licensed 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, or
- previously approved by the Tripartite Committee on the basis of its requirements. (Please see Appendix 1), or
- formally recognized as a specialist in nuclear medicine by the College of Physicians and Surgeons of Ontario, based on the “Recognition of Non-Family Medicine Specialists” policy. Documentation must be available to demonstrate full compliance with any terms, condition or limitations of their registration with the CPSO, including any supervision requirement or scope of practice definition., or
- is currently practising in Ontario and has demonstrated to the CPSO, by practice assessment, that the individual has appropriate training AND knowledge, skill and judgement based on practice experience to provide a limited scope of nuclear medicine services within an Independent Health Facility. Documentation must be available to demonstrate that the individual has successfully completed the CPSO requirements and is in full compliance with any terms, conditions or limitations of their registration with the CPSO, including any supervision requirement or scope of practice definition (*see note).
**PET/CT Procedures**

PET/CT procedures are provided by a physician who is licensed 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, or
- previously approved by the Tripartite Committee on the basis of its requirements. (Please see Appendix 1), or
- formally recognized as a specialist in nuclear medicine by the College of Physicians and Surgeons of Ontario, based on the “Recognition of Non-Family Medicine Specialists” policy. Documentation must be available to demonstrate full compliance with any terms, condition or limitations of their registration with the CPSO, including any supervision requirement or scope of practice definition.

And

- received a minimum additional 3 months of didactic and observational training with a minimum of 250 cases (CANM) and has evidence of continuing practice in PET/CT within the previous 5 years or
- has been interpreting PET/CT studies in an IHF or accredited hospital in Ontario prior to January 1, 2011.

*Note: These qualifications reflect the current indications for PET/CT in Ontario. As the indications for PET/CT change, the Task Force will address any required changes at that time.*

**Responsibilities**

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.
- any complications or problems that arise, either clinically or from the standpoint of radiation safety, informing the Quality Advisor.
being present during the intervention studies, either pharmacological or physiological, during which the patient may require immediate medical attention.

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.

Technologists

Qualifications
In Ontario, Medical Radiation Technologists MRT(N) are self-regulated professionals. They must practice in accordance with the applicable provincial legislation, the Medical Radiation Technology Act and the College of Medical Radiation Technologists of Ontario (CMRTO) standards of practice.

Medical Radiation Technologists have a current and valid certificate of registration with the College of Medical Radiation Technologists of Ontario (CMRTO) and the Canadian Association of Medical Radiation Technologists.

Technologists performing PET/CT procedures will receive additional appropriate training prior to performing the procedure with the approval of the Quality Advisor.

Responsibilities
The Technologist’s responsibilities are:

• To practice the ALARA principle using time, distance and shielding
• To perform quality control procedures on all nuclear medicine equipment, bone mineral densitometers, generator eluate and radiopharmaceuticals according to facility policies and manufacturers’ specifications
• To review and record the quality control results and take corrective action if the results are not within acceptable limits
• To ensure that equipment which comes in direct contact with the patient, that is, resuscitation devices, gamma cameras, thyroid probes, bone mineral densitometers and stress testing equipment is mechanically and electrically sound
• To perform nuclear medicine procedures and bone mineral densitometry studies on patients as ordered by a physician and in adherence with the protocols of the facility and accepted industry standards. Notifying the referring physician of contraindications to a procedure or recommending changes required to a procedure in order to proceed as stated in the protocol
• To verify the patient’s identity prior to beginning the study
To provide the patient with an explanation of the procedure which will enable the patient to give informed consent (with the help of an interpreter if required) including:
- ascertaining whether a patient (10-55 y.o.) is pregnant
- consulting with the referring physician or nuclear medicine physician concerning the requirement to proceed with the study if a patient is pregnant
- the risks to the fetus in pregnancy or possible pregnancy (10-55 y.o. patients)
- the restrictions on breast feeding where applicable
- the possible side effects of the radiopharmaceutical
- the radioactive nature of the pharmaceutical to be administered
- notification of the administration of X-rays where applicable
- the risks of undergoing stress testing (exercise or pharmacological)
- the methods of decreasing radiation dose
- a description of the procedure and the time involved
- answers to all of the patient’s questions concerning the study
- procuring written consent from patients where applicable

Carry out examination or treatment only with the informed consent of the patient, or the patient’s substitute decision maker.

To protect the patient by administering the correct dose of the correct radiopharmaceutical, which has been visually inspected and has not expired

To adhere to the principles of aseptic technique and to follow the facility’s policies regarding infection control

To evaluate the images and results of a procedure for technical adequacy and diagnostic quality and to label all images with patient identity and positioning markers. Record for the reporting nuclear medicine physician, any procedural changes which were required to successfully perform the study

In the case of possible drug reaction, to inform the manufacturer, Health Canada, the attending physician (if applicable) and the report physician

To initiate emergency response procedures in cases of adverse reactions to radiopharmaceuticals or injury

To treat all patients with dignity and to respect a patient’s right to privacy by protecting the confidentiality of patient records

To protect the staff, patients and the general public through the correct use, storage and disposal of radiopharmaceuticals according to facility policies and the regulations of the Canadian Nuclear Safety Commission

To protect staff, patients and the general public by conducting tests for radioactive contamination according to the Canadian Nuclear Safety Commission Regulations
To maintain all patient documentation, quality control records, radiopharmaceutical receipt, storage and disposal records for the period stipulated by the applicable governing agency or according to facility policies.

**Technologists Performing BMD Studies**

Technologists are registered by the College of Medical Radiation Technologists of Ontario. Technologists other than MRT(N), must show evidence of successful completion of a recognized technologist’s course in the performance of Bone Mineral Densitometry studies, such as from the International, or Canadian Society of Clinical Densitometry.
Chapter 2 - Facilities, Equipment and Supplies

Overview
There is adequate space, facilities, equipment and supplies to perform the nuclear medicine procedures in a safe and efficient manner, ensuring the effective care and privacy of patients.

Facilities, Equipment and Supplies
In a facility where stress tests are performed, there is appropriate medical supervision and other skilled staff. An emergency cart and resuscitation equipment is immediately available. All staff is trained in emergency procedures which are appropriate to the role they would assume in an emergency.

Appropriate safety precautions are maintained against electrical, mechanical, and chemical and radiation hazards, as well as against fire and explosion, so that personnel and patients are not endangered.

All equipment is of a contemporary standard which is properly maintained and calibrated. Written records of the instrumentation quality control program are available.

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

The facility must have a selection of current nuclear medicine textbooks, on general and specific topics, in clinical applications and basic sciences. In addition, there should be a selection of various nuclear medicine journals available for reference.

The facility is a “latex-safe” environment. The prevalence of latex allergic reactions has increased since the introduction of Body Substance Precautions. The use of latex-free supplies protects both the patient and the health care worker. The facility has latex-free alternatives to supplies that may cause latex allergic reactions through contact with skin or inhalation. (See Appendix III).
Chapter 3 - Developing Policies and Procedures

Overview
There are current written policies and procedures to provide the staff with clear direction on the scope and limitations of their functions and responsibility for patient care.

Developing Policies and Procedures
The procedure manual is available within the department for consultation, and is reviewed at least annually, revised as necessary, and dated to indicate the time of the last review or revision. Procedures in the manual include, but are not limited to:

- specific protocols for the techniques performed at the facility, including appropriate patient preparation, radiopharmaceutical dose, and specific patient instructions following the procedure.
- policies regarding requisition of tests from referring physicians and reporting mechanisms.
- special considerations with regard to emergency requests.
- methods to handle patients requiring emergency medical attention.
- radiation safety policies and radiopharmaceuticals quality control procedures 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 misadministered e.g., incorrect radiopharmaceutical or overdosage.
- policies and procedures for establishing and maintaining a program to evaluate the technical performance of the instruments used for imaging, radiation monitoring and film processing. This includes procedures for testing instruments according to manufacturers’ guidelines and any applicable regulations.
- a policy regarding methods of reducing latex allergic reactions, including how to recognize a reaction, the types of supplies used by the facility that may contain...
latex, the latex-free alternatives available in the facility and the latex containing supplies for which there are no latex-free alternatives. If the facility does not routinely use latex-free supplies, how are staff and patients screened for latex allergy and what procedures are in place to protect vulnerable patients and staff (see Appendix III)?

**Infection Control**

Routine practices to prevent infection are described in detail in the CPSO guidelines *Infection Control in the Physician’s Office 2004 Edition* booklet that is available for all physicians.
Chapter 4 - Requesting and Reporting Mechanisms

Overview

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.

Guidelines for Picture Archiving and Communication Systems (PACS) are appended to this document (See Appendix IV, Page 77).

Requesting and Reporting Mechanisms

Written requisitions are completed for all nuclear medicine procedures.

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

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 physicians who are to receive copies of the report
- 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.

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.
PET/CT requisitions must be in compliance with PET Scans Ontario requirements (www.petscans.ontario.ca)

Reports reach the referring physician as quickly and as efficiently as possible. Independent health facilities are likely to differ widely in their reporting methods. A mechanism is in place to identify urgent requests and to communicate critical examination results on a timely basis.

Copies of all reports and written requests are considered part of the patient record. These documents are maintained in a systematic manner and retained for a period stipulated by the regulations under the Independent Health Facilities Act, 1990. See Appendix II, Independent Health Facilities Act-Ontario Reg. 57/92 -Amended to O.Reg. 14/95.

A mechanism is in place which enables the reporting physician to solicit follow-up information for the medical outcome component of the quality management program.
Chapter 5 - Providing Quality Care

Overview
A Quality Advisory Committee is established as per the IHF Act. The advisory committee shall consist of health professionals who provide health services in or in connection with the independent health facility. Regular meetings are held and minutes maintained (IHF Act Regulation 57/92).

| 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 her/her office practice. |

To provide quality of care, there is evidence that patients’ needs for nuclear medicine services are assessed. The services planned and provided are consistent with those needs and assure diagnostic reliability and patient safety.

Providing Quality Care
A quality management program is a planned, systematic, and comprehensive strategy which permits internal and external review of the measures taken to provide the highest possible quality of medical care and patient safety.

To comply with O.Reg 57/92 s.5 (Appendix II), the facility establishes and maintains a system to monitor the results of the services provided. The quality management program is designed to assure high standards and to promote optimal patient health care in Ontario.

The facility establishes a quality management program appropriate for its volume and the type of service provided. It is recognized that facilities will vary depending on their size, scope of practice and geographical considerations.

The facility's quality management program and associated documentation are subject to assessment by the College of Physicians and Surgeons of Ontario.

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

All procedures adhere to the ALARA concept in order to protect the patient, the facility staff, the public and the environment.

The ALARA concept is that radiation exposure should be kept “as low as is reasonably achievable”.

Radiation safety policies, as outlined in Chapter 3 Developing Policies and Procedures, are implemented.
Radiopharmaceuticals

Radiopharmaceutical policies outlined in the Chapter 3 on Developing Policies and Procedures are implemented.

The quality management program meets the regulatory requirements of the Canadian Nuclear Safety Commission and the Health Protection Branch of Health Canada.

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.

Instrumentation

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

Equipment Testing

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 is carried out.

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.

PET/CT Scanners

Routine PET/CT scanner quality control procedures as specified by the manufacturer must be performed and results logged for future comparisons.

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.

**Film Processor**
The film processor receives regular service and chemicals are renewed.

**Dual Energy X-ray Absorptiometers (bone densitometers)**
Routine bone densitometer quality control procedures must be performed and the results logged for future reference. The quality control performed will depend on the make and model of the bone densitometer. Procedures may include but are not limited to:

• Daily quality control which involves scanning a phantom. Each manufacturer of bone densitometers provides a phantom to be used for daily quality control.

• Periodic precision studies to calculate the precision error of the equipment and the operator. May be performed by the service personnel or the technologist.

• Preventative maintenance every six months as required under the HARP Act.

**Additional Components of Quality Management**
Additional components of quality management include a review of:

• goals and objectives
• policies and procedures
• incidents, adverse drug reactions, complications
• clinical data e.g. assessing accuracy of interpretation, appropriateness of examinations.
• recommendations from other assessing bodies such as the Canadian Nuclear Safety Commission and the Health Protection Branch, Health Canada.
• staff performance appraisals
• mechanisms for evaluating diagnostic efficacy
• patient and referring physician satisfaction mechanisms.

All staff at the facility receives the results of such reviews.

All staff at the facility participates in planning strategies to overcome any deficiencies and to continuously improve the services provided to patients.
Chapter 6 - Clinical Practice Parameters

Overview

The following chapters summarize the most common nuclear medicine procedures currently in clinical use. It reflects the opinion of the Nuclear Medicine Task Force of The College of Physicians and Surgeons of Ontario on the appropriate indications and use of these procedures.

While pregnancy and breastfeeding are relative contraindications to the use of radiopharmaceuticals, the nuclear medicine physician needs to be consulted prior to administration. The balance between the risks and the benefits of performing the test(s) will be considered.

During the explanation of the NM study the patient should be questioned as to whether he/she will be traveling by air, or traveling to the United States by car within the next three day period and if so, the patient should be provided with a letter from the facility advising they have just undergone a NM study using a radiopharmaceutical.

A nuclear medicine report should consist of a description of the findings and an interpretation of those findings which may include differential diagnosis, correlation with other studies and recommendations for further evaluation.

The physician has experience in interpreting tomographic images, as well as knowledge of the technical aspects of tomographic acquisition and reconstruction so that artifacts will be recognized.

Performing Appropriate Tests

The physician practising nuclear medicine ensures that the appropriate tests are performed for the appropriate indications. Where various modalities and tests are used to diagnose similar conditions, the physician practising nuclear medicine satisfies him/herself that there is no redundancy and that the additional test is of clinical significance.

It is the responsibility of the Independent Health Facility to ensure that billing practices meet the current fee schedule.

Note: Taking into account the patient's best interests and being aware of the current status of available resources, the Task Force discourages the use of “screening” tests or “routine” studies that do not have a clinical indication.
Chapter 7 - First Transit without Blood Pool Images

Overview
After the intravenous injection of a radionuclide bolus, dynamic imaging of the first transit (blood flow) is recorded. Immediate or blood pool images are not performed when the information to be gained does not contribute to the diagnostic process.

Clinical Indications
The test may be performed in conjunction with radiocolloid liver-spleen scanning, hepatobiliary scanning, Meckel's diverticulum scanning, 99m Tc brain perfusion, thyroid scanning, salivary gland scanning and other scans where additional diagnostic information may be relevant.

The clinical indications of radionuclide angiography are very wide and varied. From a technical standpoint, this test can be incorporated into many scanning procedures. However, it is important that the physician practising nuclear medicine consider the expected diagnostic value or clinical significance of the information to be gained prior to adding radionuclide angiography to other scanning procedures.

Reporting Guidelines
The results of the test are reported in conjunction with the organ functional images.
Chapter 8 - First Transit with Blood Pool Images

Overview
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.

Prerequisites
Radionuclide blood flow studies may be requested by the referring physician for their inherent diagnostic value in specific clinical situations. More often, however, 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.

In general, to make this decision, the physician practising nuclear medicine takes into account whether by knowing the vascularity of the examined part, he/she is better able to interpret the test by pinpointing the diagnosis or by narrowing the differential diagnosis under consideration. In this regard, a normal or an abnormal result can add valuable information. The immediate or blood pool images are performed in conjunction with the flow study when the information to be gained is expected to contribute to the diagnostic process.

Clinical Indications
The clinical indications are very wide and varied. Detailed lists of indications are beyond the scope of this document.

However, before adding the blood flow study or blood pool images to any test, the physician practising nuclear medicine needs to consider the diagnostic yield or clinical significance of the information to be gained, as well as the implication of a false negative or a false positive result.

Reporting Guidelines
The test results are reported in conjunction with the organ functional image.
Chapter 9 - Myocardial Perfusion Scintigraphy

Overview
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 or Tc 99m labelled products distribute in myocardial tissue proportional to regional blood. Consequently, those regions with relatively higher blood flow at the time of injection appear more intense on scintiscan compared to regions with a relatively lower blood flow.

When using FDG those regions that have maintained glucose metabolism will show increased FDG uptake as compared to those area that have poor glucose metabolism. Prior to proceeding with the FDG study the patient’s glucose level should be determined and if abnormal it should be corrected prior to FDG administration. The patient should also be fasting either 4 hours or after midnight depending on the time of booked study.

The current standard of practice for perfusion scintigraphy requires SPECT for optimal localization as well as increased sensitivity and specificity of diagnosis. If the facility does not have the capability of SPECT, the perfusion study should not be performed.

When assessing glucose metabolism with FDG a dedicated PET scanner preferably with CT should be used.

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.

Clinical Indications
Clinical indications for performing myocardial perfusion scintigraphy and/or metabolism 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 or FDG
The use of FDG for myocardial viability is appropriate when:
A previous myocardial viability assessment using another modality was equivocal or demonstrated.
The patient has severe ischemic left ventricular dysfunction (left ventricular ejection fraction less than or equal to 40%) despite maximal medical therapy and is a suitable candidate for cardiac revascularization procedure or cardiac transplant.

**Reporting Guidelines**
Myocardial perfusion studies are interpreted in light of the stress test and other clinical information. FDG viability studies are interpreted based on the FDG viability information mentioned above. The following information is reported:

1. A description of the results of the test.
2. A clinical impression.
3. Recommendations for further procedures, if indicated.
Chapter 10 - Myocardial Wall Motion Studies with Ejection Fraction

Overview
This may be performed with 99mTc labelled red blood cells, or by gated SPECT myocardial perfusion images, at rest or during exercise. Consequent 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.

Clinical Indications
Clinical indications for performing myocardial wall motion studies include the need to assess:

- cardiac function and morphology in congenital heart disease.
- coronary artery disease (ischemia or infarction).
- intrinsic myocardial disease.
- cardiac valvular disease.
- response to therapy (drug, angioplasty, bypass).
- complications of chemotherapy.

Reporting Guidelines
The following information is reported:

1. Ejection fraction and other cardiac parameters available i.e. diastolic functions, ventricular volumes, etc.
2. Description of morphology or heart chambers and major vascular structures, where applicable.
3. Description of wall motion, response to exercise.
5. Suggestions for further relevant investigation.
Chapter 11 – Thyroid Uptake and Repeat Uptake

Overview
Initially the extrathyroidal iodine pool is labelled with orally or IV administered 131 I or 123 I. 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.). Thyroid uptake may also be approximated in a similar fashion following the intravenous administration of 99m Tc Pertechnetate.

Prerequisites
Inquiry should be made to determine if the patient is taking any medications that may interfere with the test and this information should be recorded and taken into account.

Clinical Indications
Clinical indications for performing a thyroid uptake include the need to assess:
- thyroid function in hyperthyroidism.
- thyroid function in hypothyroidism.
- function following medical therapy including ablation or suppression.
- thyroid function in response to diagnostic intervention (e.g., T3 suppression test).

Reporting Guidelines
There may be a slight regional variation depending on the iodine content of the referral population's diet. The facility's normal range is included in the report.
Thyroid uptake is also interpreted in the context of numerous potential influencing factors including systemic illness, medications, and an altered iodine pool.
Chapter 12 - Thyroid Scintigraphy with Tc 99m, I-131, I-123, or FDG

Overview
When I-131, I-123, Tc 99m or FDG is administered, the images generated provide a map of the distribution of function or glucose metabolism within the thyroid gland either in thyroidal or non-thyroidal locations.

Prerequisites
Inquiry should be made to determine if the patient is taking any medications that may interfere with the test and this information should be recorded and taken into account. In addition, with FDG imaging the patient’s glucose levels should be known, and if abnormal steps should be taken to correct these levels prior to the administration of FDG. The patient should also be fasting either 4 hours or after midnight depending on the time of booked study.

Clinical Indications
Clinical indications for performing thyroid scintigraphy include the need to assess the:

- distribution of function within the thyroid gland.
- function of a specific thyroid lesion.
- function of ectopic or malpositioned thyroid tissue.
- function of malignant thyroid tissue in a thyroidal or non-thyroidal location.
- response of the thyroid gland or contained lesion to therapy or diagnostic intervention.
- FDG imaging is only presently indicated for the assessment of thyroid cancer when standard imaging studies, including I-131 scan and/or neck ultrasound, are negative or equivocal, and recurrent or persistent disease is suspected on the basis of an elevated and/or rising thyroglobulin level(s).
Reporting Guidelines

The accuracy of thyroid scintigraphy is augmented by correlating the findings with palpation or ultrasound and/or other imaging modalities such as CT or MRI.

A nodule which concentrates Tc 99m may still have malignant potential. A follow-up study with radio-iodine may be recommended by the Nuclear Physician to further assess this potential.

When FDG imaging is performed the interpreting physician’s report should contain the following information:

1. Time of imaging post radiotracer injection.
2. Whether imaged with and without attenuation correction.
3. Use of SUV Max if calculated, and method of calculation used.
4. Comments on relevant anatomic correlation findings.
5. Whether whole body (eyes to mid-thighs) or single site.
Chapter 13 - Biliary Scintigraphy

Overview
Radionuclide hepatobiliary imaging has proved to be extremely useful in diagnosing a wide variety of disorders of the liver and biliary tract. The lack of morbidity and mortality of the procedure has resulted in rapid and widespread clinical acceptance.

The 99m Tc 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. The test has a very high sensitivity and specificity rapidly allowing the physician to arrive at an accurate diagnosis.

In certain instances pharmacological intervention (i.e., IV cholecystokinin) can simulate physiological functions such as eating. Such provocative testing further increases the clinical utility of the test.

Prerequisites
Patient should fast for approximately four hours, but not for more than 24 hours, as this may result in normal gall bladders not filling. The appropriate technetium radiopharmaceutical should be administered.

When pharmaceutical intervention is given it should be under the supervision of a Physician.

Clinical Indications
Clinical indications for performing hepatobiliary scintigraphy include the need to:

- evaluate the patency of the biliary tract in patients who are suspected of having intrahepatic, cystic, or common bile duct obstruction or biliary atresia.
- assess the function of the hepatobiliary system following pharmacological intervention when chronic cholecystitis, calculus, cholecystitis or biliary dyskinesia are a clinical concern.
- perform a post-cholecystectomy evaluation of the biliary tract to assess for duct patency, bile leak, or cystic duct remnant.
- evaluate biliary enteric anastomoses.
- evaluate other surgical anastomoses involving the gastro-intestinal tract such as Billroth I, Billroth II, and Whipple resection.
- evaluate duodenogastric reflux.
- evaluate liver transplant patients.
- detect bile leaks.
Reporting Guidelines

The following information is reported:

1. In the case of pharmacological intervention, the name, dosage, and route used to administer the drug. The presence or absence of adverse effects.
2. A description of test results.
3. A clinical impression.
Chapter 14 - Liver and Spleen Scintigraphy

Overview
The liver and spleen are both principle organs of the reticuloendothelial system. RES function can be assessed by recording the distribution of intravenously administered microcolloids labelled with a radionuclide. 99m Tc Sulfur Colloid is the most common agent used, but other similar compounds are commercially available. For detecting haemangioma, liver imaging with 99m Tc labelled red cells is advised. Imaging should be SPECT unless the patient cannot tolerate the procedure then planar imaging can be considered.

Clinical Indications
Clinical indications for performing a liver and spleen scintigraphy include the need to:

- assess functional imaging of liver and spleen to evaluate structural lesions detected by anatomic imaging technologies like ultrasound, CT, MR.
- assess hepatosplenic involvement in diffuse hepatic disease processes including those of a neoplastic, inflammatory, or metabolic nature.
- assess hepatosplenic involvement in the presence of vascular disease including venous thrombosis, arterial infarct, and portosystemic shunting.
- detect haemangiomas with labelled RBC’s.

Reporting Guidelines
Radionuclide liver scans are complimentary to other imaging modalities, and in some situations, comparing the nuclear scan findings with other imaging techniques is advised.
Chapter 15 - Dynamic Renal Scintigraphy

Overview
This study consists of sequentially imaging the kidneys, ureters and bladder following an intravenous injection of a radiopharmaceutical which is excreted through the urinary tract.

Clinical Indications
This test is used as a means of evaluating renal morphology, function and drainage. Common clinical indications include hypertension, urinary obstruction, renal infarction, infection, neoplasm, renal failure, urinary leaks or trauma, and evaluating renal transplants.

Reporting Guidelines
The following information is requested:

• describe and interpret the data. If applicable, correlate data with other information or imaging tests.
• if warranted, recommend other tests.
Chapter 16 - Computer Assessed Renal Function
(includes first transit)

Overview
This test assesses renal blood flow and function. The radionuclide is given as an intravenous bolus and data is dynamically collected by computer for about 30 minutes. Data analysis yields qualitative and quantitative information for each individual kidney. In some patients, delayed static renal imaging may be required, usually at 1-3 hours after radionuclide is administered.

Radiopharmaceuticals Used
The appropriate technetium radiopharmaceutical should be administered.

Prerequisites
Unless there is a fluid restriction, the patient is usually well hydrated orally before the test. The appropriate technetium radiopharmaceutical should be administered.

Clinical Indications
The test assesses the renal blood flow and function in many situations, including pre-renal, renal, and post-renal causes. The test is often required to evaluate individual renal function. For example: congenital renal abnormalities, vascular problems, renal parenchymal disease from multiple causes, space occupying lesions, obstructive uropathy, renal trauma, renal transplant, etc.

Reporting Guidelines
The following information is requested:

1. Describe and interpret the data. If applicable, correlate data with other information or imaging tests.
2. If warranted, recommend other tests.
Chapter 17 - Repeat Computer Assessed Renal Function after Pharmacological Intervention

Overview
An assessment of the renal blood flow and function using computer assisted quantification may be repeated on the same day with pharmacological intervention using:

- furosemide in patients with possible obstructive uropathy.
- ACE inhibitors (captopril is the most common drug used) in patients with possible renal artery stenosis.

Prerequisites

**Intervention with furosemide**
Diuresis will establish if obstructive uropathy is present or not in patients with hydronephrosis or hydroureter. Furosemide is a potent diuretic. When administered intravenously it is given under the supervision of a physician who is familiar with its possible side effects and the necessary precautions for its use.

**Intervention with ACE inhibitors**
Intervention is aimed at assessing the effect of the ACE inhibitor on the kidney to improve the sensitivity and specificity of the renal study for the diagnosis of renovascular hypertension.

Before the test, obtain a detailed history of the drugs the patient is taking or was recently receiving. Some medications may have to be discontinued before the test but this must be cleared with the consent of the referring physician when appropriate.

A supervising physician approves the administration of the ACE inhibitor for the specific patient. This is because ACE inhibitors may cause side effects or interact with other drugs. Active treatment may be required if complications arise after its use. When administered it is given under the supervision of a physician who is familiar with its possible side effects and the necessary precautions for its use.

A baseline blood pressure measurement is obtained before administering the ACE inhibitor. The blood pressure is measured repeatedly during the first hour after it is administered and at the end of the procedure.
Clinical Indications
Intervening with furosemide to establish whether obstruction is present or not in patients with dilatation of the renal pelvis or ureter.
Intervening with ACE inhibitors: in patients with possible renovascular hypertension.

Contraindications and Precautions
The patient is well hydrated and haemodynamically stable prior to the administration of furosemide or captopril.

Drug Allergy
Please see above prerequisites concerning the use of the interventional drugs. See also the prerequisites and contraindications under chapter 16 Computer Assessed Renal Function (includes first transit).

Reporting Guidelines
The test findings are reported quantitatively, including comparing the results with the pre-intervention data. If any side effects occur as a result of using such drugs, these are reported along with any treatment given.
Chapter 18 - Static Renal Scintigraphy

Overview
This test is performed to evaluate renal morphology and may be performed as a separate study or in conjunction with dynamic renal imaging. If it is performed as part of dynamic imaging, it is usually performed after 1-2 hours delay, at which time the collecting systems and pelvis have fully drained. Additional views of the kidney (obliques or magnified images) may be required.

Usually, static renal imaging of the parenchyma uses those radiopharmaceuticals which preferentially bind to the tubules.

If required, Single Photon Emission Computed Tomography (SPECT) imaging may be performed.

Renal differential function should be calculated when feasible.

Clinical Indications
Clinical indications for this test include the need to assess renal size, shape, location, and function, particularly in evaluating congenital abnormalities, space occupying lesions (tumour vs hypertrophy), renal parenchymal scarring in inflammatory disease, trauma, etc.

Reporting Guidelines
The following information is requested:

1. Describe and interpret the data. If applicable, correlate data with other information or imaging tests.

2. If warranted, recommend other tests.
Chapter 19 - Bone Scintigraphy

Overview
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.

Clinical Indications
Clinical indications for performing a bone scan include the need to:

- detect skeletal metastatic disease. This may be performed in the initial staging, periodic follow-up, or evaluation of therapy.
- detect skeletal lesions in symptomatic patients where radiographs are normal. This could include traumatic, inflammatory, arthritic, or other causes of occult bone pain.
- evaluate the metabolic activity of abnormalities seen on radiographs (i.e. incidental sclerotic densities, old vs new fracture, activity of Paget's disease etc.).
- evaluate viability of bone when there are circulatory disturbances (i.e. avascular necrosis, bone grafts, or post-trauma).
- detect traumatic, inflammatory, or arthritic conditions, to evaluate their metabolic activity, response to treatment, or complications of the disease or its treatment.
- detect complications or to follow the healing response following surgical procedures to the skeletal system.
- detect soft tissue lesions such as heterotopic ossification, myositis, metastatic calcification, and other conditions which may show uptake of the radiopharmaceutical.

In various other disease processes affecting the musculoskeletal system or joints, where determining increased or decreased metabolic activity will compliment clinical, laboratory or other diagnostic imaging techniques in the evaluation of the disease, or its treatment.

Reporting Guidelines
The following information is requested:

1. Describe and interpret the data. If applicable, correlate data with other information or imaging tests.
2. If warranted, recommend other tests.
Chapter 20 - Sepsis, Inflammation and/or Tumour Scintigraphy

Overview

Planar, SPECT or PET/CT studies may be undertaken. Depending on the clinical circumstances, bowel preparation may be used. If PET imaging is being performed, the patient should be fasting either a minimum of 4 hours or after midnight depending on the time of book study and blood glucose levels assessed prior to tracer injection. If the levels are abnormal, they must be corrected prior to the procedure being performed.

Presently FDG is used and as new positron emitting radiopharmaceuticals are approved these standards will be updated.

Clinical Indications

Clinical indications for performing scintigraphy include the need to investigate and evaluate inflammatory and related processes which include:

Sepsis or inflammation detection. Most commonly:

- pyrexia of unknown origin.
- pulmonary inflammatory diseases including:
  - infections
  - granulomatous disease
  - drug and radiation induced injury

- abdominal and pelvic inflammations including:
  - localized and diffuse infections
  - retroperitoneal fibrosis
  - renal parenchymal and peri-renal infections

- inflammatory disease of the skeleton including:
  - osteomyelitis
  - joint space infection
  - discitis
  - assessment of post-operative complications

- cardiac and mediastinal structures
Tumour detection, staging, and assessment. Most commonly:

- Burkitt's lymphoma, Hodgkin's, and non-Hodgkin's lymphoma
- malignant melanoma
- hepatocellular carcinoma
- lung carcinoma
- haematologic malignancies
- sarcomas
- seminomas

**PET/CT Clinical Indications:**

- Solitary pulmonary nodule (SPN) for which a diagnosis could not be established by needle biopsy due to:
  - Unsuccessful attempted needle biopsy
  - The SPN is inaccessible to needle biopsy
  - The existence of a contraindication to the use of a needle biopsy.

- Thyroid Cancer for which standard imaging studies, including I-131 scan and/or neck ultrasound, are negative or equivocal and recurrent or persistent disease is suspected on the basis of an elevated and/or rising thyroglobulin level(s). Refer to Chapter 12 *Thyroid Scintigraphy with Tc99m, I-131, I-123, or FDG.*

- Germ Cell tumours for which recurrent or persistent disease is suspected on the basis of:
  - Elevated tumour marker(s) (beta human chorionic gonadotropin HCG and/or alpha fetoprotein) in the presence of negative or equivocal standard imaging studies; or
  - The presence of a residual mass after primary treatment for seminoma when curative surgical resection is being considered.

- Colorectal cancer for which standard imaging studies are negative or equivocal and recurrent disease after surgical resection is suspected on the basis of elevated and/or rising carcinoembryonic antigen (CEA) level(s).

- Lymphoma
  - For the evaluation of residual mass(es) following chemotherapy, in a patient with Hodgkin’s or non-Hodgkin’s lymphoma when further potentially curative therapy (such as radiation or stem cell transplantation) is being considered; or
  - For the assessment of response in early stage of Hodgkin’s lymphoma following 2 or 3 cycles of chemotherapy when chemotherapy is being considered as the definitive single modality of therapy.
• Non-small cell lung cancer (NSCLC)
  o For which curative and surgical resection is being considered based on negative standard imaging tests; or
  o For clinical stage III NSCLC which is being considered for potentially curative combined modality therapy with radical radiotherapy and chemotherapy.

• Limited disease small cell lung cancer (SCLC) for evaluation and staging where combined modality therapy and chemotherapy and radiotherapy is being considered.

Reporting Guidelines
The following information is reported:

1. Times at which imaging was carried out and any bowel preparation undertaken.
2. Whether SPECT or planar images were obtained.
3. Description of test results.
4. Correlation with other imaging modalities, if available.
5. An opinion to include further recommendations if appropriate.

In addition, PET/CT imaging reports should contain the following information:

1. Time of imaging post radiotracer injection.
2. Whether imaged with and without attenuation correction.
3. Use of SUV max if calculated, and comment on method of calculation.
4. Comments on relevant anatomic correlations.
5. Whether whole body (eyes to mid-thighs) or single site.
Chapter 21 - Bone Mineral Content by Dual Energy Absorptiometry (DEXA)

A patient may be identified as high risk or low risk.

| Note: For the purpose of this service “high risk patient” means a patient at risk for accelerated bone loss due to either states of high bone turnover such as primary hyperthyroidism and glucocorticoid induced osteopenia, or due to such other conditions as have been determined by the Scientific Advisory Board of the Osteoporosis Society of Canada which prevail at the time the service is rendered. “Low risk patient” means any patient who is not a high risk patient (Extract from OHIP Schedule of Benefits) |

Overview

It is established that, where there is a progressive loss of bone throughout the skeleton associated with aging and other metabolic bone disorders, the risk of fractures is increased due to decrease in bone strength. This condition is commonly referred to as osteoporosis, but in fact bone mineral density (BMD) measures osteopenia, of which osteoporosis is only one cause.

Bone Densitometry

Decreased bone mineral density is an important public health concern that will worsen in the future as the population ages. Bone mass is measured safely, accurately, and precisely by dual energy x-ray absorptiometry.

There are current therapies available for preserving or increasing bone mass in those people who are thought to be at a significant fracture risk.

It is important to realize that bone mass measurement is not intended to be a diagnostic test for fracture. Rather, it measures a risk factor and as such, is performed primarily on those individuals who by age, sex, longterm glucocorticoid therapy, or associated medical illnesses are known to be susceptible to bone mineral loss.

An appropriate location for the test should be available, respecting patient privacy. The studies must be performed on a contemporary dual photon x-ray densitometer. Daily Quality Control must be performed, and the results stored for reference.
Prerequisites
A comprehensive questionnaire to elicit clinical information and other factors that might compromise this test, such as radiological contrast agents, radioactive materials, and any previous surgery.

Clinical Indications
The following represents a list of potential indications. These indications are subject to change as the equipment becomes more precise and longitudinal data on the results of therapeutic programs become available. Bone densitometry is indicated in:

- estrogen deficient women to diagnose significantly low bone mass and to make decisions about appropriate replacement therapy.
  - estrogen deficiency following menopause, oophorectomy, or prolonged amenorrhea from any cause associated with bone loss.

- individuals with vertebral abnormalities or roentgenographic osteopenia, to diagnose spinal osteoporosis and to make decisions about further diagnostic evaluation and therapy. There is evidence that many individuals with vertebral abnormalities do not have significant osteoporosis and therefore would not benefit from therapy which is costly and has risks.

- individuals receiving long-term glucocorticoid therapy to diagnose low bone mass and to adjust therapy.

- individuals with primary asymptomatic hyperparathyroidism to diagnose low bone mass in order to identify those at risk of severe skeletal disease who may be candidates for surgical intervention.

- individuals with evidence of osteomalacia such as low serum calcium, low serum phosphorus, and/or elevated alkaline phosphatase.

- individuals with one or more risk factors:
  - hypogonadism
  - ethanol abuse
  - osteoporosis on radiograph
  - fracture with minor trauma or atraumatic fracture.

- patients with prolonged immobilization (more than 2 months) and especially if the disability is likely to be prolonged and/or permanent.

- individuals with renal disease with a creatinine clearance of less than 50 ml/ min. or renal tubular disorders.

- patients with rheumatoid arthritis or ankylosing spondylitis that has been active/symptomatic over a prolonged period (5 years or more).
• individuals who use anticonvulsant therapy over a prolonged period (5 years or more).
• individuals who have been on thyroid replacement over a prolonged period (10 years or more).

Bone densitometry is also indicated to evaluate and monitor the treatment program.

The frequency of repeat studies for “high risk” and “low risk” patients is according to the Schedule of Benefits.

**Reporting Guidelines**

The interpretation of BMD studies must reflect age, sex, weight, ethnic origin, and risk factors as well as comparison with the young normal data base.

The absolute measurement of bone mass in gm/cm², the percentage value and/or standard deviation, T scores or Z scores where appropriate compared to the young normal control group and to the age-matched group is incorporated into a narrative paragraph that is meaningful to the referring physician. When possible, the report should suggest to the referring physician the necessity of a repeat assessment at an appropriate time interval.

A tool to assess the risk of osteoporotic fracture. Based on the “Recommendations for Bone Mineral Density Reporting in Canada”

1. Obtain information from the referring physician: Does the patient have risk factors that influence bone mineral density (BMD) results or interpretation?
2. Collect completed patient questionnaire.
3. Perform and analyze BMD scan for the following sites:
   • Lumbar spine
   • Proximal femur (total hip, trochanter, and femoral neck)
   • If either hip or spine is not valid then forearm BMD may be assessed
4. Report whether scan results are valid with regard to artifact.
5. Report for each valid site as per the Osteoporosis Canada Guidelines.
Chapter 22 - Brain Scintigraphy with Single Photon Emission Computed Tomography

Overview
The appropriate technetium radiopharmaceutical should be administered.

Clinical Indications
Clinical indications for performing this test include:

- cerebrovascular disease (stroke, transient ischaemic attack (TIA), vasculitis)
- epilepsy
- dementia
- neuropsychiatric disorders
- extrapyramidal disorders
- brain tumours
- HIV brain related disorders
- herpes simplex encephalitis
- subarachnoid haemorrhage
- brain death
- head injury
- migraine headaches.

Reporting Guidelines
The following information is requested:

1. Describe and interpret the data. If applicable, correlate data with other information or imaging tests.
2. If warranted, recommend other tests.
Chapter 23 - Perfusion and Ventilation Scintigraphy

Overview

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 labelled 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.

Clinical Indications

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

- diagnose suspected pulmonary embolism.
- evaluate shortness of breath, obstructive lung disease, abnormal blood gases or chest pain.
- assess chronic obstructive pulmonary disease (COPD) or lung cancer, including pre-operative assessment with quantification.
- evaluate congenital heart or lung disease.
- quantify aerosol washout studies for inflammatory lung disease.
**Contraindications**

Severe pulmonary hypertension and severe right to left shunts are relative contraindications for perfusion lung scans.

**Reporting Guidelines**

A lung scan to diagnose pulmonary embolism is treated as an emergency request. A positive lung scan could indicate a high probability for a pulmonary embolism. This condition requires the nuclear medicine physician to communicate with the referring physician.

When the lung scan is abnormal it is good clinical practice to correlate this information with the chest x-ray results.

| Note: | If the chest x-ray is not available for comparison with an abnormal lung scan, the reporting physician must ensure that the referring physician is alerted to make the appropriate correlation. |
Chapter 24 - Scintimammography

Overview
Scintimammography has high sensitivity for detecting palpable breast lesions (> 1 cm). 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 (< 1 cm), scintimammography should not be used as a screening test for breast carcinoma. Sometimes, scintimammography is also able to demonstrate axillary metastasis.

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

1. Patients with dense breast tissue
2. Patients with history of architectural distortion of breast tissue due to: previous breast surgery, biopsy or radiation. (This is particularly applicable to high risk patients, e.g. genetic or familial predisposition, prior breast malignancy, hyperproliferative breast on prior breast biopsy and prior radiation to breast for breast or other cancers.)
3. Patients with palpable breast mass and normal or equivocal mammogram
4. Patients with breast implants
5. To provide additional information in patients who have an abnormal mammogram but who are hesitant to undergo biopsy/resection or in whom the procedure may be relatively contraindicated
6. To assess for breast carcinoma in patients with axillary adenocarcinoma of unknown primary origin
7. Lumpectomy candidates with dense breast tissue to exclude multi-focal disease

Reporting Guidelines
Interpretation of images should be done on a computer with appropriate grey scale manipulation. The report should include but is not limited to:

1. A description of any increased activity seen in the breasts, e.g. focal or diffuse, the extent of the increased activity, the intensity of the increased activity and the location of the increased activity.
2. A description of any increased activity in the axillary regions.
3. The presence of any palpable abnormality should be mentioned and correlated with scintigraphic abnormality.
4. The study should be correlated with mammography +/- ultrasound whenever possible.

5. An interpretation section should include an opinion of whether a lesion is benign, equivocal or malignant.

6. Further evaluation or follow-up should be recommended, if appropriate.
Independent Health Facilities: Clinical Practice Parameters and Facility Standards: Nuclear Medicine

VOLUME 3
TELERADIOLOGY (PACS)
CAR Standards for Teleradiology

Approved: May 2008

These Standards were developed, in collaboration with the Canadian Association of Medical Radiation

Technologists by PACS / Teleradiology Committee members, Benvon Cramer M.D., Gregory Butler M.D., Jean Chalaoui M.D., Kelly Silverthorn M.D., Luigi Lepanto M.D., David Koff M.D.

The standards of the Canadian Association of Radiologists (CAR) are not rules, but are guidelines that attempt to define principles of practice that should generally produce radiological care. The physician and medical physicist may modify an existing standard as determined by the individual patient and available resources. Adherence to CAR standards will not assure a successful outcome in every situation. The standards should not be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed to obtaining the same results. The standards are not intended to establish a legal standard of care or conduct, and deviation from a standard does not, in and of itself, indicate or imply that such medical practice is below an acceptable level of care. The ultimate judgment regarding the propriety of any specific procedure or course of conduct must be made by the physician and medical physicist in light of all circumstances presented by the individual situation.

I. DEFINITION

Teleradiology is the electronic transmission of diagnostic imaging studies from one location to another for the purposes of interpretation and/or consultation.

This definition includes interfacility PACS networks as well as remote teleradiology. An onsite supervising qualified radiologist provides the optimum clinical environment for patients and referring physician providing daily interaction, input and consultation. Where there is difficulty in filling manpower
needs, teleradiology will provide support for night, weekend and vacation leave, for excess workload and for interpretation of complex cases.

Teleradiology must be a quality centered, patient focused method of augmenting services. It must never compromise the radiologist responsibility to provide quality professional services.

Teleradiology will also allow more timely and efficient interpretation of radiological images, give greater access to secondary consultations and improve continuing education. To achieve this, appropriate technology must be utilized according to the CAR standards (see below).

It is recommended that teleradiology is directed by the local radiologist if present and provided in all circumstances preferentially at local, regional, and provincial centers respectively prior to being sent nationally.

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Radiologists

A Radiologist is a specialist physician, who uses imaging based modalities and techniques in the practice of medicine for diagnosis and treatment. Teleradiology is one of these imaging based techniques.

Radiologists involved in the performance, supervision and interpretation of teleradiology must have a Fellowship or Certification in Diagnostic Radiology with the Royal College of Physicians and Surgeons of Canada and/or the Collège des médecins du Québec.

Also acceptable are equivalent foreign Radiologist qualifications if the Radiologist is certified by a recognized certifying body, holds a valid Canadian provincial license and is appropriately credentialed in the site where the imaging was performed.

As new imaging modalities and interventional techniques are developed additional clinical training, under supervision and with proper documentation, should be obtained before radiologists interpret or perform such examinations or procedures independently. Such additional training must meet with pertinent provincial/regional regulations. Continuing professional development must meet with the requirements of the Maintenance of Certification Program of the Royal College of Physicians and Surgeons of Canada.

The official interpretation of images must be done by a radiologist with an understanding of the basic technology of Teleradiology including its strengths and limitations. Provision must be made by the reporting radiologist to provide a consultative service. The reporting radiologist has a pivotal role in all aspects of the diagnostic imaging examination. This includes appropriateness screening, supervision of technical standards and procedures, image interpretation and consultation. This safeguard allows teleradiology to be equivalent to on-site radiology in selected instances.

The radiologist workload for teleradiology and on site should be at a level that quality of care and interpretation accuracy are not compromised. The local, or if unavailable, reporting radiologist should therefore be involved in decisions involving teleradiology. If there is no local radiologist, then the reporting radiologist or another radiologist must regularly visit the department for quality control.
B. Technologists
The Medical Radiation technologist must meet the certification requirements for the province in which they are practising. For most provinces, for MRT this would be certification by either the CAMRT or the Ordre des technologues en radiologie du Quebec. For Sonographers, this would be certification by ARDMS or CARDUP.

Under the overall supervision of the radiologist, the technologist will have the responsibility for evaluation and operation of the equipment and the applicable quality assurance program. In remote sites, technologists need ongoing feedback and supervision from the radiologist responsible for the teleradiology system's quality assurance program.

Continuing education of technologists must meet the Provincial regulations. Sonologists performing tele-ultrasound should receive hands on experience, preferably under the guidance of the radiologist supervising the tele-ultrasound facility.

C. Others
Teleradiology services must have access to medical physicists, bioengineers and image communications specialists, or image management system specialists on-site or as consultants on an "as needed" basis.

III. EQUIPMENT STANDARDS
Digital imaging sent by Teleradiology will usually originate from a PACS system. In occasional circumstances, the digital conversion of hard copy or analogue images may be necessary if the transmitting site does not have PACS. The scanner used must not reduce the digital resolution below that considered an acceptable threshold as indicated in the next section.

A. Specific Standards
Specifications for equipment used in teleradiology will vary depending on the individual facility's needs, but in all cases it should provide image quality and availability appropriate to the clinical need. Compliance with the current DICOM and Canadian IHE standard is required for all new equipment acquisitions, and consideration of periodic upgrades incorporating the enhancements recommended in that standard should be part of the continuing quality improvement program.

Equipment guidelines cover two basic categories of teleradiology when used for rendering the official interpretation: small matrix size (e.g., computed tomography [CT], magnetic resonance imaging [MRI], ultrasound, nuclear medicine, digital fluorography, and digital angiography) and large matrix size (e.g., digital radiography and digitized radiographic films). For small-matrix, the data set should provide a minimum of 512 x 512 matrix size at a minimum 8-bit pixel depth for processing or manipulation with no loss of matrix size or bit depth at display. For large-matrix, the data set should allow a minimum of 2.5 lp/mm spatial resolution at a minimum 10-bit pixel depth.
These pixel depths are the standard in the absence of compression, and will need adjustment if compression is used as per the lossy compression standards when these are implemented.

**B. Acquisition or Digitization**

Initial image acquisition should be performed in accordance with the appropriate CAR modality or examination guideline or standard.

1. **Direct image capture**

The entire image data set produced by the digital modality in terms of both image matrix size and pixel bit depth, should be transferred to the PACS / teleradiology system. The DICOM standard must be used.

2. **Secondary image capture**

a. Small-matrix images: Each image should be digitized to a matrix size as large as or larger than that of the original image by the imaging modality. The images should be digitized to a minimum of 8 bits pixel depth. Film digitization or video frame grab systems conforming to the above specifications are acceptable.

b. Large-matrix images: These images should be digitized to a matrix size corresponding to 2.5 lp/mm or greater, measured in the original detector plane. These images should be digitized to a minimum of 10 bits pixel depth.

These pixel depths are the standard in the absence of compression, and will need adjustment if compression is used as per the lossy compression standards when these are implemented.

**C. Mammography and Fluoroscopy and Ultrasound**

i) **Mammography:**

Digital Mammography is evolving rapidly but at this time primary reading is not performed on PACS systems. This standard will be updated as tele-mammography technology matures.

ii) **Fluoroscopy:**

At present the standard for fluoroscopy is to have a radiologist performing the examination. If physician extenders are to be utilized in the future, it is also recommended that there is a supervising radiologist on-site. There may be exceptions when fluoroscopic images can be transmitted for interpretation via teleradiology.

iii) **Tele-Ultrasound**

A radiologist must be available for consultation with the sonographer on a case by case basis. Ideally the radiologist should be on-site and available to participate actively in the ultrasound examination when required. It is recognized however that the geographic realities in Canada do not permit the presence of an on-site radiologist in all locations. Adequate documentation of each examination is critical and should include sonographer annotations and if necessary video clips. As with all aspects of teleradiology, the reports must be timely and the radiologist must be available by telephone for consultation with the sonographer and the referring physician. The radiologist should visit the facility on a regular
basis to provide on-site review of ultrasound procedures and sonographer supervision.

D. General Standards

1. Image Management

Most teleradiology systems are now PACS systems with network connections with a few remaining point to point systems. All systems shall include an integrity checking mechanism to ensure that all transmitted information from the site of origin is received intact by the reviewing site as well as:

a. Capability for the selection of the image sequence for transmission and display at all the reviewing sites.

b. The patient must be identified accurately and unambiguously. This may include patient name, identification number, date and time of examination, film markers, institution of origin, type of examination, degree of compression (if used) and a brief patient history. This information should be bundled with the image file but may also be transmitted by other secure means e.g. fax.

c. Capacity to obtain prior examinations and reports.

d. The issue of compression is currently under investigation by members of the CAR PACS /Teleradiology committee who hope to define and recommend compression levels for varying modalities. In the interim compression should be used judiciously.

e. Image storage at either the acquisition or reviewing site as well as transmission must be arranged such that patient confidentiality is maintained and that the system is secure.

f. The provider must ensure that the image quality is the same at the acquisition site and reviewing site(s).

E. Transmission of Images and Patient Data

Communications protocols, file formats and compression shall conform to the current DICOM and Canadian IHE standard. There should be provision for the selection of appropriate compression for improved transmission rates and reduced archiving/storage requirements. There must be no reduction in clinically diagnostic image quality. The types and ratios of compression used for different imaging studies transmitted and stored by a system must be selected and periodically reviewed by the responsible physician to ensure appropriate clinical image quality. A more specific recommendation will be provided following the compression study that is currently in progress.

F. Display Capabilities

Display workstations employed for teleradiology / PACS systems must provide the following characteristics:

1. Luminance of the gray-scale monitors of at least 50 foot-lamberts.

2. Display stations must accurately reproduce the original study and must include:
a. brightness and contrast and/or interactive window and level function  
b. a magnification function  
c. the capability of rotating and flipping the displayed images  
d. the capability of accurate linear measurements and CT Hounsfield units  
e. the capability of inverting the gray-scale values of the displayed image  
f. the capability to display clinically relevant parameters

G. Patient Database
For radiological images transmitted by PACS / Teleradiology, a database must be available that includes.

1. patient name, identification number and date  
2. type of examination e.g. Chest  
3. modality e.g. CT, MRI etc.  
4. number of images  
5. image acquisition site  
6. date and time of acquisition and availability for review

H. Security
Teleradiology systems must provide network and/or software protocols to protect the confidentiality of the patient's record(s), image(s), interpretation(s) and other data and insure that the system is secure and used only on an as needed basis by those authorized by the patient in accordance to provincial privacy of information legislation and CMA guidelines.

I. Reliability and Redundancy
Quality patient care may depend on timely availability of the image interpretation. There should be an internal redundancy system, backup telecommunication links, and a disaster plan.

IV. STORAGE OF RECORDS
The legal requirements for the storage and retention of images and reports will vary from province to province and the providers of the teleradiology service are responsible for adhering to these requirements. Images stored at either the acquisition or reviewing site shall meet the jurisdictional requirements of the acquisition site. Images interpreted off-site need not be stored at the reviewing facility provided that they are stored at the acquisition site. The policy on record retention should be in writing and may in part reflect the accreditation requirements of the two facilities involved.

V. DOCUMENTATION
Communication is a critical component of teleradiology. Radiologists interpreting teleradiology examinations shall render reports in accordance with the CAR Standard of Communication.

VI. QUALITY CONTROL FOR TELERADIOLOGY

The interpreting radiologist has to ensure that the quality of the images being reviewed is of acceptable standard.

It must be stressed that the images at the reviewing site can only be as good as the images generated at the acquisition site. It is imperative that a radiologist should visit the acquisition site on a regular basis to ensure that the equipment is functioning properly and that the technologists are adequately supervised and trained.

Both the acquisition and reviewing sites must have documented policies and procedures for monitoring and evaluating the effective management, safety, proper performance of imaging, transmitting, receiving and display equipment.

The quality control program should be designed to minimize patient, personnel and public risks, and to maximize the quality of the diagnostic information. Equipment performance must be monitored at intervals consistent with proper quality control.

Important parameters must be accompanying the transmitted study when used for the official authenticated written interpretation. These will include, at a minimum, the matrix size, bit depth, compression (if used), and what kind of image processing, if any, was used (edge enhancement etc.).

A radiologist must be involved in the selection of imaging systems at both the reviewing and acquisition sites. In this period of fiscal restraint, it is important to ensure that the scarce healthcare resources are used to acquire diagnostically acceptable equipment, which has been approved by a duly qualified diagnostic imager.

VII. QUALITY IMPROVEMENT

The use of teleradiology does not reduce the responsibilities for the management and supervision of diagnostic imaging. Procedures must be systematically monitored and evaluated as part of the overall quality improvement program of the facility. Monitoring shall include the evaluation of the accuracy of the interpretations as well as the appropriateness of the examination. Incidence of complications and adverse events must be reviewed to identify opportunities to improve patient care.

With the increasing use of PACS technology, radiologists should ensure that institutions identify and train PACS administrators (image management specialist). Their responsibilities would include the monitoring of quality and confidentiality of transmitted images and to maintain a viable system.

The increased use of networking also allows for remote auditing and peer review when required.

VIII. LICENSING, CREDENTIALING AND LIABILITY
a) In order to protect the patient, the radiologist must be licensed in the province in which the patient undergoes the examination. The radiologist must also comply with the regulations of the jurisdiction where he or she is physically present during the performance of the interpretation.

b) The radiologist must be appropriately credentialed at the site in which the examination is performed when this is required by that site.

The radiologists who are involved in practicing teleradiology will conduct their practice in a manner consistent with the bylaws, rules, and regulations for patient care at the site in which the patient undergoes the examination.

c) The radiologist must carry appropriate malpractice coverage. This must be valid in the province in which the patient undergoes the examination.

**ACR/NEMA** - the American College of Radiology and the National Electrical Manufacturers Association

**Bit (Binary Digit)** - the smallest piece of digital information that a computing device handles. It represents off or on (0 or 1). All data in computing devices are processed as bits or strings of bits.

**Canadian IHE** – Integrating the Healthcare Enterprise. A national vision of a connected and interoperable healthcare infrastructure

**Data Compression** - methods to reduce the data volume by encoding it in a more efficient manner, thus reducing the image processing and transmission times and the storage space required.

**DICOM (Digital Imaging Communications in Medicine)** - a standard for interconnection of medical digital imaging devices, developed by the ACR/NEMA committee.

**Digitize** - the process by which analog (continuous wave) information is converted into digital (discrete value) information. This process is a necessary function for computer imaging applications because visual information is inherently in analog format and most computers use only digital information.

**Gray Scale** - the number of different shades or levels of gray that can be stored and displayed by a computer system. The number of gray levels is directly related to the number of bits in each pixel: 6 bits = 64 gray levels, 7 bits = 129 gray levels, 8 bits = 256 gray levels, 10 bits = 1024 gray levels and 12 bits = 4096 gray levels.

**K (Kilo)** - stands for the number one thousand (1,000). It is used primarily when referring to computer storage and memory capacities. E.g. 1 Kbytes = 1024 bytes.

**Lossless** - no loss of the original digital information upon reconstruction of the digital image.

**Matrix** - an image formed by distinct points in both the horizontal and vertical directions. E.g. a 512 matrix is made up of 512 points in one axis and 512 points in the other.

**PACS** – Picture Archival and Communication System

**Resolution** - the ability of an imaging system to differentiate between objects.
Sonographer - a technologist approved by the regional licensing body to perform diagnostic ultrasound services.
OAR Telera diology Practice Standard

OAR TELERADIOLOGY PRACTICE STANDARD

Definition
Telera diology 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 credentialling (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**

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

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

3. 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.

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

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

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

7. 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.

8. 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.

9. 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.

10. 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**

1. **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:

   a. The clinical evaluation and data is provided with the request for the examination.
   
   b. The requirements of the Healing Arts Radiation Protection Act (HARP) (including justification, appropriate techniques, optimization, and good procedure) are fulfilled.
   
   c. 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.
   
   d. 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.
   
   e. 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.

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

3. 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. Knowledge of referring doctors can make specific reports more appropriate. 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.

a. 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.

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

c. 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.

d. 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.

e. 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.

f. 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.

g. 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.

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

1. 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.

2. 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.

3. 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.

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

5. 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.

6. 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.

7. 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.

8. 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.

9. 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.

10. 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.

11. 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.

12. 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.

13. 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.

14. 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.
References


21. THOMSEN HS, MORCOS SK. In which patients should serum creatinine be measured before iodinated contrast medium administration? Eur Radiol 2005;15:749-54.


35. BUSH WA. Update on Metformin (Glucophage®) Therapy and the Risk of Lactic Acidosis: Change in FDA-approved Package Insert. ACR Bulletin 1998;54.


37. RADIOLOGISTS TRAANZCO. Guidelines for Metformin Hydrochloride and Intravascular Contrast Media, 2003 (vol 2006).


CPSO Telemedicine Policy

Telemedicine

APPROVED BY COUNCIL: April 2007

TO BE REVIEWED BY: April 2012

PUBLICATION DATE: July 2007

KEY WORDS: Telemedicine, Jurisdiction


COLLEGE CONTACT: Physician Advisory Service
TELEMEDICINE

COLLEGE POLICY

The College recognizes the value of telemedicine and, in particular, the way in which it enables patients to have greater access to care. ‘Telemedicine’ has been defined as “the use of telecommunications technologies to create audio/visual linkages between physicians and patients in different locations, in actual or stored time.”

Telemedicine provides physicians with another means to interact with patients but it does not modify any of the practice expectations that apply to a physician-patient relationship. This means the College expects physicians practicing telemedicine to:

• Be in accord with established clinical practice standards;
• Use technology that is of sufficient quality to enable the physician to provide quality care; and
• Ensure that patient information remains confidential (for example, ensure the locations of the physician and patient are secure, and the lines of communication are protected from interference).

One of the ways to ensure that the technology is of sufficient quality and the practice environment is secure is to carry out telemedicine sessions within a facility accredited by the Ontario Telemedicine Network.

The College recognizes that telemedicine enables physicians to deliver health services across provincial/territorial and international borders. In many cases, physicians in Ontario refer patients or provide patients’ information to a specialist located outside of the province. Where this occurs and the physician outside of the province is not registered with the CPSO, the College expects the physician in Ontario to inform the patient of that fact and that any potential complaint would need to be considered outside of the province (for example, in the jurisdiction of the specialist).

Providing this information is part of the process for obtaining the patient’s informed consent to the medical consultation.

For Ontario physicians providing care to patients outside of the province via telemedicine, the College suggests that they:

• comply with the licensing requirements of any province/territory/country in which they are providing medical services; and
• in addition, understand that the College maintains jurisdiction over its members wherever they may practice and therefore is required to review any complaint made to it about a member, even if made by a patient located in another jurisdiction. This is based on the principle that patients must be protected from harm and physicians held accountable for the quality of services they perform. Ontario physicians with a certificate of registration in another jurisdiction should also be aware that the College may review concerns arising in the other jurisdiction and may take action with respect to the physician’s certificate of registration in Ontario.

Telemedicine is in a constant state of evolution as technology provides endless opportunities for developing new approaches to the delivery of health services. In recognizing the tremendous potential for growth in this area, the College acknowledges that telemedicine will likely be one of the greatest influences on the way medicine is practiced in the future. For this reason, the College will continue to monitor future developments and provide additional information, in particular, on jurisdictional issues and certificates of registration. It also views telemedicine as an impetus for the future development of a national medical registry.

For questions regarding telemedicine practice, physicians may contact the Physician Advisory Service at the College or the Ontario Telemedicine Network for information. They are also advised to contact a lawyer for any legal advice.
Appendix I  Ontario Tripartite Nuclear Medicine Advisory Committee Criteria for Physicians in Medical Charge of an In Vivo Nuclear Medicine Facility (original text)

Overview
The physician in medical charge of an in vivo nuclear medicine service in Ontario shall have such formal qualifications and training as shall allow the Tripartite Nuclear Medicine Advisory Committee to recommend licensing of the facility to the Atomic Energy Control Board [currently the Canadian Nuclear Safety Commission]. The Committee recognizes the standard on Royal College Certification in nuclear medicine for medical directors as established in CMA General Council resolution #8770, but appreciates the need for a period of transition. As at January 1990, physicians with the following qualifications are acceptable to the Tripartite Committee, a licensed Ontario physician:

Category 1
- certified by the Royal College of Physicians and Surgeons of Canada as a specialist in nuclear medicine.

Category 2
- A licensed Ontario physician who is not certified in nuclear medicine, but who has practiced comprehensive nuclear medicine substantially full-time for five years prior to January 1, 1986, or who was the designated physician on an AECB [currently the CNSC] licence issued prior to January 1, 1986.

Note:  As of January 1, 1991, this option will cease to exist for applicants who are not already designated as medical directors on an existing in vivo nuclear medicine licence.

Category 3
- In the absence of a physician in categories 1 and 2, as an interim measure for a hospital facility, the Advisory Committee may accept a licensed Ontario physician certified by the Royal College of Physicians and Surgeons of Canada as a specialist in an area other than nuclear medicine but having a minimum of one year of full-time nuclear medicine training in a University-affiliated program. This one year of training should be within the five years immediately preceding the 1st of January of the year in which an application for licensing from the involved facility is first received.

The Advisory Committee will review the appropriateness of this designated physician on each AECB [now the CNSC] licence renewal.
A physician designated under Category 3 cannot transfer this authority to another facility.

**Note:** As of January 1, 1991 this category will no longer apply to new applicants.

In summary, as of January 1, 1991, physicians acceptable to take medical charge of a nuclear medicine facility will be:

- a licensed Ontario physician certified by the Royal College of Physicians and Surgeons of Canada as a specialist in nuclear medicine,

or

- a licensed Ontario physician uncertified in nuclear medicine who was a supervising physician approved by the Ontario Tripartite Nuclear Medicine Advisory Committee as of December 31, 1990.

- a supervising physician approved under Category 3 prior to December 31, 1990. This physician, however, cannot transfer this supervisory authority to another facility.

**Information Sheet**

The licensee, that is the institution, holds ultimate responsibility for radiation safety in the licensed facility. Nothing in the following should be construed as altering this. The physician in medical charge of an in vivo nuclear medicine service assumes the following responsibilities for the service:

- selecting, establishing, supervising and regularly revising all investigations and procedures offered by the service.

- preparing and maintaining an up-to-date procedure manual for each investigation and procedure offered by the service.

- establishing and maintaining an appropriate safe environment and appropriate medical supervision for patients undergoing procedures in the nuclear medicine department.

- establishing and maintaining a continuing mechanism for competent, experienced and clinically relevant reporting of investigations. This is of particular importance when the physician in charge is not based full time at the location of the facility in question.

- if nominated as the Radiation Safety Officer for the service, he or she will carry out the appropriate duties. Otherwise, the physician must meet regularly with and receive reports from the Radiation Safety Officer to be assured that radiation safety is maintained. The physician must be available for consultation with the Radiation Safety Officer should an urgent problem arise.

- establishing and supervising quality control practices and medical audit activities.

- participating in the appointment, supervision, training and discipline of the technological and professional staff of the laboratory to the extent necessary to be
assured that all clinical procedures are carried out as safely, effectively and efficiently as possible.

The physician shall be on the premises of the laboratory for a period of time commensurate with the above responsibilities and the work load of the laboratory.

The proposed medical supervision will be assessed by the Tripartite Committee prior to making its recommendation to the AECB.

The physician shall be a member of the medical staff of any hospital in which the service is located. Preferably, the physician should have a contract with the facility in respect of his or her responsibilities for the Nuclear Medicine service.
Appendix II  Independent Health Facilities Act - Ontario Regulation 57/92 Amending to O. Reg. 14/95

Note: Ontario Regulation 57/92 has previously been amended. Those amendments are listed in the Table of Regulations - Legislative History Overview which can be found at www.e-laws.gov.on.ca.

Facilities are encouraged to check the Government Website for updates.

Quality Advisor and Advisory Committee

1 (1) Every licensee shall appoint a quality advisor to advise the licensee with respect to the quality and standards of services provided in the independent health facility.

(2) If the quality advisor dies or ceases to be the quality advisor, the licensee shall appoint a new quality advisor forthwith.

(3) The quality advisor must be a health professional who ordinarily provides insured services in or in connection with the independent health 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.

(4) It is a condition of a licence that the quality advisor be a physician if all the insured services provided in the independent health facility that support the facility fees that the licensee may charge are provided by physicians.

(5) In subsection (4), an insured service supports a facility fee if the facility fee is for or in respect of a service or operating cost that supports, assists or is a necessary adjunct to the insured service.

(6) A licensee who is qualified under subsection (3) may appoint himself or herself as the quality advisor only if there is no other health professional who is qualified to be the quality advisor who will consent to be the quality advisor. O Reg 57/92, s.1.

2 (1) Every licensee shall appoint an advisory committee to advise the quality advisor.

(2) The advisory committee shall consist of health professionals who provide health services in or in connection with the independent health facility.

(3) The quality advisor shall be the chair of the advisory committee.

(4) Every licensee shall use his or her best efforts to ensure that there is a representative on the advisory committee from the health profession and each specialty and sub-specialty of medicine, practitioners of which provide health services in or in connection with the independent health facility. O Reg. 57/92, s.2.
3 (1) Every licensee shall give the Director the name of the quality advisor in writing forthwith after the quality advisor is appointed.

(2) If the quality advisor dies or ceases to be the quality advisor, the licensee shall inform the Director in writing forthwith.

(3) Every licensee shall give the Director, on request, the names of the members of the advisory committee in writing. O. Reg. 57/92, s.3.

Standards

4 (1) Every licensee shall ensure that all aspects of the services provided in the independent health facility are provided in accordance with generally accepted professional standards.

(2) Every licensee shall ensure that the persons who provide services in the independent health facility are qualified, according to generally accepted professional standards, to provide those services.

(3) If the quality advisor has reasonable grounds to believe that this section is not being complied with, he or she shall inform the Director forthwith. O. Reg. 57/92, s.4.

5 Every licensee shall keep a system to monitor the results of the services provided in the independent health facility. O. Reg. 57/92, s.5.

6 (1) Every licensee shall ensure that all tissues removed from a patient during an operation or curettage performed in an independent health facility are sent to a laboratory for examination and report unless the physician performing the operation or curettage is of the opinion that it is not necessary according to generally accepted medical standards.

(2) The licensee shall ensure that a short history of the case and a statement of the findings of the operation or curettage are sent with the tissues. O. Reg. 57/92, s.6.

Records of Employees

7 (1) Every licensee of an independent health facility shall maintain, for each employee of the facility who is not a physician, an employment record setting out the employee’s qualifications and employment history including a record of any registration with or licensing by the governing body of a health profession.

(2) Every licensee shall retain an employee’s employment record for at least two years after the employee ceases to be an employee. O. Reg. 57/92, s.7.

8 (1) Every licensee of an independent health facility shall maintain a record of qualifications and work history for:

   (a) each person the licensee contracts with to manage the facility; and
(b) each person who is not a physician who the licensee contracts with to provide patient-related services in the facility.

(2) The record shall include a record of any registration with or licensing by the governing body of a health profession.

(3) Every licensee shall retain the record for a person the licensee contracts with for at least two years after the licensee ceases to contract with the person. O. Reg. 57/92, s.8.

9 (1) Every licensee shall maintain a declaration of professional standing for each physician who provides professional services in the independent health facility.

(2) A declaration of professional standing must include the following information:

1. The physician’s name

2. The physician’s registration number with the College of Physicians and Surgeons of Ontario

3. The physician’s number registered with the Health Insurance Division of the Ministry of Health.

4. The class of the physician’s licence issued under Part III of the Health Disciplines Act and any terms and conditions attached to it.

5. The physician’s specialty.

(3) Every licensee shall give the Director a copy of each declaration of professional standing, forthwith after the obligation to maintain it begins under subsection (1).

(4) Every licensee shall give the Director a written statement of any change in a declaration of professional standing forthwith after the change.

(5) Subsections (3) and (4) do not apply with respect to physicians providing services on a temporary basis for less than twelve weeks. O. Reg. 57/92, s.9.

**Patient Records**

10 (1) Every licensee of an independent health facility shall keep, for each person who is or was a patient, a health record relating to the health services provided in the facility.

(2) A patient’s health record must include:

(a) the patient’s name and home address

(b) the patient’s date of birth

(c) the patient’s health number

(d) the name of any attending physician or practitioner and his or her number as registered with the Health Insurance Division of the Ministry of Health
(e) the name of any referring physician or practitioner and his or her number as registered with the Health Insurance Division of the Ministry of Health

(f) a history of the patient

(g) a written record of any orders for examinations, tests, consultations or treatments

(h) particulars of any examination of the patient

(i) any reports of examinations, tests or consultations including any imaging media from examinations and any physicians’ interpretive or operative reports

(j) any reports of treatment including any physicians’ operative reports

(k) any orders for and reports of any discharge of the patient from supervised care

(l) any consents; and

(m) any diagnoses of the patient.

(3) A patient’s health record need not contain a history of the patient if the patient came to the independent health facility for diagnostic services only and received on such service.

(4) Every licensee shall ensure that every part of a patient’s record has a reference on it identifying the patient or the record.

(5) If information in a patient’s record is kept in the form of a chart, each entry in the chart must be dated and it must be initialled by the person authorizing the entry. O. Reg. 57/92, s.10.

11 (1) Every licensee shall retain a patient’s health record or a copy of it for at least six years following:

(a) the patient’s last visit; or

(b) if the patient was less than eighteen years old when he or she last visited the facility, the day the patient became or would have become eighteen years old.

(2) Despite subsection (1), a licensee is not required to retain imaging media from any examination other than a mammography for more than three years following:

(a) the patient’s last visit; or

(b) if the patient was less than eighteen years old when he or she last visited the facility, the day the patient became or would have become eighteen years old.

(3) Every licensee shall retain the film from a mammography for at least ten years following the patient’s last visit. O. Reg. 57/92, s.11.

(4) On the transfer of a licence under section 11 of the Act, the transferor of the licence shall transfer to the transferee of the licence, in a manner that will protect the privacy of the records, the records maintained under section 10 of this Regulation, and the transferee of the licence shall retain those records in accordance with this section.
Section 12 of the Regulation is revoked and the following substituted:

12 (1) No licensee shall allow any person to have access to any information concerning a patient that is not subject to the Personal Health Information Protection Act, 2004 except in accordance with subsection (3).

(2) The reference to “information concerning a patient” in subsection (1) includes information or copies from a health record, even if anything that could identify the patient is removed.

(3) A licensee may provide information described in subsection (1) to the following persons if anything that could identify the patient is removed from the information:

1. Any person, if the information is to be used for health administration or planning or health research or epidemiological studies and the use is in the public interest as determined by the Minister.

2. Cancer Care Ontario. O Reg. 346/04, s.2.

Books and Accounts

12.1 (1) This section applies to licensees of independent health facilities that are funded under section 24 of the Act, other than independent health facilities whose funding is based solely on the Ministry of Health publication titled “Schedule of Facility Fees”.

(2) Every licensee shall keep the following records in relation to the independent health facility:

1. Current financial records showing:
   (i) the amounts paid by the Minister to the licensee under section 24 of the Act.
   (ii) the revenue earned by the licensee from facility fees charged by the licensee for or in respect of services or operating costs that support, assist or are a necessary adjunct to the primary insured services set out in the licensee’s licence, and
   (iii) the expenditures, assets and liabilities of the facility that relate to the costs paid by the Minister under section 24 of the Act.

2. A reporting record listing each service provided in the facility that is a primary insured service set out in the licensee’s licence and each service provided in the facility that is a funded service under section 24 of the Act and showing how many of each of such services are provided.

3. An annual income and expense statement showing the income received and the expenses incurred by the licensee in connection with the services mentioned in paragraph 2.
4. An annual inventory of the assets of the facility that have an acquisition cost exceeding $3,500 and that relate to the costs paid by the Minister under section 24 of the Act.

(3) Every licensee shall ensure that the records required under section (2):

(a) are kept in the independent health facility; and

(b) are kept in a bound or looseleaf book or are recorded by a system of mechanical or electronic data processing or any other information storage device.

(4) Every licensee shall ensure that any part of a record required under subsection (2) that relates to a period of time is retained for at least six years following the end of the period.

(5) Every licensee shall ensure that the accounts of the independent health facility are audited by a person licensed under the Public Accountancy Act. O. Reg. 283/94, s.1, part.

12.2 Every licensee of an independent health facility shall furnish such information and accounts as the Director may require. O. Reg. 283/94, s.1, part.

Notices

13 Every licensee of an independent health facility,

(a) who decides to cease operating the facility at a future date shall give the Director, as soon as possible, written notice of the date; and

(b) who ceases operate the facility shall give the Director, within seven days after the date the licensee ceases to operate the facility, written notice of the date. O. Reg. 57/92, s.13.

14 Every licensee of an independent health facility shall give the Director:

(a) if the licensee is a corporation, written notice of any change in the location of the licensee’s head office within ten days after the change; and

(b) written notice of any change in the name under which the licensee carries on business within ten days after the change. O. Reg. 57/92, s.14.
**Miscellaneous**

15 It is a condition of a licence that the licensee post the first page of the licence in a conspicuous
place in the independent health facility. O. Reg. 57/92, s.15.

16 (1) The fee for a licence is $100.

(2) The fee for the transfer of a licence is $100.

(3) The fee for the renewal of a licence is $100. O. Reg. 57/92, s.16.

17 The administrative charge for the purposes of section 36 of the Act is $50. O. Reg. 57/92,
s.17.
Appendix III - Recommended Guidelines for Preventing Allergic Reactions to Natural Rubber Latex

Definition
Natural latex is a milky fluid obtained from the hevea braziliensis (rubber) tree found in Africa and South-east Asia. Various chemical agents such as vulcanizers, accelerators, stabilizers and anti-oxidants are added natural latex.

Background
The latex allergy is an enormous public health problem faced by health care workers and patients. Healthcare workers have become the fastest group to experience latex sensitivity and more often its adverse affects.

Latex is a common component in health care products and consumer products. In 1989 there were 400 reported anaphylactic reactions and 15 deaths due to latex contact.

The implementation of universal precautions in 1987, to prevent HIV and other blood borne pathogens infections resulted in an increased demand for gloves. Manufacturing processes may have temporarily changed to meet this dramatically increased demand for gloves, resulting in latex products with higher allergic and irritant properties being produced and used. Repeated exposure to latex products can cause hypersensitivity reactions locally and systemically. Reducing exposure to latex products will definitely decrease sensitization and symptoms. There is no treatment for latex allergy except complete avoidance of latex.

Goals in Management
The two major goals in the management of latex reactions are successful identification and treatment of all dermatitis, to prevent future sensitization and identification of latex allergy to prevent serious life treating sequelae whenever possible.
Types of Reactions to Latex

Irritant contact dermatitis
- most common type of reaction
- not an allergic reaction involving the immune system but rather a skin irritation caused by the chemicals added to the latex during the manufacturing of the glove powder itself, repeated irritation from sweating under the gloves or from gloves rubbing against the hands, characterized by dry, flaky skin and papules, redness, fissures an thickening of skin

Allergic contact dermatitis: Type IV
- Delayed type hypersensitivity
- A cell-mediated allergic reaction to the chemicals used during the processing of latex. The more common sensitizers/allergens are thiurams and carbamates (accelerators)
- Results from prolonged contact with these chemicals in gloves
- Symptoms usually appear 6 to 48 hours after exposure
- Characterized by localized redness, clustered vesicles, swelling, itching, cracking eczema and fingertip fissures

Immediate allergic reaction: Type I
- An immediate immunoglobulin E mediated allergic response to the latex protein themselves
- Reaction usually occurs 5 to 30 minutes after exposure
- The response is introduced by direct contact with latex on non-intact skin resulting in sensitization before manifesting as a generalized reaction
- Once sensitivity has been initiated, any contact with latex may cause a recurrence of the reaction
- The protein allergens have been found in water-soluble extracts from latex rubber film. It may also be absorbed by glove powder, which may become airborne
- The severity of the immediate reaction will depend in the route of exposure; cutaneous, mucosal, inhalation and parenteral , the amount of latex allergen and the degree of individual sensitivity
- Mild reactions involve skin redness-hives-itchiness
- More severe reactions may imply edema, itching, conjunctivitis around the eyes, rhinitis, nasal itching, sneezing, shortness of breath, asthma, airway obstruction due to bronchospasm, anaphylactic shock
Risk Factors for Latex Sensitivity and Allergy

- Persons with spina bifida
- Patients and congenital urogenital defects, history of indwelling urinary catheters or repeated catheterizations
- Patients who have undergone recurrent surgical procedures
- Workers with ongoing latex exposure – health care workers, housekeepers, food handlers, tire manufacture workers, workers in industry who use gloves regularly
- Atopic individuals – persons with multiple allergic conditions, eczema, asthma, rhinitis
- Individuals allergic to certain food, banana, avocado, chestnut, apricot, kiwi, papaya, passion fruit, pineapple, peach, nectarine, plum, cherry, melon, fig, grape, potato, tomato and celery may cause a cross reactivity with latex protein
- No treatments are available to cure latex allergy. The best treatment is to avoid exposure. The treatment for individual allergic to latex is to ensure a safe environment. Medications are available to alleviate the allergy symptoms

Recommendations

Patients

- All patients are assessed for adverse reactions or contraindicated substance during their admission assessment. We should provide a latex safe environment for patients allergic and sensitive to latex.
- History for presence of allergies such as hay fever, childhood or adult eczema, asthma and food allergies
- Multiple surgeries
- Undiagnosed reactions or complications during surgery anesthesia or dental work – angioedema, shortness of breath, rash
- History of latex exposure: type of latex device, nature and duration of exposure
- History of latex allergy such as cutaneous symptoms (dermatitis-eczema-urticaria) respiratory symptoms, (rhinitis, wheezing, coughing, sneezing, shortness of breath)
- Any respiratory symptoms experienced when in contact with products containing rubber
- Other systems such as itchy hands, conjunctivitis, localized angioedema, possible systemic anaphylactic symptoms with the use of household latex cleaning gloves, balloons, condoms and diaphragms
If a patient has any of the above categories the following measure should be taken:

- Patients with severe documented allergy to latex should be assessed for the need of a private room
- A cart containing all latex free supplies that are necessary for patient care from admission to discharge. This cart will follow patient to other departments
- Wear non-latex examination and sterile gloves. Vinyl gloves should be changed every 15 minutes to protect the health care worker from borne pathogens
- Identify chart, patient, bed, medication profile, kardex, physicians order sheet with latex allergy stickers
- Post latex allergy sign on patient’s door
- Wear a cover gown if the possibility that our uniform contains residues of powder from latex gloves
- Tape over IV tubing ports and do not use
- Do not inject via T-connectors, buritrol or IV bag, inject and administer medication only through plastic stopcock
- Remove stoppers from vial then draw up medication. Needle puncturing a rubber stopper can shear off particles of latex, and cause a systemic reaction
- Glass syringe or latex free syringe must be used, if plastic syringe are used, the solution must be injected immediately after being drawn up
- If pulse oximetry is used, cover finger with tegaderm then apply probe. The inside surface of most pulse oximeters is covered with latex
- Avoid skin contact with the bulb and tubing of the blood pressure cuff by placing cloth under the rubber to shield the skin
- Stethoscope tubing can be covered with a stockinette
- If catheterization is necessary, use silastic foley catheter
- Utilize single dose ampoules for parenteral medication
- Patients that are highly reactive may require medications at the bedside. Epinephrine should be available if an anaphylactic shock occurs
- If the patient develops an allergic reaction, remove suspected allergen and provide immediate care
- All staff interacting with this patient must follow proper hand washing procedures before caring for these patients in order to minimize the exposure to and transfer of latex protein
**Health Care Workers**

Health care workers should protect themselves from latex exposure and allergy in the workplace:

- Use non-latex gloves for activities that do not involve contact with blood or body fluid
- For activities where contact with infectious materials is expected and latex gloves are used, choose a reduced protein, powder free glove
- Workers with hand dermatitis should never wear oil hand cream or lotion with latex gloves. Oil breaks down latex, damages the glove barrier and releases additional allergen. Detergents and other chemicals also degrade latex gloves
- After removing gloves, wash hands with soap and dry thoroughly, never re-use glove
- If you experience any symptoms possibly related to latex allergy, report it to Health and Safety Department, avoid contact with latex gloves until you see your allergist
- Attend latex allergy education session

**If allergic to latex:**

- Avoid contact with latex gloves, latex containing products and objects such as computer keyboards, telephones, that have been contaminated with latex gloves or glove powder
- Avoid areas where you might inhale the powder from latex gloves worn by other workers
- Wear medical alert bracelet
- Attend latex allergy education session
- Carry an emergency epinephrine auto-injector
- Avoid cross-reacting food such as: kiwi, avocado, chestnut
- Follow your physician’s instructions for dealing with allergic reaction to latex

**Institution**

To eliminate or reduce the risk for latex sensitization of asymptomatic staff and minimize the risk of latex exposure to staff already sensitized:

- Eliminate unnecessary use of latex gloves by providing workers with non-latex gloves when there is minimal potential for contact with blood or bodily fluid
• When selecting a latex glove for barrier protection from infectious materials, choose a reduced protein, powder free glove. Glove should be approved by the Canadian General Standard Board

• Provide education to employees about latex allergies, hand care and the importance of early care for dermatitis or other allergy symptoms. Identify and instruct worker in work practices to prevent exposure

• Implement a latex allergy assessment protocol including a screening history questionnaire and protocol of evaluation and treatment of latex reaction symptoms

• Conduct a worksite evaluation, identify areas contaminated with latex dust and make sure cleaning is done more frequently. Ensure that filtration and ventilation systems provide adequately re-circulated air in area with high levels of latex aerosols

• Alternative latex free devices must be available

• Identification of medical product containing latex

• Incorporate latex allergy education as part of the annual safety and infection control program, orientation program and also conduct in services

Once a diagnosis of latex allergy is confirmed, the employee should accommodate the affected workers. Extremely sensitive individuals may have to be re-assigned to areas where no latex gloves