THE COLLEGE OF PHYSICIANS AND SURGEONS OF ONTARIO

INDEPENDENT HEALTH FACILITIES

Clinical Practice Parameters and Facility Standards

Nuclear Medicine – 5th Edition, January 2018

The College of Physicians and Surgeons of Ontario

Vision Statement

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.

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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.

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THE COLLEGE OF PHYSICIANS AND SURGEONS OF ONTARIO

Independent Health Facilities

Clinical Practice Parameters and Facility Standards

Nuclear Medicine 5th Edition – January 2018

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Preface

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

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

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

Purpose of Clinical Practice Parameters

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

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

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.

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Role of the College of Physicians and Surgeons of Ontario

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

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

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

Task Force members ensure that:

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

Responsibilities of the College

Responsibilities of the College include:

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

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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 are subject to periodic review, and amendments may be issued from time to time. Such updates will be mailed automatically to all relevant Independent Health Facilities. 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.

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Independent Health Facilities: Clinical Practice Parameters and Facility Standards

Nuclear Medicine

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VOLUME 1 FACILITY STANDARDS

Chapter 1 Staffing a Facility

1.1 Overview

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

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

- There is a current written plan describing the organization of the facility and its services.
- There are sufficient numbers of qualified physicians, medical radiation technologists, and clerical personnel available to meet the stated goals and objectives.
- Physicians must be licensed to practice in Ontario by the CPSO in order to refer to themselves as physicians or doctors in any setting relating to an IHF. In order to practise medical radiation technology in Ontario, a medical radiation technologist (MRT) must be registered with the CMRTO.
- The duties and responsibilities of all nuclear medicine imaging staff are specified in job descriptions. They are kept up to date and on site.
- Quality Advisors, physicians, medical radiation technologists (MRTs), and licensees review their legal obligations to obtain professional liability insurance. If it is not a legal requirement, obtaining professional liability insurance may be considered, as there is potential for liability issues in IHFs.
- Adequate education and training of staff responsible for cleaning, disinfecting, sterilizing, and/or reprocessing of medical equipment, including manufacturer's training. To determine appropriate training, the Quality Advisor must complete Infection Prevention and Control's Checklist for Infection Prevention and Control (IPAC) CORE Elements in Clinical Office Practice.
- All staff remains current with the standards for infection control by obtaining online training through Public Health Ontario, which must be done on annual basis, and must be documented/signed-off and maintained on site.
- Staff obtains education/training (which is documented and maintained on site) in areas mandated by the Ontario Government, such as the following:
    - Workplace Hazardous Materials Information System 2015 (WHMIS 2015);
    - Health and Safety Awareness;
    - Workplace violence and sexual harassment, and;
    - Accessibility for Ontarians with Disabilities
- Staff are educated in radiation safety legislation and policies and are familiar with and understand privacy, and confidentiality legislation and policies.
- At least one staff member with current Basic Cardiac Life Support (BCLS) certification is on site at all times during hours of operation. Documentation regarding BCLS

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certification is maintained on site. It is expected that the training includes being certified in both theory and hands-on components.

1.2 Qualifications of Interpreting Physicians

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

Nuclear medicine services are provided by physician(s):

- certified by the Royal College of Physicians of Canada (FRCPC) in Nuclear Medicine

or

- approved by the Registration Committee of the College of Physicians and Surgeons of Ontario to practice independently in Nuclear Medicine.

or

- a non-Nuclear Medicine physician who has been approved or is being overseen by the College of Physicians and Surgeons of Ontario for a change in scope of practice to report nuclear medicine services in an IHF setting.

1.2.1 Responsibilities of the Interpreting Physician

Interpreting Physicians are responsible for:

- maintaining a level of competence for the range of studies being offered. This is accomplished by attending nuclear medicine review courses or conferences, reviewing current nuclear medicine literature, etc.
- contacting the Quality Advisor for advice regarding quality of care matters.
- managing any complications or problems that arise, either clinically or from the standpoint of radiation safety, informing the Quality Advisor.
- ensuring a physician is present in the facility during the intervention studies, either pharmacological or related to cardiac stress testing, 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.

1.2.2 Continuing Professional Development

All interpreting physicians in Ontario are required to participate in, and to track their credits in a CPD program that meets requirements set by the Royal College of Physicians and Surgeons of Canada.

In addition, CPD should be relevant to the nuclear medicine services within the IHF where interpreting services are provided.

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The Quality Advisor ensures that this information from the Royal College of Physicians and Surgeons of Canada is made available upon request to ensure that physicians providing interpreting services within the IHF are in compliance.

1.3 Quality Advisor

The Quality Advisor (QA) must be a physician licensed to practice in Ontario by the College of Physicians and Surgeons of Ontario and meet the qualifications as outlined above.

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

1.3.1 Role of the Quality Advisor

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

Each IHF licensee is responsible for operating the facility and providing services in accordance with the requirements of the IHFA. Pursuant to O. Reg. 57/92 under the *Independent Health Facilities Act (see Appendix I), "*every licensee is required to appoint a Quality Advisor to advise the licensee with respect to the quality and standards of services provided in the IHF. The Quality Advisor must be a **physician** who ordinarily provides insured services in or in connection with the facility and whose training enables him or her to advise the licensee with respect to the quality and standards of services provided in the facility".

1.3.2 Duties and Responsibilities of a Quality Advisor

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

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

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- Shall ensure all QA Committee meetings are documented.
- Obtain copies of assessment reports from the licensee/owner/operator. If deficiencies were identified in the assessment, the Quality Advisor shall review same with the QA Committee and document such review. The Quality Advisor's signature is required on any written plan submitted by the licensee to the College.

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

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

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- **Establishing and/or updating system(s)** for monitoring the results of the service(s) provided in the facility.

1.3.2.1 Quality Advisor Duty to Report to Director IHF

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

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

1.3.2.2 Quality Advisor Duty for Infection Control

In order to determine appropriate Infection Control training of staff, the Quality Advisor must complete Infection Prevention and Control's Checklist for Infection Prevention and Control (IPAC) CORE Elements in Clinical Office Practice, and must verify completion of relevant training by all staff.

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

Independent Health Facilities are required to have one Quality Advisor noted on the IHF license. For IHFs that have been licensed for more than one service such as Diagnostic Imaging/Pulmonary Function Studies/Nuclear Medicine/Sleep Medicine, where the Quality Advisor's scope of practice does not include all services provided on the licence, she or he must appoint Medical Lead(s) for each applicable service. Specifically, the Medical Lead must be a physician with adequate expertise to **assist** with IHF staff compliance with policies and procedures set out by the Quality Advisor, especially as it relates to monitoring and reporting on the quality of services for each additional service.

1.5 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.

The RSO must be:

- A Fellow of the Royal College of Physicians and Surgeons of Canada (Nuclear Medicine Specialty), or
- A Member of the Professional Corporation of Physicians of Quebec certified as a specialist in nuclear medicine, or
- A Member or Fellow of the Canadian College of Physicists in Medicine, or

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- A registered technologist certified in nuclear medicine by the Canadian Association of Medical Radiation Technologists (CAMRT) or CMRTO or by the Ordre des Techniciens en Radiologie du Quebec, or
- A person approved in writing by the CNSC. Submission of Request to Appoint a New Radiation Safety Officer Nuclear Substances and Radiation Devices Licence is required acknowledging his/her willingness to be designated as the applicant's RSO and acceptance of the responsibilities described in the submitted job description.

For additional information, please access the following sites:

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

1.5.1 Duties and Responsibilities of the RSO

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

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

1.6 Radiation Protection Officer

According to the HARP Act, a Radiation Protection Officer (RPO) must be designated if the facility has one or more x-ray tubes (for example computed tomography, and/or DEXA). This role may be assumed or designated by the Quality Advisor.

The minimum requirements an RPO must abide by are indicated in O. Reg. 543 the X-ray Safety Code under the *Healing Arts Radiation Protection Act* (HARP Act).

However, if an RPO chooses to implement further facility safety policies as part of their duties and responsibilities, then it is at their discretion to do so. The ACR-AAPM RSO document contains numerous standards the RPO may choose to implement presented below, along with the requirements falling under the *HARP Act*.

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1.6.1 Duties and Responsibilities of the RPO

The OAR published a paper outlining the roles and responsibilities of the RPO:

1. Radiation Protection (ALARA) Program
    - To the extent practical, the RPO should assure that the facility uses procedures and engineering controls based on sound radiation protection principles to achieve occupational doses and doses to members of the public that are in line with ALARA.
2. Radiation Dose Limits
    - Radiation dose limits are specified by the X-ray Safety Code
3. Personal Radiation Monitors
    a. Who must be monitored?
        - Adults likely to receive greater than 5 mSv/year
        - Minors (less than 18-year-old) likely to receive greater than 1 mSv/year or a lens dose equivalent in excess of 1.5 mSv
        - Declared pregnant women. The fetus must not receive more than 5 mSv during the entire pregnancy
        - Individuals working with medical fluoroscopic equipment.

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

4. Occupational Dose Limits
    a. Adults
    - i. Annual limit of adults
        - 50 mSv, however 20 mSv is recommended averaged over 5 years, with no single year exceeding 50 mSv.
    - ii. Annual limits to tissues/organs include the following:
        - Lens: 150 mSv;
        - Skin or extremities: 500 mSv

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b. Dose limits for individual members of the public

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

5. General X-ray Safety Policies

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

6. Registration of Radiation Machine Facilities

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

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

7. Equipment Surveys

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

8. X-ray Room Shielding

New or remodeled facilities or facilities whose use changes in a way that may change radiation exposure levels must have a shielding plan developed by a qualified expert (e.g., qualified medical physicist) and, approved by the XRIS. By regulation, acceptance testing must be submitted by 60 days after installation. Ideally, this should be completed prior to clinical use.

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

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

Radiation Protection Surveys may be performed after shielding is installed and as needed thereafter to assure that individual exposures do not exceed regulatory limits. If performed, the surveys should adhere to the standards in NCRP 147.

9. X-ray Equipment Servicing and Services

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

10. Records

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

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11. Quality Assurance Program

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

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

12. Research Involving Radiation

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

1.7 Medical Radiation Technologists

In Ontario, Medical Radiation Technologists (MRTs) are self-regulated registered professionals with the College of Medical Radiation Technologists of Ontario (CMRTO). The practice of medical radiation technology is the use of ionizing radiation, electromagnetism and other prescribed forms of energy for the purposes of diagnostic and therapeutic procedures, the evaluation of images and data related to the procedures and the assessment of the condition of the patient before, during and after the procedure. MRTs must practice in accordance with the applicable provincial legislation, the Medical Radiation Technology Act (MRT Act), the College of Medical Radiation Technologists of Ontario (CMRTO) standards of practice and the policies and procedures of the facility.

Medical Radiation Technologists must have a current and valid certificate of registration with the College of Medical Radiation Technologists of Ontario (CMRTO), and should only perform the services and procedures that fall within the scope of the profession. Please refer to CMRTO Standards of Practice.

1.7.1 MRTs Performing Bone Mineral Densitometry

MRTs registered in any of the specialties of CMRTO are authorized to operate a dual energy x-ray absorptiometry (DXA) unit provided they have sufficient knowledge, skills and judgement to comply with the HARP requirements and to operate the x-ray bone mineral densitometry (BMD) machine.

In addition, MRTs performing BMD must obtain certification through either the Ontario Association of Radiologists (OAR) or the International Society of Clinical Densitometry (ISCD).

1.7.2 Duties and Responsibilities of MRTs

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

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- Adhere to the facility policies, procedure & protocols
- Perform quality control procedures on all nuclear medicine equipment, bone mineral densitometers, generator eluate and radiopharmaceuticals according to facility policies and manufacturers' product monograph.
- Review and record the quality control results and take corrective action if the results are not within acceptable limits.
- 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
- Adhere to all relevant provincial and federal legislation and guidelines governing the practice of the profession including:
    - CMRTO Standards of Practice
    - CMRTO Code of Ethics
    - CMRTO by-laws
    - CMRTO's sexual abuse prevention program
    - *Personal Health Information Protection Act*
    - *Health Care Consent Act*
    - *Canadian Nuclear Safety Commission*
- Provide ethical, competent and compassionate care in each patient/client interaction
- Use appropriate aseptic techniques and infection control procedures in the course of the diagnostic procedure as per PIDAC/IPAC guidelines.
- Follow all facility policies and procedures regarding cleaning of all equipment including ancillary equipment (e.g. resuscitation devices, gamma cameras, thyroid probes, bone mineral densitometers and stress testing equipment computer keyboards, etc.)
- Maintain full records of incidents, unusual occurrences, reactions as per site policies & protocols etc.
- Record and report any equipment faults or problems to appropriate personnel, as per site policies & protocols

Patient Examination:

- Follow facility policy regarding situations where the use of chaperones may be appropriate
- Ensure the room is prepared for the procedure specified in the order
- Select and set up the equipment and materials needed for the procedure specified in the order
- Ensure correct patient identification (e.g., confirmation of patient name, date of birth, examination to be performed, and physician/authorized health professional authorization is present)

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- Confirm that the order is appropriate based on the patient history
- Ask if female patient is or may be pregnant before starting the exam
- Ensure that the worklist contains the correct patient information (if applicable)
- Obtain informed consent (oral or written as per facility policy) before each examination (after explaining the procedure & answering any questions)
- Ensure pertinent clinical history is available and supplement as necessary
- Inquire about & record any contraindications as per facility policy (e.g. allergies to latex)
- Follow the facility examination protocols
- Follow facility protocols when unexpected findings are found that would require immediate attention

Throughout the Examination:

- Assess the patient's condition before, during and after the procedure or course of treatment and make modifications to procedures based on the patient's physical, medical and/or emotional status and needs
- Instruct the patient to remove only the clothing and items that will interfere with the procedure, providing the patient with a gown or sheet to cover areas where clothing was removed and explaining to the patient when and where the MRT may touch them and why
- Maintain patient comfort, privacy and dignity at all times
- Stop procedure if at any time the patient withdraws consent and record withdrawal of consent & reason
- Utilize personal protection devices as required (masks/gloves etc.) and as indicated
- Ensure that the orientation of the body and other pertinent parameters are marked correctly on the image and data
- Ensure that patient examination images and data contains patient name, ID#, date of examination and type of examination
- Each patient record has the MRT identifier to verify who performed the examination
- Keep all patient information confidential except when necessary to facilitate diagnosis or treatment of the patient, or when legally obliged or allowed to disclose such information. Comply with any applicable privacy & confidentiality legislation such as the *Personal Health Information Protection Act* (Ontario)

1.7.5 Continuing Professional Development for MRTs

Medical Radiation Technologists must participate in the CMRTO's Quality Assurance Program as part of maintaining and improving their competence.

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Chapter 2 Facilities, Equipment and Supplies

2.1 Overview

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

2.2 Facilities, Equipment and Supplies

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

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

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

- Fire extinguisher
- SDS information
- First Aid Kit
- Appropriate emergency cart and resuscitation equipment

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

The facility has alternate materials available for patients with known or suspected latex allergies.

2.2.1 Infection Control

Basic supplies for infection prevention and control are on-site and used appropriately as per current provincial guidelines/policies. Resources are available through the Provincial Infectious Diseases Advisory Committee of Public Health Ontario.

2.2.2 Eye Wash Stations

IHFs must ensure that an emergency eyewash station is available for its employees as per PIDAC requirements. If High Level Disinfection (HLD) is done, then the eye wash station must be installed at this sink.

The Ministry of Labour adheres to the American National Standards Institute (ANSI) Standard Z348.1-2004 that emergency eyewash stations (whether plumbed or self-contained) shall be capable of:

- Activating within 1 second or less.
- Flushing both eyes simultaneously.
- Delivering flushing “tepid” temperature fluid to both eyes of no less than 1.5L per min, (0.4 gpm) for 15 minutes.

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- Providing hands-free operation.
- A softened water flow so the force does not drive contaminants into the optic system.

2.2.3 Radiopharmaceuticals

Radiopharmaceutical policies outlined in the Chapter 3 on Policies and Procedures as well as Chapter 23 on Radiopharmacy Best Practices 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.

2.2.4 Instrumentation

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

2.3 Equipment Quality Control

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

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

2.3.1 Gamma Cameras

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

flood field uniformity

isotope energy peaking, or pulse height analysis

SPECT centre of rotation

Gamma camera safety systems.

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

2.3.2 Well Counter, Dose Calibrator, and Survey Meters

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

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

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2.3.3 Dual Energy X-ray Absorptiometers (bone densitometers)

Bone Mineral Densitometry

Equipment and Quality Control activities must meet the Canadian Association of Radiologists Technical Standards for Bone Mineral Densitometry Reporting (2013).

Facilities are also encouraged to obtain facility accreditation through the Ontario Association of Radiologists' (OAR's) Canadian Bone Mineral Densitometry (CBMD) Accreditation Program (which includes a requirement for physicist acceptance testing, as well as annual preventative maintenance on the BMD unit). The minimum required activities must include: Shewhart testing on each clinical day of operation and an up-to-date precision study for each MRT and machine. Up-to-date refers to a precision study that has met the following criteria:

a) Precision study data is no older than 5 years

b) New MRT is performing DXA exams on patients (at least 5% of the weekly volume)

A new precision study is to be performed if an additional unit is installed in the facility. If the additional unit is of the same make and model, then all models must be tested to allow for interchangeability between machines of the same make and model should this be desired. Shewhart and Precision calculators are available through the Ontario Association of Radiologists website.

2.4 Nuclear Medicine Reporting Stations

Please refer to Volume 4 Teleradiology (PACS).

2.5 Aging Equipment

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

If a facility chooses to extend the lifecycle of its BMD machines (past the CAR Lifecycle Guidance for Medical Imaging Equipment in Canada for low utilization), then it is required to obtain the services of a Qualified Medical Physicist to evaluate and determine if the radiographic units are still appropriate for routine clinical use. Evaluations must be done once every 3 years by a Qualified Medical Physicist (or a delegate, but overseen by the Qualified Medical Physicist), with final reports being reviewed and signed-off by a Qualified Medical Physicist.

A Qualified Medical Physicist is an individual who is competent to practice independently in one or more of the subfields in medical physics. The Qualified Medical Physicist must be certified in the appropriate subfield(s) by the American Board of Radiology (ABR), the Canadian College of Physics in Medicine, or by the American Board of Medical Physics (ABMP). The appropriate subfield of medical physics for this document is Diagnostic Medical Physics. (Previous medical physics certification including Radiological Physics, Diagnostic Radiological Physics, and Diagnostic Imaging Physics are also acceptable.

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

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Chapter 3 Policies and Procedures

3.1 Overview

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

3.2 Radiation Safety and Dose Reduction (ALARA Principles)

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

The ALARA principle (As Low As Reasonably Achievable) must be considered for all examinations using ionizing radiation to minimize radiation exposure to the patient and staff.

Policies and procedures should be developed under the direction of the radiation safety officer (RSO).

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

3.3 Developing Policies and Procedures

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

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

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

3.3.1 Facility

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

- scope and limitations of diagnostic imaging services provided by the facility, including professional guidelines, such as:

  CMRTO Standards of Practice

  CMRTO Code of Ethics

- patient-booking systems
- documentation of and method for receiving written and telephone referrals for consultation

3.3.2 Facility Staff

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

- delegated acts and medical directives. Refer to CPSO policy on Delegation of Controlled Acts

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- supervision of staff, e.g. physicians who may be working at a facility while in the process of pursuing approval through the CPSO for change in scope
- staff roles for emergency procedures, which are appropriate to the role they would assume in an emergency (e.g. fire, power failure, other emergency evacuation, etc.)
- Staff responsible for cleaning, disinfecting, sterilizing, and/or reprocessing of medical equipment must complete appropriate training, including manufacturer's training. To determine appropriate training, the Quality Advisor must complete the Infection Prevention and Control's Checklist for Infection Prevention and Control (IPAC) CORE Elements in Clinical Office Practice.
- All staff remains current with the standards for infection control by obtaining online infection control training through Public Health Ontario, which must be done on annual basis, and must be documented/signed-off and maintained on site.
- Safety education/training for medical and non-medical staff (which is documented and maintained on site) that addresses areas mandated by the Ontario Government, such as the following:
    - Workplace Hazardous Materials Information System 2015 (WHMIS 2015);
    - Health and Safety Awareness;
    - Workplace violence and sexual harassment, and;
    - Accessibility for Ontarians with Disabilities

  For more information, please refer to the Guide to the Occupational Health and Safety Act.
- orientation for all new staff to ensure adequate training. This must include a review of policy and procedure manuals, modality specific protocols, and all safety training. The employee must sign off indicating that they have successfully completed all of the above training.
- Written performance evaluations for all staff at completion of probationary period, and thereafter as defined by the facility, preferably annually.
- specific protocols for the techniques performed at the facility, including appropriate patient preparation, radiopharmaceutical dose, and specific patient instructions following the procedure. Refer to the following guidelines:

  Society of Nuclear Medicine and Molecular Imaging

  European Association of Nuclear Medicine and

  British Nuclear Medicine Society

3.3.3 Records and Communication/ Reporting & Privacy Principles

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

- Policies regarding requisition of tests from referring physicians
- Special considerations with regard to emergency requests

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- Verbal reports: a written policy and procedure must be in place to ensure verbal reports are communicated to the referring physician by the nuclear medicine physician or his/her designate
- Urgent findings: a written policy and procedure be in place to ensure that all positive findings are relayed to the referring physician by the nuclear medicine physician or designate

- Use of cameras and videos to take pictures or make videos are not permitted in the clinical setting – unless mutually agreeable to the parties involved
- Patient consent, written or verbal, based on the scope of practice in the facility and in accordance with the *Health Care Consent Act*
- Maintenance of requisitions, imaging media and interpretation reports *(see Appendix I, Independent Health Facilities Act- Ontario Regulation 57/92)*
- Confidentiality for staff and patients
- Privacy and release of health record information, including Bill 31 the Personal Health Information Protection Act 2004. (PHIPA). Information available at www.ipc.on.ca

3.3.4 Pharmaceutical Safety

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

- radiation safety and radiopharmaceuticals quality control including:
  - emergency procedures for minor and major spills.
  - acquisition, storage, security, preparation, administration, and disposal of radiopharmaceuticals.
  - optimum dosage of radiopharmaceutical for patients of different ages.
  - methods for reducing organ doses in various procedures.
  - precautions to be followed in women of reproductive age
  - protocols to be followed in case radiopharmaceuticals are administered incorrectly, e.g., incorrect radiopharmaceutical or over-dosage.
  - Radiopharmaceutical substitution may be permitted provided equivalency.
- establishing and maintaining a program to evaluate the technical performance of the instruments used for imaging, and radiation monitoring. This includes procedures for testing instruments according to manufacturers' guidelines and any applicable regulations.

For more information on radiopharmaceutical safety, please refer to Chapter 23 on Radiopharmacy Best Practice Standards.

3.3.5 Equipment Maintenance

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

- routine maintenance, calibration, and evaluation of image quality of all diagnostic equipment. The activities should be performed as a minimum on an annual basis. This

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should include frequency of testing, responsibility for following up on recommendations, documentation and maintenance of records for all of the above. Please refer to Chapter 2 on Facilities, Equipment and Supplies for more details.

3.3.6 Emergency Procedures and Safety Policies

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

- Specific first aid measures to be followed in an adverse health event, including a description of the arrangements for transferring patients to an acute care facility when required
- Protocol to be followed to deal with emergencies, e.g. fire, evacuation, disaster, violent/behavioural situation, cardiac arrest, bomb threats, missing patient, hazardous spill, hostage situation, etc.
- At least one staff member with current Basic Cardiac Life Support (BCLS) certification is on site at all times during hours of operation.
- 70% alcohol-based hand rub be available for staff and patients at all points of care
- A hands-free eyewash station be installed in the facility (as per WHMIS)
- Latex anaphylaxis
- Safety Data Sheets (SDS) for all chemicals maintained in the facility
- Infection control. Resources are available through the Provincial Infectious Diseases Advisory Committee of Public Health Ontario
- Accessibility for Ontarians with Disabilities Act (AODA)
- Workplace safety and harassment
- Personal Protective Equipment (PPE)

3.3.7 Quality Management (See Chapter 5)

3.3.8 Infection Control

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

- Routine Practices and Additional Precautions to prevent infection transmission are in keeping with provincial guidelines. Resources are available through the Provincial Infectious Diseases Advisory Committee's (PIDAC's) Infection Prevention and Control for Clinical Office Practice document**.**
- Hand hygiene – see PIDAC Best Practices for Hand Hygiene in Health Care Setting
- Environmental Cleaning – see PIDAC Best Practices for Environmental Cleaning in Health Care Settings
- Cleaning, Disinfection, Sterilization and Reprocessing of reusable medical devices and equipment - see PIDAC Best Practices for Cleaning, Disinfection and Sterilization in Health Care Settings and PIDAC Infection Prevention and Control for Clinical Practice Settings
- Adequate education and training of staff responsible for the disinfection of medical equipment.

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- For information about infection control within the context of radiopharmacy, please refer to Chapter 23 on Radiopharmacy Best Practice Standards.

3.3.8.1 Infection Control related to Hand Hygiene

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

- Education of staff and patients about the Ministry of Health "Hand Washing Techniques", including posting of the MOHLTC document for IHF staff and patients in designated areas
- Documentation attesting to annual staff compliance. (Refer to PIDAC's Best Practices for Hand Hygiene in All Health Care Settings, 4th edition)

3.3.8.2 Infection Control related to At Risk Patients

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

- Handling of at risk patients, for example, those who have who have any possibility of transmitting infection, at the initial contact with the patient.
- Managing patients with potentially infectious respiratory conditions.

3.3.9 Personal Protective Equipment

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

- Indications for and use of gloves, masks, gowns and eye-protective equipment for protection of patients and personnel
- Proper disposal of personal protective equipment
- Documentation attesting to annual staff compliance.

3.3.10 Disposal of Sharps

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

- Appropriate precautions to prevent injuries from sharps
- Carefully following protocols for use and handling of needles (e.g. no recapping of needles, passing needles without injuring each other, disposal in dedicated sharp containers.

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Chapter 4 Requesting and Reporting Mechanisms

The content of this chapter is based on the Canadian Association of Radiologists Practice Guidelines for Communication of Diagnostic Imaging Findings (2010) with modifications to reflect the practice of nuclear medicine.

4.1 Overview

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

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

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

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

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

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

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Policies and practice must be consistent with privacy legislation.

4.2 Requesting and Reporting Mechanisms

Written requisitions are completed for all nuclear medicine procedures.

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

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

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

An appropriate request specifies:

the basic demographic information of the patient such as name, health number, date of birth, and sex

the name of the referring physician and the names of any other regulated health professional who are to receive copies of the report

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

the service requested

a concise statement of the reason for the examination

any additional relevant history, physical findings

- ***or***

other information useful for interpreting or modifying the test procedure.

4.3The Nuclear Medicine Final Written Report

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

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

The timelines of reporting any imaging examination varies with the nature and urgency of the clinical problem. Best efforts should be made in order to ensure the written final report is

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made available to the ordering physician who is responsible for the clinical follow-up within 2 business days.

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

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

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

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

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

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

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

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

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

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

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

Previous stored imaging studies are available for the interpreting physician.

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

4.3.1 Report Attributes

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Reports of the interpretation of imaging procedures include the following:

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

the facility or location where the study was conducted.

name of the ordering physician or healthcare professional.

name of most responsible physician/healthcare professional for patients cared for by multiple clinical services.

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

name or type of examination.

date of examination.

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

dates of dictation.

- rationale: quality control.

4.3.2 Body of the Report

The effective transmission of imaging information from the nuclear medicine physician to the ordering physician/healthcare professional constitutes the main purpose of the report.

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

4.3.2.1 Procedures and Materials

A description of the examinations and/or additional procedures performed, including rationale and any contrast media (including agent, concentration, volume and route of administration, where applicable), medications, catheters, or devices if not reported elsewhere. Any known significant patient reaction or complication should be recorded.

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

4.3.2.2 Findings

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

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4.3.2.3 Limitations

Where appropriate, identify factors that can limit the sensitivity and specificity of the examination. Such factors might include technical factors, patient anatomy (e.g., dense breast pattern), and limitations of the technique (e.g., the low sensitivity of a chest X-ray for pulmonary embolism).

4.3.2.4 Clinical Issues

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

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

4.3.2.5 Comparative Data

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

4.3.2.6 Assessment and Recommendations

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

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

Give a precise diagnosis whenever possible.

Give a differential diagnosis when appropriate.

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

Any significant patient reaction should be reported.

4.4 Standardized Computer-Generated Template Reports

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

4.5 Preliminary Reports

A preliminary report may precede the final report in certain circumstances and contains limited information relevant to immediate patient management. It may be time sensitive and should

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not be expected to contain all the imaging findings. It should be generated when a timely communication is necessary in unexpected elective cases where clinical urgency mandates immediate communication of the results.

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

4.6 Reporting Guidelines

All reports must contain the following components:

1. Study identification
2. Patient demographics
3. Clinical information
4. Comparison/correlative data
5. Procedure description
6. Description of findings
7. Study Limitations
8. Impression

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Chapter 5 Quality Management

5.1 Overview

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

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

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

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

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

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

Regular agenda items must include:

- All issues raised by any assessment/accreditation (if applicable) visit. Such issues are to remain on the agenda until they are clearly finalized
- Any incidents or complaints recorded or received since the last meeting
- Any staff or staffing issues submitted to the QAC
- Review of current statistics on the time between referral and subsequent diagnostic imaging examinations
- Review of recent difficult or inconclusive cases
- All equipment or lab configuration issues new or unresolved since the last meeting that have quality assurance implications
- Review of referring physician and patient satisfaction surveys (see samples in Appendix II and Appendix III)
- Status of the systematic review of the facility's policies and procedures
- Any items from previous agendas that have not been finalized

5.2 Quality Management Program Goals

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

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

Services conducted in the facility are safe.

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

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

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5.3 Providing Quality Care

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

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

5.4 Components of a Quality Management Program

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

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

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

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

1. Review quality management goals and objectives annually.
2. Supervise and document a systematic ongoing review of the facility policy and procedures manual.
3. Review safety data on any equipment new to the facility since the last meeting, and ensure that all equipment in the facility meets safety standards.
4. Review any incident or accident report since the last meeting and document any such actions to prevent similar incidents or accidents. Provide a report of all such proceedings to the facility's Quality Advisor.
5. Review and implement recommendations from other assessing bodies such as the Ministry of Health and Long-Term Care, and Ministry of Labour.

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

6. Supervise and document a program of annual performance reviews for all staff who have patient contact, including documentation of action taken to correct any significant deficiencies in performance.
7. Ensure all registration certificates, BCLS certificates, etc., are valid and current for all staff.
8. Ensure that the CPD activities of the technical and medical staff meet the relevant College or Society requirements. For example, all specialist physicians have fulfilled their annual RCPSC Maintenance of Certification (MOC) requirements.
9. The QAC arranges regular discussions of interesting/challenging cases ascertained at the facility at least annually, and ensures any teaching points are disseminated to the staff.
10. The QAC reviews the results from regular surveys of patient, referring physician and staff satisfaction surveys at least annually, and shall document actions to address any suggestions, problems or issues raised.

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11. Implements and documents a quality review process which follows the basic principles of the CAR peer review program toward achieving the following program goals:
    - Enhances the consistency and accuracy of nuclear medicine services to improve quality of care for patients
    - Supports ongoing improvements to image interpretation skills through peer to peer learning in a non-punitive environment
    - Enables informed decisions about patient treatment, enhancement of quality programming, physician training and continuing medical education
    - Supports maintenance of ongoing learning, education and contribution to a culture of quality improvement, transparency and accountability

5.5 Monitoring the Program

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

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

Recommendations from the QA Committee shall be circulated to all staff once they are finalized. These recommendations shall be reviewed at a general staff meeting including all health care professionals who provide services in or in connection with the IHF. Quorum for such staff meetings shall be 2 or 50% of the staff whichever is greater. Staff may attend by secure conference call. Staff members who cannot attend are to review and sign off on the minutes of that meeting.

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

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

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VOLUME 2 CLINICAL PRACTICE PARAMETERS

Chapter 6 First Transit with or without Blood Pool Images

6.1 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. However, for first transit without blood pool images, the immediate or blood pool image are not performed when the information to be gained does not contribute to the diagnostic process.

6.2 Prerequisites for First Transit with and without Blood Pool Images

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

6.3 Reporting Guidelines (see Chapter 4)

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Chapter 7 Infection and Inflammation Scintigraphy

7.1 Overview

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

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

7.2 Common Clinical Indications

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

Sepsis or inflammation detection. Most commonly:

- Skeletal infection/inflammation:
    - osteomyelitis
    - joint space infection/neuropathic joint
    - discitis
    - prosthetic aseptic loosening and infection

- Soft tissue infection/inflammation including:
    - abscess localization
    - assessment of inflammatory bowel disease
    - renal parenchymal and peri-renal infections

7.3 Reporting Guidelines (Refer to Chapter 4)

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Chapter 8 Myocardial Perfusion Scintigraphy

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

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

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.

8.2 Common Clinical Indications

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

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

8.3 Reporting Guidelines (see Chapter 4)

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Chapter 9 Myocardial Wall Motion Studies with Ejection Fraction

9.1 Overview

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

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

9.2 Common Clinical Indications

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

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

9.3 Reporting Guidelines (see Chapter 4)

DRAFT

Chapter 10 Thyroid Uptake and Repeat Uptake

10.1 Overview

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

10.2 Prerequisites

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

(http://snmmi.files.cms-plus.com/docs/Thyroid_Scintigraphy_1382732120053_10.pdf)

10.3 Common Clinical Indications

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

- thyroid function in hyperthyroidism.

10.4 Reporting Guidelines (see Chapter 4)

DRAFT

Chapter 11 Thyroid Scintigraphy

11.1 Overview

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

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

11.2 Prerequisites

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

http://snmmi.files.cms-plus.com/docs/Thyroid_Scintigraphy_1382732120053_10.pdf)

11.3 Common Clinical Indications

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

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

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

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

11.4 Reporting Guidelines (see Chapter 4)

DRAFT

Chapter 12 Parathyroid Scintigraphy

12.1 Overview

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

12.1.1 Radiopharmaceuticals Used

Dual-phase: Tc-99m sestamibi/tetrofosmin

Tc-99m sestamibi/Tc-99m pertechnetate

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

12.2 Prerequisites

- Documented elevated level of serum calcium and parathyroid hormone.

12.3 Common Clinical Indications

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

12.4 Reporting Guidelines (see Chapter 4)

DRAFT

Chapter 13 Hepatobiliary Scintigraphy

13.1 Overview

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

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

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

13.2 Prerequisites

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

13.3 Common Clinical Indications

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

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

13.4 Reporting Guidelines (see Chapter 4)

DRAFT

Chapter 14 Liver and Spleen Scintigraphy

14.1 Overview

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

14.2 Common Clinical Indications

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

- Differentiating hepatic hemangiomas and focal nodular hyperplasia from other liver lesions.
- Identifying functional splenic tissue.

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

14.3 Reporting Guidelines (see Chapter 4)

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Chapter 15 Renal Scintigraphy

15.1 Overview

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

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

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

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

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

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

15.2 Common Clinical Indications

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

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

15.3 Reporting Guidelines (see Chapter 4)

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Chapter 16 Bone Scintigraphy

16.1 Overview

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

16.2 Common Clinical Indications

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

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

16.3 Reporting Guidelines (see Chapter 4)

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Chapter 17 Tumour Scintigraphy

17.1 Overview

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

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

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

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

17.2 Common Clinical Indications

Common clinical indications for performing tumour scintigraphy include:

- Neuroendocrine tumours
- Thyroid malignancies

17.3 Reporting Guidelines (see Chapter 4)

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Chapter 18 Brain Scintigraphy with Single Photon Emission Computed Tomography

18.1 Overview

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

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

18.2 Common Clinical Indications

Common clinical indications for performing this test include:

- Dementia

18.3 Reporting Guidelines (see Chapter 4)

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Chapter 19 Perfusion and Ventilation Scintigraphy

19.1 Overview

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.

19.2 Common Clinical Indications

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

- diagnose suspected pulmonary embolism.

19.3 Reporting Guidelines (see Chapter 4)

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Chapter 20 Scintimammography

20.1 Overview

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

20.2 Common Clinical Indications

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

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

20.3 Reporting Guidelines (see Chapter 4)

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Chapter 21 Solid Gastric Emptying

21.1 Overview

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

The standard meal and standard imaging protocol has established by the Society of Nuclear Medicine and American Neurogastroenterological and Motility Society should be used to ensure validity and reproducibility of the results as reference values have been obtained through a large multicenter trial. Please refer to: http://interactive.snm.org/docs/GES_Consensus_Manuscript_4-23a-2007.pdf

21.1.1 Radiopharmaceuticals Used

Technetium labelled sulfur colloid.

21.2 Common Clinical Indications

Common clinical indications include:

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

21.3 Reporting Guidelines (see Chapter 4)

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Chapter 22 Radiopharmacy Best Practice Standards

22.1 Overview

The preparation of high quality, safe and efficacious Radiopharmaceuticals is critical to providing patient-centered clinical services in nuclear medicine. Facilities preparing Radiopharmaceuticals must follow best practice guidelines based on the relevant scope of Radiopharmaceutical production activities.

NOTE: All records and documentation related to the production, distribution and administration of radiopharmaceuticals must be made available to the assessor upon request.

22.2 Regulatory oversight for Radiopharmaceutical Preparation

- Facilities engaged in Radiopharmacy production must possess a Health Canada Drug Establishment license if there is a direct sale of the final product to an end-user. These facilities will be designated as manufacturing facilities and must comply with Health Canada cGMP (Current Good Manufacturing Practice) Compliance directives
- Facilities engaged in Radiopharmaceutical production for internal-use (no sale of final product) are designated as compounding facilities and must follow best practice standards for the preparation of Compounded Sterile Parenterals (CSPs).

  {http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/docs/pol_0051-eng.php}
- Facilities producing Radiopharmaceuticals for internal/in-house use must adopt Best-practice standards e.g. USP<797>; USP <800>; EU Current Good Radiopharmacy Practice (cGRPP); NAPRA Hazardous Preparation Standards; etc. must be consulted when designing Policies and Procedures relating to Radiopharmacy Practice and will be referenced in this chapter

22.3 Components of a Radiopharmacy Quality Management Program

22.3.1 Policies and Procedure Manual

- Must be designed to clearly describe all Radiopharmacy operations to ensure quality, safety and efficacy of the Radiopharmaceutical drug product.
- Compounding personnel must ensure Radiopharmaceutical CSPs are compounded according to their best professional judgement and training, local procedures, applicable vendor use instructions (e.g. package inserts).
- Standard operating procedures (SOPs) should include the following examples;

  Generator Elution's; Kit reconstitution; Equipment validation and maintenance; sanitation records; PPE; Quality control; Staff Job descriptions and Radiopharmacy responsibilities; Training; Inventory Traceability; etc.

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22.3.2 Personnel Training and Evaluation in Aseptic Manipulation skills

- Personnel who prepare Radiopharmaceutical CSPs must possess the applicable knowledge skills and judgement and be trained by Radiopharmacy subject matter experts (Radiopharmacists; Nuclear Medicine Technologists; Nuclear Medicine Physicians), who employ didactic and practical training on aseptic Radiopharmaceutical manipulations.
- Training must be documented and should include annual refresher training.
- Training should encompass: preparation; release; quality control and analytical techniques; sanitation; calibration of equipment; dose compounding and dispensing; documentation; etc.
- Training records must be retained and made available for inspector review.
- Personnel responsibilities should be outlined in job descriptions approved by senior management.

22.3.3 Facilities

- As per USP <797>, the microbial risk level assigned to Radiopharmaceutical CSPs is **Low-Risk**. Low risk compounding applies to Radiopharmaceutical CSPs that are compounded according to manufacturer's product monograph specifications and meet quality assurance requirements with regards to shelf-life and environmental controls.
- Low-Risk CSPs should be prepared by qualified personnel in an ISO Class 5 laminar-airflow workbench (LAFW).
- Should a LAFW not be available, extra effort must be directed to sanitation and environmental control SOPs to mitigate the risk of microbial contamination.
- This includes (but not limited to): Robust disinfection procedures; retrospective sterility tests; media-fill challenge; aseptic garbing; etc. Hot lab facility must be well secured always.
- All equipment used in the production of Radiopharmaceuticals must have documented installation and operational qualifications prior to use/during clinical use.
- Equipment required for Hot-Lab compounding activities include: LAFW; Dose Calibrator; Single/Multi-channel analyzer (for QC testing); Vial and syringe shields; Engineering controls (e.g. L-block shields; forceps)

22.3.4 Compounding and Dispensing Best Practices

- Standard operating procedures describing all stages of radiopharmaceutical preparation must be implemented and approved by the authority holder.

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- Facilities which do not possess a Health Canada Drug Establishment License must adhere to product monograph and other manufacturer's specifications related to RP production.
- Production records must be available for each compounded product and should contain the following information:
    - Lot Numbers of all products used in the production (e.g. generator, cold kit, saline, etc.), to ensure traceability.
    - Specify preparation parameters (e.g. quantity of activity added to the cold kit; volume of saline added; total kit volume; ID of generator eluate used; quality control results; initials of the compounder.
    - Product records must be reviewed daily and approved by the authorized personnel (e.g.charge technologist, nuclear medicine physician, etc.)

22.3.5 Quality Assurance Program and Quality Control

- Radiopharmaceutical Product quality must be verified prior to patient administration.
- Valid rationale should exist for any deviations from product monograph preparation parameters.
- Should a valid rationale exist for deviation from product monograph specifications, stability testing must be completed to assure product integrity and safety.
- Radiopharmaceuticals are administered for indications according to manufacturer's specifications or there is documentation to validate its efficacy of the off-label use.

Note: In rare instances, radiopharmaceuticals may be used for indications other than specified in product monograph (for example 99mTc MDP is used in lieu of 99mTc DTPA for aerosol lung imaging). In these instances, there is documentation to validate the practice of using alternate radiopharmaceuticals.

Dose calibrators are critical equipment employed for dose verification and should be subject to quality testing as described in the facilities SOPs. These tests must include dose calibrator Linearity; Constancy; Accuracy and Geometry.

- Quality control testing procedures must be documented in approved SOPs. QC tests must adhere to product monograph, other manufacturer specifications or Pharmacopeial standards (e.g. BP, USP, etc.) and includes (but not limited to):
    - Radio Nuclidic Purity testing (e.g. Molybdenum Breakthrough testing)
    - Radiochemical Purity testing (e.g. radio-chromatography)
    - Chemical testing (e.g. Generator Aluminum breakthrough tests)
    - Particle sizing and density for particulate RP's (e.g. Tc-99m MAA)

- Product Inspection and release parameters must be assessed to ensure:
    - The dose label is complete and accurate

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- Total radioactivity listed on the label should not deviate more than +/-10% of the prescribed activity and must be verified using a calibrated dose calibrator
- No visible particulate contamination (e.g. Coring)

22.3.6 Dispensing

- Dispensing of Patient doses should be based on the physician prescription.
- All syringes and applicable containers must contain: preparation name and lot number; quantity of radioactivity dispensed at calibration time; date of dispensing; initials of the dispenser; radioactive trefoil

22.3.7 Documentation and Record Keeping

- All records should be maintained at the radiopharmaceutical dispensing location and must be made accessible to inspectors and must be readily available for review and/or copying by inspectors.
- Written documentation related to Radiopharmacy production activities must be verified, analyzed and signed by the authorizing personnel and must be retained for a period designated by federal/ provincial/ territorial regulations. Good documentation practices involve:
  - Investigating RP production anomalies, non-compliance and deviations from protocols.
  - Identify trends concerning product/ process failure with diligent root-cause analyses and corrective and preventive actions e.g. compiling deviation reports.
- Record Keeping applies to (but not limited to): Inventory receipt and reconciliation records; production and QC records; staff training records; equipment validation and maintenance records; sanitation records; disposal and waste records; associated Radiation safety records (e.g. contamination and exposure monitoring records; etc.); records of adverse events and mis-administrations.
- Radiopharmaceuticals should be prepared according to manufacturer's specifications. If not, documentation must be produced to validate product stability and/or efficacy of the off-label use.
- All relevant radiopharmaceutical information is documented and remains a permanent part of the patient record (e.g. radiopharmaceutical, dose, lot number, route, site, date, time, identity of person administering, and known interstitial injection.)

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References

1) United Sates Pharmacopeia Chapter <797>
2) Health Canada Policy on Manufacturing and Compounding Drug Products in Canada (POL-0051):
http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/docs/pol_0051-eng.php
3) NAPRA: Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations
4) cGRPP-guidelines, version2 March 2007 EANM Radiopharmacy Committee:
http://www.eanm.org/publications/guidelines/gl_radioph_cgrpp.pdf
5) IAEA: Operational Guidance on Hospital Radiopharmacy: A Safe and Effective Approach, 2008:
http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1342/Pub1342_web.pdf
6) CARS: Report of the Canadian Association of Radiopharmaceutcials Scientists (CARS) Task Force on USP<797 Standards in Canada:
http://radiopharmacycanada.com/pdfs/USP797%20CARS%20Final%20Nov%202013%20W%20BIBLIO%20Apr%202016.pdf
7) SNMMI PROCEDURE GUIDELINE FOR RADIOPHARMACEUTICAL USE • Callahan et al.

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Independent Health Facilities: Clinical Practice Parameters and Facility Standards

Nuclear Medicine

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

Chapter 23 FACILITY STANDARDS FOR PET-CT

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

23.1 Staffing a Facility

23.1.1 Interpreting Physician Qualifications

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

a specialist certified in nuclear medicine by the Royal College of Physicians and Surgeons of Canada after 2014, or

approved by the Registration Committee of the College of Physicians and Surgeons of Ontario to practice independently in nuclear medicine services, including PET-CT or

a physician who does not meet either of the above criteria, must contact the CPSO to clarify suitability to include PET-CT as part of their practice in accordance with the CPSO Changing Scope of Practice policy.

23.1.2 Medical Radiation Technologists

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

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

23.2 Facilities, Equipment and Supplies

23.2.1 Equipment Quality Control

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.

23.2.2 Equipment Testing

PET/CT Scanners

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

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Chapter 24 CLINICAL PRACTICE PARAMETERS FOR PET-CT

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

24.1 Cancer Imaging with PET/CT

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

24.1.1 Common Clinical Indications

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

24.2.2 Reporting Guidelines (see Chapter 4)

24.2 Cardiac Imaging with PET/CT

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

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

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.

24.2.1 Common Clinical Indications

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

24.2.2 Reporting Guidelines (see Chapter 4)

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VOLUME 4 TELERADIOLOGY (PACS)

OAR Teleradiology Practice Standard

June 2007

OAR TELERADIOLOGY PRACTICE STANDARD

Definition

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

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

Preface

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

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

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

Role of a Diagnostic Radiologist

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

- Evaluating the clinical information produced by referring physician clinicians
- Deciding which test is appropriate

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- Establishing and assuming responsibility for the imaging protocols, quality parameters and a host of other technical factors that are integral to the creation of the diagnostic image and report
- Being responsible for the technical staff/standards involved in the diagnostic imaging facility
- Optimizing the study and assisting the referring physician colleague
- Evaluating the study and relating it to the clinical findings
- Having knowledge of the practice of referring physicians
- Reviewing previous examinations and their interpretations to compare them with the current study
- Identifying further appropriate management including diagnostic investigations essential to obtain a comprehensive diagnosis and treatment, and reviewing those recommendations with referring physicians
- Reviewing all *clinical data* in a multi-disciplinary environment
- Performing interventional therapeutic and diagnostic procedures
- Assuming responsibility for the appropriate management of the patient during the diagnostic imaging procedure
- Contributing radiological expertise to the management of the diagnostic imaging service to ensure the highest possible quality assurance and quality control
- Being responsible for patient safety by ensuring minimal exposure to radiation dose and other matters that could compromise patient care
- Adhering to all provincial and federal regulations, statutes relating to the delivery of medical services generally and diagnostic imaging services provincially; meeting and exceeding the standard of care in the delivery of diagnostic imaging services in the province; maintaining membership in all of the licensing bodies and fulfilling the requirements of that licensure regime
- Ensuring the selection and use of appropriate and modern equipment, properly trained staff and other elements in the high quality delivery of diagnostic imaging
- Where relevant, teaching radiology residents and fellows according to national training program requirements
- Where relevant, participating in radiology research
- Auditing the delivery of radiology services in the sites where the radiologist works
- Ensuring timely communication of urgent findings
- Maintaining appropriate records/confidentiality as mandated by legislation

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

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

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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.

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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.

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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.

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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.

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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.

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CAR Standards for Teleradiology

As per the *Health Insurance Act*, the reporting nuclear medicine physician must be physically in Ontario at the time of reviewing and reporting.

http://www.car.ca/uploads/standards%20guidelines/Standard_Teleradiology_EN.pdf

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.

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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.

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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

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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

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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

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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 (O 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.

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ACR White Paper on Teleradiology Practice: A Report From the Task Force on Teleradiology Practice

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Teleradiology services are now embedded into the workflow of many radiology practices in the United States, driven largely by an expanding corporate model of services. This has brought opportunities and challenges to both providers and recipients of teleradiology services and has heightened the need to create best-practice guidelines for teleradiology to ensure patient primacy. To this end, the ACR Task Force on Teleradiology Practice has created this white paper to update the prior ACR communication on teleradiology and discuss the current and possible future state of teleradiology in the United States. This white paper proposes comprehensive best-practice guidelines for the practice of teleradiology, with recommendations offered regarding future actions.

Key Words: Quality of care, technology, teleradiology, teleradiologist, teleradiology company, regulatory issues, end-user standards, patient primacy, business standards of practice, disintermediation

J Am Coll Radiol 2013;10:575-585. Copyright © 2013 American College of Radiology

BACKGROUND

Introduction and Definitions

The rapid evolution of the corporate business model and the absence of a public ACR statement on acceptable practices and quality standards for teleradiology companies impelled John A. Patti, MD, chairman of the ACR Board of Chancellors, to establish the ACR Task Force on Teleradiology Practice in January 2012. The outcome of our work is this white paper. Its goals are neither to commend nor to condemn the practice of teleradiology but to comment on the current status of domestic teleradiology, propose guidelines for best practice, and recommend possible actions to the ACR.

In taking on this responsibility, the task force considered any instance in which diagnostic images are transmitted for purposes of interpretation to a location in the United States, beyond the immediate vicinity of where the images were acquired, to represent *domestic teleradiology*. A *teleradiologist* is the physician providing these interpretive services, and a *teleradiology company* is an entity that employs multiple teleradiologists and engages in the management of workflow and image distribution. We refer to the site at which the images are actually acquired as the *transmitting site*. The site at which either a preliminary or a final interpretation is provided is the *receiving site*.

Prior ACR Comments on Teleradiology

Several extant ACR documents address the topic of teleradiology. In 1994, the ACR Council adopted a resolution concluding that state licensing boards should require licensure of out-of-state physicians who provide official, authenticated written radiological interpretations of examinations that are performed on patients in the licensing state but interpreted in another jurisdiction, provided that such law or regulation does not restrict the ability of

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© 2013 American College of Radiology
0091-2182/13/$36.00 • http://dx.doi.org/10.1016/j.jacr.2013.03.018

radiologists to provide second opinion radiological consultations requested by physicians in states in which the consulting radiologist is not licensed. [1]

In 2005, the ACR Task Force on International Teleradiology studied legal, regulatory, reimbursement, insurance, quality assurance, and other issues associated with the practice of international teleradiology, whereby interpretations were generally outsourced and preliminary in nature [2]. The ACR, along with the American Association of Physicists in Medicine and the Society for Imaging Informatics in Medicine, recently adopted and issued an updated 2012 ACR technical standard for the electronic practice of medical imaging [3] that defines the goals and qualifications for the use of digital image data, including the electronic transmission of patient examinations from one location to another for the purposes of interpretation. The forthcoming *ACR IT Reference Guide for the Practicing Radiologist* provides IT and informatics guidance on a wide range of topics across the practice of radiology, many of which are particularly relevant to teleradiologists practicing in a remote setting.

Current State of Teleradiology

After the 2005 ACR publication on international teleradiology, the teleradiology model of outsourced, preliminary after-hours interpretations experienced continued growth, but evidence suggests that market penetration peaked in 2010 at 50% (ie, half of radiology practices in the United States outsourced their call). Recent reports indicate that the preliminary interpretation market is decreasing as a sizable percentage of practices are "taking back the call" they previously outsourced [4].

In contrast to international teleradiology, in which the interpretations are preliminary, domestic teleradiology often provides final interpretations and represents a shift in the business model. Some domestic teleradiology providers offer a full complement of on-site and off-site imaging services, including procedures requiring the physical presence of a radiologist, subspecialty interpretations of images, and general management of the radiology department. This rapid evolution has led to the emergence of large public and private companies that often compete with established community and academic radiology group practices [5]. Some of these teleradiology companies are financially integrated subcontractors of larger health care systems [6]. These companies are under substantial pressure to demonstrate growth and profitability [4].

Given the saturated nature of the outsourced, preliminary teleradiology market and the need for large teleradiology companies to grow, the companies' focus has recently expanded to the acquisition of existing hospital radiology contracts [4]. For example, one company, Radisphere, sponsored a webinar titled "How to Run a Successful RFP Process," which included templates of the documents necessary to initiate the process of displacing a radiology group [7].

Despite the aggressive behavior of some companies, their success is not assured. Virtual Radiologic (vRad), a major national teleradiology firm, recently announced that it would cut the pay of its contracted radiologists [8]. Uncertain market forces have compelled other teleradiology companies to rebrand or retrench [9,10]. One example is the 2010 acquisition of NightHawk Radiology Inc by vRad, which merged the two biggest publicly traded teleradiology companies into one large private equity – controlled group [11].

Positives and Negatives of Teleradiology. Teleradiology has the potential to bring both positives and negatives to patient care. Radiologists have used teleradiology to simplify geographic and overnight coverage challenges as well as to strengthen subspecialty expertise. An important virtue of teleradiology is that many smaller hospitals that struggle to maintain adequate off-hour and subspecialty coverage can rapidly provide high-quality interpretations around the clock. Centralized image distribution hubs allow efficient access to qualified teleradiologists by hospitals and emergency departments needing quality reports for their imaging services. These hubs can also assist small groups to match manpower capacity with volume fluctuations or vacation coverage, obviating the need for more expensive on-site solutions.

Unfortunately, some teleradiology companies focus exclusively on report delivery. Besides devaluing our specialty and undermining the role of the radiologist as an independent expert in diagnostic imaging and a fully engaged member of the consulting team, this practice further commoditizes the product of our efforts [12].

The End Users. The principal end users of teleradiology services include hospitals, radiology groups, referring physicians, and patients. Among the largest of these are hospitals that directly contract with teleradiology service providers, typically providing a combination of on-site and teleradiology coverage. There is also a significant number of contractual relationships between radiology groups and teleradiology service providers whereby the teleradiology companies provide supplemental after-hours coverage or bolster subspecialty coverage that would otherwise be inadequate, intermittent, or nonexistent. Additionally, radiology groups frequently participate in teleradiology off-site coverage arrangements with remote regional hospitals or local imaging centers. Referring physicians, including emergency room physicians, can be considered end users because they base clinical management decisions on teleradiology reports and conduct telephone and video consultations with teleradiology physicians. Additionally, there is a small but growing group of patients seeking direct access to interpreting radiologists or second opinions on their imaging studies [13,14].

The variety of teleradiology end users and their complex interrelationships present a need for guiding princi-

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ples that address most situations and are sufficiently precise and rigorous to ensure that a critical threshold of quality and safety is achieved in all arrangements. To satisfy this need, the task force defined 4 guiding principles that should underlie all teleradiology activities. These principles are consistent with the professional practice standards for any imaging activity. The recommendations that follow in this paper are based on these important principles:

1. Patients are the primary focus. First and foremost, all teleradiology relationships should be patient centered. Therefore, teleradiology relationships should adhere to the Institute of Medicine's [15] call for accessible, safe, accurate, and timely care. Secondary incentives, financial or otherwise, should never supersede patient primacy.
2. On-site coverage is preferred. Radiologists are the recognized experts in medical imaging, and their contribution to the health care team goes beyond simply providing interpretive reports [16]. Teleradiology services, ideally, are supplemental to a comprehensive on-site radiology practice. An intangible benefit of the on-site practice component is that the physician is tied to the community, providing motivation to deliver a higher level of care.
3. There should be a single high professional standard of quality for both teleradiology providers and on-site radiologists. Using different standards based on the location of the radiologist does not support the best patient care. Any model of radiology coverage, including teleradiology, should meet the standards of long-term, on-site coverage.
4. Teleradiology service should be incorporated into the local operations related to safety and quality within the radiology practice, hospital, or imaging center and be assimilated into the usual medical staff credentialing and privileging process.

TASK FORCE RECOMMENDATIONS

The Teleradiologist

A critical component of teleradiology services is the teleradiologist, who must possess and maintain appropriate professional qualifications. These qualifications relate to licensure, medical staff membership and privileges, board certification, and malpractice insurance coverage.

Licensure. States mandate and enforce medical licensure through legislation and regulation by the states' medical boards. To ensure that the full resources of a state are available for the protection of patients, medical practice is considered to occur at the location of the patient [17]. The task force endorses the ACR's 2012 Technical Standard for Electronic Practice of Medical Imaging [3] requirement that radiologists be familiar with the licensure requirements for providing teleradiology services at both the transmitting and receiving sites and obtain licensure as appropriate. Under current law, that would typically involve licensure in the transmitting state, but not necessarily the receiving state.[1,2]

The teleradiologist must maintain all appropriate licensures and should be in good standing with the appropriate state medical board(s), and any pending or closed malpractice cases should be disclosed to all parties, as should previous offenses incurred during the delivery of care. The teleradiologist should not have been excluded from any federal health care program. In any case, regulations should not restrict the ability of radiologists to provide second-opinion consultations when requested in a jurisdiction where the consulting radiologist is not licensed [1].

Medical Staff Membership and Privileges; Malpractice Coverage. The task force recommends that teleradiologists possess medical staff membership and appropriate privileges at all transmitting hospitals and facilities and have professional liability insurance coverage in the transmitting and receiving states.[3]

Board Certification. Teleradiologists should fulfill all requirements for initial training and maintenance of competence set forth in the applicable ACR practice guidelines and technical standards for the examinations they interpret [19].

Continued Quality Improvement. Teleradiologists, like all physicians, should participate in quality improvement initiatives. This includes meeting the requirements for continuing medical education (CME) and continu-

[1] Most states require a full and unrestricted license to practice telemedicine. Many states have adopted formal telemedicine policies, but in the states that have remained silent, it is implied that telemedicine is no different from any practice of medicine requiring licensure [18].

[2] There is no specific language, however, from the Federation of State Medical Boards or the individual state medical boards to support the requirement for licensure in a state other than that in which the patient resides, nor is there a clear legal basis for states to have authority over actions affecting only citizens of another state. The AMA has adopted language supporting full and unrestricted licensure for out-of-state physicians practicing medicine via telemedicine, but it does not require that a teleradiologist who interprets studies that occur in another state maintain a license in the state in which the interpretation is provided (ie, the receiving site) [19]. Furthermore, the ACR Task Force on International Teleradiology limited its recommendation to requiring licensure in the transmitting state [2].

[3] The 2012 ACR Technical Standard for Electronic Practice of Medical Imaging states, "When interpreting images from a hospital, physicians should be credentialed and obtain appropriate privileges at that institution. Physicians providing domestic and international teleradiology services should consult with their professional liability carrier to ensure coverage in both the sending and receiving sites (state or jurisdiction). The malpractice insurance coverage and claims jurisdiction should be determined by those contracting to receive teleradiology services" [3]. Therefore, teleradiologists should have malpractice insurance coverage at the transmitting and receiving sites. The amount of coverage should meet all local requirements for coverage, satisfy contractual obligations with facilities, originate from a rated carrier, and be verifiable upon request.

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ing experience (CE) required for state licensure and accreditation of facilities served by the teleradiologist.

Peer Review. The teleradiology provider should regularly participate in an established quality assurance program, including formal peer review, to ensure patient safety. Such programs should address physician education and error reduction, enable longitudinal follow-up, provide an opportunity for a second opinion when the local caregivers raise concern, and include a process of remediation for low-performing radiologists. A number of well-established approaches exist, notably the ACR's RADPEER™, which assesses the accuracy of diagnosis performed by colleague radiologists using prior studies. CMS, third-party payers, and The Joint Commission have also initiated radiology peer review programs [20].

The Teleradiologist's Work Environment

It is the responsibility of the teleradiology company to ensure the appropriate ergonomic conditions, monitor characteristics, and privacy and security protocols are in place for their teleradiologists.

Ergonomic Factors. With the now universal use of computer workstations to view images and generate imaging reports, the role of ergonomics must be considered. A well-designed work environment reduces fatigue and repetitive stress injuries, such as neck pain and carpal and cubital tunnel syndromes.

The positions of the work chair, workstation table, keyboard, mouse, and monitors, as well as environmental factors such as ambient room lighting, temperature, and noise, should be considered to maximize comfort, efficiency, and accuracy of interpretations. Other applications, such as speech recognition software, electronic medical records, e-mail, and telecommunications, should be appropriately placed and integrated into the workstation. The recommendations of Harisinghani et al [21] and Goyal et al [22] are useful guides in these regards.

Monitor Characteristics. Currently, radiologists almost exclusively view imaging tests on computer monitors. Liquid crystal display monitors are preferable to cathode ray tube monitors, and a two-monitor PACS display setup is considered more functional. A third monitor can display radiology information system and speech recognition applications [23-25].

Viewing stations used by teleradiologists interpreting mammographic images fall under technical requirements set forth by the Mammography Quality Standards Act of 1992 [26], which states that a viewing workstation must follow the same quality control methods and technology as set forth by the medical manufacturer of the imaging modality. Image display calibration, monitor resolution size, and display calibration frequency on any remote diagnostic workstation must conform to the imaging modality manufacturer. To date, most imaging modalities that have applied for FDA [27] approval did so with 5-megapixel monitors.

Privacy and Security. Teleradiology groups are covered entities under the HIPAA privacy and security rules [28], which set standards for the electronic exchange of health information and for training, risk analysis, and security. Teleradiology providers must ensure compliance with the privacy and security rules, recognizing that teleradiology's unique nature may present compliance challenges. All equipment and transmittal interfaces should follow the security requirements mandated by HIPAA, regardless of the reading location or setting. This may be daunting for larger providers, who may have 100 or more interpreting radiologists, many of whom practice in their own homes.

Interpretive Services

The task force considered 3 important principles relevant to image interpretation: (1) the importance of patient primacy; (2) the requirement that all professional services and interpretations be accessible, safe, accurate, and timely; and (3) the condition that the teleradiologist be responsible for the quality of all images interpreted. Interpretive services provided by all radiologists, including teleradiologists, represent a continuum that begins before image acquisition and extends beyond the rendering of the report. Teleradiologists should be engaged at all points in this continuum. Specifically, teleradiologists should be engaged, directly or in a supervisory role, in the following activities before the actual acquisition of the study: selection of the appropriate imaging tests, supervision of the protocoling of studies and patient preparation, decisions regarding the use of intravenous contrast agents, and radiation safety.

After the image is acquired and interpreted, the teleradiologist should be engaged in the communication of results, particularly critical findings. A teleradiology provider should always be available for consultation with referring physicians or on-site radiologists, even if the request comes days after the date of interpretation. Moreover, peer review and quality improvement should continue long after the patient encounter. Importantly, this level of engagement requires trouble-free, reliable communication channels between teleradiologists and end users.

Ghost Reading. The ACR had previously commented on the practice of radiologists' signing reports initially read by teleradiologists without reviewing the images, so-called ghost reading. In response to reports of this practice, the Council addressed its ethical implications:

> It is unethical and likely fraudulent for a physician who has not personally interpreted the images obtained in a radiologic examination to sign a report of that examination in a manner that causes the reader of that report to believe that the signing radiologist was the interpreter. This practice, known as ghost reporting, should be strictly prohibited. [29]

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The task force believes that this definition should be updated to indicate that ghost reading is definitely fraudulent on the basis of the recent conviction of a radiologist on 40 counts of fraud and obstruction of justice related to signing thousands of radiology reports neither he nor another radiologist actually viewed [30].

Relevant Prior Imaging and Reports and Electronic Medical Record Integration. Interpretations should be made with complete availability of relevant collateral information, including previous imaging studies, electronic medical records, and details on the patient's clinical symptoms and suspected diagnoses. This recommendation creates unique challenges for teleradiology companies that provide services to outside organizations. Under these arrangements, teleradiologists may not have adequate access to prior reports, images, or other pertinent patient information. This shortcoming may negatively affect the teleradiologist's ability to determine whether a finding is important. The lack of proper comparisons and relevant information yields less value to the patient and potentially causes the patient to incur the unnecessary costs and anxiety of additional testing. To minimize this problem, all efforts should be made to ensure meaningful comparisons of imaging studies across all settings.

When this shortcoming occurs, radiologists, referring physicians, and patients should be made aware of this potential disparity between on-site and teleradiology interpretations in terms of completeness, quality, and overall value. It may be preferable in these circumstances for the teleradiologist to render a preliminary report only, outlining the limitation, which could be corrected in the final report.

Physician-to-Physician Communication. In general, communication between the interpreting radiologist and the referring provider or their representatives should be readily and bidirectionally available and consistent with the ACR Practice Guideline for Communication of Diagnostic Imaging Findings [31]. Pathways of easy and prompt communication should be well established, agreed upon, and facilitated by both parties. Although various delivery formats are available, including a landline telephone, smart phone, electronic medical record, e-mail, and voicemail, the delivery method should be the choice of the referring provider.

The communication of critical test results, a Joint Commission National Patient Safety Goal, is important to the practice of radiology because failures in this process can lead to patient morbidity and mortality. It is also one of the major contributors to malpractice claims in radiology [32,33]. Different levels of acuity and criticality should be predefined and should include the time frame during which critical test results should be communicated. Some results may require synchronous (usually via telephone) physician-to-physician communication. Given the potential for delays and the importance of the information, teleradiologists should escalate their efforts to communicate when a provider cannot be reached immediately. The parameters for escalation should be predetermined and the process terminated only when the appropriate provider acknowledges receipt of the report.

An important component of critical test result communication is an audit trail. This includes return receipt for all asynchronous communications and detailed documentation of communication in the finalized radiology report. If critical test result management software is used, it must store audit trails that include active acknowledgment of report receipt, as well as time and date.

There should be a defined process for resolving discrepancies between preliminary and final interpretations. The interpreting physician should be available for consultation with the ordering clinician and with local radiologists. A process should be in place to provide additional review upon obtaining additional historical examinations or clinical information, as well as the production of appropriate addenda to the final report. There should be a means to request an overread in a case in which a clinician or local radiologist has questions or concerns regarding the initial interpretation. The discordant interpretations should be incorporated into both the hospital and the teleradiology peer-review process.

Turnaround Times. Rather than setting a precise standard for the allowable time between imaging completion and interpretation communication (ie, turnaround time), the task force believes that turnaround times for teleradiology interpretations should be set in accordance with accepted hospital and departmental requirements. The provider may choose to define specific metrics determined by a multidisciplinary team that could include local radiologists, emergency department physicians, at-large members of the local medical staff, and hospital administration. Turnaround times should be commensurate with other intradepartmental policies and should not be more or less stringent than for on-site radiology except for compelling patient-centered reasons.

Communication Between Radiologists and Radiology Technologists (RTs). The task force emphasizes that all RTs and sonographers must function under the supervision of a qualified licensed physician. Therefore, maintaining communication between the radiologist and RT or sonographer is critical to the teleradiologist's role across the imaging enterprise. Such communications are critical to ensuring overall quality and patient safety by fulfilling 3 critical needs: (1) quality control, (2) transmission of relevant patient information, and (3) addressing RT or sonographer queries regarding study appropriateness.

This presents unique challenges for teleradiologists when traditional nonstructured verbal and paper-based communication mechanisms are not available. The out-

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side teleradiologist will not have met and therefore will not have established a relationship with the RT or sonographer, meaning that a barrier in communication may exist between these individuals. Reliable communication is particularly important for ultrasound technologists, with whom seamless bidirectional feedback may be necessary during the examination itself (ie, while the patient is in the examination room).

Communication by any means must be timely. Failure to implement a responsive communications system for addressing RTs' questions and concerns can lead to a number of adverse events, including failure to diagnose a condition because of an inappropriate examination and unnecessary radiation exposure from an unnecessary study. Failure to have an adequate communications system in place prevents RTs from fully complying with their obligation under principle 6 of the American Registry of Radiologic Technologists' code of ethics, which requires RTs to "obtain pertinent information for the physician to aid in the diagnosis and treatment of the patient" [34].

Payment and Regulatory Considerations

In general, teleradiology services are paid under the same conditions as in-person physician services. However, the nature of teleradiology is such that the professional component (PC) of an examination is performed at a different physical address from where the technical component (TC) is performed. This difference in location affects billing, Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) [35] accreditation, medical directors' duties and supervision, and place of service as it relates to claims filing.

General Billing for Services. Earlier in this paper, the task force emphasized the importance of teleradiologist involvement from the time of ordering to well beyond the generation of the report. A teleradiologist who bills Medicare submits a CMS-1500 form, which certifies that the teleradiologist provided the entire service associated with any specific procedure [36,37].

Accreditation for Offices (MIPPA). MIPPA mandates the accreditation of suppliers of the TC of advanced diagnostic imaging. MIPPA defines advanced diagnostic imaging procedures as MR, CT, and nuclear medicine or PET but excludes x-ray, ultrasound, fluoroscopy, and mammography.

Medical Directors' Duties. MIPPA-accredited facilities must have medical directors whose roles are supervisory and who serve to fulfill a number of regulatory, professional, administrative, educational, and quality initiatives. Medical directorship is required for optimal imaging facility functionality, whether the facility is part of a hospital network, a physician-owned practice, or an independent diagnostic testing facility (IDTF) [38].[4]

If a teleradiologist is to act in the role of medical director for an imaging center or department, he or she must fulfill these roles to ensure that the facility meets its obligations to payers and patients. Ideally, at the outset of the relationship, the medical director should visit the facility to ensure that policies and procedures are established and followed within the department. If this is not possible, a conversation with the managers and review of policies and procedures is acceptable. After the initial visit or phone discussion, the medical director should be readily available to the staff to address any issues that arise. Annual review of the records, policies, and procedures with management is encouraged. If the facility is designated as an IDTF, the medical director must fulfill all CMS requirements, including but not limited to serving as medical director for no more than 3 IDTFs [38].

Place of Service. Teleradiologists, and facilities employing their services, must understand and comply with CMS place-of-service rules as they relate to reporting the correct location for where the teleradiologist's services were performed. There are 3 general issues related to place of service: (1) reporting the correct physical location on the claim forms, (2) submitting the professional or global claims to the correct carrier or insurance company, and (3) filing claims with the appropriate carrier or insurer as this relates to enrolment issues. Adding to this complexity are the differing requirements between Medicare and commercial insurers and the practice of medicine across payment jurisdictions and state lines.

Since April 1, 2004, CMS has required that physicians specify where services were provided when submitting their claims. More recently, on October 11, 2012, CMS issued Transmittal 2613, clarifying certain aspects of the rule but leaving the general requirement intact. Essentially, CMS requires teleradiologists to submit the address where they were physically located when performing their interpretations as the work address, regardless of where the TC was performed. The only exception to this is when "the professional interpretation was furnished at an unusual and infrequent location for example, a hotel, the locality of the professional interpretation is determined based on the Medicare enrolled location where the interpreting physician most commonly practices." In addition to identifying the teleradiologist's work location, CMS requires that claims for the teleradiologist's services be submitted to "the B/MAC [Part B Medicare carrier] which processes claims for the payment

[4] The medical director collaborates with the administrative director of the facility to devise the policies and procedures for the facility and to review them at least annually. They are responsible for ensuring that all professional and technical staff members meet the obligations set by the policies and procedures. The medical director may at times also have disciplinary responsibilities if professional or technical staff members fail to meet these obligations [38].

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locality where the . . . service was furnished" (ie, the Part B Medicare carrier that has jurisdiction over the teleradiologist's work address reported on the claim) [39].

The combination of these 2 rules has significant implications for the billing of teleradiology services to Medicare:

1. It requires teleradiologists to report the physical location where they performed their work, not simply report the address where the TC was performed (unless that is where they performed the interpretation).
2. Each teleradiologist's work location must be separately and appropriately enrolled with the Medicare carrier that has jurisdiction over that geographic area.
3. It will frequently require teleradiologists to enroll with and submit claims to a carrier that is different from the carrier to which the TC was submitted.
4. Global billing is prohibited unless the billing entity is the same for both the PC and TC, and both components are performed within the same Medicare payment locality [39].

Requirements governing the submission of commercial insurance claims vary and are subject to numerous state laws, as well as the terms of the contract between insurer and provider, and are therefore too numerous to address here. However, the ACR believes that, absent state and contractual laws to the contrary, it is best practice to enroll each teleradiologist's work location with the insurer and report the teleradiologist's physical location when performing the interpretation as the service location on the claim form.

Antimarkup. Teleradiology services are frequently provided to IDTFs and physician practices performing services covered by the federal Stark self-referral law under its in-office ancillary services exception [40]. Because of the unique nature of these radiologic services and of teleradiology itself, many of these arrangements involve the reassignment of the PC from the teleradiologist to the facility performing the test, with the facility billing and collecting for the PC and paying the teleradiologist for his or her services at a prenegotiated fee. Through the antimarkup rule, CMS forbids the billing facility from "marking up" the claim for the professional services beyond what the providing physician would otherwise receive.[5,6]

It is incumbent upon both the facility contracting with teleradiologists for the provision of PC services as well as the teleradiologists to understand and comply with the antimarkup limitation as it pertains to such arrangements.

Technology-Specific Considerations

The electronic practice of radiology imposes a variety of technology requirements, regardless of setting. Many of these are outlined in both the ACR Technical Standard for Electronic Practice of Medical Imaging and the forthcoming *ACR IT Reference Guide for the Practicing Radiologist*. Basic infrastructure demands include appropriate and auditable measures to ensure redundancy, reliability, recoverability, privacy, and security. Connectivity demands are particularly important because there must be sufficient and reliable network bandwidth to work efficiently and meet contractual requirements that serve patient interests. Local systems, where applicable, will need to conform to guidance in areas such as monitor display, clinical workflow, and systems integration designed to minimize error.

Systems integration challenges are particularly important, such as those that avoid manually entering patient identifiers. The Institute of Medicine [43] report on redesigning health care emphasizes that safety must be a property of the tools physicians use and must not rely purely upon vigilance to prevent harm. For example, the emerging practice today is to directly integrate between the PACS and the dictation reporting system.

Integration with the ordering process is important so that the report generated will be accessible to the referring physician. Manually associating the report to the order leads to a higher level of patient misidentification errors and can lead to an adverse event through omission [44,45]. Detecting and repairing errors in these processes can take days, during which time fatalities have been reported [46].

[5] In 2008, CMS imposed an antimarkup limitation on the PC of diagnostic tests provided to IDTFs [41]. The antimarkup limitation is triggered when the facility bills and collects for the PC on behalf of the physician providing the PC service and then pays the physician for having performed the service. For services subject to the antimarkup limitation, "the payment from the facility to the physician who provided the PC may not exceed the lowest of the following amounts: [1] The performing supplier's net charge to the physician or other supplier; [2] The billing physician or other supplier's actual charge; or (3) The fee schedule amount for the test that would be allowed if the performing supplier billed directly." In 2009, CMS extended the antimarkup payment limitation on the PC of diagnostic tests to those that are performed under the in-office ancillary services exception of the Stark law [40,42]. This rule applies to the PC of diagnostic tests that are ordered by the billing physician or other supplier if the PC is outright purchased or if the PC is not performed in the office of the billing physician or other supplier.

[6] Although there are exceptions to the antimarkup rule, they are generally reserved for situations involving a direct employer-employee relationship between the physician office performing services under the in-office ancillary service exception and the teleradiologist. (The employment exception does not apply to IDTFs.) Because few teleradiologists are direct employees of transmitting sites, most teleradiologists' compensation arrangements will be subject to the antimarkup rule [40].

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PRACTICAL CONSIDERATIONS FOR RADIOLOGY PRACTICES

Contract Considerations

Because of the large variety of situations in which teleradiology services are used, it is not possible to provide highly prescriptive recommendations for all the various components of the relationship between a teleradiology provider and a hospital or a local radiology group. The following is meant to provide a list of issues that should be considered and addressed during negotiations or within a contract for services. This is not meant as legal advice, nor is it all-inclusive of the issues that should be considered.

- Definitions of examinations and interpretations: There should be a clear statement of what constitutes a study or examination. Interpretations may be preliminary reports, with subsequent final interpretations provided by the contracting local radiologists, who will ultimately bill for the service. Alternatively, the teleradiology provider may issue a final or official interpretation and directly bill the insurer or patient. There may be different performance expectations for reporting time, completeness of the interpretation, and comparison with historical examinations for preliminary versus final interpretations.
- Hours of coverage.
- Minimum and maximum volumes of examinations: Teleradiology companies may seek to negotiate additional fees if minimum volumes are not met.
- Response time: There should be a defined time for most reports to be available. There may be different times for emergency examinations and routine studies or for preliminary reports versus final reports. Care should be taken in defining what starts the clock and what determines the end point. There should be provisions for rapid evaluation and communication of findings in emergent life-threatening situations. Critical results reporting should meet established institutional policies.
- Modalities covered: The specific modalities to be covered should be specified. There may be agreement for different response times and qualifications of the interpreting physician for different modalities, especially for specialized examinations such as coronary CT angiography and CT colonography.
- Subspecialty interpretations: A clear definition of what constitutes a subspecialist should be agreed upon. The specific examinations requiring interpretation by subspecialists should be defined. It is important that all parties have a clear understanding of how examinations are assigned. For examinations that require special attention, there should be a defined process for informing the teleradiology provider and routing the examinations to appropriate interpreting radiologists.
- Credentialing: Processing credentialing applications for a teleradiology provider can be a lengthy and costly process because there are advantages to obtaining privileges for a large number of providers. How many teleradiologists will be granted privileges and who is responsible for any associated fees should be understood.
- Quality assurance: The teleradiology provider should have an established quality assurance program including formal peer review. There should be a defined process for resolving discrepancies between preliminary and final interpretations. The interpreting physician should be available for consultation with the ordering clinician and with local radiologists. A process should be in place to provide additional review upon presenting new historical images or clinical information, as well as for dictating appropriate addenda to the final report. There should be a means to request second opinions in cases in which clinicians or local radiologists have questions or concerns regarding the initial interpretations.
- Malpractice coverage: The teleradiology provider should meet all local requirements for malpractice coverage.
- Accreditation: The teleradiology provider should meet all requirements for the facility's accreditation processes, including ACR accreditation.
- Records: The contract should define who owns records and is responsible for storage and HIPPA compliance.
- IT requirements: Responsibility for network connections, how issues are reported and resolved, and hours of tech support should be defined. Emergency downtime processes should be understood.
- Standard contractual issues: There should be delineation of typical requirements for contracts, such as the term of the contract, termination, warranties and covenants, indemnification, and confidentiality. Many contracts will include clauses for exclusivity on behalf of one or both parties.

COMPETITIVE MARKET FORCES

Members of traditional group practices have expressed concern regarding what they perceive as unfair competition potentially disrupting contractual relationships. Examples of radiology groups recently displaced from longstanding hospital coverage have generated considerable discussion of "predatory" business practices by teleradiology providers and raised the notion that outsourcing to teleradiology firms facilitates such upheaval [5,47,48]. As discussed earlier in this paper, some teleradiology companies are aggressively seeking to replace incumbent radiology groups. The term *disintermediation* refers to the exclusion of the local radiology group when direct contract negotiations occur between hospitals and teleradiology companies [4].

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There is no doubt that the evolution of technology allowing remote image interpretation has lowered the barriers to competition. However, it does not necessarily follow that such competition is "predatory," which in business practice usually refers to pricing below cost to drive out competition. The activities of these companies are more confrontational and less collegial than radiology groups have experienced in the past. No longer are teleradiology companies passively waiting for groups to reach out to them; these companies are aggressively marketing themselves to hospital decision makers, a trend that shows little sign of slowing [4].

If not predatory, do these examples violate some business ethic, or are they simply examples of successful competition? In a recent ACR Chair's Memo, Patti [49] wrote of the ACR's "moral and legal obligation to objectively represent its entire membership" and therefore its "inability to take sides in business conflicts between competing members, even if that competition exceeds the boundaries of what once was a collegial process." However, Patti noted, the ACR can develop and advocate quality and performance guidelines, or best practices. These operational and regulatory guidelines for teleradiology are discussed elsewhere in this document. From the perspective of business practice, the burden of protecting existing contractual relationships between radiology groups and hospitals or imaging centers falls on the contracted radiology group.

First and foremost, radiology groups must understand that they create opportunity for competitors when they fail to satisfy the legitimate demands and expectations of their hospitals. Failure to provide rapid turnaround, subspecialty interpretations, or adequate coverage can force hospitals to consider alternatives. Hospitals may resent the competition of radiologist-owned imaging centers or the lack of flexibility in solving turf battles. Cost may be a reason as well, but it is harder for a hospital to displace a high-quality group that provides top-level service to the medical staff and community over disagreement on price alone [5]. It is important for radiology groups to remain aligned with the hospital system's strategic goals. Even better, radiologists would be well served to involve themselves in the planning process. Understanding the needs of the hospital, maintaining focus on quality and service, and aligning the incentives of the group with those of the hospital are important steps to preserve longevity in hospital relationships.

What precautions should be taken by radiology groups considering contracting with teleradiology providers? A simple step would be to include a noncompete clause in any contract with a teleradiology provider that the teleradiology company and any of its subsidiaries or successors will not seek business directly with the hospital or with any of the radiology group's existing customers. An additional consideration would be a notification clause requiring that the teleradiology provider disclose any communication that occurs directly between the hospital and teleradiology company, regardless of whether that communication was initiated by the provider or the hospital.

Radiology groups should explore the business focus of the teleradiology provider in advance of any consideration of a contract. Does the provider focus on contracts with other radiology groups, or does it also seek direct contracts with hospitals, imaging centers, and other entities? What public information is available about the company on its website or in public documents? What is the mission statement of the company? Have others experienced unreasonable competition or changes in a relationship? Are there references?

What about the radiology group's professional services contract with the hospital? Is there any language in the contract that describes circumstances under which the group can be displaced? Is it required that the current service levels and staffing be maintained or improved should displacement of the group occur? Can a hospital switch radiology providers without cause? Does the group contract include noncompete language for its own members so that the hospital cannot "cherry-pick" individual radiologists directly from the group to cover certain subspecialty areas and then substitute a teleradiology provider for the remainder of the group? The group's contract with the hospital should require the hospital to immediately disclose any communication with a teleradiology company, whether that company directly contracts with the group or not.

What obligations does a teleradiology provider have in this regard? At a minimum, there should be full disclosure of business strategy to potential customers; that is, companies should be willing to share and discuss whether and how they intend to market their services in the same market as any radiology group for which they provide services. Teleradiology providers should honor any noncompete contracts.

RECOMMENDATIONS TO THE ACR

1. The task force acknowledges the benefits teleradiology services can bring to patient care, including improved access to radiologic services and subspecialty expertise in settings in which it otherwise may not be available. Therefore, the ACR should continue to refine the guidelines and standards for teleradiology practice and work to develop protocols and software to better enable the bidirectional communication between physicians, technologists, imaging managers, and the like. Similarly, better protocols for electronic medical record integration, peer review interfaces, and nonmanual communications with dictation systems should be developed.
2. The task force is concerned that the emerging model of full-service teleradiology companies' assuming the professional contracts for facilities may be evolving

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faster than the development of appropriate safeguards and acceptable work processes. Specifically, the evolving nature of teleradiology and the potential shortcomings described in this document could increase the possibility of communication errors, incomplete and nonactionable reports, and harm to patients ranging from increased radiation to major lapses in treatment. The ACR should continue monitoring the practice of teleradiology and work with its providers to ensure the use of teleradiology achieves the same high standards we expect from the more traditional practice model. The ACR should also remain watchful that incumbent radiology providers strive to maintain practices that are at least of the same quality as teleradiology providers.

1. Although the task force understands and appreciates the benefits teleradiology brings to the profession and the communities we serve, we also believe the traditional practice model of having on-site, local radiology groups may better serve the overall interests of most communities. The task force recommends that the ACR educate and inform its members as to how they should be changing to enhance their provision of noninterpretive services that may become critical to maintaining a presence at their respective facilities. This includes training for leadership roles within the hospital system, particularly as such roles relate to broader strategic planning. More important, every radiologist practicing within a group should strive to participate as fully as possible in the best quality patient care. Radiology groups that do not engage in such activities may find themselves more easily replaced by a corporate entity.

ACKNOWLEDGMENTS

We wish to acknowledge the work and effort of the entire Task Force on Teleradiology Practice for the research, insight, and analysis they contributed to this project. Task force members include Robert M. Barr, MD (chair, Business Standards of Practice Workgroup), Paul Berger, MD, Giles W. L. Boland, MD, Michael Bohl, RT (chair, Regulatory Issues Workgroup), Jonathan Breslau, MD, Lawrence A. Liebscher, MD, Woojin Kim, MD, (chair, Technology Workgroup), Paul Nagy, PhD, Samir S. Shah, MD, MMM, Cynthia Sherry, MD (chair, End User and Standards Workgroup) and James Tierney. We also acknowledge the contributions of Brent Savoie, MD, JD. In addition, we are deeply indebted to ACR staff members Tom Hoffman, JD, CAE, Mike Tilkin, and Shavouna Farmerie for their ongoing support, guidance, and diligence. Lastly, we thank the many peripheral consultants to whom we turned for guidance on specific matters within their respective fields of expertise.

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CPSO Telemedicine Policy

http://www.cpso.on.ca/CPSO/media/documents/Policies/Policy-Items/Telemedicine.pdf?ext=.pdf

APPROVED BY COUNCIL: April 2007

REVIEWED AND UPDATED: December 2014

TO BE REVIEWED BY: December 2019

PUBLICATION DATE: Issue 4, 2014

KEY WORDS: Telemedicine; technology; information and communication technologies; standard of care; consultation; referral; privacy; confidentiality; jurisdiction; out-of-province

REFERENCE MATERIALS: Cavoukian, Ann. Encryption by Default and Circles of Trust: Strategies to Secure Personal Information in High-Availability Environments (Toronto: Information and Privacy Commissioner of Ontario, Sunnybrook Health Sciences and CryptoMill Technologies Ltd., 2012).

Cavoukian, Ann, Stuart Shapiro & R. Jason Cronk, Esq. Privacy Engineering: Proactively Embedding Privacy, by Design (Toronto: Information and Privacy Commissioner of Ontario, MITRE Corporation and Enterprivacy Consulting Group, 2014).

Canadian Medical Protective Association. Telemedicine – Challenges and obligations (Ottawa: CMPA, 2013).

COLLEGE CONTACT: Public and Physician Advisory Service

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CPSO TELEMEDICINE POLICY

Introduction

Telemedicine is both the practice of medicine and a way to provide or assist in the provision of patient care at a distance[1] using information and communication technologies[2] (hereinafter "telemedicine").

Telemedicine is in a constant state of evolution; advancements in technology provide opportunities for new approaches to the delivery of care. The CPSO recognizes the value of telemedicine and, in particular, the way in which it can benefit patients, physicians and other health-care providers, and the broader health-care system by improving access to care, and increasing efficiencies in the delivery of care.

Whether telemedicine is an appropriate way to provide or assist in the provision of patient care will depend on the circumstances of each case. This policy sets out the CPSO's expectations of physicians who practise telemedicine.

Principles

The key values of professionalism articulated in the CPSO's Practice Guide – compassion, service, altruism and trustworthiness – form the basis for the expectations set out in this policy. Physicians embody these values and uphold the reputation of the profession when practising telemedicine by:

1. Always acting in the patient's best interest;
2. Demonstrating professional competence, which includes meeting the standard of care and acting in accordance with all relevant and applicable legal and professional obligations to provide the highest possible quality of care;
3. Maintaining patients' privacy and confidentiality when collecting, using or disclosing personal health information;
4. Communicating and collaborating effectively with patients, physicians and other health-care providers;
5. Recognizing and appropriately managing conflicts of interest, and avoiding situations where there may be a perceived conflict of interest; and
6. Participating in the self-regulation of the medical profession by acting in accordance with the expectations set out in this policy.

Purpose & Scope

This policy sets out the CPSO's expectations of physicians who practise telemedicine.

This policy applies to all physicians who are members of the CPSO, regardless of where the physician or patient is physically located when telemedicine is practised. Expectations are

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provided in relation to providing or assisting in the provision of patient care via telemedicine, which includes consulting with and referring patients to other health-care providers, and practising telemedicine across borders. This policy applies broadly to the practice of telemedicine, regardless of the specific area of practice or practice setting in which telemedicine is used.

In addition, this policy sets out the CPSO's expectations of physicians who are not members of the CPSO, but who practise telemedicine by providing or assisting in the provision of care to patients who are physically located in Ontario at the time of care. These expectations are set out in the last section of the policy, titled 'Expectations for Non-CPSO Members'.

Policy

Physicians must act in accordance with the expectations set out in this policy in all instances when telemedicine is practised.

1. General Expectations for Telemedicine

The practice of telemedicine is the practice of medicine; physicians' existing legal and professional obligations with respect to practising the profession are not altered simply because care is provided via telemedicine as opposed to in-person. Accordingly, physicians are reminded that a physician-patient relationship is established via telemedicine in the same circumstances as when the relationship is established in-person.[3]

Physicians must use their professional judgment to determine whether telemedicine is appropriate in a particular circumstance each and every time its use is contemplated for patient care, consultations and referrals.[4] In doing so, physicians must consider whether practising telemedicine will enable physicians to satisfy all relevant and applicable legal[5] and professional[6] obligations, and meet the standard of care.

Physicians must:

- Consider the patient's existing health status, specific health-care needs and specific circumstances, and only use telemedicine if the risks do not outweigh the potential benefits and it is in the patient's best interest.
- Identify what resources (e.g., information and communication technology, equipment, support staff, etc.) are required, and only proceed if those resources are available and can be used effectively.
- Ensure the reliability, quality[7] and timeliness of the patient information obtained via telemedicine is sufficient, and the patient is accurately identified.
- Protect the privacy and confidentiality of the patient's personal health information. More specifically,
    - Evaluate whether the information and communication technology and physical setting being used by the physician has reasonable security protocols[8,9,10] in place to ensure compliance with physicians' legal[11] and

professional[12] obligations to protect the privacy and confidentiality of the patient's personal health information.
    - Take reasonable steps to confirm the information and communication technology and physical setting being used by the patient permits the sharing of the patient's personal health information in a private and secure manner.
- Ensure the physical setting in which the care is being delivered is appropriate and safe; there must be a plan in place to manage adverse events and/or emergencies.

2. Specific Expectations for Practising Telemedicine Across Borders

In addition to the general expectations for telemedicine set out above, there are a number of specific expectations regarding the practice of telemedicine across provincial, territorial and international borders. These expectations are grounded in the CPSO's duty to serve and protect the public interest,[13] which includes ensuring physicians provide quality care to patients regardless of where physicians and patients are physically located.

a) Expectations for CPSO Members

Physicians are reminded that the CPSO maintains jurisdiction over its members[14] regardless of where (i.e., physical location) or how (i.e., in-person or via telemedicine) they practise medicine. In keeping with its statutory obligations as a medical regulatory authority, the CPSO will investigate any complaints made about a member,[15] regardless of whether the member or patient is physically located in Ontario.

When providing or assisting in the provision of patient care in another province, territory or country via telemedicine, physicians must comply with the licensing requirements of that jurisdiction. The medical regulatory authority of the jurisdiction where the physician and/or patient are physically located when telemedicine is practised may require that physicians hold an appropriate medical licence in that jurisdiction.

Out-of-province consultations and referrals

There may be circumstances when physicians consult with out-of-province physicians regarding their patients[16] or refer patients to out-of-province physicians for care via telemedicine.

Before consulting with or referring patients to out-of-province physicians for care via telemedicine, physicians must take reasonable steps to assure themselves that the consultation or referral is appropriate, just as they would when consulting with or referring patients to physicians who are physically located in Ontario. Physicians must have reasonable grounds to believe that the out-of-province physician with whom they are consulting or to whom they are referring patients for care via telemedicine is appropriately licensed.

When physicians consult with or refer patients to out-of-province physicians for care via telemedicine, they must inform their patients that the out-of-province physician is not physically located in Ontario, and may or may not be licensed in Ontario. It is recommended that physicians alert patients to the 'patient information sheet' appended to this policy, and communicate the relevant content contained in that document, as appropriate.

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b) Expectations for Non-CPSO Members

The CPSO recognizes that Ontario patients may seek care via telemedicine from non-CPSO members who are physically located outside of Ontario, independent of any involvement of a CPSO member. The CPSO expects that non-CPSO members will comply with licensing requirements in their jurisdiction, and will provide care in accordance with the standard of care.

If the CPSO becomes aware of concerns about care provided to an Ontario patient via telemedicine by a non-CPSO member, the CPSO may share that information with the regulatory authority that has jurisdiction over the member, so that appropriate action can be taken by that regulatory authority.

Endnotes

[1.] Patients, patient information and/or physicians may be separated by space (e.g., not in same physical location) and/or time (e.g., not in real-time).

[2.] The specific technology that can be used is constantly evolving. Some current examples include, but are not limited to, the use of telephones (e.g., land lines and mobile phones), email, video and audio conferencing, remote monitoring and telerobotics.

[3.] The existence of a physician-patient relationship will be established having regard to the nature and frequency of the treatment provided, whether there is a medical record, whether the physician bills for the services provided, and any other relevant factors.

[4.] Physicians must make this determination when using telemedicine for the first time for a particular patient and each subsequent time its use is contemplated to ensure using telemedicine is still appropriate for that patient.

[5.] Including, for example, legal obligations with respect to privacy and confidentiality as set out in the *Personal Health Information Protection Act, 2004*, S.O. 2004, c. 3, Schedule A (hereinafter *PHIPA*), and mandatory liability coverage as set out in Section 50.02 of the *General By-Law*, enacted under Section 94(1) of the *Health Professions Procedural Code*, Schedule 2 of the *Regulated Health Professions Act, 1991*, S.O. 1001, c.18 (hereinafter *HPPC*).

[6.] Professional expectations set out in the CPSO's Practice Guide and policies.

[7.] For example, diagnostic images must be of sufficient quality.

[8.] The security standards for information and communication technology are constantly evolving, so physicians may want to contact the Office of the Information and Privacy Commissioner of Ontario and/or the Canadian Medical Protective Association for the most up-to-date advice. Physicians can also refer to the following resources: Ann Cavoukian, Stuart Shapiro & R. Jason Cronk, Esq., *Privacy Engineering: Proactively Embedding Privacy, by Design* (Toronto: Information and Privacy Commissioner of Ontario, MITRE Corporation and

Enterprivacy Consulting Group, 2014); Ann Cavoukian, *Encryption by Default and Circles of Trust: Strategies to Secure Personal Information in High-Availability Environments* (Toronto: Information and Privacy Commissioner of Ontario, Sunnybrook Health Sciences and CryptoMill Technologies Ltd., 2012); Canadian Medical Protective Association, *Telemedicine – Challenges and obligations* (Ottawa: CMPA, 2013).

[9.] One of the ways to ensure that the technology being used has reasonable security protocols in place is to carry out telemedicine sessions within a facility accredited by the Ontario Telemedicine Network.

[10.] Physicians may consult with an information and communication technology and/or privacy expert if they are unsure as to whether the technology and/or physical setting is secure.

[11.] *PHIPA*. See footnote 5 in this policy for more information.

[12.] As set out in the CPSO's Practice Guide and Confidentiality of Personal Health Information policy.

[13.] Section 3(2) of the *HPPC*.

[14.] Sections 13 and 14 of the *HPPC*.

[15.] Section 25(1) and (4) of the *HPPC*.

[16.] For example, by sending patient information (e.g., patients' diagnostic images or tests) to out-of-province physicians for an opinion.

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Independent Health Facilities: Clinical Practice Parameters and Facility Standards

Nuclear Medicine

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APPENDICES

Appendix I Independent Health Facilities Act - Ontario Regulation 57/92

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 licencee 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.

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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

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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.

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(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".

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(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 loose-leaf 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 to 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.

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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.

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Appendix II Sample Referring Physician Satisfaction Survey

Physician Initials (optional): _____

DATE: _____

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

REFERRING PHYSICIAN SATISFACTION SURVEY

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

Facility Name	Street Address	City / Town	Private Tel #

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

DO YOU REQUIRE MORE REQUISITION PADS Y ☐ N ☐ PDF REQ? ☐

Which EMR do you work with: _____

Please provide your Email address: _____

Physician emergency contact number - *after hours/weekend use only*: _____

Appendix III Sample Patient Satisfaction Survey

Gender: O Male O Female

Age: O Less than 18 O19 – 45
O 46 – 65 O 66 – 75
O 76 and over

This questionnaire is being completed by:

O Self(patient) O Caregiver/parent

Clinic: _____ Date of Visit _____

EMAIL ADDRESS: _____

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

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

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

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

COMMENTS:

_____
_____
_____
_____
_____