CPSO

# INDEPENDENT HEALTH FACILITIES

## Clinical Practice Parameters and Facility Standards

## Diagnostic Imaging – July 2018

*Revised: September 2020*

## College of Physicians and Surgeons of Ontario Mandate

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

### What we do:

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

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

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

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

## Our Mission

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

## Our Regulatory Principles

We commit to being accountable, respectful and responsive.

We will demonstrate professionalism and excellence.

We will value communication and compassion.

# Independent Health Facilities

## Clinical Practice Parameters and Facility Standards

*Diagnostic Imaging – July 2018*

*Revised: September 2020*

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# Preface

The Independent Health Facilities Act (IHFA), proclaimed in April 1990, amended in 1996 and 1998, gives the College of Physicians and Surgeons of Ontario (CPSO) the primary responsibility for carrying out quality assessments in Independent Health Facilities. These non-hospital facilities may provide some of the following insured services:

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

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

## Purpose of Clinical Practice Parameters

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.

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

## Role of the College of Physicians and Surgeons

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

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

## Radiology Guiding Principles

Extracted from the first edition (February 1995) of Clinical Practice Parameters and Facility Standards for Diagnostic Imaging, Appendix I: Goals and Objectives.

A diagnostic imaging practice is a consultative physician service rendered by qualified specialists who have completed an accredited residency program in diagnostic radiology which includes using all modalities in the imaging portrayal of human morphology and physiological principles in medical diagnosis.

The elements of a radiologic consultation include:

- pre-examination evaluation by a referring physician;
- a request for radiologic consultation. The request includes pertinent clinical findings, a working diagnosis, and signature of referring physician or other qualified health professional;
- a safe patient environment in which the radiologist supervises qualified staff whose efforts are directed at producing a radiologic examination yielding maximum diagnostic information and consistent with the least possible exposure to radiation.

Diagnostic imaging is a patient care specialty and it is an important function of the radiologist to advise referring physicians about the best sequence of examinations for resolving a clinical problem expeditiously and with the least risk and cost.

It is not possible to establish a “minimum” or “optimum” standard of care. Guiding principles and attributes for appropriate care in diagnostic imaging can be summarized as follows.

- Examinations and procedures are performed with the greatest benefit and least risk to the patient.

- Examinations and procedures are interpreted with the highest degree of competence using all available information including comparison with previous examinations and procedures.
- Examination/procedure findings and conclusions are communicated promptly and expeditiously to the referring physician.
- Referring physicians are consulted in order to select and perform only the most useful examinations/procedures.
- Flow of data including storage, retrieval, and general handling of images and reports are managed efficiently.
- Patient services provided are considerate of the human side of care as well as the purely technical component of care.
- Patient services are managed so that productivity is maintained and optimal use of available resources is assured.

These principles should constitute the basis for the evaluation of desirable and undesirable practice patterns.

# Independent Health Facilities: Clinical Practice Parameters and Facility Standards

## *Diagnostic Imaging*

## VOLUME 1 FACILITY STANDARDS

# Chapter 1 Staffing a Facility

## 1.1 Overview

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

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

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

## 1.2 Qualifications of Physicians Providing Diagnostic Services

Physicians must have a current, valid, and active certificate of registration with The College of Physicians and Surgeons of Ontario.

Diagnostic imaging services are provided by physician(s):

- certified by the Royal College of Physicians of Canada (FRCPC) in Diagnostic Radiology

**or**

- certified by the Royal College of Physicians and Surgeons of Canada (FRCSC & FRCPC) to conduct ultrasound services within the scope of their practice and demonstrates knowledge, skills and judgement to perform these studies. They have active hospital privileges with an equivalent scope of practice and have documentation of their training that meets the standards set out by the Royal College of Physicians and Surgeons in Diagnostic Radiology.

**or**

- approved by the Registration Committee of the College of Physicians and Surgeons of Ontario to practice independently in Diagnostic Radiology (Refer to the CPSO Specialist Recognition Criteria in Ontario policy for more information).

### *1.2.1 Duties and Responsibilities of Physicians Providing Diagnostic Services*

Physicians providing diagnostic imaging services are responsible for:

- maintaining a level of competence for the range of services being offered. This is accomplished by attending courses or conferences, reviewing current literature, etc.
- contacting the Quality Advisor for advice regarding quality of care matters.
- managing any complications or problems that arise clinically and informing the Quality Advisor as needed.

## 1.3 Radiologists Involved in Interpreting Nuclear Medicine Examinations

Radiologists certified by the Royal College of Physicians and Surgeons of Canada (FRCPC) who wish to report nuclear medicine examinations in an IHF setting must apply to the College of Physicians and Surgeons of Ontario for a change to their scope of practice and specifically comply with the requirements in the Changing Scope framework: Radiologists Intending to Interpret and Supervise Nuclear Medicine Studies in Independent Health Facilities.

## 1.4 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 must be:

- certified by the Royal College of Physicians of Canada (FRCPC) in Diagnostic Radiology

**or**

- approved by the Registration Committee of the College of Physicians and Surgeons of Ontario to practice independently in Diagnostic Radiology (Refer to the CPSO Specialist Recognition Criteria in Ontario policy for more information).

**or**

- for facilities that perform only ultrasound, certified by the Royal College of Physicians and Surgeons of Canada (FRCSC & FRCPC) to conduct ultrasound services within the scope of their practice and demonstrates knowledge, skills and competency to perform these studies. They have active hospital privileges with an equivalent scope of practice and have documentation of their training that meets the standards set out by the Royal College of Physicians and Surgeons in Diagnostic Imaging.

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

***NOTE: In instances where a facility provides more than one type of service and the Quality Advisor does not possess the appropriate specialty background associated with a particular service, then he or she must appoint a Medical Lead for each additional service (refer to 1.5).***

### *1.4.1 Role of the Quality Advisor*

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

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

### *1.4.2 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 infection prevention and control; review of cases; policies and procedures; quality control matters on equipment; incidents, medical and technical issues.
- Shall ensure all QA Committee meetings are documented.
- Obtain copies of assessment reports from the licensee/owner/operator. If deficiencies were identified in the assessment, the Quality Advisor shall review same with the QA Committee and document such review. The Quality Advisor's signature is required on any written plan submitted by the licensee to the College.

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

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

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

- **Health professional staff hiring decisions,** in order to ensure that potential candidates have the appropriate knowledge, skill and competency required to provide the types of services provided in the facility.

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

#### 1.4.2.1 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.

#### 1.4.2.2 Quality Advisor Duty for Infection Prevention and Control

In order to determine appropriate infection prevention and control training of staff, the Quality Advisor must annually complete the Checklist for Infection Prevention and Control (IPAC) Core Elements in Clinical Office Practice, and, if applicable, also complete annually the Checklist for Reprocessing of Medical Equipment/Devices in Clinical Office Practice and must verify completion of relevant training by all staff. Evidence of completion of the Checklists must be maintained on file at the facility.

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

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

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

## 1.6 Facility Lead for IHFs that Perform Mammography

If an IHF provides mammography services, it is preferred that the Quality Advisor (QA) assume the role of the Facility Lead. The Facility Lead at an IHF must:

- Have the qualifications of a physician providing diagnostic services (see "Qualifications of Physicians Providing Diagnostic Services" specified earlier in this Chapter) and,
- Report mammography services at a facility*

If the QA does not meet the criteria of a Facility Lead, then the QA is responsible (in coordination with the Regional Lead as needed) for appointing a Facility Lead who meets these qualifications, documenting this in the IHF, and informing the CPSO and the Quality Management Partnership of this change.

***In situations where there is a multi-site facility, each site does not need a separate Facility Lead. However, the Facility Lead must be reading mammography in at least one of the sites.***

### *1.6.1 Duties and Responsibilities of a Facility Lead for Mammography Quality Management Program (QMP)*

The Facility Lead has the following duties and responsibilities:

1. Receive Quality Management Partnership information and act as a liaison between IHF staff and the Partnership including:
    - Communicating with facility staff about tools, guidelines or other initiatives related to the mammography QMP and documenting any feedback
    - Providing Facility Lead and QA names (if not the same person), addresses, email addresses and telephone numbers to the Partnership
    - Participating in Partnership surveys

2. Tracking that the IHF has received facility and provider level mammography QMP reports from the Partnership (Cancer Care Ontario) by:
    - Reviewing and documenting Partnership reports with all appropriate staff
    - Identifying and documenting issues and opportunities for quality improvement (QI)
    - Facilitating and documenting a QI plan to address opportunities for improvement with applicable IHF physicians and all IHF staff (e.g. MRTs, and other staff involved in mammography services) related to the QMP reports
    - Documenting the implementation of the QI plan with all applicable IHF physicians and IHF staff

***Note: Guidance to above: The Facility Lead (if different from the Quality Advisor) is accountable to the Quality Advisor and must participate in and document regular communication with the Quality Advisor regarding quality management report findings and improvement activities.***

3. The Facility Lead (if different from the Quality Advisor) must act on and report to the QA and Regional Lead any persistent and/or serious deviations where provider level quality indicators and facility level quality standards reflected in QMP reports are not being met.
4. The Facility Lead (if different from the Quality Advisor) must communicate with the QA, to identify and document patient safety concerns and any persistent and/or serious deviations in the provider level indicators and facility level quality standards, in accordance with Partnership processes.
5. The Quality Advisor in coordination with the Facility Lead (if not the same person) and the Regional Lead must make any decisions about referring patient and/or facility safety concerns to the CPSO in a timely way and document all decisions made in accordance with Partnership processes.

***NOTE: IHFs providing mammography services are required to participate in the Ontario Breast Screening Program (OBSP). For further information on how to join the OBSP, please contact your Regional Cancer Program.***

## 1.7 Radiation Protection Officer

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

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

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

- ensuring that every person who operates an x-ray machine in the facility is qualified to operate the machine;
- establishing and maintaining procedures and tests for the x-ray machine (s) and x-ray equipment to ensure compliance with the Regulation;

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

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

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

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

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

4. Occupational Dose Limits

a. Adults

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

b. Dose limits for individual members of the public

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

5. General X-ray Safety Policies

Policies and procedures are required for protection of staff, as well as patients and other visitors/persons, including monitoring of X-ray utilization.

6. Registration of Radiation Machine Facilities

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

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

7. Equipment Surveys

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

8. X-ray Room Shielding

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

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

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

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

9. X-ray Equipment Servicing and Services

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

10. Records

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

11. Quality Assurance Program

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

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

12. Research Involving Radiation

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

## 1.8 Medical Radiation Technologists

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

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

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

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

medicine (MRT(N)) also may perform BMD, CT, and other services or procedures for which they have the necessary knowledge, skills and judgement to perform the procedures safely and effectively.

***Fluoroscopy***

It is the responsibility of the radiologist to ensure that all fluoroscopic procedures (including but not limited to barium enemas, small bowel follow-through, upper GIs, and barium swallows) are performed correctly and without complication. The radiologist must be available on site during the procedures. The interpretation must be done by the radiologist.

### *1.8.1 Duties and Responsibilities of MRTs*

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

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

1. Adhere to all relevant provincial and federal legislation and guidelines governing the practice of the profession, including the following:
   - CMRITO Standards of Practice
   - CMRITO Code of Ethics
   - CMRITO By-laws
   - CMRITO's sexual abuse prevention program
   - *Personal Health Information Protection Act*
   - *Health Care Consent Act*
   - Canadian Nuclear Safety Commission regulatory documents

2. Adhere to the facility policies, procedure and protocols including:
   - Quality Control assessments
   - Cleaning of all equipment including ancillary equipment (e.g. patient tables, imaging machines lead protective equipment, computer keyboards,)
   - Maintain full records of incidents, unusual occurrences, reactions
   - Record and report any equipment faults or problems to the appropriate personnel
   - Use appropriate aseptic techniques and infection prevention and control practices in the course of the diagnostic or therapeutic procedure as per PIDAC/IPAC best practices (refer to 3.3.8 Infection Prevention and Control policies and procedures)

**Patient Examination:**

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

- Confirm that the order is appropriate based on the patient history
- Inquire about and record any contraindications (e.g. pregnancy/ anaphylaxis) before starting the exam, as well as obtain and record the direction of the physician/authorized health professional to proceed, modify, or halt the exam as per facility policy
- Ensure that the worklist contains the correct patient information (if applicable)
- Obtain informed consent (oral or written as per facility policy) before each examination (after explaining the procedure and answering any questions)
- Ensure pertinent clinical history is available and supplement as necessary
- 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
- Follow the facility examination protocols
- Follow facility protocols when unexpected findings are found that would require immediate attention (e.g. pneumothorax)

**Throughout the Examination:**

- Assess the patient's condition before, during and after the procedure or course of treatment and make modifications to procedures based on the patient's physical, medical and/or emotional status and needs
- Maintain patient comfort, privacy and dignity at all times
- Stop procedure if at any time the patient withdraws consent and record withdrawal of consent and reason as per site protocol
- Use radiation protection devices and other patient protection devices, as required, and record
- Use personal protection equipment (masks/gloves etc.) and devices (lead shields) as required for the procedure and as indicated by personal risk assessment
- Make sure physical markers are present in the x-ray field but not within the anatomy of interest (electronic markers are considered a last resort only)
- Ensure appropriate collimation is used. This can be verified by viewing the raw image
- Ensure that the orientation of the body and other pertinent parameters are marked correctly on the image and data
- Ensure the processed image provides diagnostic image quality while using minimal radiation (ALARA – As Low As Reasonably Achievable). Take corrective action if necessary and record explanation of sub-optimal imaging
- Exposure factors must be taken from technique charts (either manually posted in the control booth or electronically programmed into the anatomical programming of the generator control). Pediatric technique charts are available by weight for infant, toddler and child.
- Ensure the door to the examination room is self-closing and therefore closed during radiation exposures
- Ensure film and or CR cassettes are stored appropriately and not left in the examination room

- Ensure correct anatomy is displayed on image for accuracy of positioning
- Ensure that patient examination images and data contains patient name, ID number, date of examination and type of examination
- Ensure that each patient record has the MRT identifier to verify who performed the examination
- Comply with privacy and confidentiality legislation such as the Personal Health Information Protection Act (Ontario).

## 1.9 Diagnostic Medical Sonographers

In Ontario, Diagnostic Medical Sonographers (DMSs) are self-regulated registered professionals with the College of Medical Radiation and Imaging Technologists of Ontario (CMRITO). The scope of practice of diagnostic medical sonography, as defined under the *MRT Act*, is the use of soundwaves for diagnostic ultrasound for the purpose of diagnostic procedures, the evaluation of images and data relating to the procedures and the assessment of an individual before, during and after the procedures.

DMSs must have a current, valid, and active certificate of registration with the CMRITO and should only perform the services and procedures for which they have the necessary knowledge, skills and judgement.

### *1.9.1 Duties and Responsibilities of DMSs*

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

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

1. Adhere to all relevant provincial and federal legislation and guidelines governing the practice of the profession, including:
    - CMRITO Standards of Practice
    - CMRITO Code of Ethics
    - CMRITO By-laws
    - CMRITO's sexual abuse prevention program
    - *Personal Health Information Protection Act*
    - *Health Care Consent Act*

2. Adhere to practice standards as described by
    - Sonography Canada: most up-to-date National Competency Profile for entry to practice Sonographers
    - American Institute of Ultrasound in Medicine (AIUM) and Canadian Association of Radiology (CAR) standards

3. Adhere to the facility policies, procedure and protocols including:
    - Quality Control assessments
    - Cleaning of all equipment including ancillary equipment (e.g. ultrasound machines, transducers and transducer cords, computer keyboards)

- Maintain full records of incidents, unusual occurrences, reactions
- Record and report any equipment faults or problems to the appropriate personnel
- Use appropriate aseptic techniques and infection control procedures in the course of the diagnostic or therapeutic procedure as per PIDAC/IPAC guidelines

**Patient Examination:**

- Ensure appropriate delegations (when required), and appropriate knowledge, skills and judgement are in place for all examinations
- Follow facility policy regarding situations where the use of chaperones may be appropriate
- Post appropriate signage to restrict access to the patient exam room
- Ensure the room is prepared for the procedure specified in the order
- Select and set up the equipment and materials needed for the procedure specified in the order
- Ensure correct patient identification (e.g. confirmation of patient name, date of birth, examination to be performed, and physician/authorized health professional authorization is present)
- Confirm that the order is appropriate based on the patient's clinical history
- Inquire about and record any contraindications (e.g. anaphylaxis) before starting the exam, as well as obtain and record the direction of the physician/authorized health professional to proceed, modify, or halt the exam as per facility policy
- Ensure that the worklist contains the correct patient information (if applicable)
- Obtain informed consent (oral or written as per facility policy) before each examination (after explaining the procedure and answering any questions)
- Ensure pertinent clinical history is available, supplement as necessary and record on the technical impression worksheet
- 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 DMS may touch them and why (e.g. during reactive maneuvers, such as augmentation of the patient's calf during a lower extremity venous Doppler ultrasound to rule out DVT)
- Follow the facility examination protocols
- Write a technical impression as per site protocol
- Follow facility protocols when unexpected findings are found that would require immediate attention (e.g. appendicitis, ectopic pregnancy)
- Allergies to latex must be identified and non-latex transducer covers must be utilized - this information must be recorded on the sonographers' technical impression worksheet

**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
- Maintain patient comfort, privacy and dignity at all times

- Stop procedure if at any time the patient withdraws consent and record withdrawal of consent and reason as per site protocol
- Use personal protection equipment (masks/gloves etc.) and devices as required for the procedure and as indicated by personal risk assessment
- Ensure that patient examination images and data contains patient name, ID number, date of examination and type of examination and number of images
- Ensure correct annotation on all images as per site protocol
- Ensure the processed image provides diagnostic image quality while minimizing patient exposure to soundwaves (ALARA – As Low As Reasonably Achievable). Take corrective action if necessary and record explanation of sub-optimal imaging
- Ensure that each patient record (including the technical impression worksheet) has the DMS identifier to verify who performed the examination
- Comply with privacy and confidentiality legislation such as the *Personal Health Information Protection Act* (Ontario).

**Transvaginal/Endocavity Ultrasounds: include the criteria above plus**

- Transvaginal/endocavity transducer ID number (individual to each transducer) must be identified on the technical impression worksheet and on the reprocessing sheet
- Upon exam completion follow Provincial Infectious Diseases Advisory Committee (PIDAC) or manufacturers guidelines for transducer cleaning.

# 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 diagnostic imaging services.

### *2.1.1 Mobile Services*

- Mobile services are provided by facilities that use mobile equipment to deliver services (x-ray and ultrasound) to approved sites (as per Schedule A of their Licence) to enhance patient accessibility to services when they are unable to attend a fixed site.
- Mobile equipment is defined as portable equipment affixed with wheels for mobile application and is moved between incidents of use. Mobile equipment must not be used at fixed location sites.
- A facility providing mobile services must obtain prior approval from the Director, IHF program, Ministry of Health under the *Independent Health Facilities Act*.
- The facility must have sufficient equipment and supplies available for the number of procedures scheduled for the duration of each site visit.

## 2.2 Facilities, Equipment and Supplies

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

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

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

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

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

The thermoluminescent dosimeter (TLD) monitoring service of the Personnel Dosimetry Services of Health Canada, Bureau of Radiation and Medical Devices, is used and documented to ensure the safety of personnel. Records are available in the facility for staff information.

***Note: According to the Ontario Ministry of Labour, Medical Radiation Technologists that perform mammography exclusively are not required to wear TLD badges due to the relatively low penetrating voltage and resultant scatter emitted by the patient and the engineered requirement of needing to be behind the leaded glass/plexiglass shield in order to operate the x-ray machine. While no longer a requirement, MRTs should be strongly encouraged to continue to wear their TLD badges for their own personal safety.***

### *2.2.1 Infection Prevention and Control*

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

### *2.2.2 Endocavity Transducer Reprocessing (See Chapter 3)*

### *2.2.3 Eye Wash Stations*

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

## 2.3 Equipment Quality Control

### *2.3.1 Radiography*

General:

All radiation emitting equipment undergoes HARP compliance evaluations at six-month intervals. Written records of preventive maintenance, equipment calibration, and quality control evaluations are maintained for six (6) years. Any issues found on any of these evaluations must be followed-up on in a timely manner and include documentation that they have been resolved.

***Note: Even if equipment passes a HARP evaluation, it is incumbent upon the facility to ensure that equipment produces diagnostic quality images. HARP evaluations do not assess for image quality.***

Appropriate lead protective equipment (whole body, gonadal shielding, and thyroid shielding at least 0.5 mm) is available in each radiation examination room. The protection devices must be evaluated (visually and irradiated) at least on an annual basis for cracks, wear and tear.

Doors leading to all radiation examination rooms are self-closing.

#### 2.3.1.1 Screen-film Systems

Appropriate equipment should be on site for the performance of quality control activities. Equipment should include, but not be limited to:

- densitometer (if processing).
- sensitometer (if processing).
- processor thermometer (if processing).
- splash glasses, protective apron and gloves.

Quality Control activities should include, but not be limited to:

- regular (at least annual) processor cleaning, maintenance and monitoring (if applicable).
- screen contact testing.
- screen cleaning.

- repeat/reject analysis (monthly).

### 2.3.1.2 Computed Radiography (CR) and Digital Radiography (DR)

The key aspects of ongoing quality control (QC), listed below are all strongly encouraged to be implemented in a facility's QC program. These recommendations are based, in part, on the American Association of Physicists in Medicine (AAPM) Task Group 151 (Ongoing Quality Control in Digital Radiography; https://www.aapm.org/pubs/reports/RPT_151.pdf). Please refer to Appendix II. Brief descriptions of the QC aspects that should be implemented from this report are described below.

Quarterly (Monthly Preferred):

1) Rejected image analysis: Rejected image data should be collected and analyzed on a regular basis and corrective action taken when necessary. Documentation should be available for review during an assessment.

2) Exposure analysis: Data relating to patient exposures, including DAP or exposure indicators, should be collected and analyzed on a regular basis. Such data can be compared to published reference levels to identify areas for improvement Documentation should be available for review during an assessment.

3) Artifact identification: Artifacts are not eliminated when changing from screen-film (SF) to digital imaging, and the types of artifacts that occur in digital radiography are different than those seen in SF imaging. Therefore, it is important that MRTs and radiologists be knowledgeable to identify common digital imaging artifacts. In addition, MRTs should carefully analyze each digital image for artifacts so that corrective action, including restriction of equipment use, can be taken to eliminate the artifact. For this reason, it is critical that the monitors used by the MRT to review images be suitable for this task.

- This is recommended to be performed following a dropped detector and after a detector calibration. Follow the recommended procedure for artifact analysis in the TG 151 report or one can use the manufacturer's phantom and procedures.

The results of the QC program should be monitored at least annually by the Quality Advisor. If measured values of QC parameters fall outside the control limits, then the Quality Advisor should consult with an appropriately qualified individual to initiate appropriate investigative or corrective actions.

### 2.3.1.3 Acceptance Testing, Performance Evaluation, and Quality Control (Routine)

Facilities are encouraged to perform the following quality control parameters. Some of these parameters overlap with the required parameters outlined in the X-ray Safety Code. Where this overlap occurs, the X-ray Safety Code parameters supersede those shown below.

Acceptance testing is required to be performed and the report sent to the XRIS within 60 days of installation. Facilities are encouraged to have this performed before clinical use.

Performance Evaluations should be performed semi-annually after acceptance testing or if a major change to the equipment itself, or its use, has occurred.

Quality Control (routine) should be performed by the facility, in addition to the three aspects outlined above (e.g. Rejected Image Analysis, Exposure Analysis, and Artifact Identification).

Preventive Maintenance should be performed according to manufacturer's recommendations. If no recommendations exist, then an annual frequency after acceptance testing should be adhered to.

Minimum Evaluations Required:

| Acceptance Testing | Performance Evaluation | Routine QC |
|---|---|---|
| HARPA Reg. 543 requirements | HARPA Reg. 543 requirements | AAPM TG 151 recommendations |
| *Detector Uniformity and Artifact Analysis*:<br><br>CR: using at least 1 plate of each size or all plates if artifacts are found on the initially evaluated plates.<br><br>DR: one exposure per digital detector<br><br>General Notes: Facilities may use manufacturer's phantom and procedure or appropriate substitute | *Detector Uniformity and Artifact Analysis*:<br><br>CR: using at least 1 plate of each size or all plates if artifacts are found on the initially evaluated plates.<br><br>DR: one exposure per digital detector<br><br>General Notes: Facilities may use manufacturer's phantom and procedure or appropriate substitute | |
| MRT review monitor(s) – SMPTE pattern or AAPM TG 18-QC pattern visual check (if possible to install) | MRT review monitor(s) – SMPTE pattern or AAPM TG 18-QC pattern visual check (if possible to install) | |
| Radiologist interpretation monitors (if on-site) - SMPTE pattern or AAPM TG 18-QC pattern visual check | Radiologist interpretation monitors (if on-site) - SMPTE pattern or AAPM TG 18-QC pattern visual check | |

Any parameters that the IHF facility wishes to have evaluated beyond the minimum evaluation requirements is at the discretion of the Quality Advisor. Such evaluations could include what is presented in the ACR–AAPM TECHNICAL STANDARD FOR DIAGNOSTIC MEDICAL PHYSICS PERFORMANCE MONITORING OF RADIOGRAPHIC EQUIPMENT.

### *2.3.2 Fluoroscopy*

**Acceptance Testing, Performance Evaluation, and Quality Control (Routine)**

Facilities are encouraged to perform the following quality control parameters. Some of these parameters overlap with the required parameters outlined in the X-ray Safety Code. Where this overlap occurs, the X-ray Safety Code parameters supersede those shown below.

Acceptance testing is required to be performed and the report sent to the XRIS within 60 days

of installation. Facilities are encouraged to have this performed before clinical use.

Performance Evaluations should be performed semi-annually after acceptance testing or if a major change to the equipment itself, or its use has occurred.

No routine quality control procedures are required to be performed by the facility.

Preventive Maintenance should be performed according to manufacturer's recommendations. If no recommendations exist, then an annual frequency after acceptance testing should be adhered to.

Minimum Evaluations Required:

| Acceptance Testing | Performance Evaluation | Routine QC |
|---|---|---|
| HARPA Reg. 543 requirements | HARPA Reg. 543 requirements | None |
| Detector Uniformity – using manufacturer's phantom and procedure or appropriate substitute | Detector Uniformity – using manufacturer's phantom and procedure or appropriate substitute | |
| MRT review monitor(s) – SMPTE pattern or AAPM TG 18-QC pattern visual check (if possible to install) | MRT review monitor(s) – SMPTE pattern or AAPM TG 18-QC pattern visual check (if possible to install) | |
| Radiologist interpretation monitors (if on-site) - SMPTE pattern or AAPM TG 18-QC pattern visual check | Radiologist interpretation monitors (if on-site) - SMPTE pattern or AAPM TG 18-QC pattern visual check | |

Any parameters that the IHF facility wishes to have evaluated beyond the minimum evaluation requirements is at the discretion of the Quality Advisor. Such evaluations could include what is presented in the ACR–AAPM TECHNICAL STANDARD FOR DIAGNOSTIC MEDICAL PHYSICS PERFORMANCE MONITORING OF FLUOROSCOPIC EQUIPMENT.

### *2.3.3 Ultrasound*

Lighting during diagnostic imaging examinations is best controlled by a dimmer switch.

All diagnostic ultrasound machines (and their probes) have a regular program of preventive maintenance and routine QA program. Preventive maintenance should be performed according to manufacturer's recommendations. If no recommendations exist, then an annual frequency should be adhered to. Written records of preventive maintenance and equipment calibration are maintained.

Ultrasound gels are in use in accordance with Infection Prevention and Control (IPAC) Position Statement on Medical Gels (December 2017) recommended practices *(see Appendix III).*

#### 2.3.3.1 Acceptance Testing, Performance Evaluation, and Quality Control (Routine)

There are no legal requirements as defined by the *HARP Act* and X-ray Safety Code for ultrasound machines. However, it is strongly encouraged that facilities implement a dedicated Quality Control program for each of their ultrasound machines. The following table lists the requirements.

Acceptance testing must be performed before clinical use.

Performance Evaluations should be performed annually after acceptance testing or if a major change to the equipment itself, or its use has occurred.

Minimum Evaluations Required:

| Acceptance Testing | Performance Evaluation | Routine QC |
|---|---|---|
| Physical and Mechanical Inspection (overall unit and transducers) | Physical and Mechanical Inspection (overall unit and transducers) | None |
| Image Uniformity and Artifact Survey (for each transducer port used clinically) - manufacturer's phantom and procedure or appropriate substitute<br><br>Note: Once a single transducer has been evaluated across all ports, all other transducers may be evaluated using only a single port | Image Uniformity and Artifact Survey (for each transducer used clinically) - manufacturer's phantom and procedure or appropriate substitute | |
| Acquisition/Review MRT display - SMPTE pattern or applicable substitute visual check (if possible to install) | Acquisition/Review MRT display - SMPTE pattern or applicable substitute visual check (if possible to install) | |
| Radiologist interpretation monitors (if on-site) - SMPTE pattern or AAPM TG 18-QC pattern visual check | Radiologist interpretation monitors (if on-site) - SMPTE pattern or AAPM TG 18-QC pattern visual check | |

Any parameters that the IHF facility wishes to have evaluated beyond the minimum evaluation requirements is at the discretion of the Quality Advisor. Such evaluations could include what is presented in the ACR–AAPM TECHNICAL STANDARD FOR DIAGNOSTIC MEDICAL PHYSICS PERFORMANCE MONITORING OF REAL TIME ULTRASOUND EQUIPMENT.

### *2.3.4 Mammography*

All facilities providing mammography services must have continuous, uninterrupted CAR-MAP accreditation. Equipment and Quality Control activities meet the CAR-MAP requirements. These QA requirements are overseen by the CCPM certified mammography physicist.

### *2.3.5 Bone Mineral Densitometry*

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

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

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

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

## 2.4 Radiologist Reporting Stations

Please refer to Volume 3 Teleradiology (PACS).

## 2.5 Aging Equipment

Modern diagnostic equipment is highly computerized with continuous technical modifications and innovations that enhance patient care. It is therefore expected that equipment will be kept up to date and ultimately replaced when no longer able to meet the standard of practice. A clear upgrade pathway, including up-to-date software, defined to keep the technology current, must be implemented by the facility. In recognition of changing technology standards, machines need to be upgradeable to future state-of-the-art requirements.

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

X-Ray, BMD, and Fluoroscopy: With regard to x-ray, BMD, or fluoroscopy machines, if a facility chooses to extend the lifecycle of these machines past the CAR guidelines for low utilization (e.g. 14 years is the low utilization timeframe for a general radiographic unit), then the facility must obtain the services of a Qualified Medical Physicist to evaluate and determine if the radiographic and fluoroscopic units are still appropriate for routine clinical use. Evaluations must be done once every three (3) years by a Qualified Medical Physicist. The Qualified Medical Physicist may choose to delegate this work, but the final report must be signed off by the Qualified Medical Physicist.

***Notes:***

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

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

***(iii) For non-digital equipment that is at the end of its life cycle and which is being replaced by new equipment, facilities are encouraged to replace it with digital equipment.***

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 Canadian College of Physicists in Medicine (CCPM), American Board of Radiology (ABR), or by the American Board of Medical Physics (ABMP). The appropriate subfields of medical physics in order to meet this requirement are either: Diagnostic Radiological Physics, Diagnostic Medical Physics, Radiological Physics, or Diagnostic Imaging Physics.

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

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

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

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

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

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

# Chapter 3 Policies and Procedures

## 3.1 Overview

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 and Ultrasound Safety and Dose Reduction (ALARA Principles)

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

Wherever possible the application of ionizing radiation should be limited to the anatomical area of concern using collimation and specific anatomical shielding should be used when appropriate (e.g., gonadal lead protection).

## 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, MRTs, DMSs and other staff. In addition, it should also include a copy of the MOH form outlining the name of the Quality Advisor.

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

**Mobile Services:** Facilities providing mobile services are expected to have a policies and procedures manual that accompanies the mobile equipment from site to site. The manual must include policies and procedures for every section outlined in this Chapter. In particular, the manual must identify the designated fixed location site that is responsible for reprocessing equipment, as well as the process used by the facility for handling the equipment during transit and how it is transferred to the approved location site (as per Schedule A of the Licence).

### *3.3.1 Facility*

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

- a description of the scope and limitations of diagnostic imaging services provided by the facility
- patient-booking systems
- patient requests for fetal ultrasound for non-medical reasons (e.g. gender identification) must not be performed. Fetal ultrasound should only be performed for diagnostic purposes on the order of a physician or other authorized health care professional.

- patient requests for a chaperone for intimate examinations, or any other common patient requests related to examinations/procedures; facilities must provide options where possible;
    - procedures must include specific chaperone signage posted in the facility; for example:
        - Chaperone Policy: Are you being examined? If you wish, we can provide another member of staff to be present; or a friend or family member can accompany you. PLEASE ASK THE DOCTOR OR NURSE. In the event that we are unable to provide you with a chaperone, you will be given the option of rebooking for a new date.
- timing and permission of family/friend presence during the performance of any examination
- documentation of and method for receiving written and telephone referrals for consultation

### *3.3.2 Facility Staff*

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

- professional guidelines, such as:

  CAMRT Best Practice Guidelines

  CMRITO Standards of Practice

  CMRITO Code of Ethics

  Sonography Canada's Professional Practice Guidelines and Policy Statements
- delegated acts and medical directives. Refer to CPSO policy on Delegation of Controlled Acts.
- review of all regulated health professionals' (RHP) education and experience including any certifications, examinations, courses and/or other training in order to ensure that all RHPs have the necessary knowledge, skills, and judgement to perform their specific services or procedures. Documentation that confirms the aforementioned must be kept up-to-date and on site.
- supervision of staff who may be working at an IHF while in the process of pursuing specialized training in a particular area specific to the type of patients seen in the facility. Supervision will continue until staff acquires the knowledge, skill and judgement through the training and if available, the applicable certification, examination, and/or course.
- staff roles for emergency procedures, which are appropriate to the role they would assume in an emergency (e.g. fire, power failure, other emergency evacuation)( see Appendix IV)
- The Licensee, Quality Advisor and staff working in the IHF are up-to-date on the standards for infection prevention and control, and have an ongoing process to ensure current infection and prevention control practices are reflected in staff training, policies and procedures (3.3.8), as well quality management (5.1). To meet this requirement, facilities must, at a minimum, review the following:
    - Public Health Ontario's newsletter, which informs subscribers about updates to Provincial Infectious Diseases Advisory Committee (PIDAC) documents. To sign up for newsletters, use the following link: https://www.publichealthontario.ca/en/EUM/Pages/Register.aspx

- Public Health Ontario's Infection Prevention and Control online training courses: IPAC Core Competencies Course and Reprocessing in Community Health Care Settings Course.

- Staff responsible for cleaning, disinfecting, sterilizing, and/or reprocessing of medical equipment must complete appropriate training, including manufacturer's training. To determine appropriate training, the Quality Advisor must complete Infection Prevention and Control's Checklist for Infection Prevention and Control (IPAC) CORE Elements in Clinical Office Practice , and if applicable, also complete the Checklist for Reprocessing of Medical Equipment/Devices in Clinical Office Practice. Refer to 3.3.8 Infection Prevention and Control policies and procedures for links to PIDAC/IPAC best practices.

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

  For more information, please refer to the Guide to the Occupational Health and Safety Act.

- There is a Joint Health and Safety Committee (based on number of workers). Refer to the Guide for Health and Safety Committees and representatives.

- Orientation for all new staff to ensure adequate training. This must include a review of policy and procedure manuals, modality specific protocols, infection and prevention control practices, and all safety training. The employee must sign off indicating that they have successfully completed all the above training.

- Written performance evaluations for all staff at completion of probationary period, and annually thereafter, or as defined by the facility.

- Annual review of continuing professional development (CPD) of all regulated health professionals to ensure each RHP's CPD meets their regulatory body's CPD requirements. Documentation that confirms the aforementioned must be kept up-to-date and on site.

### *3.3.3 Diagnostic Services*

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

- Instructions regarding routine preparation of patients
- Every exam must have the MRT/DMS name recorded
- Appropriate technique charts for all diagnostic imaging services performed in the facility. A separate technique chart for pediatric imaging, by age and weight
- Technical worksheets for DMSs
- MRTs to record exposure factors if they do not transfer automatically
- Use of personal patient protective devices including procedures on proper collimation and shielding
- Physical markers be present during the exposure and electronic markers be used in rare instances.

- Holding of patients during an exposure, and use of appropriate restraining equipment where necessary, e.g. Pigg-O-Stat.
- Process for staff to deal with any contraindications to the procedure, e.g. female patients for an x-ray procedure who may be pregnant or are pregnant; this includes notifying the physician/authorized health professional of the contraindication, and obtaining direction to proceed, modify or halt the procedure.
- Imaging protocols that subscribe to the ALARA principles, which should be developed under the direction of the radiation protection officer (RPO) to ensure compliance with the HARP Act and other applicable legislation.
- Performance of additional views and examinations, i.e. any additional views or examinations are identified in the imaging report with reasons
- MRTs/DMSs do not give preliminary interpretation.

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

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

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

### *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 including ultrasound transducers, and CR readers. These activities should be performed as a minimum on an annual basis. This should include frequency of testing, who is responsible for following up on recommendations, documentation and maintenance of records for all the above. Please refer to Chapter 2 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
- At least one staff member with current Basic Life Support (BLS) certification is on site at all times during hours of operation
- 70-90% alcohol-based hand rub be available for staff and patients at all points of care
- A hands-free eyewash station be installed in the facility (as per WHMIS). If HLD is used, then a reprocessing sink as per PIDAC
- Anaphylaxis (if facility not latex free)
- Safety Data Sheets (SDS) for all chemicals maintained in the facility
- Workplace safety and sexual harassment.

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

### *3.3.8 Infection Prevention and Control*

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

- Routine Practices and Additional Precautions to prevent infection transmission are in keeping with 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 sterilization and reprocessing of medical equipment. Please visit the CPSO website for an approved list of courses specific to reprocessing and sterilization.

#### 3.3.8.1 Infection Prevention and Control related to Equipment

There must be written policies and procedures relating to equipment cleaning /disinfection/ sterilization and storage (e.g. tables, ultrasound transducers, non-endocavity/endocavity transducers, and utensils) that require sterilization.

Facilities providing mobile services must also identify the designated fixed location site that is responsible for reprocessing equipment, as well as the process used by the facility for handling the equipment during transit and how it is transferred to the approved location site (as per Schedule A of the Licence).

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

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

Auxiliary equipment must be cleaned between patients with a Low Level Disinfectant (LLD) (for guidance on LLD, please refer to PIDAC Best Practices for Environmental Cleaning in Health Care Settings). Paper sheets and pillowcases on exam tables must be changed between patients, and tables must be cleaned and disinfected between patients and/or when visibly soiled.

#### *3.3.8.1.1 Non-Endocavity Transducers Reprocessing*

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

- Transducers and cords should be wiped clean of gel with a dry wipe and then a hospital grade low-level disinfectant (LLD) wipe (approved by manufacturer) after each examination.
- According to Infection Prevention and Control (IPAC) for Clinical Office Practice, a hospital grade disinfectant is an LLD that has a drug identification number (DIN) from Health Canada indicating its approval for use in Canadian hospitals. An LLD is a chemical agent that achieves low-level disinfection when applied to surfaces or items in the environment.
- The use of ultrasound for non-intact skin, infection, contagious disease and translabial that includes the use of gel, probe covers and cleaning/HLD if required.

  For more information, refer to IPAC Infection Prevention and Control for Clinical Office Practice.

#### *3.3.8.1.2 Endocavity Transducers Reprocessing*

##### 3.3.8.1.2.1 Physical Space

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

- The IHF Facility must have a dedicated area for reprocessing medical equipment/devices. This area must have one-way flow from dirty to clean to avoid cross contamination. The reprocessing area must have a decontamination sink that meets the needs of the equipment being reprocessed or sterilized. This sink must be designed and arranged to facilitate soaking, washing and rinsing of equipment/devices with minimal movement or delay between steps. This area should be adjacent to waterproof counter tops and a backsplash.
- If using HLD that requires a fume hood for venting/absorbing the high-level disinfection gases; the fume hood must be installed and inspected annually (Figure 12; CSA, 2008).

According to PIDAC's Best Practices for Cleaning, Disinfection and Sterilization of Medical Equipment/Devices In All Health Care Settings, 3rd edition, May 2013, a HLD is a chemical agent that achieves high-level disinfection when applied to surfaces or items in the environment. HLD processes destroy vegetative bacteria, mycobacteria, fungi and enveloped (lipid) and non-enveloped (non-lipid) viruses, but not necessarily bacterial spores. Medical equipment/devices must be thoroughly cleaned prior to high-level disinfection.)

- An eyewash station must be available in each location where equipment is reprocessed.
- Hand hygiene facilities should be readily accessible and located in all personnel support areas and at all entrances to, and exits from, the decontamination area. Hand hygiene facilities should include hand washing sinks with hands-free controls, soap dispensers and paper towels; and/or 70 to 90% alcohol-based hand rub (ABHR).

**3.3.8.1.2.2 Use and Pre-Cleaning of Transducers in the Examination Room**

- Single one time use transducer covers should be used on all endocavity transducers. Non-latex one-time use transducer covers/ gloves should be available for latex sensitive patients.
- All transducers used to perform biopsies should use a disposable sterile transducer cover, and aseptic technique..
- Sterile or bacteriostatic gels should be used to lubricate the exterior of the transducer covers (Appendix III: IPAC Position Statement on Medical Gel)
- Transducer covers should be removed using gloves and disposed of immediately. Care must be taken not to contaminate the transducer or splash the health care professional with the patient's secretions.
- Following each exam, the gross soiling (excess gel and patient secretions) should be wiped off the transducer and the entire cable cord with a single-use soft, lint-free dry wipe followed by an LLD wipe as recommended by MIFUs (Figure 5; CSA, 2008). The transducer is disconnected and transported to the reprocessing area.
- The transducer must be dry (if wet) before being placed in the HLD.
- Perform hand hygiene after cleaning the transducer and cable cords and between patients. (Figure 8; CSA, 2008). See PIDAC Best Practices for Hand Hygiene in Health Care Setting.
- Hand hygiene must be performed before drying, handling and storing the disinfected transducer..

**3.3.8.1.2.3 Cleaning Process**

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

- **All reprocessing staff should wear personal protective equipment (PPE) (gloves, mask, gown and protective eyewear), based on personal risk assessment and as required by the manufacturer.**
- After the exam, while wearing gloves, the transducer cover is removed carefully so as not to contaminate oneself or the environment.

- **Do not** use ammonium chloride or over-the-counter hydrogen peroxide (LLD) on transducers as the HLD; **accelerated** hydrogen peroxide is an HLD and is permitted.
- Pre-clean the transducers with a dry wipe to remove gross soiling (excess gel and patient secretions); then wipe the transducer with an LLD/wipe in the exam room; disconnect the transducer from the ultrasound unit and transport it to the reprocessing area in a sealed container. Follow the manufacturer's instruction for use (MIFU) regarding disinfection with HLD/enzymatic solution.
- Ensure that the transducer is dry before placing in HLD.
- Follow the HLD MIFUs to ensure correct contact time is achieved. Care must be taken to ensure that the solution does not enter the device or connector.
- Hand washing must be done in accordance with PIDAC Best Practices for Hand Hygiene in Health Care Setting.
- The transducer must be thoroughly rinsed as per MIFUs with potable water after use of an HLD solution. Do not allow any solutions to air dry on the transducer. (Figure 7; CSA, 2008).
- A neutralizing substance may be used to neutralize the disinfectant before it is poured down the contamination sink drain as per the HLD MIFUs.
- There must be a process in place to identify dirty versus reprocessed transducers.
    - The reprocessed transducer should have a "HLD" label placed on it and be kept in an area labelled as an HLD area. The transducer must be labelled to identify it from other HLD transducers in the facility.
- After high-level disinfection of the transducer, the DMS should document the reprocessing procedure with:
        - patient's unique identifier (i.e. exam number)
        - transducer unique identifier (i.e. serial number)
        - soaking time (in and out)
        - Name of the person who cleaned the transducer and date. (Figure 9; CSA, 2008)

#### 3.3.8.1.2.4 Daily Testing

- All HLD solutions should be tested on a daily basis using HLD test strips. Record the Lot # of the disinfectant, date and name of tester and the result of the test. (Figure 10; CSA, 2008)
- Once the test strip bottle is opened, record the expiry date on the bottle (usually six months once opened but not past the manufacturer's expiry date)
- There should be a log book to record all high-level disinfection solution changes (Figure 11; CSA, 2008).
- Solution must be changed if the test strip fails or as per MIFUs (usually two weeks).
- After changing the solution, test the concentration of the solution and record the results in the logbook.
- All documentation/logbooks must be maintained for six years.

- Endocavity transducer should be examined regularly for any damage, and preventive maintenance should be performed annually. If damage is evident, discontinue use of the transducer and contact the manufacturer. (Figure 15; CSA, 2008)
- A review and update of the reprocessing techniques should be done on an annual basis. (Figure 16; CSA, 2008)

#### *3.3.8.1.3 Sterilization*

- Sterilization is the elimination of all disease-producing microorganisms, including spores. Sterilization is used on critical medical equipment/devices and, whenever possible, semi-critical medical equipment/devices.
- Develop written policies and procedures for sterilization of medical equipment/devices used in the clinical office setting that include cleaning, drying, inspection, disassembly, wrapping, sealing and labelling.
- Ensure that the manufacturer's instructions for installation, operation, cleaning and preventive maintenance of the sterilizing equipment are followed.
- Staff must be trained to operate sterilizers. Staff performing sterilization must complete an approved reprocessing/sterilization course (visit the CPSO website for a list).
- Test all sterilizers for performance using physical, chemical and biological monitors and indicators
- Sterilizers must be cleaned weekly and have annual preventive maintenance
- A procedure shall be established for the recall of improperly reprocessed medical equipment/devices
- Policy regarding the storage of sterile equipment/devices and shelf life
- The physical space requirements are the same as those for HLD of endocavity transducers (see 3.3.8.1.2.1 Physical Space).

**3.3.8.1.3.1 Monitoring the Sterilization Process**

The sterilization process shall be tested, monitored with results recorded and audited. All sterilizers shall be tested for performance using physical, chemical and biological indicators:

- A logbook must be kept for each sterilizer load. Performance monitoring includes physical, biological and chemical indicators and all three processes shall be used:
- Physical indicators (time, temperature, pressure) as indicated on displays, mechanical printouts, or USB from the sterilizer must be checked and signed for each sterilizer cycle by the person sterilizing the instrument.
- A biological indicator (BI) shall be used to test the sterilizer once each day the sterilizer is used and for each type of cycle used that day.
- An external chemical indicator (class 1) shall be placed on the outside of each package, container or bundle that is undergoing sterilization.
- An internal chemical indicator (class 4 at a minimum) shall be placed inside each package, container or bundle that is undergoing sterilization.

- If a dynamic air removal-type sterilizer (pre-vacuum) is used, an air removal test with a Class II chemical indicator shall be performed every day the sterilizer is used.

For more information about reprocessing and sterilization, see PIDAC'S Best Practices for Cleaning, Disinfection and Sterilization in all Health Care Settings, Third Revision, May 2013.

### 3.3.8.2 Infection Control related to Use of Medical Gel

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

***NOTES:***

***(i) As indicated in the IPAC Canada Position Statement on Medical Gels "Containers of gel should never be washed and refilled for use but should be discarded when empty" (see Appendix III)***

***(ii) **Do not warm gel due to increased risk of bacterial multiplication.***

- Containers/dispensing nozzles must not come in direct contact with a patient's skin, staff, instrumentation, or the environment and if there is any doubt about the integrity of the gel, it should be discarded. The more the tip is touched or manipulated the greater the opportunity for it to become contaminated with microorganisms.

  ***NOTE: If the tip of the gel bottle or the outside of the bottle comes into contact with the patient, then the bottle must be discarded.***

- Before opening the bottle, verify the expiry date.
- When a new bottle is opened, the bottle should be dated and discarded after one month or if it has been compromised.
- Once opened, the bottle must be capped between uses.
- For infrequent procedures, use small or single-use packets or containers (verify expiry date).

Sterile, one-time use gel should be used for:

- Non-intact skin
- All droplet or contact isolation cases
- All examinations performed on intact mucous membranes (e.g. esophageal, gastric, rectal or vaginal)
- "Whenever a biopsy, puncture of any kind, or imminent surgery is to be performed regardless of body site" as per IPAC Canada Position Statement (e.g. needle aspiration, Sonohysterogram)

### 3.3.8.3 Infection Prevention and Control related to Hand Hygiene

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

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

#### 3.3.8.4 Infection Prevention and Control related to Infectious Patients

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

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

### *3.3.9 Personal Protective Equipment*

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

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

### *3.3.10 Disposal of Sharps*

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

- Appropriate precautions to prevent injuries from sharps

**Disposal guidelines and requirements for dedicated sharps containers3.3.10.1 Needle Safety**

- Under the Occupational Health and Safety Act, the Needle Safety section states, *"when a worker is to do work requiring the use of a hollow-bore needle, the employer shall provide the worker with a safety-engineered needle that is appropriate for the work. O. Reg. 474/07, s. 3(1)".* Therefore, IHFs shall provide appropriate access to safety-engineered needles as required.

# Chapter 4 Requesting and Reporting Mechanisms

The content of this chapter is largely derived from the Canadian Association of Radiologists Practice Guidelines for Communication of Diagnostic Imaging Findings (2010). **Last accessed: February 2018**

## 4.1 Overview

Communication is a critical component of the art and science of medicine and is especially important in Diagnostic Imaging. It is incumbent upon radiologists and the facilities in which they work to ensure that the results of diagnostic studies 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 radiologist 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 Imaging 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 imaging 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 radiologist 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 radiology consultations irrespective of the technology used including teleradiology, Picture Archival Communication System (PACS) or an equivalent electronic workstation with an archival system (refer to Volume 3: Teleradiology (PACS).

In order to afford optimal care to the patient and enhance the cost-effectiveness of each diagnostic examination, radiological consultations should be provided and images interpreted within a known clinical setting. No screening radiological examination should be performed unless evidence-based or part of an organized population-based screening program.
The Canadian Association of Radiologists supports radiologists who insist on clinical data with each consultation request and the IHF 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 department managers and all imaging personnel including radiologists to ensure patient privacy. This includes institution of appropriate privacy procedures, and appropriate departmental regulation of procedures for release of images or reports from medical images to third parties.

Policies and practice must be consistent with privacy legislation: www.ipc.on.ca

## 4.2 Requesting Procedures

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

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

Recognizing that the diagnostic imaging physician does not initiate the request for imaging and has limited interaction with the patient, it is of the utmost importance that the referring physician/health care provider provides adequate clinical information for interpretation of the study. It is also important that the referring physician/health care provider follow best practice guidelines as it is ultimately the responsibility of the referring physician/health care provider to ensure that the imaging they have requested is appropriate.

An appropriate request for all radiological consultations specifies:

- basic demographic information of the patient such as name, health number, date of birth, and sex.
- name of the ordering physician/health care provider and the names of any other physicians who are to receive copies of the report.

***Note: If patient information is entered electronically, clinic staff must ensure that the patient demographic information, including the requesting physician noted on the requisition, is current and correct. Any changes to update the information must be made prior to the performance of the study.***

- the type of procedure requested for the patient including any special instructions where applicable.
- pertinent clinical information including indications, pertinent history, and provisional diagnosis. There must be enough relevant clinical information to justify the examination – routine screening is not a sufficient indication.
- imaging examinations for specific organ systems or body regions listed separately on the requisition form. Routine bundling of examinations is not appropriate.

  an option for unilateral examinations. Routine bilateral examinations are not appropriate.

***Note: This is the responsibility of the ordering physician/health care provider. If a patient arrives with a requisition containing incomplete information, the diagnostic imaging physician or designated staff member should attempt to contact the ordering physician/health care provider or interview the patient to obtain the necessary information prior to conducting the procedure.***

***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 ordering physician/health care provider, the date and time of the request, and signs the record of the request.***

## 4.3 MRT/DMS Documentation

MRTs and DMSs must include their name on the film bag, technical impression worksheet or equivalent at the time of the examination in order for the interpreting physician to identify the MRT/DMS performing the examination.

## 4.4 The Diagnostic Imaging Final Written Report

The final report is considered to be the definitive means of communicating to the ordering physician or other health care providers 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 or health care provider who is responsible for the clinical follow-up. The ordering physician or other health care provider 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. The final report should be made available within 1 to 2 business days to the ordering physician or health care provider who is responsible for the clinical follow-up.

The final report should be proofread carefully to avoid typographical errors, accidentally deleted words, and confusing or conflicting statements, and should be authenticated by the reporting radiologist, whenever possible.

***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 radiologist must appear as such on the report.

A copy of the diagnostic image is retained as the permanent record for the appropriate length of time as prescribed by regulations.

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

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

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

A copy of the final report should be archived by the imaging facility as part of the patient's medical record (paper or electronic) and be retrievable for future reference. It is of sufficient quality to record permanent findings, to be used for comparison with subsequent examinations, and enable third party radiologists 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 diagnostic images are available for the interpreting physician.

### *4.4.1 Report Attributes*

Reports of the interpretation of imaging procedures include the following:

> name of patient and another identifier, such as gender, birth date, pertinent identification number or office identification number.
>
> the facility or location where the study was conducted.
>
> name of the ordering physician or health care provider.
>
> name of most responsible physician/health care provider for patients cared for by multiple clinical services.
>
> - rationale: To provide more accurate routing of the report to one or more locations specified by the ordering physician/health care provider. Each facility has a policy to ensure proper distribution of the written report to the most responsible physician and/or other physicians/health care providers.
>
> name or type of examination.
>
> date of examination.
>
> - whenever possible, the month should be spelled rather than risking the ambiguity of US and international formats (e.g., 03 July 2010 rather than 03/07/10 or 07/03/10).
>
> dates of dictation.
>
> - rationale: quality control.
>
> date transcribed

### *4.4.2 Body of the Report*

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

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

#### 4.4.2.1 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.

#### 4.4.2.2 Findings

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

#### 4.4.2.3 Limitations

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

#### 4.4.2.4 Clinical Issues

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

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

***Note: For example, to rule out pneumothorax, state "there is no evidence of pneumothorax" or to rule out fracture, state "there is no evidence of fracture". It is not appropriate to use universal disclaimers such as "the mammography examination does not exclude the possibility of cancer" as it is expected that the ordering physician understands that even a well performed diagnostic exam does not necessarily have a 100% sensitivity. Descriptive reporting that offers no opinion, or guidance for resolution of the clinical question should generally be avoided.***

#### 4.4.2.5 Comparative Data

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

#### 4.4.2.6 Assessment and Recommendations

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

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

Give a precise diagnosis whenever possible.

Give a differential diagnosis when appropriate.

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

Any significant patient reaction should be reported.

## 4.5 Standardized Computer-Generated Template Reports

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

## 4.6 Preliminary Report

A preliminary report may precede the final report in certain circumstances and contains limited information relevant to immediate patient management. It may be time sensitive and should not be expected to contain all the imaging findings. It should be generated when a timely communication is necessary in unexpected elective cases where clinical urgency mandates immediate communication of the results. It is acknowledged that not all serious findings require a preliminary report if they are already known or could have been reasonably expected by the referring physician/health care provider (e.g., bowel cancer on a barium enema) as long as the final report is generated within 24-48 hours.

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 and appropriately labelled as a preliminary report, distinct from the final report.

***Note: MRTs and DMSs are not permitted to provide preliminary findings of any examination either directly to the patient and/or the ordering physician without first consulting the radiologist. The radiologist must then decide, based on the preliminary findings who will convey the information to the ordering physician.***

## 4.7 Verbal or Other Direct Communication

Radiologists should attempt to co-ordinate their efforts with those of the ordering physician/health care provider in order to best serve the patient's well-being. In some circumstances, such co-ordination may require direct communication of unusual, unexpected or urgent findings to the ordering physician in advance of the formal written report. These include:

The detection of conditions carrying the risk of acute morbidity and/or mortality which may require immediate case management decisions.

The detection of disease is sufficiently serious that it may require prompt notification of the patient, clinical evaluation or initiation of treatment.

Detection of life or limb threatening abnormalities which might not have been anticipated by the referring physician.

Any clinically significant discrepancy between an emergency or preliminary report and the final written report should be promptly reconciled by direct communication to the ordering physician or his/her representative.

In these circumstances, the radiologist or his/ her representative, should attempt to communicate directly (in person or by telephone) with the ordering physician/health care provider or his/ her representative. Alternative methods including fax, or secure email (see PHIPA - Information and Privacy Commissioner/Ontario, Suite 1400, 2 Bloor Street East, Toronto, ON M4W 1A8 www.ipc.on.ca) could be used for these purposes if there is a way of verifying receipt of the report. The timeliness of direct communication should be based upon the immediacy of the clinical situation.

Documentation of actual or attempted direct communication may be a desirable facility policy.

It is incumbent upon ordering physicians/health care provider to make available a way of communicating results to an alternative provider in circumstances such as holiday, sickness or restricted office hours.

## 4.8 Retention of Patient Records

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

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

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

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

When previous images and reports are required from another IHF in order to make a comparison, the acceptable turnaround time for requests that are received by the IHF would be for the images and reports to be made available for courier or pickup within 3 working days of receiving the request. Based on the above turnaround time couriered images and reports must be received by the requesting party within a maximum of 5 working days of the IHF receiving the original request. For example, refer to the ACR-AAPM-SIIM Technical Standard for Electronic Practice of Medical Imaging guidelines.

# 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 health professionals (e.g. physician, MRT, DMS) 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, as needed).

QAC meeting agendas must, at a minimum, include:

- Approval of minutes from previous meetings
- Business arising from Minutes (confirmation of completed items, and discussion of outstanding actions)
- Goals and objectives:
    i. Staff changes/New staff
    ii. Staff under supervision - progress on examinations/courses/accreditation
    iii. Expansion/relocation plans
    iv. General practice goals
- Recommendations from Assessment/Accreditation Visit/Ministry of Health X-ray Inspection Services and HARP (if applicable). Such issues are to remain on the agenda until they are clearly finalized
- Policies and procedures (including but not limited to):
    i. Policy and Procedures Manual – general updates, staff sign-off
    ii. Technical – general practice guidelines for facility
    iii. Infection Prevention and Control
    iv. Safety Data Sheets
    v. Other
- Review of IPAC requirements and staff orientation/training
- Equipment – problems, upgrades, training or facility configuration issues
- Incidents or complaints, adverse drug reactions, complications
- Review of the results of the Facility's quality review process
- Review of current statistics on the time between patient referral and examination/treatment
- Review of difficult or inconclusive cases and how they were dealt with
- Referring physician/patient survey results (see sample surveys in Appendix V and VI)
- Staff performance appraisals & training – when, who, how often

## 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 performance of diagnostic imaging examinations complies with current Canadian Association of Radiologists (CAR) Guidelines accepted by the College of Physicians and Surgeons of Ontario and in the absence of current standards and guidelines generally accepted medical standards of practice.

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

## 5.3 Providing Quality Care

A diagnostic imaging physician must be available for consultation with the MRT/DMS on a case-by-case basis. Ideally, the imaging physician should be on-site and available to participate in the examination when required.

Diagnostic imaging 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.

***NOTE: Quality Management for Mammography: Facility Leads have specific duties and responsibilities relating to mammography services. Please refer to Chapter 1 Staffing a Facility for details.***

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

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

1. Review quality management goals and objectives annually.
2. Supervise and document a systematic ongoing review of the facility policy and procedures manual.
3. Review safety data on any equipment new to the facility since the last meeting and ensure that all equipment in the facility meets safety standards.

4. Review any incident or accident report since the last meeting and document any such actions to prevent similar incidents or accidents. Provide a report of all such proceedings to the facility's Quality Advisor.
5. Review and implement recommendations from other assessing bodies such as the Ministry of Health, and Ministry of Labour.

***Review and implement recommendations from HARP and Preventative Maintenance (PM) reports***

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

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

# Chapter 6 The 11 to 13-week ultrasound

## 6.1 Overview

All pregnant women in Ontario should be offered prenatal screening for Down syndrome. The screening combines levels of pregnancy-related chemical markers and a nuchal translucency (NT) measurement (a measurement of the fluid at the back of the fetal neck) performed between 11 and $13^{+6}$ weeks of pregnancy.

This ultrasound also provides important information for accurate gestational age assessment, number of foetuses, and chorionicity of multiple pregnancies. In addition, some fetal structural anomalies can be detected. An enlarged nuchal translucency (>3.5 mm) can predict for other genetic syndromes and some structural anomalies such as fetal cardiac defects. Thus the 11 to $13^{+6}$ week scan should be offered to women even when Down syndrome screening is not requested, and/or if Non Invasive Prenatal Screening (NIPT) has been done.

It is an international standard that DMSs/sonologists who perform and report 11 to $13^{+6}$ week ultrasounds participate in standardized certification and ongoing quality assurance programs, particularly of the nuchal translucency measurement itself.

11 to $13^{+6}$ week ultrasounds should be performed by accredited DMSs who have completed the Fetal Medicine Foundation (FMF) certification program for the 11-$13^{+6}$ week scan.

When this scan is being done in the context of prenatal screening for Down syndrome, the patient should present with a prenatal screening requisition with the top and bottom sections already completed by the referring health provider. The DMS (under the supervision of a reporting physician) is responsible for the relevant ultrasound information, including their unique identifying DMS number, upon which periodic audits can be performed. The patient then takes this form to any Ontario registered clinical laboratory for the blood tests, preferably on the same day as the ultrasound is done.

## 6.2 Quality Assurance

The Better Outcomes Registry and Network (BORN) Ontario is the province's prescribed perinatal registry. BORN collects all prenatal screening records in the province; including all NT/CRL paired measurements. These data are uploaded to BORN along with the ID of the DMS who provided the measurements, which allows for ongoing population of the BORN Ontario *DMS-Specific NT audit curve*.

BORN Ontario provides a provincial quality assurance framework for all Ontario DMSs and allows each DMS to track NT measurement performance over time. Each registered DMS can access their individual curve through the secure BORN Information System (BIS) (see contact details in 6.4). Performance data is password-protected and accessible only to the DMS.

## 6.3 Physicians Involved in Nuchal Translucency Reporting

Physicians must have adequate training to report the 11 to $13^{+6}$ week scan. For example, training during residency, completion of the Fetal Medicine Foundation internet course, or equivalent course would be acceptable. Reporting/supervising physicians are responsible for

the quality of the NT measurements that are reported by their facility, and thus need to ensure ongoing quality assurance for DMSs they are supervising.

## 6.4 DMSs Performing the 11 to $13^{+6}$ week scan

New DMSs performing the 11 to $13^{+6}$ week scan must complete the following steps:

1. Completion of the free Fetal Medicine Foundation Internet course on the 11-13 Weeks Scan
2. Receipt of The Fetal Medicine Foundation 11-13 weeks Scan Certificate of Competence following successful uploading and submitting of 3 satisfactory NT images. This step will provide the DMS with their unique FMF ID number, which will be registered with the Fetal Medicine Foundation in the UK.
3. Once #2 is complete, register with the Prenatal Screening Program at BORN Ontario, providing the FMF certification number.
4. Registrants will receive an application form from BORN Ontario, along with instructions for application to the Ontario Prenatal Screening Program (see below for contact information).
5. DMSs will be required to submit 15 further NT/CRL paired measurements for initial audit and enrolment with Ontario's Prenatal Screening Program.

DMSs currently performing NT scans must also register with BORN Ontario to access their NT audit curve and track their performance. Each IHF must make this audit practice a part of ongoing quality assurance.

### *6.4.1 Nuchal Translucency Audit Curve*

Audit data are accessible through the BORN Information System (BIS). In order to access their individual NTQA audit curve, enrolled DMSs must:

1. Register with the Prenatal Screening Program at BORN Ontario, either as a new DMS as outlined above, or as an existing DMS.
2. Follow-up with the Prenatal Screening Program to obtain a BORN User ID and temporary password along with instructions on how to access the NTQA audit curve.
3. Log on to the BIS, obtain their permanent personal password, and access their individual NTQA curve, which can be exported and saved as required.

**Key Points:**

- DMSs performing NT scans in Ontario must use ONLY their own unique DMS ID number.
- DMSs registered in the Ontario program will be required to perform a minimum of **thirty** 11 to 13-week scans per year to allow accurate ongoing audit of their performance. If the minimum requirement of thirty scans per year cannot be met, additional auditing may be required.

## Ontario Prenatal Screening Contact Information

**Ontario's Prenatal Screening Program**

**1 (833) 351-6490**

**www.prenatalscreeningontario.ca**

**prenatalscreening@bornontario.ca**

**Ontario Regional Prenatal Screening Laboratories:**

*Trillium Health Partners; Credit Valley Site*
(905) 813-4104

*Mount Sinai Hospital*
(416) 586-8510, option 2

*North York General Hospital*
(416) 756-5996

For more information on the performance of NT please visit:
http://prenatalscreeningontario.ca/for-sonographers-and-supervisors/

# Independent Health Facilities: Clinical Practice Parameters and Facility Standards

## *Diagnostic Imaging*

## VOLUME 2 CLINICAL PRACTICE PARAMETERS

# Chapter 7 Position Statement from the IHF Diagnostic Imaging Task Force

**It is the position of the IHF Diagnostic Imaging Task Force that Radiologists and facilities are complying with the current CAR Practice Guidelines that are applicable to the services provided in Independent Health Facilities.**

**To ensure that radiologists and facilities are in compliance with current CAR Practice Guidelines, the radiologist and facility staff are responsible for, at least annually, reviewing the Canadian Association of Radiologists website to ensure that they have obtained and are in compliance with the most current standards of practice for the profession.**

## Practice Guidelines

Refer to the CAR Practice Guidelines.

***Note: The radiologist and facility staff should refer to the CAR website first, and where the CAR does not have specific Practice Guidelines available, the American College of Radiology website should then be accessed.***

### *Mammography - Breast Imaging*

In addition to complying with the CAR Practice Guidelines for Mammography, IHFs providing mammography services are required to participate in the Ontario Breast Screening Program (OBSP). For more information, please refer to the OBSP.

### *Referral Guidelines*

Refer to the CAR Diagnostic Imaging Referral Guidelines – A Guide for Physicians 2012

***All Clinical Practice Parameters referenced within this document should be read in conjunction with the Facility Standards (Volume 1) developed by the IHF Diagnostic Imaging Task Force. A guiding principle should be that Diagnostic Imaging examinations only be performed for a valid medical reason with the minimum exposure that provides the image quality necessary for an adequate diagnostic examination.***

# Chapter 8 Routine Chest Radiography in a Primary Care Setting

The content of this chapter is taken from the article:

Tigges S., Roberts, D.L., Vydareny, K.H., Schulman, D.A. (2004). Routine chest radiography in a primary care setting. Radiology, 233(2), 575-578


## Abstract

**PURPOSE:**

To determine the frequency, diagnostic yield, outcomes, cost, and rate of false-positive results of routine chest radiography performed in asymptomatic patients in the primary care setting.

**MATERIALS AND METHODS:**

Radiography reports on all patients who underwent routine or screening poster anterior and lateral chest radiography at a university-affiliated primary care clinic in 2001 were reviewed. Radiographic results were coded as normal or minor findings or as major abnormalities, such as pulmonary nodules, requiring further diagnostic evaluation. Outcomes of patients with major abnormalities were established by using chart reviews or reviewing additional radiographs. Costs were estimated by using 2002 Medicare reimbursement rates. The main measures assessed were frequency, costs, and rate of false-positive results of routine chest radiography.

**RESULTS:**

Of 3812 radiographs obtained at the primary care clinic, 1282 (34%) were ordered for routine or screening purposes by the referring physician. Nine hundred twenty-two radiographs were obtained in male patients and 360 were obtained in female patients; their mean and median age was 49 years (age range, 4-87 years). Fifteen chest radiographs showed major abnormalities. No patient younger than 40 years had a major abnormality. Fourteen of the 15 findings of major abnormalities proved to be false-positive. No disease requiring treatment was diagnosed as a result of radiographic findings. The total cost for follow-up radiography and computed tomography was US dollar 46,609.49.

**CONCLUSION:**

Routine chest radiography has low diagnostic yield in asymptomatic primary care patients.

# Independent Health Facilities: Clinical Practice Parameters and Facility Standards

## *Diagnostic Imaging*

## VOLUME 3 TELERADIOLOGY (PACS)

# Teleradiology Standards

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

## CPSO Telemedicine Policy

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

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

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

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

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

**CAR Teleradiology Standards**

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

# OAR Teleradiology Practice Standard

Ontario Association of Radiologists

May 2015

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

**Originally Approved June 2007 Definition**

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

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

## Preface

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

Teleradiology has advantages but it must be done properly to ensure that a high quality of care is provided to patients and to maintain the radiologist interaction with their clinical colleagues. It is also important that those radiologists providing the service are properly trained, are registered with the appropriate authorities, and undergo continuing update through Continuing Medical Education (CME). The services provided must be

open to audit and the ability to discuss cases with those reporting the studies must be available. This standard has been developed to provide guidance to radiologists, managers of health care facilities, patient's representatives and governments on appropriate standards for teleradiology services.

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

## Role of a Diagnostic Radiologist

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

Evaluating the clinical information produced by referring physician clinicians

Deciding which test is appropriate

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

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

Optimizing the study and assisting the referring physician colleague

Evaluating the study and relating it to the clinical findings

Having knowledge of the practice of referring physicians

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

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

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

Performing interventional therapeutic and diagnostic procedures

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

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

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

Adhering to all provincial and federal regulations, statutes relating to the delivery of medical services generally and diagnostic imaging services provincially; meeting and exceeding the standard of care in the delivery of diagnostic imaging services in the province; maintaining membership in all of the licensing bodies and fulfilling the requirements of that licensure regime

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

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

Where relevant, participating in radiology research

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

Ensuring timely communication of urgent findings

Maintaining appropriate records/confidentiality as mandated by legislation

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

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

## **Key Principles**

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

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

Only fully qualified diagnostic radiologists should provide the teleradiology service. They must be properly accredited, registered, and licenced in Ontario. The radiologist should be subject to licensing and quality assurance requirements of the provincial health authority; legislative and professional requirements of the facility providing the service; the provincial College of Physicians and Surgeons, accreditation and be in good standing with the Royal College of Physicians and Surgeons of Canada.

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

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

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

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

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

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

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

## Key Management Issues

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

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

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

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

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

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

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

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

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## Real and Potential Problems

### *Clinico-Radiological Communication*

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

### *Team Working*

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

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

### *Communication*

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

### *Wording of Report and Clinical Impact*

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

Modern imaging commonly demonstrates an abundance of reportable findings, some of which are clinically relevant and some of which are incidental findings/pseudo-disease. Multiple pathologies can exist in the same patient. The clarity and certainty conveyed in the text is particularly important in converting a report that is merely ‘diagnostically accurate’ into one that has a diagnostic outcome and potentially a therapeutic outcome for the patient. Clinicians are more likely to act on the nuances intended in a report

generated by a radiologist with whom they regularly liaise compared with a report generated by a third party teleradiology service from someone they never met. Specific wording of reports for general family doctors may be necessary, which is different from the reports to specialists within their sphere of interest. Familiarity with the referring doctors can make specific reports more appropriate and useful. Health care delivery varies between different jurisdictions. Recommendations for further imaging/specialist referral, which might be appropriate in the locale where a teleradiology service is provided, may be inappropriate in the area where the patient is located.

### *Access to Previous Examinations/Interpretations*

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

### *Downstream Costs*

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

### *Quality Control and Quality Assurance*

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

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

### *Legal Issues*

There are a number of potential legal issues.

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

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

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

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

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

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

There is increasing awareness of the need to reduce the radiation dose that many patients receive, particularly CT scanning. When creating teleradiology contracts, it must be made clear who has responsibility for defining the protocol of an individual imaging study, e.g. high or low dose depending on clinical indication. Teleradiology providers need to comply with pertinent directives mandated in the provincial jurisdiction.

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

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

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

### Legal Interpretation

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

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

## Guidelines for the Development and Appropriate Use of Teleradiology

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

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

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

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

Teleradiology services developed for rural, remote and/or under-serviced areas should be linked to other facilities in the province of Ontario and the service should be managed by the receiving department/clinic unless there is a radiologist at the originating centre who may elect to assume that responsibility or share it with the receiving centre radiologist. The radiologists involved in providing the service should have close communication with the referring clinicians and patients and should understand any particular local disease and cultural factors.

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

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

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

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

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

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

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

The legal arrangements must be clearly defined between the user and the provider so that proper restitution may be made to patients, if errors are made. If the service is less than optimal, patients should not be required to litigate in the foreign country in the event of a complaint unless they have consented formally to the transfer of their rights for local litigation in addition to initial image transfer.

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

# Independent Health Facilities: Clinical Practice Parameters and Facility Standards

## *Diagnostic Imaging*

## APPENDICES

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

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

# Appendix II Ongoing Quality Control in Digital Radiography: Report of AAPM Imaging Physics Committee Task Group 151

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Quality control (QC) in medical imaging is an ongoing process and not just a series of infrequent evaluations of medical imaging equipment. The QC process involves designing and implementing a QC program, collecting and analyzing data, investigating results that are outside the acceptance levels for the QC program, and taking corrective action to bring these results back to an acceptable level. The QC process involves key personnel in the imaging department, including the radiologist, radiologic technologist, and the qualified medical physicist (QMP). The QMP performs detailed equipment evaluations and helps with oversight of the QC program, the radiologic technologist is responsible for the day-to-day operation of the QC program. The continued need for ongoing QC in digital radiography has been highlighted in the scientific literature. The charge of this task group was to recommend consistency tests designed to be performed by a medical physicist or a radiologic technologist under the direction of a medical physicist to identify problems with an imaging system that need further evaluation by a medical physicist, including a fault tree to define actions that need to be taken when certain fault conditions are identified. The focus of this final report is the ongoing QC process, including rejected image analysis, exposure analysis, and artifact identification. These QC tasks are vital for the optimal operation of a department performing digital radiography.
 [http://dx.doi.org/10.1118/1.4932623]

Key words: quality control, digital radiography, repeat analysis, exposure analysis

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## 1. INTRODUCTION

The American Society for Quality defines Quality Assurance (QA) and Quality Control (QC) as follows:[1]

*Quality Assurance*: "The planned and systematic activities implemented in a quality system so that quality requirements for a product or service will be fulfilled."

*Quality Control*: "The observation techniques and activities used to fulfill requirements for quality."

These definitions indicate that quality assurance is a proactive process that seeks to prevent defects in products or deliverables, e.g., medical images, while quality control is a reactive process that seeks to identify defects in products or deliverables. The major focus of this report is quality control in medical imaging, that is, examining the deliverable, the medical image, and the process used to create it for deficiencies.

QC in medical imaging is often viewed as a series of regular (often annual), detailed evaluations of a piece of medical imaging equipment by a qualified medical physicist (QMP). However, QC should be viewed as an ongoing process that occurs on an image-by-image basis. The QC process involves key personnel in the imaging department, including the radiologist, radiologic technologist, and QMP. The radiologist administers and oversees the QC program, which is carried out by the radiologic technologist. The QMP consults with the radiologist in the design and implementation of the QC program, works with the technologist to triage problems, and carefully evaluates the imaging equipment on a regular basis for proper calibration, function, and compliance with applicable regulations.

Ongoing QC was inherent in the screen-film imaging workflow, where rejected image rates were calculated by counting rejected films. Improperly exposed films resulted in images that were too dark or light and were repeated out of necessity, and the rejected films counted. During the early years of the shift to digital imaging in radiography, ongoing QC was largely abandoned, owing to both a perceived lack of need and difficulty in performing ongoing QC with early digital imaging systems, which lacked standardized exposure indicators and tools for counting rejected images.

The initial work of this task group included reviewing historical data from QC programs offered by equipment manufacturers and other historical QC data, as well as performing specific QC tests on a frequent basis. Task Group 151 also worked closely with Task Group 150, whose charge was to outline a set of tests to be used in the acceptance testing and quality control of digital radiographic imaging systems, to design tests and avoid overlap in our efforts. No key *equipment performance characteristics* that varied on a time scale short enough to warrant ongoing testing by a radiologic technologist under the supervision of a QMP were identified by TG-151. However, it was noted that key *aspects of a QC program* were often lacking in imaging departments and in published recommendations and practice guidelines.

Therefore, the focus of this final report is the ongoing QC process, including rejected image analysis, exposure analysis, and artifact identification. These QC tasks are vital for the optimal operation of a department performing digital radiography.

## 2. REJECTED IMAGE ANALYSIS

Repeated and rejected images represent both unnecessary radiation exposure to patients and inefficiency in the imaging operation owing to wasted time and resources. Rejected images are inherent to projection radiography, where patient positioning and alignment are integral components of image quality. With screen-film imaging systems, the relatively narrow exposure latitude available for creating a clinically useful image sometimes necessitates repeated images owing to under- or overexposure of the film. Patient motion, positioning, and

artifacts unique to the image receptor technology can result in repeated images as well. Therefore, repeat/reject analysis is an integral part of a QA program for radiography. Repeat/reject analysis is mandated by the United States government for mammography[2] and is recommended for projection radiography by multiple organizations and accrediting bodies.[3–5]

In screen-film imaging departments, a Reject Analysis Program (RAP) relies on the physical collection of rejected images in containers, the contents of which are periodically sorted by reason for rejection and normalized by the total number of films consumed during the period to determine reject rates.[6] This system is often complicated by the time-consuming task of determining reasons for rejection "after the fact" and determining the total number of films consumed.[7]

During early clinical experience with digital radiography (DR), it was proposed that this new technology might eliminate rejected images and render any RAP obsolete.[8] However, imaging departments quickly realized that this was not the case[9] and that a RAP was still a vital part of a QA program. In fact, DR has made rejected image analysis more complicated, and ironically, may facilitate the repetition of images owing to the ease of acquisition, especially with cassette-less systems where no manual intervention occurs between receptor exposure and image readout. Physical evidence of rejected images no longer exists for tallying, and on many early digital imaging systems, radiographers can simply delete unwanted images, which are ultimately never accounted for.[9,10] Even if deletion is not an option, rejected images often simply reside in the system until they are removed to free space for more images.

### 2.A. The continued need for rejected image analysis

The adoption of digital imaging, and specifically soft-copy interpretation, has forced radiology departments to develop innovative RAP. Early methods used for RAP included manual collection of data from acquisition stations,[11,12] manual tagging of rejected images by a QC radiologic technologist (RT),[10] manipulation of examination and demographic information in rejected images along with the use of routing tables to segregate rejected images,[9] and extraction of information from the Digital Imaging and Communications in Medicine (DICOM) header.[13] Most of these methods involved manual collection of data and were subject to similar problems, including lack of RT compliance,[9–11] intentional circumvention of the program,[10] accidental deletion of data,[12] and false negative or false positive results.[13] Recently, several studies have described sophisticated server-based RAPs that automatically collect, parse, and analyze data from many different acquisition systems spread throughout an institution.[14–17] This type of RAP avoids many of the difficulties associated with manual data collection and analysis.

It is likely that a number of causes have contributed to the demise of rejected image analysis in digital imaging departments, including a reduction in the number of images rejected owing to exposure errors, abandonment of programs owing to a perceived lack of need in digital imaging, the lack of physical evidence for collection, and the general difficulty of performing rejected image analysis on digital imaging systems, especially in high-volume departments. Whatever the reason for the abandonment of rejected image analysis, many authors have made clear the continued need for rejected image analysis programs.[9,14–16] Consider the fact that 281 000 000 projection x-ray examinations were performed in 2006 (Ref. 18) in the United States. These exams accounted for 73% of all radiographic and nuclear medicine procedures, excluding dental, and 11% of the total medical exposure to the U.S. population. Assuming conservatively a reject rate of 8%,[10–12,14,16,19] it is clear that repeated images are a large contributor to, and perhaps the number one cause of, undue patient exposure in projection radiography. A study of repeat rates among 18 radiology departments determined that 14% of patient exposure in projection radiography was due to repeated images.[19] These concerns are in line with the as low as reasonably achievable (ALARA) principle and are especially relevant in light of recent initiatives in the medical imaging community, including pay for performance,[20,21] image gently,[22] and image wisely.

### 2.B. Performing rejected image analysis

In digital radiography, the rejected image rate in its simplest form can be calculated as the ratio of the number of rejected images to the total number of images acquired. In screen-film imaging departments, the rejected image rate also includes wasted films,[23] which contribute to increased costs but not to increased patient exposure, the focus of this report. It is important to note that it may not be possible to identify and track images that are repeated but not rejected.

#### *2.B.1. Rejected image analysis in screen-film departments*

Radiology departments using screen-film receptors should abide by all of the recommendations outlined in this report, keeping in mind that thresholds for corrective action may require adjustment owing to the increased probability of exposure errors when using screen-film image receptors.

#### *2.B.2. Data collection*

Data should be collected daily if accessible remotely, otherwise it should be collected on a monthly basis to prevent accidental loss.

#### *2.B.3. Data analysis*

A RAP can be a powerful tool for practice improvement and QC, but only if the maximum amount of useful information is extracted from the available data. Simply calculating the overall rejected image rate is likely to be insufficient for identifying and correcting practice problems. After calculation of the overall rejected image rate, the data should be stratified by body part and view, clinical area, and technologist. Stratification of the data will allow for identification and correction of practice problems, including problematic views or struggling technologists. The ability to stratify rejected image rates into these categories would require the stratification of examination

totals, which is discussed in more detail later in this report. Collected data should be analyzed on at least a quarterly basis, but preferably on a monthly basis. Corrective action, when taken, should be documented as part of the rejected image analysis program. It is suggested that limits for corrective action be both positive and negative, e.g., for a target rate of 10%, investigation and possible corrective action would be triggered at ±2%, i.e., for a rate less than 8% or greater than 12%. This strategy considers the fact that abnormally low rejected image rates can signal poor compliance with the analysis program or acceptance of poor quality images.

#### 2.B.4. Corrective action

Corrective action should be taken when rejected image rates fall outside predetermined thresholds, which should be set by the administrator of the program in conjunction with a radiologist and the QC technologist. It is important to realize that rejected image rates will vary based on practice and setting. Differences in rejected image rates of a factor of three have been demonstrated between different types of hospitals.[24] One would expect a lower rejected image rate for a commonly performed view such as a PA chest as compared to a seldom-performed, technically challenging view such as facial bones, and this has been demonstrated.[14,16] The presence of trainees will also impact the rejected image rate. All of these factors must be considered when determining thresholds for corrective action.

A review of the literature revealed that repeated image rates hovered around 10% in screen-film departments, with approximately 45% of images repeated owing to exposure errors, which are expected to be greatly reduced in digital imaging.[9,11,12,23,25–27] Rejected image rates in digital departments have been reported to range from 4% to 8%.[10–12,14,16] Therefore, this task group recommends that 8% be used as a target for overall rejected image rate, and 10% as a threshold for investigation and possible corrective action. As mentioned previously, this rate should be adjusted to reflect the operator's clinical practice. Repeated image rates in pediatric imaging departments have been reported to be approximately 3%–5%,[7,9] and the task group recommends that a target of 5% be used in pediatric imaging, and 7% as a threshold for investigation and possible corrective action. When rejected image rates are stratified—for example, by technologist, view, or clinical area—the threshold for investigation and potential corrective action should be determined based on clinical practice. For example, target rates for trainees may be set higher than those for staff, or target rates for an area performing only chest radiography may be set lower than an area performing a variety of views.

The task group also recommends the adoption of a lower threshold rejected image rate for investigation and potential corrective action. An unusually low rejected image rate can signal poor compliance with the analysis program or acceptance of images with marginal or poor image quality. It has been proposed that there is a baseline repeat rate of 5%, below which radiographic quality is sacrificed and further reduction is not cost-effective.[9] This baseline number may be lower in digital radiography, as several authors have found rejected image rates of less than 3% in certain clinical areas.[11,14,16] As with the upper threshold for investigation and potential corrective action, the lower threshold should be set considering clinical practice, as some views or clinical areas may be characterized by lower than typical rejected image rates. The task group recommends that a lower threshold of 5% be used as a threshold for investigation and possible corrective action unless clinical data indicate this threshold should be lower.

#### 2.B.5. Record keeping

Rejected image rates, including stratified rates, if applicable, should be analyzed and documented at least quarterly, but preferably monthly, and kept for the greater period of one year or the length of time required by applicable regulatory agencies. Also, any corrective action taken in response to abnormally low or high rejected image rates should be documented, along with the results of the corrective action.

#### 2.B.6. Standardized reasons for rejection

Standardized reasons for rejection should be included in all RAP programs, and the option to add additional user-specified reasons should also be available. Standardized reasons for rejection should include the following:

1. Positioning
2. Exposure error
3. Grid error
4. System error
5. Artifact
6. Patient motion
7. Test images
8. Study canceled
9. Other

Also helpful would be the ability to subdivide the reasons listed above. As an example, suggested subdivisions of the standardized reasons are listed below.

1. Positioning
   a. Rotation
   b. Anatomy cutoff
   c. Incorrect projection
   d. Incorrect marker
2. Exposure error
   a. Overexposure
   b. Underexposure
3. Grid error
   a. Cutoff
   b. Decentering
   c. No grid
   d. Grid lines
4. System error
5. Artifact
   a. Detector
   b. Foreign object (jewelry, clothing, etc.)

c. Contrast media
d. Table/support/x-ray tube

6. Patient motion
7. Test images
8. Study canceled
9. Other

#### *2.B.7. Collection and storage of data*

Collecting certain data and demographic information is necessary for a RAP to be useful. Table I lists data that are required for a functional RAP ("required") and data that would make a RAP simpler and more useful ("optional"). For example, a technologist can be linked to a study via the accession number, but this requires that data from the radiology information system (RIS) be incorporated into the program, making the process more complex. A system that requires a technologist to log in or enter an ID before beginning a study, and links this information to that study, would be simpler.

Data should be stored locally in hard disk memory until downloaded by the program administrator, at which time it can be deleted. Data should be collected daily if accessible remotely, otherwise it should be collected on a monthly basis to prevent accidental loss. Also, data should be downloaded prior to any equipment service event to prevent its loss.

The calculation of rejected image rates also requires a denominator equal to the total number of images acquired during the analysis period. Ideally, this information would also be available on the acquisition station and would not require the information to be retrieved from the RIS. The ability to stratify the number of acquired images by body part and view would make the information more useful for rejected image analysis.

*2.B.7.a. Other useful information.* The inclusion of additional information not required in Sec. 2.B.7 is encouraged. Examples of additional information include examination of technical factors or downsized copies of rejected images stored in the local database. These images could be compared with the reason for rejection as a quality control measure on the rejected image analysis data. This feature itself could be further enhanced by the inclusion of the reason for rejection either as an overlay or burned into the pixel data. Such additional information adds value to the RAP and may be useful as an educational tool.

### 2.C. Access to data

After collection of data, the administrator of the RAP must be provided with access to the stored data. The data should be retrievable from the database in a suitably delimited, cross-platform format such as comma separated value (CSV) or extensible markup language (XML). In addition, the administrator should be able to select data from a specified date range for download or export. Implementation and administration of large-scale RAPs is very difficult if the only means to download data is external storage, e.g., CD or USB memory. Therefore, the task group strongly recommends that these data also be accessible remotely through hospital networks. This can be accomplished in several ways, including using file transfer protocol (FTP), shared folders, or digital dashboards.[28] Storing and providing data in this manner would facilitate server-based systems that collect, archive, and analyze RAP data from many different systems. This feature will be especially vital to participants in efforts such as the American College of Radiology's General Radiology Improvement Database,[29] which includes rejected image rates as one of its metrics. Information security and patient privacy must be carefully considered when making such data available over hospital networks. Information that is not accessible over hospital networks should be downloadable to USB or CD memory.

### 2.D. DICOM

It would be advantageous to use or modify an existing DICOM structure to accomplish the goals outlined in this report. It has previously been suggested that DICOM should be preferred owing to its wider acceptance by vendors.[30]

TABLE I. Data stored for rejected image analysis.

| Field | Function | Required/optional |
|---|---|---|
| Acquisition station/digitizer | Can identify specific stations with problems | Required |
| Accession number | Links study to technologist through RIS | Required |
| Exam date and time | Allows temporal sorting of data | Required |
| Body part | Allows sorting of data by body part | Required |
| View | Allows sorting of data by view | Required |
| Exposure indicators (EI)[a] | Allows exposure analysis/troubleshooting | Required |
| Reject category | Allows reject analysis | Required |
| Technologist ID | Alternative method of linking technologist and study | Required[b] |
| Reject comments | Further clarifies reason for rejection–free field | Optional |
| Technologist name | Allows sorting of data by technologist name | Optional |
| Technique factors | Troubleshooting | Optional |
| Thumbnail image | QC of reason for rejection | Optional |

[a]The target EI and DI should also be included, if available.
[b]Optional if separate user names are provided for each technologist who uses the system.

Two intriguing possibilities exist within DICOM: modality performed procedure step (MPPS) and the structured report (SR).

#### 2.D.1. MPPS

MPPS involves the transfer of information between a modality and another system, such as the RIS.[31] Typically, this transfer happens at the beginning and the end of a procedure, but it may also occur after each image instance is created. Information passed may include patient demographics and information about events that occurred during the procedure. Fields for additional information such as radiation dose exist currently in the MPPS report. Data for rejected image analysis could be included by altering the MPPS report to include fields for the total number of images acquired, the number of images transferred to picture archiving and communications system (PACS)/permanent storage, and the body part and view for each image acquired. This information would be sent to RIS or another selected system upon the conclusion of the study. The information could be extracted from RIS and analyzed, or analyzed in RIS, depending on the level of sophistication of the RIS. MPPS may not be ideal as a vehicle for rejected image analysis, however, owing to its lack of widespread use and difficulty in achieving system-wide integration.

#### 2.D.2. DICOM SR

Radiation dose information generated during computed tomography[32] and fluoroscopy[33] procedures has been incorporated into a DICOM SR. A SR could be used to log and store information essential to the performance of rejected image analysis. For example, an instance could be created for each image acquisition, and would include information such as body part, view, and image archival status at the conclusion of the study. In addition, the SR would contain data on both archived and rejected images. The format of the SR could be designed to make extraction of useful information as simple as possible. It is likely that analysis software would be developed that would facilitate analysis of the data, and that current RIS vendors would adapt their systems to include features for analyzing rejected image data, if a rejected image analysis SR was defined.

## 3. EXPOSURE ANALYSIS

The end goal of any projection radiography study is to produce an image that is suitable for interpretation by a radiologist, i.e., a *diagnostic* image. A diagnostic image must necessarily possess several qualities, including proper patient positioning, a lack of significant artifacts, and the appropriate exposure to the image receptor. The European Commission has published guidelines on what constitutes a quality projection radiograph.[34] Achieving the appropriate exposure to the image receptor is quite challenging in screen-film imaging. Patients span a wide range of sizes and shapes, and film has narrow exposure latitude within which adequate contrast can be generated. A film provides immediate feedback about the nature of the exposure—a dark film indicates an overexposure, while a light film indicates an underexposure. A film that is sufficiently under- or overexposed lacks contrast and must be repeated, and appropriate corrective action can be taken based on the appearance of the film.

Digital radiography, on the other hand, provides both benefits and drawbacks for patient dose and image quality, particularly related to image receptor exposure. The much wider dynamic range of digital image receptors is more forgiving of exposure errors, and images can be produced with a wide range of receptor exposures, spanning three to four orders of magnitude. Lack of attention to this wide dynamic range gives rise to a phenomenon known as *dose creep*.[35,36] Because the final grayscale appearance of a digital image bears little relationship to the exposure delivered to the image receptor, overexposed images are difficult to identify and, in fact, are more pleasing to radiologists owing to reduced noise levels compared to properly exposed images. *Exposure indicators* (EI)[37–39] were introduced in an attempt to combat dose creep and reverse the trend. An EI provides feedback to the operator about the exposure used to create the image and, in some cases, how the receptor exposure relates to the target exposure. If displayed on a PACS or overlaid on a printed film, the EI provides feedback to the radiologist and facilitates radiologist oversight. The EI is also indirectly related to patient dose.

### 3.A. Assessing patient dose in digital radiography

From a QC perspective, radiation dose resulting from radiographic imaging can be considered in one of several different ways. Routine quality control tests performed on an annual basis—such as measuring x-ray output, half value layer (HVL), and assessing automatic exposure control (AEC) calibration—provide some information that relates to patient dose. However, these tests provide no information about typical or actual patient doses.

A second way to gather information about patient dose is to measure patient doses for specific examinations. Phantoms representing specific body parts, specific patient sizes, and specific radiographic projections are available for this purpose.[40–43] These phantoms can be used to perform measurements in standard geometries[40] under AEC or using manual exposures. Quantities of interest include the incident air kerma ($K_{a,i}$) and the air kerma-area product ($P_{KA}$).[44] Drawbacks, including the fact that such phantoms are bulky, may not accurately represent a "normal" patient considering the increase in average patient size in the United States,[45] and that the number of patient body parts, sizes, and radiographic views represented by existing phantoms cover only a small fraction of the possible combinations. Patient doses resulting from manual exposures can be calculated for any size patient based on known technical factors, including kVp, mAs, any added filtration, and source-to-image distance (SID) using measured data, including x-ray output, as a function of kVp and the HVL. These dose metrics can also be used to estimate effective dose ($E$) through the application of conversion factors[46–48] or by using commercially available software such as PCXMC, a Monte

Carlo program for calculating patient doses in medical x-ray examinations.[49]

While measuring or calculating "typical" doses on a regular basis is useful, one might be more interested in examining actual patient doses throughout the year so corrective action can be taken quickly when problems are identified. However, frequent use of the techniques discussed thus far is not practical, as a QMP (Ref. 50), whose expertise is required to make such measurements, may not always be available. The advent of digital radiography initiated a rapid increase in the amount of information available that is related to an imaging study. The National Electrical Manufacturers Association (NEMA) and American College of Radiology (ACR) DICOM standard has been the driving force in the availability and standardization of much of this information, and the International Electrotechnical Commission (IEC) and the American Association of Physicists in Medicine (AAPM) have also played major roles in this effort. Several metrics can be used to perform ongoing exposure analysis in projection radiography, and these are discussed in Secs. 3.A.1–3.A.3.

### 3.A.1. The EI

An EI for digital radiography has been described independently by the IEC (Ref. 39) and AAPM Task Group 116.[37,38] Details regarding the implementation of each EI can be found in the respective references. The IEC implementation of the EI is the one most likely to be adopted by manufacturers of digital radiography equipment. Therefore, this report will use the IEC definition of the exposure indicator throughout.

The EI is widely available and is in the process of being standardized as vendors implement the IEC standard. With this standardization, meaningful comparisons can be made between different equipment, including equipment from different manufacturers. Although the EI describes the dose to the image receptor, which is only indirectly related to patient dose, meaningful QC can still be performed despite this limitation.[16,52,53]

The EI provides an indication of the exposure to the image receptor and a deviation index (DI) that compares the indicated receptor exposure to the target exposure. This allows radiologic technologists to make adjustments to technical factors for repeated images, and it will also allow for determination of the approximate image receptor dose for each radiograph. While the relationship of receptor dose to patient dose depends strongly on kVp, patient size, x-ray field size, and other factors, the DI will indicate the appropriateness of the receptor dose and, therefore, can be used to identify dose creep. This use of the DI for this purpose requires that the target exposure is both known and appropriate for the examination. DICOM correction item 1024 contains specifications for the "Exposure Index Macro" to be included in the DICOM header of digital radiography images.[51]

### 3.A.2. DICOM dose information

The DICOM radiation dose information module,[54] which is part of the DICOM header, contains data that can be used to estimate the patient dose resulting from a projection radiograph. The availability of this information may vary from vendor to vendor, and perhaps vary even within the same product line or different software versions from the same vendor. The configuration of the radiographic equipment also impacts the availability of such information. For example, a digital radiography system in which the generator is fully integrated with the imaging system will be capable of populating certain fields in the radiation dose information module related to the technical factors used, while a cassette-based computed radiography system in which the generator and other x-ray-producing equipment are completely separate from the imaging system will be incapable of automatically populating the same fields.

*3.A.2.a. Entrance dose.* The "Entrance Dose" [tag (0040,0302)] or "Entrance Dose in mGy" [tag (0040,8302)], as specified in the DICOM radiation dose module,[54] refers to the air kerma at a fixed location resulting from a radiographic exposure. While this value is more closely related to patient dose than the EI, sources of inaccuracy remain, primarily in determining the location of the entrance surface of the patient with respect to the location at which these metrics are reported. The incident air kerma ($K_{a,i}$) decreases with the inverse square of the distance between the focal spot and the entrance surface of the patient. If the fixed location used to report the $K_{a,i}$ is located at the entrance surface of the patient, this quantity may represent patient exposure. However, to the extent that the entrance surface of the patient deviates from the fixed location at which the $K_{a,i}$ is reported, the estimate will be inaccurate. In addition, the $K_{a,i}$ does not completely describe the radiation dose to the patient because changes in the x-ray field size also cause variations in the radiation dose delivered to the patient, even for the same $K_{a,i}$.

*3.A.2.b. Kerma-area product (KAP).* The "Image and Fluoroscopy Area Dose Product" [tag (0018,115E)], as specified in the DICOM radiation dose module,[54] refers to the product of the x-ray field size and the air kerma. This quantity is more commonly referred to as the dose area product (DAP), KAP, or air kerma-area product ($P_{KA}$).[44] This tag can be populated with either a calculated value of $P_{KA}$ or a measured value of $P_{KA}$. A $P_{KA}$ meter can be installed on the collimator of most radiographic systems to facilitate measurement of the $P_{KA}$. The $P_{KA}$ meter will report measured $P_{KA}$ values, but the inclusion of these values in the DICOM radiation dose information module still depends on the system architecture, as discussed in Sec. 3.A.2. $P_{KA}$ can also be calculated by multiplying the measured or calculated air kerma at some point along the central ray by the measured or calculated x-ray field size at the same point. $P_{KA}$ is a desirable quantity for ongoing exposure analysis for several reasons. First, $P_{KA}$ is invariant along the x-ray source-image receptor axis, therefore the $P_{KA}$ is known at the precise location of the entrance surface of the patient. Second, the $P_{KA}$ accounts for all factors influencing the amount of radiation striking a patient during a projection radiography examination—namely, the output from the x-ray tube and the size of the x-ray field. For these reasons, $P_{KA}$ is the most desirable quantity for performing ongoing exposure analysis, as problems with both the equipment, such as low HVL or poor AEC calibration, and practice, such as improper

collimation, can be identified and corrected. The effective dose ($E$) can also be calculated from the $P_{KA}$ using published conversion factors.[47,48] Therefore, $P_{KA}$, if available, is the preferred quantity for performing ongoing exposure analysis.

*3.A.2.c. The DICOM SR.* Radiation dose information generated during computed tomography[32] and radiography/fluoroscopy[33] procedures has been incorporated into a DICOM radiation dose structured report (RDSR). The RDSR contains information that is useful for ongoing exposure analysis, including dosimetric quantities for both individual performed procedure steps as well as totals for an entire study. Ideally, the RDSR would be modified to include dose information for rejected or repeated images. A detailed description of the information contained in the DICOM RDSR can be found in DICOM Supplement 94.[33]

#### 3.A.3. Other sources of data

If none of the aforementioned data are available, other strategies can be used in an attempt to track patient exposures. One such strategy is to collect the technical factors used to acquire radiographic images, including kVp, mAs, and source-to-patient distance. The $K_{a,i}$ can be estimated from the technical factors used to acquire a radiograph by using a lookup table (LUT) created for each radiographic system using measured output values. Also, some manufacturers may display certain dosimetric quantities, some of which may be proprietary, on the acquisition workstation. A QMP can help in determining which of these quantities may be useful for ongoing exposure analysis.

### 3.B. Collecting dose information

The method(s) used to collect data for analysis will vary in complexity based on the end user. A small facility with a single radiographic system may choose to manually record dose information in a paper or electronic log, while large institutions distributed over several sites separated by long distances may choose to use a separate server to extract and archive dose information. Methods for collecting information are outlined in Secs. 3.B.1–3.B.6.

#### 3.B.1. Manual collection and recording of data

Manual collection of data is likely the most efficient method for a single site with few radiographic systems and no RIS. The radiologic technologist performing an imaging study can record selected dose metrics in a paper or electronic log at the imaging station. Manufacturers may display dose metrics other than the EI at the acquisition station. This facilitates manual collection of dose information by a radiologic technologist.

#### 3.B.2. Modality performed procedure step

Fields for radiation dose information exist currently in the MPPS report in a structure similar to the radiation dose information module. Data for exposure analysis are, therefore, already included in the MPPS report, and this information can be sent to the RIS or another network node upon the conclusion of the study. MPPS would be more useful for ongoing exposure analysis if dose information for rejected or repeated images was included in the MPPS data. MPPS may not be ideal as a vehicle for exposure analysis, however, owing to limited deployment, lack of widespread use, and difficulty in achieving system-wide integration.

#### 3.B.3. Use of the RIS to extract and archive data

If the DICOM RDSR is available, it can be sent directly to a server where dose data can be extracted, archived to a database, and sent to RIS via HL7. If MPPS is used to transfer dose information, such information can be sent to the RIS. The information could be extracted from the RIS, parsed, and analyzed, or it could be analyzed in the RIS, depending on the level of sophistication of the RIS. The RIS can also be used to assist in manual collection of exposure analysis data. Technologists may enter relevant data into designated fields within the RIS, where it will be stored in a database, facilitating extraction and analysis of data. However, manual data entry is not preferred, as it is prone to errors.

#### 3.B.4. Use of a separate server to extract and archive data

As an alternative to the use of a RIS to extract and archive dose information, a separate server can be configured as a network node on the hospital network. A DICOM storage process can be started on the server so that image data or radiation dose reports can be received from other DICOM network nodes. Image data can be sent in parallel to both the server and other necessary network nodes. Dose information can be extracted, parsed, and archived to a database on the server.

#### 3.B.5. Use of a commercial dose aggregation system

Recently, a number of commercial dose aggregation systems have been introduced to the market. These systems use one or more of the strategies discussed in this section. For example, they can be configured as a DICOM network node to which dose information, including secondary capture images or RDSR, can be archived and subsequently processed. Alternatively, DICOM query/retrieve can be used to download these same data that have been archived on a PACS system.

#### 3.B.6. Other methods

Manufacturers of radiographic equipment may provide alternative methods for extracting dose information. Most commonly, EI are recorded in a database for each exposure instance. These data can then be downloaded to external memory such as CD or flash memory for analysis.[16]

If manufacturers of radiographic equipment implement the radiation dose report, it is likely that analysis software would be developed that would facilitate analysis of the data, and

that current RIS vendors would adapt their systems to include features for exposure analysis.

### 3.C. Analysis of dose data and corrective action

Data collected as part of an ongoing exposure analysis program can be analyzed in many ways. Reference levels for specific radiographic views have been published,[34,55] and National Council on Radiation Protection Report 174 provides updated reference levels and achievable levels for specific radiographic views.[56] Also, some states have set upper limits on patient exposure for certain radiographic views.[57] However, if these limits are based on very specific patient dimensions, they may not be useful for ongoing exposure analysis. The National Evaluation of X-ray Trends (NEXT) through the FDA Center for Devices and Radiological Health (CDRH) collects and publishes information about doses for specific procedures on an annual basis.[58]

Median dose metrics should be compared to achievable levels when available. Comparisons of other descriptive statistical parameters can be made to normative datasets as they are published. Also, exposure data can be analyzed with control charts to identify special-cause variation, and the root causes of these instances can be investigated, documented, and corrective action taken, if necessary. Any cases exceeding diagnostic reference levels should be investigated, and the findings and any corrective action taken should be documented.

Stratification of exposure analysis data will likely provide additional information that is useful for quality control and quality improvement. Variations in patient exposures for the same body part and view may occur between technologists, radiographic equipment, or clinical area. Equipment or practice problems can be identified early, before they lead to the formation of habits. It was recently demonstrated that technologists adjusted their manual techniques over time in response to equipment that was poorly calibrated.[16] Also, specific technologists or certain radiographic views may be problematic, and additional training can be offered to improve patient care and operational efficiency.

This task group recommends that exposure analysis information be stratified by technologist, body part and view, and equipment or room so that maximum benefit can be derived from the data. Stratification by body part and view will also allow for comparison of exposure data to reference levels and regulatory limits. When stratifying data by body part and view, care must be taken to ensure that technologists are selecting the correct body part and view within the protocol selection interface. This task group recommends that exposure analysis data be analyzed monthly, and at a minimum quarterly. Longer intervals between data analysis provide more opportunity for patients to be overexposed and habits to be formed by technologists. Data should be maintained for the longer of a period of one year or that required by applicable regulatory agencies. Exposure data should be reviewed longitudinally over time to identify and correct dose creep if it is occurring. This task group recommends that one year's worth of data be viewed at a time, with the most recent month or quarter replacing the oldest month or quarter.

#### 3.C.1. Corrective action

Corrective action may be required if patient doses exceed reference or regulatory levels, or if certain technologists or equipment consistently deliver higher doses to patients for the same body part and view. Any corrective action taken, and the results of the corrective action, should be documented.

### 3.D. Quality control of dose metrics

Periodic QC should be performed on the dose metric(s) chosen for ongoing exposure analysis. The type of QC performed will depend on the chosen dose metric(s). For example, if an external KAP meter is used, the calibration of the meter should be verified on a routine basis by a QMP. Similarly, if a calculated $P_{KA}$ or entrance dose is used, this should be verified periodically. Finally, if the EI is used, its calibration should be verified periodically. Addressing these calibrations and QC methods is beyond the scope of this document. Guidelines for verifying the EI have been published by AAPM Task Group 116 (Refs. 37 and 38) in a report that is freely accessible, using a beam quality that is achievable by clinical medical physicists. This task group recommends that DAP meters used for exposure analysis meet the performance standards set forth by the International Electrotechnical Commission.[59]

## 4. ARTIFACT IDENTIFICATION

The radiologic technologist is the first person to view an acquired digital radiograph. The performing technologist, after deeming an image acceptable, may send the image to a QC technologist for further review. After reviewing the image for diagnostic quality—including proper patient positioning, appropriate exposure, and freedom from significant artifacts—the QC technologist sends the image to PACS and marks the study as finished so it appears in the queue of the reading radiologist. Considering the substantial and vital role played by the RT in this process, it is critical that he or she is trained in and comfortable with artifact identification and triage. The RT should be able to identify common artifacts in digital radiography and to follow a simple fault tree when an artifact is identified, including deciding whether or not to acquire further patient images prior to contacting the QMP or service engineer. A simple fault tree is provided in Fig. 1. The fault tree should identify the actors in the process as well as actions to be taken in the event of an image artifact, perhaps differentiated by artifact severity. The fault tree should be developed with input from a QMP. Appendix A of the supplementary material[60] contains images illustrating a variety of artifacts, some of which are unique to digital radiography.

### 4.A. Artifact check after detector calibration or detector drop

While artifacts are generally equally likely to appear at any time of the workday, two situations deserve additional attention—image receptor calibration and dropped detectors. Image receptor calibration may be performed either by a

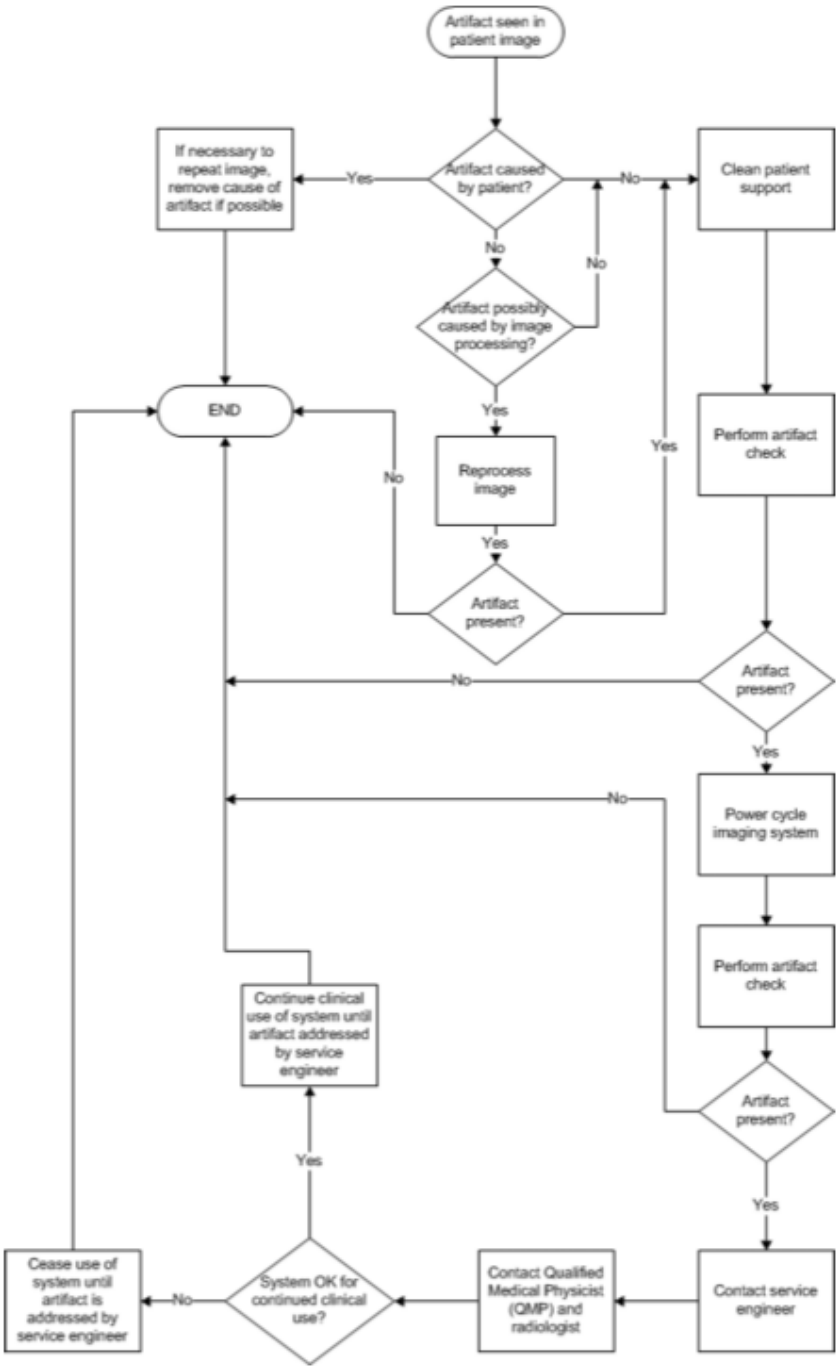


FIG. 1. Example fault tree for artifact troubleshooting.

member of the clinical technical staff (e.g., RT) or by in-house or OEM service engineers. A check for artifacts after calibration is important for two main reasons—the calibration files affect all future images acquired with the image receptor (until the next calibration), and detector calibration can "burn in" or make permanent (until the next calibration) any defects in either the x-ray production chain (e.g., collimator) or the image receptor itself. A check for artifacts after suspected damaged to the detector is important to verify proper functionality prior to patient use. In addition, many manufacturers

require detector calibration after a drop sensor is triggered. For these reasons, the task group recommends that the following check be performed immediately after detector calibration, a detector drop, or suspected damage to the detector, prior to the acquisition of patient images.

### 4.B. Protocol for performing artifact check

The steps in the protocol are as follows.

i. Acquire one image using the gain calibration conditions (kVp, mAs, added filtration) used by the manufacturer of the image receptor. If the gain calibration protocol is not known, the TG-116 EI calibration protocol may be used. If neither the gain nor EI calibration conditions are known, the default conditions described below can be used.
ii. Acquire a second image using one-half (0.5) of the mAs used in step 1, with the other conditions identical.
iii. Either the for processing images should be reviewed or a test image processing protocol that applies minimal image processing should be used to create for presentation images that will be reviewed. The window level (WL)/center should be set to the mean pixel value in the image as measured using a region of interest (ROI) placed in the center of the image. The window width (WW) should be set to 10% of the WL. For example, if the mean pixel value in the image is 500, the WW should be set to 50. Image analysis may be performed at the acquisition workstation or on PACS. The RT should evaluate both images carefully for both large-scale and small-scale nonuniformities, including grid lines, dead pixels, and dead lines. Evaluation of the image for small-scale nonuniformities should be conducted while viewing the image at acquisition size (1:1 detector pixel to display pixel ratio), which will require panning to view the entire image, and may require viewing the image on PACS.

#### 4.B.1. Configuring acquisition and image processing menus

Image acquisition and processing menus for performing the artifact check should be configured with input from the QMP and posted in the clinical area or installed on the acquisition station. Carefully labeling and saving the menus in a "Test" folder on the imaging equipment is preferred. The task group recommends that the exposure conditions listed in Table II be used if the gain and EI calibration conditions of the equipment manufacturer are unknown.

#### 4.B.2. Training staff to perform the artifact check

A sufficient number of RT staff should be trained such that a trained RT is always available, regardless of shift and vacation coverage. The training session should address acquisition of images, analysis of images, simple troubleshooting techniques, and it should include a review of the fault tree of actions to be taken if the artifact check produces unacceptable results.

#### 4.B.3. Troubleshooting

A toolbox of simple troubleshooting techniques should be provided to the trained RTs by the QMP. These techniques should include tests to isolate the cause of artifacts in flat field images to either the x-ray production equipment or image receptor. These techniques include looking for positive/negative duplications of artifacts [Fig. A29 (Ref. 60)]; rotating cassette-based image receptors or shifting the x-ray tube/collimator assembly or image receptor for cassette-less image receptors to cause movement of artifacts caused by the x-ray production equipment; and rotating the added filtration if the filtration is suspected to be causing artifacts.

## 5. TOOLS PROVIDED BY MANUFACTURERS

Many manufacturers of digital radiography equipment offer, in addition to software tools for performing rejected image and exposure analysis, hardware or software tools for performing QA of the imaging equipment itself. These tools may be provided with a digital radiography system at no additional cost, or they may be offered as an option at additional cost. Third-party companies may offer similar products. These QA tools are intended to identify deficiencies in the imaging equipment before they affect the medical image deliverable.

This task group evaluated QA programs from several manufacturers. While day-to-day variations in quality metrics were not observed, the programs did prove to be useful for long-term trend analysis. This task group recommends that QA programs provided by manufacturers at no additional cost be implemented, and that facilities consider purchasing QA programs provided at additional cost, or implement a similar program on their own.

One caveat to this recommendation is that the QA technologist will likely be the person responsible for performing

TABLE II. Default exposure conditions for artifact check.[a]

| kVp | mAs for exposure 1[b] | mAs for exposure 2 | Field of view | Anti-scatter grid | Added filtration |
|---|---|---|---|---|---|
| 70 | AEC center cell | 0.5 × mAs for exposure 1 | Fully expose detector | In | Filter provided by manufacturer for calibration (e.g., 20 mm Al). If no filter available, use suitable filter, e.g., 0.5 mm Cu. |

[a]Factors not explicitly listed (e.g., focal spot size) can be set however desired.
[b]QMP may program the reported AEC mAs (exposure 1) and mAs for exposure 2 into an acquisition menu after they are determined initially.

the manufacturer's QA program. It may be difficult to train the QA technologist to run programs requiring that specific measured exposures be made, e.g., exposing a plate to 1 mR for a particular test. While charts detailing technique factors to be used can be provided for this purpose, errors in these exposures may be a source of failure unrelated to the imaging equipment.

## 6. ADMINISTRATION AND OPERATION OF A QC PROGRAM

All personnel in a radiology department play a role in patient care, and they should also play a role in the ongoing QC process. A successful ongoing QC program requires the combined efforts of many clinical staff, including the radiologic technologist, the QMP, the radiologist, and department administrators. The roles of the QMP, QC technologist, and radiologist are outlined below.

### 6.A. Role of the QMP

The rejected image analysis and exposure analysis programs outlined in this report should be designed and implemented by a QMP in accordance with the recommendations in this report. The program should be set up with the cooperation of a radiologist and the QC technologist, including the installation of corrective action thresholds and decisions on how the data will be stratified and analyzed. The decision of which dose metric(s) to use and how they should be collected and analyzed should be coordinated by the QMP. The QMP should participate in the analysis process, including reviewing data and analysis on at least an annual basis, and be available for consultation regarding corrective action when necessary.

### 6.B. Role of the QC technologist

The QC technologist is the person responsible for the day-to-day operation of a QC program. The QC technologist should ensure that all technologists involved in the radiography practice understand their responsibilities in the process. The QC technologist should manage the data collection and analysis, keep records, and perform other necessary administrative tasks. The QC technologist should perform quality control on the selected reasons for rejection and notify the QMP and radiologist of any problems or anomalies in the process. The QC technologist should work with the QMP to implement suggestions for correcting malfunctioning equipment and practice problems.

### 6.C. Role of the radiologist

The radiologist is the person ultimately responsible for the quality of the imaging practice. Therefore, the radiologist should participate in the design of the QC program and be available for consultation with the QC technologist and QMP when problems or questions arise. The radiologist should participate in the analysis process and in the implementation of corrective action when necessary. The PACS system should be configured, if possible, to display the EI, $P_{KA}$, or other dose metric(s) used in the exposure analysis program as an overlay on patient images. This will allow the radiologist to contact the QC technologist when exceptional cases are identified. The ongoing role of the radiologist also includes identification of images of inadequate diagnostic quality that are archived to PACS instead of being rejected or repeated, as well as providing positive feedback where deserved. Tools for facilitating radiologist involvement in the QC process have been developed.[61]

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# Appendix III Infection Prevention and Control (IPAC) Position Statement on Medical Gels – December 2017

Last Accessed: February 2018

## POSITION STATEMENT

## Medical Gels

### Background

Medical gels* are used routinely in clinical practice during physician exams and diagnostic procedures. Contamination of medical gels from improper handling can result in serious health care associated infections such as bacteremia and septicaemia. [1-13]

*Medical Gels include ultrasound gels, lubricating gels, and medicated gels.

### Position Statement

*To provide for safe handling of medical gels, the following is recommended.*

1. INDICATIONS FOR PARTICULAR GELS

| Indication | Type of Gel | |
|---|---|---|
| | Sterile | Non-sterile |
| Whenever a biopsy, puncture of any kind, or imminent surgery is to be performed regardless of body site | √ | |
| Near a fresh surgical wound | √ | |
| Procedure penetrating mucous membrane | √ | |
| Endoscopies on intact mucous membranes | √ | |
| Non-endoscopic procedure on mucous membranes (e.g., vaginal/ rectal exam) | √ | |
| Non-intact skin | √ | |
| Intact skin | | √ |
| Babies in NICUs and critical pediatric patients [(11)] | √ | |

2. GENERAL CONSIDERATIONS

**a) Sterile gel:**

- Single use packaging is required for sterile gel as once opened, the contents are no longer sterile
- Sterile product should be used, employing the principles of asepsis

- Discard the opened package at end of procedure

**b) Non-sterile gels:**

- If multi-dose containers of non-sterile gel are used on intact skin, the container should be sealed correctly when not in use.[11]
- Dispensing nozzles must not come into direct contact with patients, staff, instrumentation, or the environment.[5]
- Non-sterile gel containers should never be topped up (i.e., refilled when partially empty).
- Containers of gel should never be washed and refilled for use but should be discarded when empty.[11]
- When a new bottle is opened, the bottle should be initialed by the opener, dated and discarded after 30 days or the manufacturer's expiry date if earlier.[5]
- Bulk containers of gel should not be used due to risk of contamination.

**c) Warming of Gel**

- Do not warm gel due to the increased risk of bacterial growth[12].
- Gels are generally stored at room temperature unless manufacturer's recommendations state otherwise.

**d) Storage of Gels**

- Products must be stored in clean areas where they are protected from sources of contamination such as moisture, dust, insects, etc.
- Discard the medical gel if in doubt about integrity.

This position statement was developed by Standards and Guidelines Committee:

Chair: Madeleine Ashcroft

Principal Authors: Clare Barry, Madeleine Ashcroft, Brenda Dewar, Colleen Lambert, Anne Augustin, Mary-Catharine Orvidas

**Original Date:** March 2003

**Reviewed/Revised:** March 2005, 2008, 2016, December 2017

**Glossary/Definitions**

**As per the Canadian Standard Association (CSA)**:
"SHALL" is used to express a requirement, i.e., a provision that the user is obliged to satisfy in order to comply with the standard;
"SHOULD" is used to express a recommendation or that which is advised but not required; and
"MAY" is used to express an option or that which is permissible within the limits of the standard, an advisory or optional statement.

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# Appendix IV Sample Emergency Safety Policy

Safety Training for all staff should be carried out. In addition, an emergency safety policy should be included in the policies and procedures manual. This appendix has been provided as a sample of what the policy may look like and include. Each policy must be site specific to the facility and may include but is not limited to the following areas:

**Employer Responsibilities *(in all incident cases):***

Provide first aid in accordance with the regulations.
Record first aid attention, adverse effects, incident report.
Assist to provide immediate transportation to the hospital, doctor, worker/patient's home, when/as necessary.

**Employee Responsibilities:**

*Acute Care Transfer*

Should a patient, visitor, and/or staff become ill while in the clinic the following is carried out:

1. Immediately, the technologist or clerical staff will alert the attending Radiologist of the problem.
2. In the event that the attending Radiologist is not available, contact a local GP (agreement should be made prior between facility and physician – contact numbers should be available for staff).
3. If the physician is not immediately available, call 911, identify yourself and request transfer to the nearest hospital.

*Fire Prevention and Control Plan*

1. All staff members employed at the facility is required to know the fire plan. To facilitate this, an annual review of the plan will be carried out and is mandatory for all staff members.
2. The fire plan is site-specific for the facility. Staff members are required to familiarize themselves with the plan for this location.
3. Each employee should have the ability to assess the situation quickly and initiate appropriate measures upon discovering a fire. This may vary from using a fire extinguisher to contain a fire or alerting others, evacuating the building and calling the fire department.

If you discover a fire in your area:

1. Remove patients from rooms and out of danger.
2. Turn off lights, any electrical equipment, gases, and close windows and doors.
3. Pull the alarm located closest to you.
4. Dial 911 and advise the Fire Department of the Emergency. Give them your name, location of the fire and type of fire to the communications operator (electrical, gas, other).
5. If possible (i.e. the fire is contained to a specific area) go back to the room and attempt to put out the fire using a fire extinguisher.

DO NOT ATTEMPT TO USE THE FIRE HOSE. Everyone should be removed from the office. Have a staff member positioned at the main corridor junction to direct fire fighters.

If you hear a fire alarm:

1. Collect all patients, visitors, and staff members in the facility and guide them to the closest exits.
2. DO NOT USE THE ELEVATOR. All staff members along with anyone in the office at the time of the evacuation alarm, must meet at a predetermined assembly point outside of the building.
3. Personnel will be requested to assist with duties such as checking the office before leaving ensuring that everyone is accounted for, turning off lights in the fire area, turning off gases (oxygen), turning off all electrical equipment and closing doors and windows.

*The First Aid Box*

As a minimum the first aid box should contain:

- A current edition of a first aid manual
- One card of safety pins
- Dressings, consisting of:
    - 12 adhesive dressings, individually wrapped
    - 4 sterile gauze pads, 3 inches square
    - 2 rolls of gauze bandages, 2 inches wide

# Appendix V Sample Referring Physician Survey

***Note: Surveys must be site specific.***

***Name of facility*** _____

Please answer the following questions regarding your experience with the above facility by filling in the blank or circling the number that best describes your answer.

**1. How long have you referred patients to this facility?**

**_____years or _____months**

*Please base your answers on your contact with the facility in the past 6 months.*

**2. How satisfied are you with how long it generally takes: (Please rate each item by circling the number that best describes your opinion)**

| | Not Applicable | Very Dissatisfied | Dissatisfied | Neutral | Satisfied | Very Satisfied |
|---|---|---|---|---|---|---|
| to get an appointment for a patient at this facility? | | 1 | 2 | 3 | 4 | 5 |
| to obtain written results (a written consultation) from this facility, | | 1 | 2 | 3 | 4 | 5 |
| once your patient is seen? | | | | | | |
| to get an oral report from this | | | | | | |
| facility when it is required because of an urgent or emergency | 0 | 1 | 2 | 3 | 4 | 5 |
| situation, once your patient is seen? | | | | | | |

**3. How often do you speak to a physician at the IHF regarding the patient's clinical condition before your patient receives a diagnostic work-up?**

Never Rarely Occasionally Sometimes Often Almost all the time

**4. Approximately how many patients have you referred to this facility in the past 6 months? _____(number of patients referred)**

**5. Do you refer your patients to more than one facility of this type?**

A. No *(if you circled No, please **skip to Question number 7**)* B. Yes

**6. What are the reasons you refer patients to this particular facility?** ***(Please circle all that apply.)***

a. Nearer Patient's home

b. Has specialized equipment needed for test requested

c. Turnaround time to receive the results is shortest

d. Has staff that speak other languages, and thus can better understand my patients

e. Is able to quickly see patients when feedback is urgently required

f. Has convenient hours of operation

g. Quality of the services provided

h. Other, please describe _____ ***Please skip to Question number 8.***

**7. What are the reasons you refer patients only to this facility?** ***(Please circle all that apply.)***

a. Only facility of its type in this community

b. Our group has a service contract with this facility

c. Facility is located near this practice and is thus convenient for patients

d. Has staff that speak other languages and thus can better understand my patients

e. Has specialized equipment needed for tests requested

f. Turn-around time to receive results is short

g. Nearest patients' homes

h. Is able to quickly see patients when feedback is urgently required

i. Quality of the services provided

j. Has convenient hours of operation

k. Other, please describe_____

**8. Have you been dissatisfied with a consult you received from this facility in the past six months?**

a. No b. Yes

**9. Please rate each item by circling the number that best describes your experience with the IHF based on your contacts in the last 6 months.**

| | Never | Seldom | Sometimes | Frequently | Usually |
|---|---|---|---|---|---|
| **The waiting period for a test to be done is long.** | **1** | **2** | **3** | **4** | **5** |
| **Requests for consultation are handled promptly.** | **1** | **2** | **3** | **4** | **5** |
| **The facility accommodates patients when the test is urgently required.** | **1** | **2** | **3** | **4** | **5** |
| **The interpreting physician is available to you for consultation.** | **1** | **2** | **3** | **4** | **5** |
| **This facility meets the needs of my patients whose first language is other than English or French.** | **1** | **2** | **3** | **4** | **5** |
| **The recommendations received are useful in patient management.** | **1** | **2** | **3** | **4** | **5** |
| **The recommendations are clearly stated.** | **1** | **2** | **3** | **4** | **5** |
| **The reports received are too wordy.** | **1** | **2** | **3** | **4** | **5** |
| **Reports of results are sent out in a timely fashion.** | **1** | **2** | **3** | **4** | **5** |
| **The consulting physician orders tests in addition to those you requested.** | **1** | **2** | **3** | **4** | **5** |
| **When tests are added the resulting recommendations add information important to patient care.** | **1** | **2** | **3** | **4** | **5** |
| **The interpreting physician's findings are generally consistent with your clinical findings.** | **1** | **2** | **3** | **4** | **5** |

If 2 (Yes), please explain: _____

_____

_____

10. **Overall, how satisfied are you with the contacts you have had with this facility in the past six months?**

Very Dissatisfied b. Dissatisfied c. Neutral d. Satisfied e. Very Satisfied

**Thank you for participating in this survey.** Please return the survey in the envelope provided.

Our address is:

_____

# Appendix VI Sample Patient Survey: Quality of Care

***Note: Surveys must be site specific.***

Please rate the following about your visit to this clinic in terms of whether they were poor, fair, good, very good, or excellent. Circle the number 1 for poor; 2 for fair; 3 for good; 4 for very good, and 5 if you felt it was excellent. If something doesn't apply to your visit or you don't have an opinion, please circle the number 8.

| ***Please rate each by circling the number that best describes your opinion*** | **Poor** | **Fair** | **Good** | **Very Good** | **Excellent** | **Not Applicable No Opinion** |
|---|---|---|---|---|---|---|
| **1. Waiting time: how long you had to wait to get an appointment at this clinic** | 1 | 2 | 3 | 4 | 5 | 8 |
| **2. Waiting time: how long you had to wait in the clinic waiting room for your appointment** | 1 | 2 | 3 | 4 | 5 | 8 |
| **3. Instructions: how well the clinic staff (doctors, receptionists, technologists etc.) told you how to prepare for the test(s) and what to expect both before and/or during the test(s)** | 1 | 2 | 3 | 4 | 5 | 8 |
| **4. Ease of getting information: willingness of clinic staff to answer your questions** | 1 | 2 | 3 | 4 | 5 | 8 |
| **5. Information you were given: how clear and complete the explanations were about any possible risks and complications of the test(s)** | 1 | 2 | 3 | 4 | 5 | 8 |
| **6. Concern and caring by clinic staff: courtesy and respect you were given, friendliness and kindness; how well clinic staff listened to what you had to say; how well the clinic staff understood what you thought was important** | 1 | 2 | 3 | 4 | 5 | 8 |
| **7. Safety and security: the provisions for your safety and the security of your belongings** | 1 | 2 | 3 | 4 | 5 | 8 |
| **8. Privacy: how well your privacy was considered, for example, type of gowns used, privacy while changing clothes** | 1 | 2 | 3 | 4 | 5 | 8 |
| **9. Instructions on leaving: how clearly and completely you were told what to do and what to expect when you left the clinic** | 1 | 2 | 3 | 4 | 5 | 8 |

| ***Please answer the following questions by circling 1 for Yes or 2 for No.*** | **YES** | **NO** |
|---|---|---|

| | | | | | | |
|---|---|---|---|---|---|---|
| **10. Were you told to leave the clinic before you felt ready to do so?** | | | | | **1** | **2** |
| **11. Did you have to visit a physician, walk-in clinic, emergency room, urgent care centre or hospital in the days following this service because your health got worse as a result of the service(s) received at the clinic?** | | | | | **1** | **2** |
| **12. Would you recommend the clinic to a friend or family member if they needed services that it provides?** | | | | | **1** | **2** |
| ***Please rate this item by circling the number that best describes your opinion*** | **Poor** | **Fair** | **Good** | **Very Good** | **Excellent** | **Not Applicable No Opinion** |
| **13. Overall quality of care: how you evaluate the services you received and the way you were treated** | **1** | **2** | **3** | **4** | **5** | **8** |

**14. If there were some things you could change about this visit to improve it, what would they be?**

Thank you for completing this survey. Please double check that you have answered all questions and then place the survey in the envelope provided. Your answers will be kept completely confidential.

Thank you again for your help!