



THE
COLLEGE
OF
PHYSICIANS
AND
SURGEONS
OF
ONTARIO

INDEPENDENT HEALTH FACILITIES

Clinical Practice Parameters and Facility Standards



Diagnostic Imaging – 5th Edition, August 2017

The College of Physicians and Surgeons of Ontario

Vision Statement

Quality Professionals, Healthy System, Public Trust

Our Mandate

Build and maintain an effective system of self-governance.

The profession, through and with the College, has a duty to serve and protect the public interest by regulating the practice of the profession and governing in accordance with the Regulated Health Professions Act.

Our Vision Defined

Quality Professionals, Healthy System, Public Trust.

Our new vision is the framework by which we organize ourselves.

It guides our thinking and actions into the future. It defines not only who we are, but what we stand for, the role we see for ourselves, our critical relationships, in what system we work, and the outcomes we seek.

Each component of our vision is defined below:

Quality Professionals – as a profession and as professionals, we recognize and acknowledge our role and responsibility in attaining at a personal, professional, and at a system-level, the best possible patient outcomes.

We are committed to developing and maintaining professional competencies, taking a leadership position on critical issues that impact the performance of the system, and actively partner to provide tools, resources, measurement, to ensure the optimal performance at all levels of the system.

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

- accessibility
- the interdependence of all involved
- measurements and outcomes
- continued sustainability

Public Trust – as individual doctors garner the trust of their patients, as a profession we must aim to have the trust of the public by:

- building positive relationships with individuals
- acting in the interests of patients and communities
- advocating for our patients and a quality system

Our Guiding Principles

Integrity, accountability, leadership and cooperation

The public, through legislation, has empowered the profession to regulate itself through the College.

Central to the practice of medicine is the physician-patient relationship and the support of healthy communities. As the physician has responsibility to the patient, the profession has the responsibility to serve the public through the health-care system.

To fulfill our vision of quality professionals, healthy system, public trust we will work to enhance the health of the public guided by professional competence and the following principles:

Integrity – in what we do and how we go about fulfilling our core mandate:

- Coherent alignment of goals, behaviours and outcomes;
- Steadfast adherence to a high ethical standard.

Accountability to the public and profession – we will achieve this through:

- An attitude of service;
- Accepting responsibility;
- Transparency of process;
- Dedicated to improvement.

Leadership – leading by proactively regulating our profession, managing risk and serving the public.

Cooperation – seeking out and working with our partners – other health-care institutions, associations and medical schools, etc. – to ensure collaborative commitment, focus and shared resources for the common good of the profession and public.

Independent Health Facilities

Clinical Practice Parameters and Facility Standards

Diagnostic Imaging 5th Edition – August 2017

First Edition, February 1995: **Members of the Diagnostic Imaging Task Force:**

Dr. David Hynes, Chair	Toronto
Dr. Isadore Czosniak	Toronto
Dr. Murray Miller	Toronto
Dr. Tim Richardson	Toronto
Dr. Shia Salem	Toronto
Dr. Harvey Shaul	Toronto
Dr. Harald Stolberg	Hamilton
Dr. James Davidson**	Hamilton

**Dr. James Davidson, one of the original Task Force members, contributed significantly to the initial work of the Task Force in the development of the parameters and standards. He resigned from the Task Force in September 1993.

Second Edition, July 2002: **Members of the Diagnostic Imaging Task Force:**

Dr. Margaret Sabine, Chair October 2000-February 2003	Puslinch
Dr. Colin McIver, Chair October 1993 to October 2000	Owen Sound
Dr. Barry Hobbs	London
Dr. Roberta Jong	Toronto
Dr. Donald Lee	London
Dr. Samuel Rabinovitch	Toronto
Dr. Giuseppe Tarulli	Etobicoke

Third Edition, November 2006 **Members of the Diagnostic Imaging Task Force:**

Dr. Nabil Bechai, Chair	Toronto
Dr. Pat Garces	Timmins
Dr. Alex Hartman	Toronto
Ms Joan Hatcher	Niagara-on-the- Lake
Dr. Erik Jurriaans	Hamilton
Dr. Paul O'Brien	Kingston
Dr. Mark Prieditis	Toronto
Dr. Lalitha Shankar	Toronto
Dr. Paul Voorheis	Barrie

Fourth Edition, July 2012 **Members of the Diagnostic Imaging Task Force:**

Dr. Paul Voorheis, Chair	Barrie
Dr. Isadore Czosniak	Toronto
Ms Heather Gillis	Mississauga
Ms Joan Hatcher	Niagara-on-the-Lake
Dr. Mark Prieditis	Toronto
Dr. Lalitha Shankar	Toronto
Dr. Ants Toi	Toronto
NT – Working Group Members	
Dr. Nan Okun	Toronto
Mr. John Lai	Mississauga

Fifth Edition, August 2017 Members of the Diagnostic Imaging Task Force:

Dr. Mark Prieditis, Chair	Toronto
Ms Sheena Bhimji-Hewitt	Toronto
Dr. Isadore Czosniak	Toronto
Mr. Jeff Frimeth	Toronto
Ms Annette Hornby	Toronto
Dr. David Jacobs	Toronto
Mr. John Lai	Mississauga
Ms Marlene McCarthy	Collingwood
Dr. Nan Okun	Toronto

Published and distributed by the College of Physicians and Surgeons of Ontario. For more information about the Independent Health Facilities program, contact:

Christine Grusys
Supervisor, Practice Assessment and Enhancement
College of Physicians and Surgeons of Ontario
80 College Street, Toronto, ON M5G 2E2

Toll free: 1-800-268-7096 ext. 261
IHF@CPSO.on.ca

Wade Hillier
Director, Quality Management Division
College of Physicians and Surgeons of Ontario
80 College Street, Toronto, ON M5G 2E2

Toll free: 1-800-268-7096 ext. 636
IHF@CPSO.on.ca

Table of Contents

Preface	i
Purpose of Clinical Practice Parameters	i
Role of the College of Physicians and Surgeons	i
Responsibilities of the College	ii
Updating this Document	iii
Radiology Guiding Principles.....	iii

VOLUME 1 FACILITY STANDARDS

1

Chapter 1 Staffing a Facility	2
1.1 Overview	2
1.2 Qualifications of Physicians Providing Diagnostic Services	2
1.3 Radiologists Involved in Interpreting Nuclear Medicine Examinations.....	3
1.4 Continuing Professional Development (CPD)	3
1.5 Quality Advisor	3
1.5.1 Role of the Quality Advisor	3
1.5.2 Duties and Responsibilities of a Quality Advisor	4
1.5.3 Quality Advisor Duty to Report to Director IHF	5
1.6 Medical Lead(s) for IHFs licensed by the MOHLTC for more than one service	6
1.7 Facility Lead for IHFs that Perform Mammography	6
1.7.1 Duties and Responsibilities of a Facility Lead for Mammography Quality Management Program (QMP)	6
1.8 Radiation Protection Officer	7
1.8.1 Duties and Responsibilities of the RPO	7
1.9 Medical Radiation Technologists	10
1.9.1 MRTs Performing Bone Mineral Densitometry	11
1.9.2 MRTs Performing Mammography	11
1.9.3 MRTs Performing Fluoroscopy	11
1.9.4 Duties and Responsibilities of MRTs	11
1.9.5 Continuing Professional Development for MRTs	13
1.10 Sonographers	13
1.10.1 Sonography Canada Credentials	15
1.10.2 ARDMS Credentials	16

1.10.3 Duties and Responsibilities of Sonographers	16
1.10.4 Continuing Professional Development for Sonographers	18
1.11 Medical Physicists	18
1.11.1 Duties and Responsibilities of Medical Physicists	19
Chapter 2 Facilities, Equipment and Supplies.....	20
2.1 Overview	20
2.2 Facilities, Equipment and Supplies	20
2.2.1 Endocavity Transducer Reprocessing (See Chapter 3)	20
2.2.2 Eye Wash Stations	21
2.3 Imaging Equipment Quality Control	21
2.3.1 Radiography	21
2.3.2 Fluoroscopy	24
2.3.3 Ultrasound	25
2.3.4 Mammography	26
2.3.5 Bone Mineral Densitometry	26
2.4 Radiologist Reporting Stations.....	26
2.5 Aging Equipment.....	26
Chapter 3 Policies and Procedures	28
3.1 Overview	28
3.2 Radiation Safety and Dose Reduction (ALARA Principles)	28
3.3 Developing Policies and Procedures.....	28
3.3.1 Facility	28
3.3.2 Facility Staff	29
3.3.3 Records and Communication/ Reporting & Privacy Principles	29
3.3.4 Diagnostic Services	29
3.3.5 Equipment Maintenance	30
3.3.6 Emergency Procedures and Safety Policies	30
3.3.7 Quality Management (See Chapter 5)	31
3.3.8 Infection Control	31
3.3.9 Equipment	31
3.3.10 At Risk Patients	38
3.3.11 Hand Hygiene	38
3.3.12 Personal Protective Equipment	38
3.3.13 Disposal of Sharps	38

3.3.14 Respiratory Infections	38
Chapter 4 Requesting and Reporting Mechanisms	40
4.1 Requesting Procedures	41
4.2 Overview	41
4.3 MRT/Sonographer Documentation	42
4.4 The Diagnostic Imaging Final Written Report.....	42
4.4.1 Report Attributes	43
4.4.2 Body of the Report	43
4.4.3 Procedures and Materials	44
4.4.4 Findings	44
4.4.5 Limitations	44
4.4.6 Clinical Issues	44
4.4.7 Comparative Data	44
4.4.8 Assessment and Recommendations	44
4.5 Standardized Computer-Generated Template Reports.....	45
4.6 Preliminary Report	45
4.7 Verbal or Other Direct Communication.....	45
4.8 Retention of Patient Records.....	46
4.9 Charges for Copying Patient Records (As Per MOHLTC Fact Sheet)	46
4.10 Retrieval of Images and Patient Information from another IHF/Institution	47
Chapter 5 Quality Management	48
5.1 Overview	48
5.2 Quality Management Program Goals	48
5.3 Providing Quality Care	49
5.4 Components of a Quality Management Program.....	49
5.5 Monitoring the Program	50
6.1 Overview	51
6.2 Quality Assurance	51
6.3 Physicians Involved in Nuchal Translucency Reporting.....	52
6.4 Sonographers Performing the 11 to 13 ⁺⁶ week scan.....	52
6.4.1 Nuchal Translucency Audit Curve	52
Appendix I Independent Health Facilities Act - Ontario Regulation 57/92.....	55
Quality Advisor and Advisory Committee.....	55

Standards	56
Records of Employees.....	56
Patient Records.....	57
Books and Accounts.....	58
Notices	59
Miscellaneous	59
Appendix II Ongoing Quality Control in Digital Radiography: Report of AAPM Imaging Physics Committee Task Group 151	61
Appendix III Infection Prevention and Control (IPAC) Position Statement on Medical Gels – January 2017 74	
Appendix IV Sample Emergency Safety Policy	77
Appendix V Fetal Ultrasound for Non-Medical Reasons – CPSO Policy Statement #4-10	79
Appendix VI Endocavity Transducer Reprocessing.....	82
Appendix VII Ultrasound Transmission Gel (USTG) Recommendations.....	84
Appendix VIII Sample Referring Physician Survey	85
Appendix IX Sample Patient Survey: Quality of Care.....	88
 VOLUME 2 CLINICAL PRACTICE PARAMETERS	 91
Chapter 7 Position Statement from the IHF Diagnostic Imaging Task Force.....	92
Practice Guidelines	92
Mammography - Breast Imaging	92
Referral Guidelines	92
Chapter 8 Routine Chest Radiography in a Primary Care Setting.....	93
 VOLUME 3 TELERADIOLOGY (PACS)	 95
OAR Teleradiology Practice Standard	96
CAR Standards for Teleradiology	105
ACR White Paper on Teleradiology Practice: A Report From the Task Force on Teleradiology Practice.....	111
CPSO Telemedicine Policy.....	122

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 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 and Long-Term Care (MOHLTC, Ministry), contribute to the College achieving its goals as stated in the College's Mission Statement. An important goal of the College is to promote activities which will improve the level of quality of care by the majority of physicians. The Independent Health Facilities (IHF) program helps reach this goal by developing and implementing explicit clinical practice parameters and facility standards for the delivery of medical services in Ontario, assessing the quality of care provided to patients, and as a result, promotes continuous quality improvement.

Purpose of Clinical Practice Parameters

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

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

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

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. Such updates will be mailed automatically to all relevant Independent Health Facilities. It is planned to issue new editions of the parameters and standards at intervals not greater than five years. The external review process will be repeated to validate the new parameters as they are developed.

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:

- 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, sonographers and clerical personnel available to meet the stated goals and objectives.
- Physicians must be licensed to practice in Ontario by the CPSO in order to refer to themselves as physicians or doctors in any setting relating to an IHF. Similarly, only sonographers registered with Sonography Canada or American Registry of Diagnostic Medical Sonographers (ARDMS) can call themselves sonographers in any setting relating to an IHF. In order to practise medical radiation technology in Ontario, a medical radiation technologist (MRT) must be registered with the CMRTO.
- The duties and responsibilities of all diagnostic imaging service staff are specified in job descriptions. They are kept up to date and on site.
- Quality Advisors, physicians, medical radiation technologists (MRTs), sonographers, and licensees review their legal obligations to obtain professional liability insurance. If it is not a legal requirement, obtaining professional liability insurance may be considered, as there is potential for liability issues in IHFs.
- Staff responsible for the sterilization and reprocessing of medical equipment must be adequately educated and trained. Please contact the College for an approved list of courses specific to reprocessing and sterilization.
- Staff obtains education in Workplace Hazardous Materials Information System (WHMIS) which is documented and maintained on-site for future review at the time of Ministry of Labour (MOL) inspections.
- Staff are educated in radiation safety legislation and policies and are familiar with and understand privacy, and confidentiality legislation and policies.
- At least one staff member with current Basic Cardiac Life Support (BCLS) certification is on site at all times during hours of operation. Documentation regarding BCLS certification is maintained on site. It is expected that the training includes being certified in both theory and hands-on components. To identify training courses, contact the Heart and Stroke Foundation of Ontario and/or St. John's Ambulance.

1.2 Qualifications of Physicians Providing Diagnostic Services

The physician is a member licensed to practice in Ontario by 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.

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 to request a change to their scope of practice.

1.4 Continuing Professional Development (CPD)

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

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

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

1.5 Quality Advisor

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

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

1.5.1 Role of the Quality Advisor

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

Each IHF licensee is responsible for operating the facility and providing services in accordance with the requirements of the IHFA. Pursuant to O. Reg. 57/92 under the *Independent Health Facilities Act (see Appendix I)*, “every licensee is required to appoint a Quality Advisor to advise the licensee with respect to the quality and standards of services provided in the IHF. The

Quality Advisor must be a **physician** who ordinarily provides insured services in or in connection with the facility and whose training enables him or her to advise the licensee with respect to the quality and standards of services provided in the facility”.

1.5.2 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 if the facility employs more than six full-time staff equivalents including the Quality Advisor; otherwise the QA Committee shall meet at least once a year. Regular agenda items should include: review of cases; policies and procedures; quality control matters on equipment; incidents, medical and technical 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, BCLS, etc. are current.
- Regular medical and technical staff performance appraisals.
- Patient and referring physician satisfaction surveys.

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

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

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

1.5.3 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.

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

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

1.7 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.***

1.7.1 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 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: *IHF's providing mammography services will be 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 (www.cancercare.on.ca/ocs/rcp/).*

1.8 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.

The following hyperlink refers to the minimum requirements RPOs must abide by, according to O. Reg. 543 (the X-ray Safety Code) made under the *Healing Arts Radiation Protection Act* (HARP Act): <https://www.ontario.ca/laws/regulation/900543>

However, if an RPO chooses to implement further facility safety policies as part of their duties and responsibilities, then it is at their discretion to do so. The ACR-AAPM RSO document <https://www.acr.org/~media/ACR/Documents/PDF/QualitySafety/Radiation%20Safety/ACRAAPM%20RSO%20Resources.pdf> contains numerous standards the RPO may choose to implement and these are presented below.

1.8.1 Duties and Responsibilities of the RPO

The OAR has recently published a paper outlining the roles and responsibilities of the RPO <https://oarinfo.ca/>.

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: <https://www.ontario.ca/laws/regulation/900543>

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, 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. The CPSO recommends the Qualified Medical Physicist (see definition in Section 1.11) with specialization in a Diagnostic Imaging related field for this task.

8. X-ray Room Shielding

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

Records related to shielding must 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.

Surveys must be performed after shielding is installed and as needed thereafter to assure that individual exposures do not exceed regulatory limits.

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 usually need only to be kept for three 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.

1.9 Medical Radiation Technologists

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

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

<https://www.cmrto.org/resources/publications/standards-of-practice>

Medical Radiation Technologists in the specialty of Radiography – MRT(R)

Radiography is the use of x-rays to produce images of parts of the body for the diagnosis of disease, trauma and congenital abnormalities. Medical radiation technologists registered in radiography (MRT(R)) may perform general x-rays, fluoroscopic examinations, angiography, mammography, bone mineral densitometry (BMD) and computed tomography.

It is recognized that some organizations and government agencies play a role in setting facility and equipment requirements, which may include establishing facility practice guidelines in, mammography and/or BMD. These guidelines may affect practice as an MRT in these facilities (i.e. there may be a requirement to obtain specific certification in the area of BMD and mammography). It is important to realize that if the standard set by a facility is lower than the CMRTO's Standards of Practice, members are required to adhere to the CMRTO standard.

1.9.1 MRTs Performing Bone Mineral Densitometry

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

MRTs responsible for performing BMD must successfully complete specific courses which fulfill the requirements of the OAR CBMD Facility Accreditation Program.

1.9.2 MRTs Performing Mammography

MRTs in the specialty of radiography performing mammography must have training in mammography either in his or her training curriculum or through special courses and which fulfill the CAR-MAP (Canadian Association of Radiologists - Mammography Accreditation Program) requirements.

1.9.3 MRTs Performing 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.

MRTs performing fluoroscopic procedures must have the knowledge, skills, judgement and training that comply with the facility policies, protocols and procedures.

1.9.4 Duties and Responsibilities of MRTs

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

- Adhere to the facility policies, procedure & protocols
- Perform all diagnostic imaging procedures as ordered by the authorized health professional and in accordance with the CMRTO standards of practice
- Perform quality control procedures as per facility policies & protocols
- Comply with any applicable privacy legislation such as the *Personal Health Information Protection Act*
- Comply with all relevant legislation e.g. *Health Care Consent Act*
- Adhere to all relevant provincial and federal legislation and guidelines governing the practice of the profession i.e. Standards of Practice, Code of Ethics and by-laws of the CMRTO
- Comply with the *Regulated Health Professions Act* pertaining to the prevention of sexual abuse and the CMRTO's sexual abuse prevention program
<http://www.health.gov.on.ca/en/pro/programs/hhrs/about/rhpa.aspx>
- Provide ethical, competent and compassionate care in each patient/client interaction

- Use appropriate aseptic techniques and infection control procedures in the course of the diagnostic or therapeutic procedure
- Maintain full records of incidents, unusual occurrences, reactions as per site policies & protocols etc.
- Record and report any equipment faults or problems to appropriate personnel, as per site policies & protocols

Patient Examination:

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

Throughout the Examination:

- 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 him/her and why.
- Maintain patient comfort, privacy and dignity at all times
- Stop procedure if at any time the patient withdraws consent (Record withdrawal of consent & reason)
- Use radiation protection devices and other patient protection devices as required, and record
- Utilize personal protection devices as required (masks/gloves etc.) and as indicated
- 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

- 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
- Ensure that the orientation of the body and other pertinent parameters are marked correctly on the image and data
- Ensure the exposure is recorded and provides diagnostic image quality while using minimal radiation. (ALARA) 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#, date of examination and type of examination
- Each patient record has the MRT identifier to verify who performed the examination
- Keep all patient information confidential except when necessary to facilitate diagnosis or treatment of the patient, or when legally obliged or allowed to disclose such information. Comply with any applicable privacy & confidentiality legislation such as the *Personal Health Information Protection Act* (Ontario)

1.9.5 Continuing Professional Development for MRTs

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

1.10 Sonographers

The College of Medical Radiation Technologists of Ontario (CMRTO) has received Ministerial direction to regulate diagnostic medical sonographers, commencing January 2018.

Requirements for sonographers will change. Please refer to the CMRTO website for updates at www.CMRTO.org

Sonographers must have credential certification by Sonography Canada or the American Registry of Diagnostic Medical Sonographers (ARDMS).

Sonographers should only practice in their credentialed field: Practice parameters are posted for:

- Sonography Canada <http://www.sonographycanada.ca>
- ARDMS <http://www.ardms.org> (Practice parameters are not posted)

Sonography Canada has three full credential categories for sonographers (see Table on next page):

- CRGS – Canadian Registered Generalist Sonographer
- CRCS – Canadian Registered Cardiac Sonographer
- CRVS – Canadian Registered Vascular Sonographer

Sonography Canada also has limited credentials (see Table).

Sonographers are recommended to maintain active membership with Sonography Canada or ARDMS. It is strongly recommended that sonographers obtain professional liability insurance.

It is recognized that sonographers' post-graduation from a program may be in the process of pursuing the academic credentialing exams while working at a clinical site. In this case, the sonographers must be supervised by a credentialed sonographer who is qualified in that credentialed field. Following successful completion of the credentialing exam, proof of the credential(s) must be provided to the Quality Advisor.

1.10.1 Sonography Canada Credentials Full and limited credentials are described below

National Competency Profiles (NCPs) were updated in 2013 that define the sonographic competencies required of this credential (retrieved from <http://www.sonographycanada.ca/Apps/Sites-Management/FileDownload/DataDownload/10641/Announcement%20-%20Changes%20to%20Credential%20Names%204%20Mar%2014/pdf/1/1033> on march 27,2017 and checked with SC office)

SONOGRAPHY CANADA Full Credentials		Sonographic Practice Parameters as defined in the National Competency Profile V.5 (2013 rev 2015) <i>Each subject area level of knowledge is as described in NCP 5.0 Appendixes</i>
Canadian Registered Generalist Sonographer (CRGS®)	Entry level competence in	<ul style="list-style-type: none"> • Abdomen • Obstetrics • Gynecology • Superficial Structures (Breast, Thyroid, Scrotum) • Carotid Arteries Doppler • Musculoskeletal • Lower Extremity Venous Doppler
Canadian Registered Vascular Sonographer (CRVS®)	Entry level competence in	<ul style="list-style-type: none"> • Vascular (including physiological testing)
Canadian Registered Cardiac Sonographer (CRCS®) Effective May 1st, 2014 All CRCS credentials that recognize either adult echo or pediatric echo will use only the letters AE and PE respectively.	Entry level competence in	<ul style="list-style-type: none"> • Adult Echo
Limited Credentials		
Canadian Registered Sonographer (CRS) Effective May 1st, 2014		<i>Each subject area level of knowledge is as described in NCP 5.0 Appendixes</i>
Canadian Registered Sonographer (CRS-AB)	Entry level competence in	<ul style="list-style-type: none"> • Abdomen • Superficial Structures
Canadian Registered Sonographer (CRS-OG)	Entry level competence in	<ul style="list-style-type: none"> • Obstetrics • Gynecology
Canadian Registered Sonographer (CRS-NE)	Entry level competence in	<ul style="list-style-type: none"> • Neurosonology
Canadian Registered Sonographer (CRS-AB/OG)	Entry level competence in	<ul style="list-style-type: none"> • Abdomen • Obstetrics • Gynecology
Canadian Registered Cardiac Sonographer (CRCS-AE)	Entry level competence in	<ul style="list-style-type: none"> • Adult Echo
Canadian Registered Cardiac Sonographer (CRCS-PE)	Entry level competence in	<ul style="list-style-type: none"> • Pediatric Echo

1.10.2 ARDMS Credentials (retrieved from <http://www.ardms.org/get-certified/Pages/default.aspx> on March 28, 2017)

ARDMS	Registration	Practice parameters as per credential
Registered Diagnostic Medical Sonographer® (RDMS®)	To earn a Registered Diagnostic Medical Sonographer (RDMS) credential with an AB specialty, you must pass the Sonography Principles & Instrumentation (SPI) examination and the AB examination within five years. You can then challenge the other speciality exams to obtain more credentials	<ul style="list-style-type: none"> • Abdomen (AB)- includes Thyroid & Scrotum • Breast (BR) • Fetal Echocardiography (FE) • Neurosonology Registrant • Obstetrics and Gynecology (OB/GYN) • Pediatric Sonography (PS)
Registered Diagnostic Cardiac Sonographer® (RDCS®)		<ul style="list-style-type: none"> • Adult cardiac
Registered Vascular Technologist® (RVT®)		<ul style="list-style-type: none"> • Vascular including physiologic testing
Registered Musculoskeletal™ Sonographer (RMSKS™)		

1.10.3 Duties and Responsibilities of Sonographers

Sonographers are responsible for competent practice (as defined by the Sonography Canada most updated National Competency profile for entry to practice Sonographers), adhere to the Professional Practice Guidelines (as defined by Sonography Canada) and their facility protocols in each examination that they conduct, the day-to-day operations of the facility (see as per the posted professional practice guidelines for information:

http://www.sonographycanada.ca/Apps/SitesManagement/FileDownload/DataDownload/41148/SC_ProfessionalPractice%20Eng%20Final%20copy%20October%202015/pdf/1/1033

These responsibilities include, but are not limited to the following:

- Adhere to the facility policies, procedure & protocols
- Perform all diagnostic imaging procedures as ordered by the authorized health professional
- Perform quality control procedures as per facility policies & protocols
- Comply with any applicable privacy & confidentiality Acts/legislation, e.g. *Personal Health Information Protection Act (Ontario)*
- Comply with all relevant legislation e.g. Health Care Consent Act
- Meet Sonography Canada, AIUM and CAR practice standards
- Comply with the *Regulated Health Professions Act* pertaining to the prevention of sexual abuse -
<http://www.health.gov.on.ca/en/pro/programs/hhrs/about/rhpa.aspx>
- Provide ethical, competent and compassionate care in each patient/client interaction
- Use appropriate aseptic techniques and infection control procedures in the course of the diagnostic or therapeutic procedure

- Maintain full records of incidents, unusual occurrences, reactions as per site policies & protocols etc.
- Record and report any equipment faults or problems to the appropriate personnel as per site policy & protocols

Patient Examination:

- 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 authorization is present)
- Confirm that the order is appropriate based on the patient history
- Ensure that the worklist contains the correct patient information (if applicable)
- Obtain informed consent (oral or written as per facility policy) before each examination (after explaining the procedure & answering any questions)
- Obtain pertinent clinical history from the patient and record on the technical impression worksheet.
- Obtain and record any pertinent lab data or imaging exams and record on the technical impression worksheet
- Inquire about & record any contraindications to the examination - record on the technical impression worksheet (e.g. allergies to latex) and elsewhere as per facility policy
- Follow the facility examination protocols to conduct the ultrasound examination
- Ensure that all sonographic images are diagnostic and have appropriate annotation (as per site protocols)
- Write a technical impression as per site protocol
- Follow facility protocols to refer any emergency findings i.e. appendicitis, ectopic pregnancy etc.

Trans vaginal/Endocavity Ultrasounds (including the criteria above)

- Ensure sign-off on the delegated act when performing endocavity exams
- Ensure appropriate delegations & appropriate knowledge, skills and judgement are in place for all examinations including transvaginal/ endocavity procedures
- Obtain informed consent before each examination (after explaining the procedure & answering any questions)
- Latex Allergies must be documented on the technical impression worksheet (site protocol followed in case of allergies) & non-latex transducer covers must be utilized
- Transvaginal transducer ID number (individual to each transducer) must be identified on the technical impression worksheet/reprocessing sheet
- Post appropriate signage to restrict access and offer patient privacy during the exam

- Instruct the patient to only expose the area to be scanned. Maintain maximum coverage for patient comfort and dignity at all times
- Upon Exam completion follow Provincial Infectious Diseases Advisory Committee (PIDAC) or manufacturers guidelines for transducer cleaning

Throughout the Examination:

- Assess the patient's condition before, during and after the procedure or course of treatment
- Obtain informed consent
- Stop procedure if at any time the patient withdraws consent (Record withdrawal of consent & reason) on the technical impression worksheet)
- Maintain patient comfort, privacy and dignity at all times
- Instruct the patient to expose the area to be scanned, maximize covering of patient's anatomy. Explain to the patient when and where the Sonographer may touch him/her and why (e.g. during reactive maneuvers such as augmentation of calf)
- Utilize personal protection devices as required (masks/ gloves etc.) as indicated.
- Ensure that patient examination images and data contains patient name, ID#, date of examination and type of examination and number of images
- Each patient record (including the technical impression worksheet) must include the performing Sonographers name
- Keep all patient information confidential except when necessary to facilitate diagnosis or treatment of the patient, or when legally obliged or allowed to disclose such information. Comply with any applicable privacy & confidentiality legislation such as the *Personal Health Information Protection Act* (Ontario)

1.10.4 Continuing Professional Development for Sonographers

Sonographers are members of their national and/or provincial professional organization.

Continuing Professional Development is mandatory and must be consistent with the requirements of the certification body (Sonography Canada / ARDMS)

1.11 Medical Physicists

The use of a Qualified Medical Physicist as a consultant is encouraged.

A Qualified Medical Physicist is an individual who is competent to practice independently in one or more of the subfields in medical physics. The Qualified Medical Physicist must be certified in the appropriate subfield(s) by the American Board of Radiology (ABR), the Canadian College of Physics in Medicine, or by the American Board of Medical Physics (ABMP).

The appropriate subfield of medical physics for this document is Diagnostic Medical Physics. (Previous medical physics certification including Radiological Physics, Diagnostic Radiological Physics, and Diagnostic Imaging Physics are also acceptable.

Qualified Medical Physicists meeting this definition may be found by using the National QMP Registry on the CRCPD (Conference of Radiation Control Program Directors) website (<http://qmp.crcpd.org/>).

1.11.1 Duties and Responsibilities of Medical Physicists

While there are currently no legal requirements in Ontario for a Qualified Medical Physicist to be a part of a facility's QC program, as mentioned above, facilities are encouraged to at least seek out a Qualified Medical Physicist as a consultant. Consultation with a Qualified Medical Physicist may vary, but could prove beneficial regarding XRIS plan submissions and semi-annual HARP compliance evaluations. Furthermore, the Qualified Medical Physicist may assist the facility's Quality Advisor regarding, but not limited to, the following:

- a) QC program implementation (beyond minimum HARP compliance evaluations)
 - a. HARP does not refer to any image quality evaluations
- b) Dose management
 - a. Working with a facility's radiologist(s) and MRT(s) regarding achieving necessary image quality while balancing the patient radiation exposures
- c) Patient Dose/Risk Estimations
 - a. The physician, being knowledgeable about the benefit of a procedure, combined with the Qualified Medical Physicist being knowledgeable about the radiation risk of a procedure, may be necessary when overexposures are made within a facility
- d) Specifications for Equipment Purchasing
 - a. Image acquisition equipment (e.g. general radiography, display monitors)
 - b. PACS procurement (e.g. understanding compatibility between modality and PACS)

The CCPM certified mammography physicist is required to sign off on the final medical physics report, as per CAR-MAP for mammography. There are no requirements for who could be delegated by the mammography physicist to perform the survey. The CPSO suggests that the delegate strongly be encouraged to be a Qualified Medical Physicist (as defined above) with having met at least the following:

- Conducted at least 2 mammography facility surveys
- Conducted at least 6 mammography unit surveys

These surveys must be done under the supervision of a CCPM certified mammography physicist.

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.

2.2 Facilities, Equipment and Supplies

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

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

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

- Fire extinguisher
- SDS information
- First Aid Kit

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 dosimetry 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.

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

Basic supplies for infection prevention and control are on site and used appropriately as per current provincial guidelines/policies. Resources are available through the **Provincial Infectious Diseases Advisory Committee** of Public Health Ontario at <http://www.publichealthontario.ca/en/BrowseByTopic/InfectiousDiseases/PIDAC/Pages/Infection-Prevention-and-Control-for-Clinical-Office-Practice.aspx>

2.2.1 Endocavity Transducer Reprocessing (See Chapter 3)

2.2.2 Eye Wash Stations

IHF's must ensure that an emergency eyewash station is available for its employees as per WHMIS requirements. <http://hc-sc.gc.ca/ewh-semt/occup-travail/whmis-simdtut/index-eng.php>

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

- Activating within 1 second or less.
- Flushing both eyes simultaneously.
- Delivering flushing "tepid" temperature fluid to both eyes of no less than 1.5L per min, (0.4 gpm) for 15 minutes.
- Providing hands-free operation.
- A softened water flow so the force does not drive contaminants into the optic system.

2.3 Imaging 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. Any issues found on any of these evaluations must be followed-up on in a timely manner.

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 on at least an annual basis for cracks, wear and tear.

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

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 processor cleaning, maintenance and monitoring (if applicable).
- screen contact testing.
- screen cleaning.
- repeat/reject analysis.

2.3.1.1 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 from 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 aspects to implement 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. SF imaging is largely self-policing in terms of receptor exposure, and under and overexposed films are included in the rejected image analysis process. Documentation should be available for review during an assessment.
- 3) Artifact identification: Artifacts are not eliminated when changing from 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 radiologic technologists and radiologists be knowledgeable to identify common digital imaging artifacts. In addition, radiologic technologists 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 radiologic technologist to review images be suitable for this task.
 - To be done 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 the appropriate individual, which might include a Qualified Medical Physicist, to initiate appropriate investigative or corrective actions.

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

The following parameters are encouraged for facilities to have performed. 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 XRIIS within 60 days of installation. However, we encourage that the acceptance testing be performed by a Qualified Medical Physicist and 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. This should be performed by the

Qualified Medical Physicist. This evaluation can be performed during one of the two semi-annual HARP evaluations.

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).

Minimum Evaluations Required:

<u>Acceptance Testing</u>	<u>Performance Evaluation</u>	<u>Routine QC</u>
HARP requirements	HARP requirements	Rejected Image Analysis
<p><i>Detector Uniformity and Artifact Analysis:</i></p> <p>CR: using 2-3 plates of each size or all plates if artifacts are found on the initially evaluated 2-3 plates.</p> <p>DR: one exposure per digital detector</p> <p>General Notes: Facilities may use manufacturer's phantom and procedure or appropriate substitute (the Qualified Medical Physicist can assist with this)</p>	<p><i>Detector Uniformity and Artifact Analysis:</i></p> <p>CR: using 2-3 plates of each size or all plates if artifacts are found on the initially evaluated 2-3 plates.</p> <p>DR: one exposure per digital detector</p> <p>General Notes: Facilities may use manufacturer's phantom and procedure or appropriate substitute (the Qualified Medical Physicist can assist with this)</p>	
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 https://www.acr.org/~media/ACR/Documents/PGTS/guidelines/Radiographic_Equipment.pdf.

2.3.2 Fluoroscopy

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

The following parameters are encouraged for facilities to have performed. 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 XRIIS within 60 days of installation. However, we encourage that the acceptance testing be performed by a Qualified Medical Physicist and 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. This should be performed by the Qualified Medical Physicist. This evaluation can be performed during one of the two semi-annual HARP evaluations.

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

Minimum Evaluations Required:

<u>Acceptance Testing</u>	<u>Performance Evaluation</u>	<u>Routine QC</u>
HARP requirements	HARP requirements	None
Detector Uniformity – using manufacturer’s phantom and procedure or appropriate substitute (the Qualified Medical Physicist can assist with this)	Detector Uniformity – using manufacturer’s phantom and procedure or appropriate substitute (the Qualified Medical Physicist can assist with this)	
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 [https://www.acr.org/~media/ACR/Documents/PGTS/guidelines/Fluoroscopic Equipment.pdf](https://www.acr.org/~media/ACR/Documents/PGTS/guidelines/Fluoroscopic_Equipment.pdf).

2.3.3 Ultrasound

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

All diagnostic ultrasound machines have a regular program of preventive maintenance and routine QA program. Preventive maintenance and inspection of the ultrasound equipment is conducted as per the manufacturer's recommendations. This will include regular checks using a tissue equivalent phantom as well as checks for adequacy of image recording.

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 (January 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 and it is recommended that a Qualified Medical Physicist perform this test 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. It is recommended that this be performed by the Qualified Medical Physicist.

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

Minimum Evaluations Required:

<u>Acceptance Testing</u>	<u>Performance Evaluation</u>	<u>Routine QC</u>
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 used clinically) - manufacturer's phantom and procedure or appropriate substitute (the Qualified Medical Physicist can assist with this)	Image Uniformity and Artifact Survey (for each transducer used clinically) - manufacturer's phantom and procedure or appropriate substitute (the Qualified Medical Physicist can assist with this)	
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 (<https://www.acr.org/~media/152588501B3648BA803B38C8172936F9.pdf>).

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

Equipment and Quality Control activities must meet Canadian BMD Accreditation Program (CBMD) requirements and be accredited by ISCD or CBMD by January 1, 2020. 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 it is acceptable to not perform the precision study. The Qualified Medical Physicist may assist with this. Please refer to the OAR website for freely available Shewhart and Precision calculators (<https://oarinfo.ca/cbmd/cbmd-overview>).

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. Equipment age should conform to the CAR guidelines for lifecycle guidance (see chart on next page). Under usual situation the mid- range should be appropriate. Only under exceptional circumstances should the maximum age (low utilization) be exceeded.

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.

For more information about the CAR standards for equipment lifecycle, please visit: http://www.car.ca/uploads/standards%20guidelines/CAR-LifecycleGuidance-MainReport-e_20131127.pdf

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.

Chapter 3

Policies and Procedures

3.1 Overview

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

3.2 Radiation Safety and Dose Reduction (ALARA Principles)

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

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).

“Sonography Canada recommends that sonographers adhere to the general principle of ALARA as a practice standard. This is the use of minimum acoustic power output and minimum exposure time to obtain the necessary clinical information.”

See Sonography Canada Professional Practice Guideline with link. http://www.sonographycanada.ca/Apps/SitesManagement/FileDownload/DataDownload/46650/SC_ProfPractice%20Eng%20Rev%2003Feb2017%20final/pdf/1/1033

Policies and procedures should be developed under the direction of the radiation protection officer (RPO) to ensure compliance with the HARP Act and other applicable legislation.

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

3.3 Developing Policies and Procedures

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

There is documentation to indicate who makes the policies, sets the standards, and who supervises physicians, medical radiation technologists, sonographers and other staff.

Procedures in the manual include, but are not limited to, the following:

3.3.1 Facility

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

Link to CMRTO Standards of Practice <https://www.cmrto.org/resources/publications/standards-of-practice>

Link to CMRTO Code of Ethics
<https://www.cmrto.org/resources/publications/code-of-ethics>

http://www.sonographycanada.ca/Apps/Sites-Management/FileDownload/DataDownload/41148/SC_ProfessionalPractice%20Eng%20Final%20copy%20October%202015/pdf/1/1033

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

3.3.2 Facility Staff

- delegated acts and medical directives. Refer to CPSO policy on Delegation of Controlled Acts <http://www.cpso.on.ca/policies/policies/default.aspx?ID=1554>. Examples include: transvaginal and transrectal ultrasounds.
- supervision of staff (e.g. sonographers) who may be working at an IHF while in the process of pursuing academic credentialing exams.
- safety training for medical and non-medical staff. (see Appendix IV)
- Orientation for all new staff to ensure adequate training. This must include a review of policy and procedure manuals, modality specific protocols, and all safety training i.e. AODA. The employee must sign off indicating that they have successfully completed all the above training.

3.3.3 Records and Communication/ Reporting & Privacy Principles

- Verbal reports: a written policy and procedure must be in place to ensure verbal reports are communicated to the referring physician/health care provider by the 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/health care provider by the radiologist or designate.
- Fetal ultrasound for non-medical reasons, i.e. gender identification (see Appendix VI – CPSO Policy Statement on Fetal Ultrasound for Non-Medical Reasons)
- Use of cameras 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*)
- Confidentiality for staff and patients
- Privacy and release of health record information, including Bill 31 the Personal Health Information Protection Act 2004. (PHIPA). Information available at www.ipc.on.ca

3.3.4 Diagnostic Services

- Instructions regarding routine preparation of patients
- Every exam must have the MRT/Sonographer name or initials 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 Sonographers
- 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 female patients for an x-ray procedure who may be pregnant or are pregnant
- Performance of additional views and examinations, i.e. any additional views or examinations are identified in the imaging report with reasons
- Timing and permission of additional family/friend presence during the performance of any examination
- MRTs/Sonographers do not give preliminary interpretation

3.3.5 Equipment Maintenance

- Policies/procedures which describe the 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

- 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
- At least one staff member on shift have a valid BCLS certification
- 70% alcohol-based hand rub be available for staff and patients at all points of care
- A hands-free eyewash station be installed in the facility (as per WHMIS)
- Latex anaphylaxis
- Safety Data Sheets (SDS) for all chemicals maintained in the facility
- Infection control. Resources are available through the **Provincial Infectious Diseases Advisory Committee** of Public Health Ontario at <http://www.publichealthontario.ca/en/BrowseByTopic/InfectiousDiseases/PIDAC/Pages/Infection-Prevention-and-Control-for-Clinical-Office-Practice.aspx>
- Accessibility for Ontarians with Disabilities Act (AODA)
- Workplace safety and harassment
- Personal Protective Equipment (PPE)

3.3.7 Quality Management (See Chapter 5)

3.3.8 Infection Control

Routine practices to prevent infection are in keeping with provincial guidelines. Resources are available through the **Provincial Infectious Diseases Advisory Committee** of Public Health Ontario

at <http://www.publichealthontario.ca/en/BrowseByTopic/InfectiousDiseases/PIDAC/Pages/Infection-Prevention-and-Control-for-Clinical-Office-Practice.aspx>

Staff responsible for the sterilization and reprocessing of medical equipment must be adequately educated and trained. Please contact the College for an approved list of courses specific to reprocessing and sterilization.

3.3.9 Equipment

3.3.9.2 Endocavity Transducers Sterilization and Reprocessing

3.3.9.2.1 Physical Space

The IHF Facility must have a centralized area for reprocessing medical equipment/devices. This area must have one-way flow from dirty to clean to avoid cross contamination. The reprocessing room must have a decontamination sink. 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 some type of fume hood for venting/absorbing the high-level disinfection gases must be installed and inspected annually (Figure 12; CSA, 2008)
- An eyewash station must be available in the reprocessing room.
- 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 alcohol-based hand rub (ABHR).

3.3.9.2.2 Cleaning Process

- **All reprocessing staff should wear gloves, mask and protective eyewear.**
- **Do not** use any alcohol, bleach, ammonium chloride or hydrogen peroxide on transducers.
- A neutralizing substance may be used to neutralize the disinfectant before it is poured down the contamination sink drain.
- Transducers should be soaked/washed in an enzymatic detergent prior to the high-level disinfection process. If necessary, a medical instrument brush should be used to remove any debris or blood products.
- As high-level disinfectants have much longer contact times (varies dependent on disinfectant but can range from 8 minutes to 120 minutes) than low level

disinfectant, sufficient reprocessing time as per manufacturer's directions must be given to properly clean and disinfect the endocavity transducers between uses. Care must be taken to ensure that the solution does not enter the device or connector.

- The transducer must be thoroughly rinsed with potable water after the use of a high-level disinfection solution. Do not allow any solutions to air dry on the transducer. (Figure 7; CSA, 2008)
- The highly disinfected transducer should have a "HIGH LEVEL DISINFECTION" label placed on it and be kept in an area labelled as a high-level disinfection area. (CSA, 2008)
- After high-level disinfecting of the transducer, the sonographer should document the reprocessing procedure with:
 - the patients ID number
 - transducer serial number
 - soaking time
 - Name of the person who cleaned the transducer and date. (Figure 9; CSA, 2008)

3.3.9.2.3 Using and Cleaning Transducers in the Examination Room

- Transducer covers should be used on all endocavity transducers. Non-latex condoms/ gloves should be available for latex sensitive patients.
- Sterile gel or bacteriostatic gels should be used to lubricate the exterior of the probe covers. (Health Canada, 2004)
- Transducer covers should be removed using gloves and disposed of immediately. Care must be taken not to contaminate the transducer with the patient's secretions.
- Following each exam, the transducer should be disconnected from the system and the gel should be wiped off the transducer and the entire cable cord with a single-use soft, dry wipe followed by an enzymatic solution as recommended by manufacturer. (Figure 5; CSA, 2008)
- All transducers performing biopsies should use a disposable sterile transducer cover, and aseptic technique should be used.
- Perform hand hygiene after cleaning the transducer and cable cords and between patients. (Figure 8; CSA, 2008)
- Hand hygiene must be performed before handling the disinfected transducer to dry the unit and replace back into holder.

3.3.9.2.4 Daily Testing

- All high-level disinfection solutions should be tested on a daily basis using test strips. Record the Lot # of the disinfectant. (Figure 10; CSA, 2008)
- There should be a log book to record all high-level disinfection solution changes (Figure 11; CSA, 2008)
- All documentation must be maintained for 6 years.

- Endocavity transducer s should be examined regularly for any damage, and preventative 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)

For further details on reprocessing and sterilization in health care settings can be found in the [PIDAC document: Best Practices for Cleaning, Disinfection and Sterilization of Medical Equipment/Devices, Third Revision May 2013](#)

The flowcharts on the following pages outline the appropriate steps for cleaning transducers, as well as appropriate steps for documentation of reprocessing (both flowcharts are also available in Appendix VI so that they can be photocopied and posted in the facility reprocessing area).

ENDOCAVITY REPROCESSING

Reprocessing must be in a separate designated area than scanning and include a sink.

All transducers should be labelled as "HIGH LEVEL DISINFECTION."

Sterile one-time use transducer covers and gel must be used for all endocavity exams.
Non-latex covers and gloves should be available for latex sensitive patients.



Gloves, masks and goggles should be worn as per SDS during reprocessing. An eye wash station must be available as per IPAC clinical office practice parameters.
Verify if the HLD requires venting and/or a spill kit.



After completion of the exam, the sonographer uses gloved hand to dispose of the transducer cover and their glove. (Careful not to contaminate the transducer with the patient's secretions.)



The transducer and cable is wiped with a dry cloth/tissue to remove excess gel and disconnect from the system



The transducer is wiped with a hospital grade low level disinfectant and/or washed in an enzymatic detergent in the reprocessing area. A medical instrument brush may be required to clean crevices. (All solutions/brushes should be approved by manufacturer)



The transducers must be soaked in an approved high level disinfectant solution as per the manufacture's guidelines. Care to ensure that the integrity of the transducer is intact, so that the solution does not enter the device or connector.



Once the soaking time has completed, the transducer must be thoroughly rinsed with potable water and wiped dry. DO NOT let air dry.



Perform Hand Hygiene in another area as reprocessing sink stations cannot be used for hand hygiene and return the transducer to its clean location.

Go To: DOCUMENTATION OF REPROCESSING

Integrity of Transducers

- Endocavity transducers should be examined regularly for any damage. If damage is evident, discontinue use.

Non Endocavity Transducers:

- Transducers and cords should be wiped clean of gel with a dry wipe and then a hospital grade low level disinfectant wipe after each examination. (Approved by manufacturer)

****DO NOT** use any alcohol, bleach, ammonium chloride or hydrogen peroxide on transducers.
All endocavity transducers must be cleaned according to the manufacturer's instructions.

Documentation of Reprocessing

Record the following:

- Patient's ID number
- Transducer Identifier
- Soaking Time, Date
- Name of the Person who cleaned the transducer



Testing of HLD: Record the following:

- Test strips specific to the HLD be done daily before use (record lot #)
- Test strip testing be done after solution change



HLD solution change: Change either at:

- Manufacturer's suggested time i.e. every 2 weeks
- Fails test strip testing

Solution must be discarded as per manufacture's instruction as some may require a neutralizing substance to be added before it can be poured down the drain.



Record Keeping:

All written documentation must be maintained on site for 6 years



To Ensure Compliance:

The written policy and procedure on reprocessing techniques be reviewed and updated annually by all staff.

3.3.9.3 Use of Gel

****Gel bottles are one time use only!***

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)

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

Containers/dispensing nozzles must not come in direct contact with a client’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.

Before opening the bottle, verify the expiry date.

When a new bottle is opened, the bottle should be dated and discarded after one month. 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)

For further information, please refer to

1. IPAC Canada. IPAC Canada Position Statement Medical Gels. Available at: <https://ipac-canada.org/photos/custom/Members/pdf/2017JanMedicalGel2016.pdf> (also attached as Appendix III)
2. Susan C. Oleszkowicz, Paul Chittick, Victoria Russo, Paula Keller, Matthew Sims and Jeffrey Band (2012). Infections Associated with Use of Ultrasound Transmission Gel: Proposed Guidelines to Minimize Risk. *Infection Control & Hospital Epidemiology*, 33, pp 1235-1237 doi:10.1086/668430
3. Ontario Agency for Health Protection and Promotion (Public Health Ontario), Provincial Infectious Diseases Advisory Committee. Infection Prevention and Control for Clinical Office Practice. 1st Revision. Toronto, ON: Queen’s Printer for Ontario; April 2015. Available at: http://www.publichealthontario.ca/en/eRepository/IPAC_Clinical_Office_Practice_2013.pdf
4. APIC Archives Available at: http://apic.org/Resource_/TinyMceFileManager/Education2015/Ultrasound_Gel_Journal_Citations.pdf
5. Spratt, H.G., Levine, D., Tillman, L. (2014). Physical therapy clinic therapeutic ultrasound equipment as a source for bacterial contamination. *Physiother Theory Pract*, 2014; 30(7): 507–511

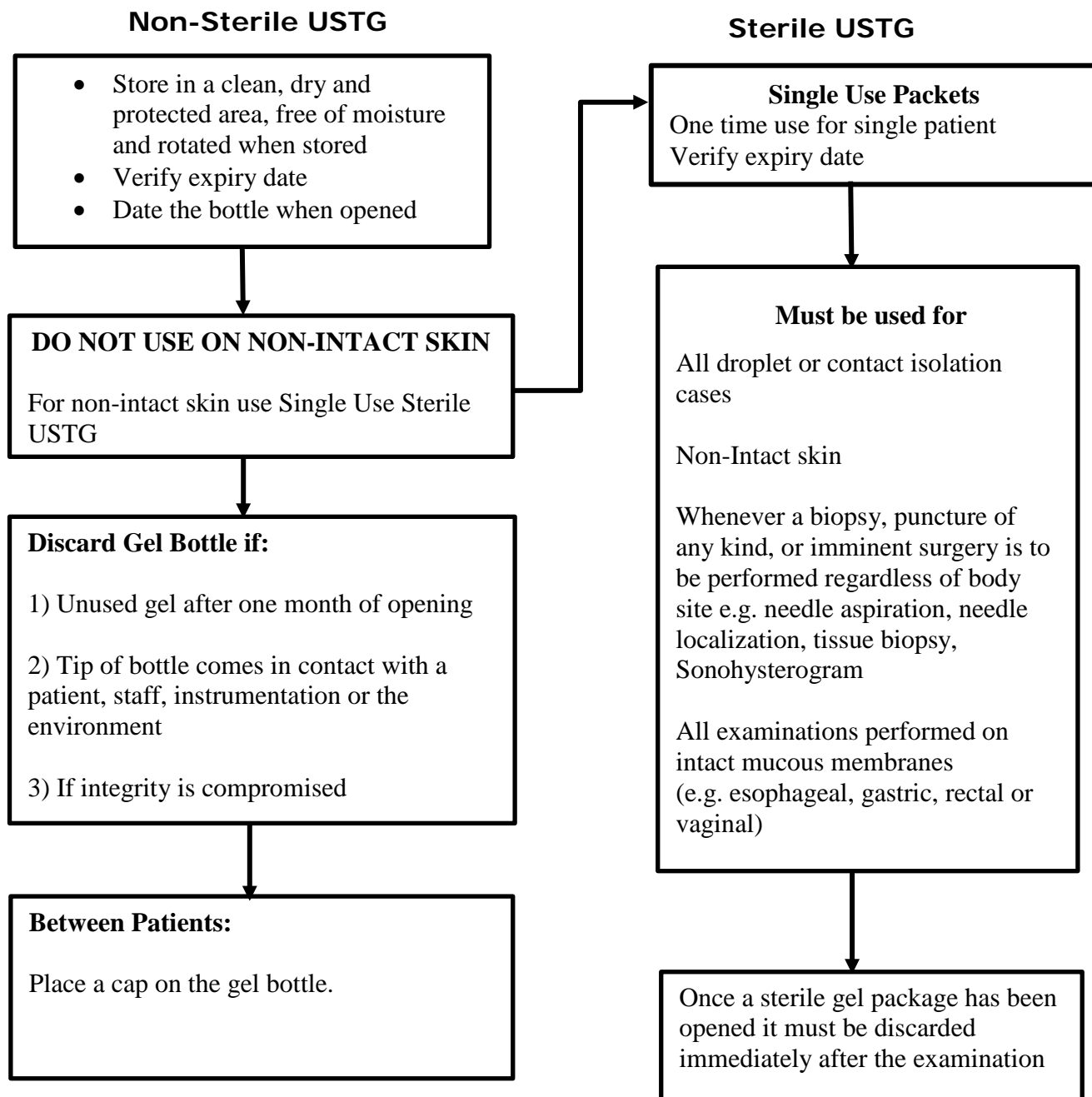
Refer to flowchart below for appropriate use of gels (this flowchart is also available in Appendix VII so that it can be photocopied and posted in facilities).

Ultrasound Transmission Gel (USTG) Recommendations: Referred to as “Gel”

***DO NOT WARM GEL**

****Gel Bottles are one time use only!**

IPAC Canada position statement on medical gels “Containers of gel should never be washed and refilled for use but should be discarded when empty.”



3.3.10 At Risk Patients

The facility must identify and manage patients who have any possibility of transmitting infection at the initial contact with the patient.

3.3.11 Hand Hygiene

It is recommended to post the Ministry of Health “Hand Washing Techniques” document for IHF staff and patients in designated areas and there should be documentation attesting to annual staff compliance. (Refer to <http://www.publichealthontario.ca/en/eRepository/2010-12%20BP%20Hand%20Hygiene.pdf>)

3.3.12 Personal Protective Equipment

Gloves, masks, gowns and eye-protection equipment must be used where and when necessary to protect both patient and personnel. Proper disposal of personal protective equipment should also be included. There should be documentation attesting to annual staff compliance.

3.3.13 Disposal of Sharps

Appropriate precautions must be taken to prevent injuries from sharps by following careful drawn protocols such as no recapping of needles and passing needles without injuring each other and disposal in dedicated sharp containers.

3.3.13.1 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.

3.3.14 Respiratory Infections

Each facility should implement a written protocol to manage all patients with potentially infectious respiratory conditions. These are the following guidelines set for outpatient clinic settings:

Outpatient Settings

Identify patients who may have infectious respiratory illnesses in outpatient settings, screen patients in the reception area about the presence of fever or respiratory symptoms.

Provide the patient a surgical face-mask.

- If possible, provide a separate waiting area where possible for patients or visitors with respiratory symptoms. If this isn’t possible, process these patients as quickly as possible to limit their exposure to staff and other patients.

Encourage practice of “respiratory etiquette” for patients and visitors:

Provide surgical masks to individuals coughing, sneezing or with other respiratory symptoms.

Provide hand hygiene products and tissues in waiting area -provide designated containers of disposal of used tissues.

All personnel should wear surgical masks, or ideally, fit-tested masks when evaluating patients with suspected infectious respiratory illnesses, and practice frequent hand hygiene.

Chapter 4 Requesting and Reporting Mechanisms

The content of this chapter has been extracted from the CAR Standard for Communication of Diagnostic Imaging Findings (2010). For further guidance, refer to: http://www.car.ca/uploads/standards%20guidelines/20101125_en_standard_communication_di_findings.pdf

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 work station 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 IHF staff and all imaging personnel including radiologists to ensure patient privacy. This includes institution of appropriate privacy procedures, and appropriate policies and procedures for release of images or reports from medical images to third parties.

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

4.1 Requesting Procedures

Written requests for radiological consultations are completed for all diagnostic imaging procedures.

4.2 Overview

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/healthcare 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/healthcare 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/healthcare provider or interview the patient to obtain the necessary information prior to conducting the procedure.*

When a consultation for a procedure is requested by telephone, the person to whom the consultation was requested writes the procedure(s) requested, the working diagnosis, the name of the ordering physician/healthcare provider, the date and time of the request, and signs the record of the request.

4.3 MRT/Sonographer Documentation

MRTs and sonographers must initial the film bag, worksheet or equivalent at the time of the examination in order for the interpreting physician to identify the MRT/sonographer 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 healthcare professionals 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 healthcare professional who is responsible for the clinical follow-up. The ordering physician or other healthcare professional 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 written final report should be made available to the ordering physician or healthcare professional who is responsible for the clinical follow-up within 1 to 2 business days.

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 email, provided appropriate security measures are in place. Facilities should seriously consider instituting “read receipt” mechanisms to identify any report that has not been picked up by the ordering physician/healthcare professional.

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

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

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

name or type of examination.

date of examination.

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

dates of dictation.

- rationale: quality control.

4.4.2 Body of the Report

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

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

4.4.3 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.

4.4.4 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.

4.4.5 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).

4.4.6 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.

4.4.7 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.

4.4.8 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/healthcare professional (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 sonographers 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/healthcare professional 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/healthcare professional 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/healthcare professionals 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 Charges for Copying Patient Records (As Per MOHLTC Fact Sheet)

http://www.health.gov.on.ca/en/public/programs/ihf/fact_sheets.aspx

If an individual requires a copy of all or any part of his/her patient record, which may include imaging media, for the provision of ongoing care by another health care provider, the IHF must provide a copy of the record(s) at no cost/charge to the patient or health care provider

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 3 working days of receiving the request.

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, the ACR-AAPM-SIIM Technical Standard for Electronic Practice of Medical Imaging guidelines

(<https://www.acr.org/~media/AF1480B0F95842E7B163F09F1CE00977.pdf>)

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 #)

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 and a minimum of 2 health professionals who provide health services in or in connection with the IHF. The QA Committee should include representation from all modalities, and PACS administration.

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 if the facility employs more than six full time staff equivalents including the Quality Advisor, otherwise the QA Committee shall meet at least once a year.

Regular agenda items must include:

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

5.2 Quality Management Program Goals

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

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

Services conducted in the facility are safe.

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

The 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/sonographer 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 Long-Term Care, 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, BCLS certificates, etc., are valid and current for all staff.
8. Ensure that the CPD activities of the technical and medical staff meet the relevant College or Society requirements. For example, all specialist physicians have fulfilled their annual RCPSC MOCOMP 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 a quality review process which follows the basic principles of the CAR peer review program http://www.car.ca/uploads/standards%20guidelines/20120831_EN_Peer-Review.pdf, which includes documentation of the activity to work 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 fetuses, 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 sonographers/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 sonographers who have completed the Fetal Medicine Foundation (FMF) certification program for the 11-13⁺⁶ week scan (<https://fetalmedicine.org/education/the-11-13-weeks-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 sonographer (under the supervision of a reporting physician) is responsible for the relevant ultrasound information, including their unique identifying sonographer 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 sonographer who provided the measurements, which allows for ongoing population of the BORN Ontario *Sonographer-Specific NT audit curve*.

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

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 sonographers they are supervising.

6.4 Sonographers Performing the 11 to 13⁺⁶ week scan

New sonographers 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. <https://fetalmedicine.org/education/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 sonographer 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 BORN Ontario at <https://www.bornontario.ca/en/partnership-projects/nuchal-translucency-quality-assurance/> , 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 service, through one of 4 provincial prenatal screening laboratories (see below for contact information).
5. Sonographers will be required to submit 15 further NT/CRL paired measurements for initial audit and enrolment in the Ontario prenatal screening program.

Sonographers 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 sonographers must:

1. Register with BORN Ontario, either as a new sonographer as outlined above, or as an existing sonographer.
2. Contact their primary prenatal screening laboratory 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:

- Sonographers performing NT scans in Ontario must use **ONLY** their own unique sonographer ID number.
- Sonographers 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.

Ontario Regional Prenatal Screening Laboratories Contact Information

Trillium Health Partners; Credit Valley Site

(905) 813-4104

Mount Sinai Hospital

(416) 586-8510, option 2

North York General Hospital

(416) 756-5996

London Health Sciences Centre

(519) 667-6592

For more information on the performance of NT please visit:

<https://fetalmedicine.org/education/the-11-13-weeks-scan>

APPENDICES

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

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

Quality Advisor and Advisory Committee

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

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

(3) The quality advisor must be a health professional who ordinarily provides insured services in or in connection with the independent health facility and whose training enables him or her to advise the licensee with respect to the quality and standards of services provided in the facility.

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

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

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

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

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

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

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

3(1) Every licensee shall give the Director the name of the quality advisor in writing forthwith after the quality advisor is appointed.

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

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

Standards

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

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

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

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

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

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

Records of Employees

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

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

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

(A) each person the licensee contracts with to manage the facility; and

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

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

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

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

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

1. The physician's name

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

3. The physician's number registered with the Health Insurance Division of the Ministry of Health.
4. The class of the physician's licence issued under Part III of the Health Disciplines Act and any terms and conditions attached to it.
5. The physician's specialty.

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

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

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

Patient Records

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

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

- (a) the patient's name and home address
- (b) the patient's date of birth
- (c) the patient's health number
- (d) the name of any attending physician or practitioner and his or her number as registered with the Health Insurance Division of the Ministry of Health
- (e) the name of any referring physician or practitioner and his or her number as registered with the Health Insurance Division of the Ministry of Health
- (f) a history of the patient
- (g) a written record of any orders for examinations, tests, consultations or treatments
- (h) particulars of any examination of the patient
- (i) any reports of examinations, tests or consultations including any imaging media from examinations and any physicians' interpretive or operative reports
- (j) any reports of treatment including any physicians' operative reports
- (k) any orders for and reports of any discharge of the patient from supervised care
- (l) any consents; and
- (m) any diagnoses of the patient.

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

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

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

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

(a) the patient's last visit; or

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

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

(a) the patient's last visit; or

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

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

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

Section 12 of the Regulation is revoked and the following substituted:

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

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

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

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

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

Books and Accounts

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

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

1. Current financial records showing:

(i) the amounts paid by the Minister to the licensee under section 24 of the Act.

(ii) the revenue earned by the licensee from facility fees charged by the licensee for or in respect of services or operating costs that support, assist or are a necessary adjunct to the primary insured services set out in the licensee's licence, and

(iii) the expenditures, assets and liabilities of the facility that relate to the costs paid by the Minister under section 24 of the Act.

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

3. An annual income and expense statement showing the income received and the expenses incurred by the licensee in connection with the services mentioned in paragraph 2.

4. An annual inventory of the assets of the facility that have an acquisition cost exceeding \$3,500 and that relate to the costs paid by the Minister under section 24 of the Act.

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

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

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

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

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

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

Notices

13 Every licensee of an independent health facility,

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

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

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

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

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

Miscellaneous

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

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

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

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

17 The administrative charge for the purposes of section 36 of the Act is \$50. O. Reg. 57/92, s.17.

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

A. Kyle Jones^{a)}

Department of Imaging Physics, The University of Texas MD Anderson Cancer Center, Houston, Texas 77030

Philip Heintz

Department of Radiology, University of New Mexico, Albuquerque, New Mexico 87104

William Geiser

Department of Imaging Physics, The University of Texas MD Anderson Cancer Center, Houston, Texas 77030

Lee Goldman

Hartford Hospital, Hartford, Connecticut 06102

Khachig Jerjian

Hoag Memorial Hospital, Newport Beach, California 92658

Melissa Martin

Therapy Physics, Inc., Gardena, California 90248

Donald Peck

Henry Ford Health System, Detroit, Michigan 48202

Douglas Pfeiffer

Boulder Community Foothills Hospital, Boulder, Colorado 80303

Nicole Ranger

Landauer, Inc., Glenwood, Illinois 60425

John Yorkston

Carestream Health, Inc., Rochester, New York 14615

(Received 16 February 2015; revised 31 July 2015; accepted for publication 19 August 2015; published 26 October 2015)

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.

© 2015 American Association of Physicists in Medicine. [<http://dx.doi.org/10.1118/1.4932623>]

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

TABLE OF CONTENTS

1	INTRODUCTION.....	6659	2.B.2	Data collection.....	6660
2	REJECTED IMAGE ANALYSIS.....	6659	2.B.3	Data analysis.....	6660
2.A	The continued need for rejected image analysis.....	6660	2.B.4	Corrective action.....	6661
2.B	Performing rejected image analysis.....	6660	2.B.5	Record keeping.....	6661
2.B.1	Rejected image analysis in screen-film departments.....	6660	2.B.6	Standardized reasons for rejection...	6661
			2.B.7	Collection and storage of data.....	6662
			2.B.7.a	Other useful information..	6662
			2.C	Access to data.....	6662

2.D	DICOM	6662
2.D.1	MPPS	6663
2.D.2	DICOM SR	6663
3	EXPOSURE ANALYSIS	6663
3.A	Assessing patient dose in digital radiography	6663
3.A.1	The EI	6664
3.A.2	DICOM dose information	6664
3.A.2.a	Entrance dose	6664
3.A.2.b	Kerma-area product (KAP)	6664
3.A.2.c	The DICOM SR	6665
3.A.3	Other sources of data	6665
3.B	Collecting dose information	6665
3.B.1	Manual collection and recording of data	6665
3.B.2	Modality performed procedure step	6665
3.B.3	Use of the RIS to extract and archive data	6665
3.B.4	Use of a separate server to extract and archive data	6665
3.B.5	Use of a commercial dose aggregation system	6665
3.B.6	Other methods	6665
3.C	Analysis of dose data and corrective action	6666
3.C.1	Corrective action	6666
3.D	Quality control of dose metrics	6666
4	ARTIFACT IDENTIFICATION	6666
4.A	Artifact check after detector calibration or detector drop	6666
4.B	Protocol for performing artifact check	6668
4.B.1	Configuring acquisition and image processing menus	6668
4.B.2	Training staff to perform the artifact check	6668
4.B.3	Troubleshooting	6668
5	TOOLS PROVIDED BY MANUFACTURERS	6668
6	ADMINISTRATION AND OPERATION OF A QC PROGRAM	6669
6.A	Role of the QMP	6669
6.B	Role of the QC technologist	6669
6.C	Role of the radiologist	6669

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 mammography² 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 case⁹ 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 $\pm 2\%$, 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

^aThe target EI and DI should also be included, if available.

^bOptional 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 tomography³² and fluoroscopy³³ 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 gener-

ated. 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 geometries⁴⁰ 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 tomography³² and radiography/fluoroscopy³³ 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 material⁶⁰ 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

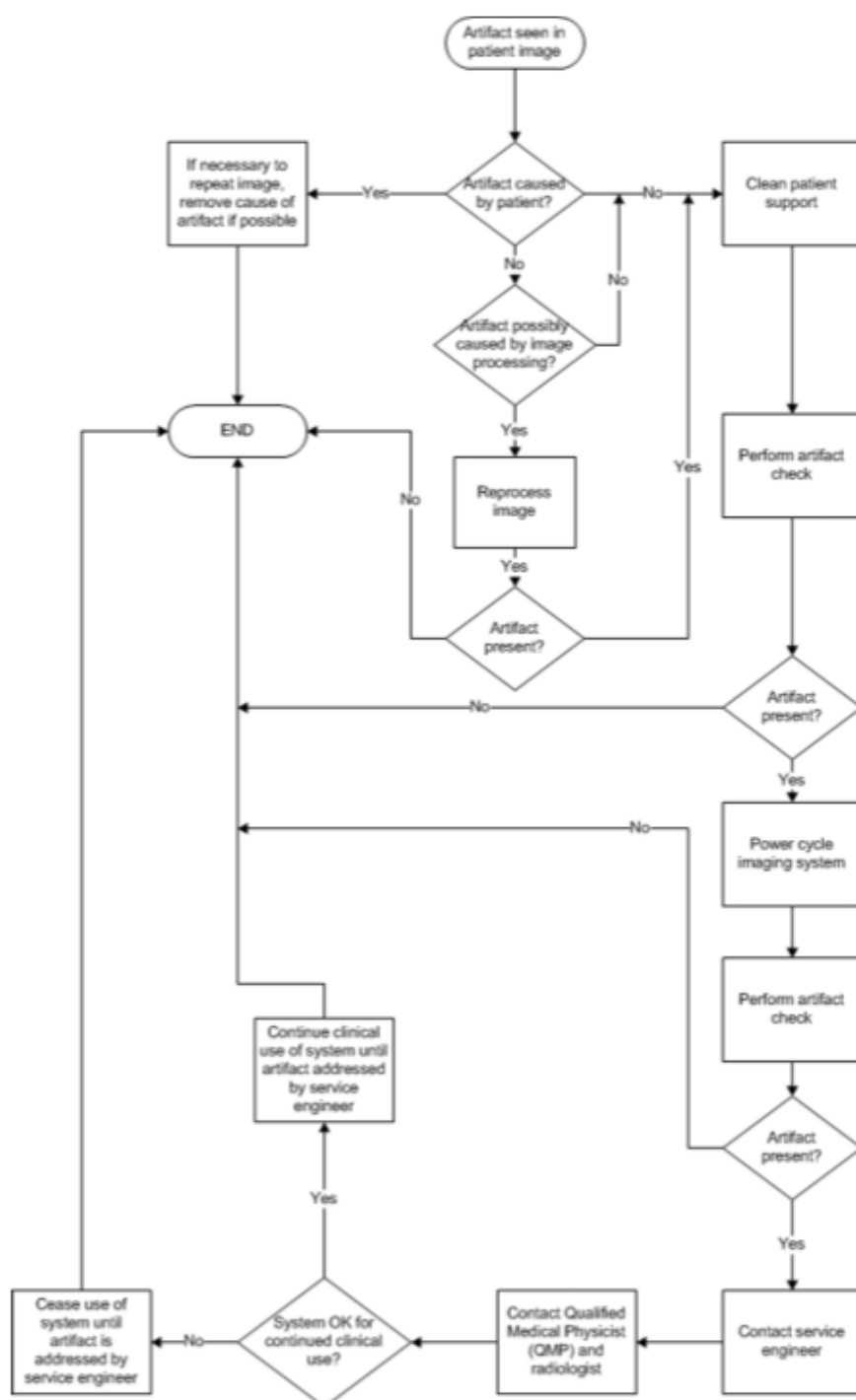


FIG. 1. Example fault tree for artifact troubleshooting.

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 damage 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	ABC 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.

^aFactors not explicitly listed (e.g., focal spot size) can be set however desired.

^bQMP may program the reported ABC 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

^{a)}Author to whom correspondence should be addressed. Electronic mail: kyle.jones@mdanderson.org

¹American Society for Quality Definitions of Quality Assurance and Quality Control, available at <http://asq.org/learn-about-quality/quality-assurance-quality-control/overview/overview.html>, accessed January 2013.

²United States Food and Drug Administration: Code of Federal Regulations, 21CFR900.12(e)(3)(ii), 2008.

³National Council on Radiation Protection and Measurements, "Quality assurance for diagnostic imaging," NCRP Report 99 (NCRP, Bethesda, MD, 1988).

⁴American Association of Physicists in Medicine, "Quality control in diagnostic radiology," Report 74 (Medical Physics, Madison, WI, 2002).

⁵American College of Radiology, *ACR Technical Standard for Diagnostic Medical Physics Performance Monitoring of Radiographic and Fluoroscopic Equipment* (Reston, VA, 2006), pp. 1139–1142.

⁶J. E. Gray, N. T. Winkler, J. Stears, and E. D. Frank, *Quality Control in Diagnostic Imaging* (Aspen, Inc., Gaithersburg, MD, 1983).

⁷W. K. Chu, S. Ferguson, B. Wunder, R. Smith, and J. J. Vanhoutte, "A two-year reject/retake profile analysis in pediatric radiology," *Health Phys.* **42**, 53–59 (1982).

⁸GE Medical Systems Revolution XQ/i Digital Radiographic Imaging System, Pub 98-5502:1–8, 1998.

⁹R. Honea, M. E. Blado, and Y. Ma, "Is reject analysis necessary after converting to computed radiography?," *J. Digital Imaging* **15**(Suppl. 1), 41–52 (2002).

¹⁰J. Nol, G. Isouard, and J. Mirecki, "Digital repeat analysis; setup and operation," *J. Digital Imaging* **19**, 159–166 (2006).

¹¹S. Peer, R. Peer, M. Walcher, M. Pohl, and W. Jaschke, "Comparative reject analysis in conventional film-screen and digital storage phosphor radiography," *Eur. Radiol.* **9**, 1693–1696 (1999).

¹²G. C. Weatherburn, S. Bryan, and M. West, "A comparison of image reject rates when using film, hard copy computed radiography and soft copy images on picture archiving and communication systems (PACS) workstations," *Br. J. Radiol.* **72**, 653–660 (1999).

¹³C. Prieto, E. Vano, J. I. Ten, J. M. Fernandez, A. I. Iñiguez, N. Arevalo, A. Litcheva, E. Crespo, A. Floriano, and D. Martinez, "Image retake analysis in digital radiography using DICOM header information," *J. Digital Imaging* **22**, 393–399 (2009).

¹⁴D. H. Foos, W. J. Schnert, B. Reiner, E. L. Siegel, A. Segal, and D. L. Waldman, "Digital radiography reject analysis: Data collection methodology, results, and recommendations from an in-depth investigation at two hospitals," *J. Digital Imaging* **22**, 89–98 (2009).

¹⁵R. Polman, A. K. Jones, C. E. Willis, and S. J. Shepard, "Reject analysis tool," in *Proceedings of Society for Information Management in Medicine (SIIM)* (SIIM, Leesburg, VA, 2008), pp. 38–40.

¹⁶A. K. Jones, R. Polman, C. E. Willis, and S. J. Shepard, "One year's results from a server-based system for performing reject analysis and exposure analysis in computed radiography," *J. Digital Imaging* **24**, 243–255 (2011).

¹⁷L. Trestrail, D. J. Sandoval, P. H. Heintz, S. Luan, D. Sanchez, and D. Z. Chen, "A web-based automatic QA analysis program for digital image tracking," in *Proceedings of Radiological Society of North America*, 2009.

¹⁸F. A. Mettler, Jr., B. R. Thomadsen, M. Bhargavan, D. B. Gilley, J. E. Gray, J. A. Lipoti, J. McCrohan, T. T. Yoshizumi, and M. Mahesh, "Medical radiation exposure in the U.S. in 2006: Preliminary results," *Health Phys.* **95**, 502–507 (2008).

¹⁹K. D. Rogers, I. P. Matthews, and C. J. Roberts, "Variation in repeat rates between 18 radiology departments," *Br. J. Radiol.* **60**, 463–468 (1987).

- ²⁰Institute of Medicine Crossing the Quality Chasm: A New Health System for the 21st Century (National Academy, Washington, DC, 2001).
- ²¹B. Reiner and E. Siegel, "Pay for performance (P4P) in medical imaging: The time has (finally) come," *J. Digital Imaging* **19**, 289–294 (2006).
- ²²The Alliance for Radiation Safety in Pediatric Imaging, www.imagegently.org, accessed 19 November 2009.
- ²³A. Addler, R. Carlton, and B. Wold, "An analysis of radiography repeat and reject rates," *Radiol. Technol.* **63**, 308–314 (1992).
- ²⁴R. J. Berry and R. Oliver, "Letter: Spoiled films in x-ray departments and radiation exposure to the public from medical radiology," *Br. J. Radiol.* **49**, 475–476 (1976).
- ²⁵B. C. Dodd, "Repeat analysis in radiology: A method of quality control," *Can. J. Radiogr. Radiother. Nucl. Med.* **14**, 37–40 (1983).
- ²⁶M. A. Al-Malki, W. H. Abulfaraj, S. I. Bhuiyan, and A. A. Kinsara, "A study on radiographic repeat rate data of several hospitals in Jeddah," *Radiat. Prot. Dosim.* **103**, 323–330 (2003).
- ²⁷A. A. Mustafa, C. M. Vasisht, and S. J. Sumanasekara, "Analysis of wasted x-ray films: Experience in two Kuwait hospitals," *Br. J. Radiol.* **60**, 513–515 (1987).
- ²⁸T. R. Minnigh and J. Gallet, "Maintaining quality control using a radiological digital x-ray dashboard," *J. Digital Imaging* **22**, 84–88 (2009).
- ²⁹American College of Radiology: General Radiology Improvement Database Metrics, available at https://nrd.acr.org/portal/HELP/GRID/ACR_GRID_metrics.pdf, accessed 5 February 2009.
- ³⁰H. Oosterwijk, "DICOM versus HL7 for modality interfacing," *J. Digital Imaging* **11**, 39–41 (1998).
- ³¹R. Noumeir, "Benefits of the DICOM modality performed procedure step," *J. Digital Imaging* **18**, 260–269 (2005).
- ³²Digital Imaging and Communications In Medicine (DICOM), Supplement 127-CT Radiation Dose Reporting (Dose SR), available at http://medical.nema.org/medical/dicom/final/sup127_ft.pdf, accessed 19 November 2009.
- ³³Digital Imaging and Communications In Medicine (DICOM), Supplement 94-Diagnostic X-Ray Radiation Dose Reporting (Dose SR), available at http://medical.nema.org/medical/dicom/final/sup94_ft.pdf, accessed 19 November 2009.
- ³⁴"European guidelines on quality criteria for diagnostic radiographic images," in *Publication EUR 16260 EN* (European Commission, Brussels, Belgium, 1996).
- ³⁵M. Freedman, E. Pe, and S. K. Mun, "The potential for unnecessary patient exposure from the use of storage phosphor imaging systems," *Proc. SPIE* **1897**, 472–479 (1993).
- ³⁶D. Gur, C. R. Fuhman, and J. H. Feist, "Natural migration to a higher dose in CR imaging," in *Proceedings of the Eight European Congress of Radiology* (European Society of Radiology, Vienna, Austria, 1993), p. 154.
- ³⁷American Association of Physicists in Medicine, "An exposure indicator for digital radiography," Report of AAPM Radiography and Fluoroscopy Subcommittee Task Group 116 (AAPM, 2009).
- ³⁸S. J. Shepard, J. Wang, M. Flynn, E. Gingold, L. Goldman, K. Krugh, D. L. Leong, E. Mah, K. Ogden, D. Peck, E. Samei, J. Wang, and C. E. Willis, "An exposure indicator for digital radiography: AAPM Task Group 116 (executive summary)," *Med. Phys.* **36**, 2898–2914 (2009).
- ³⁹International Electrotechnical Commission, Medical electrical equipment—Exposure index of digital x-ray imaging systems—Part 1: Definitions and requirements for general radiography, IEC 62494-1, International Electrotechnical Commission ed. 1.0, Geneva, 2008.
- ⁴⁰American Association of Physicists in Medicine, "Standardized methods for measuring diagnostic x-ray exposures," Report of AAPM Diagnostic X-ray Imaging Committee Task Group 8 (AAPM, 1990).
- ⁴¹American National Standards Institute, "Method for the sensitometry of medical x-ray screen-film processing systems," in *ANSI PH2.43* (ANSI, New York, NY, 1982).
- ⁴²B. J. Conway, P. F. Butler, J. E. Duff, T. R. Fewell, R. E. Gross, R. J. Jennings, G. H. Koustenis, J. L. McCrohan, F. G. Rueter, and C. K. Showalter, "Beam quality independent attenuation phantom for estimating patient exposure from x-ray automatic exposure controlled chest examinations," *Med. Phys.* **11**, 827–832 (1984).
- ⁴³B. J. Conway, J. E. Duff, T. R. Fewell, R. J. Jennings, L. N. Rothenberg, and R. C. Fleischman, "A patient-equivalent attenuation phantom for estimating patient exposures from automatic exposure controlled x-ray examinations of the abdomen and lumbo-sacral spine," *Med. Phys.* **17**, 448–453 (1990).
- ⁴⁴International Committee on Radiation Units and Measurement, "Patient dosimetry for x rays used in medical imaging," ICRU Report 74 (2005).
- ⁴⁵C. Shah, A. K. Jones, and C. E. Willis, "Consequences of modern anthropometric dimensions for radiographic techniques and patient radiation exposures," *Med. Phys.* **35**, 3616–3625 (2008).
- ⁴⁶M. Rosenstein, "Handbook of selected tissue doses for projections common in diagnostic radiology," U.S. Department of Health and Human Services HHS Publication (FDA) 89–8031, 1988, available at <http://www.fda.gov/downloads/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MedicalX-Rays/ucm117933.pdf>, accessed April 2011.
- ⁴⁷D. Hart, D. G. Jones, and B. F. Wall, Estimation of effective dose in diagnostic radiology from entrance surface dose and dose-area product measurements: NRPB-R 262, National Radiological Protection Board, Oxon, England, 1994.
- ⁴⁸J. C. Le Heron, "Estimation of effective dose to the patient during medical x-ray examinations from measurements of the dose-area product," *Phys. Med. Biol.* **37**, 2117–2126 (1992).
- ⁴⁹PCXMC—A PC-based Monte Carlo program for calculating patient doses in medical x-ray examinations, STUK, Helsinki, Finland, available at http://www.stuk.fi/sateilyn_kaytto/ohjelmat/PCXMC/en_GB/pcxmc/, accessed October 2011.
- ⁵⁰American Association of Physicists in Medicine, "Definition of a qualified medical physicist," available at http://www.aapm.org/medical_physicist/fields.asp, accessed April 2011.
- ⁵¹National Electrical Manufacturer's Association, DICOM Correction Item CP 1024, NEMA, Rosslyn, VA, 2010.
- ⁵²M. D. Cohen, M. L. Cooper, K. Piersall, and B. K. Appgar, "Quality assurance: Using the exposure index and the deviation index to monitor radiation exposure for portable chest radiographs in neonates," *Pediatr. Radiol.* **41**, 592–601 (2011).
- ⁵³B. K. Stewart, K. M. Kanal, J. R. Perdue, and F. A. Mann, "Computed radiography dose data mining and surveillance as an ongoing quality assurance improvement process," *Am. J. Roentgenol.* **189**, 7–11 (2007).
- ⁵⁴National Electrical Manufacturer's Association, *Digital Imaging and Communications in Medicine (DICOM) Part 3: Information Object Definitions (PS 3.3-2009)* (NEMA, Rosslyn, VA, 2009), pp. 325–327 available at http://medical.nema.org/medical/dicom/2009/09_03pu3.pdf, accessed April 2011.
- ⁵⁵J. E. Gray, B. R. Archer, P. F. Butler, B. B. Hobbs, F. A. Mettler, Jr., R. J. Pizzutiello, Jr., B. A. Schueler, K. J. Strauss, O. H. Sulciman, and M. J. Yaffe, "Reference values for diagnostic radiology: Application and impact," *Radiology* **235**, 354–358 (2005).
- ⁵⁶National Council on Radiation Protection and Measurements, "Reference levels and achievable doses in medical and dental imaging: Recommendations for the United States," NCRP Report 174 (NCRP, Bethesda, MD, 2012).
- ⁵⁷Texas Regulations for Control of Radiation, "Use of radiation machines in the healing arts," in *25 Texas Administrative Code Section 289.227(j)* (2004), pp. 227–217.
- ⁵⁸Nationwide Evaluation of X-Ray Trends, FDA Center for Devices and Radiological Health, available at <http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/NationwideEvaluationofX-rayTrendsNEXT/default.htm>, accessed May 2014.
- ⁵⁹International Electrotechnical Commission, Medical electrical equipment—Dose area product meters, IEC 60580, International Electrotechnical Commission ed. 2.0, Geneva, 2000.
- ⁶⁰See supplementary material at <http://dx.doi.org/10.1118/1.4932623> for Appendix A containing artifact images.
- ⁶¹P. G. Nagy, B. Pierce, M. Otto, and N. M. Safdar, "Quality control management and communication between radiologists and technologists," *J. Am. Coll. Radiol.* **5**, 759–765 (2008).

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

POSITION STATEMENT

Medical Gels

Background

Medical gels are used routinely in clinical practice during physician exams and diagnostic procedures. Contamination of gels* from improper handling can result in serious health care associated infections such as bacteremia and septicemia. (1,2,5,7,8,9,10,11,12)

*Medical Gels include ultrasound gels, lubricating gels, and other 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		
	Single dose Sterile	Bacteriostatic	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 an opened sterile gel package is no longer sterile
- Sterile product must be used employing the principles of asepsis
- Discard the opened package at end of procedure

b) Nonsterile gels.

- Non-sterile gel containers must never be topped up (i.e., refilled when partially empty)
- If multidose containers of nonsterile gel are used on intact skin, the container must be sealed correctly when not in use (11)
- 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 dated and discarded after 1 month or expiry date if earlier(5)
- Bulk containers of gel are not recommended due to risk of contamination, therefore their use should be discouraged.

c) Warming of Gel

- Do not warm gel due to the increased risk of bacterial multiplication (13).

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: Chair: Madeleine Ashcroft

Principal Authors:

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

References

1. Gaillot, O., Maruéjols, C., Abachin, E., Lecuru, F., Arlet, G., Simonet, M., & Berche, P. (1998). Nosocomial outbreak of *Klebsiella pneumoniae* producing SHV-5 extended-spectrum- β -lactamase, originating from a contaminated ultrasonography coupling gel. *Journal of Clinical Microbiology*, 36(5), 1357-1360.
2. Weist, K., Wendt, C., Petersen, L.R., Versmold, H., & Rüden, H. (2000). An outbreak of pyoderms among neonates caused by ultrasound gel contaminated with methicillin-susceptible *Staphylococcus aureus*. *Infection Control and Hospital Epidemiology*, 21(12), 761-764.
3. Laboratory Center for Disease Control. (December 1998). Hand Washing, Cleaning, Disinfection and Sterilization in Health Care. Canada Communicable Disease Report, 24(S8).
4. Association for Professionals in Infection Control and Epidemiology, Inc. (2016). APIC text of infection control and epidemiology. Washington, DC: Author.

5. Health Canada. Health Products and Food Branch. Notice to Hospitals: Important safety information on ultrasound and medical gels. December 14, 2004.
6. Capital Health Infection Prevention and Control (IPAC). Position Statement on Safe Use of Medical Gels: December 2011.
7. Hutchinson, J., Runge, W., Mulvey, M., et al. (2004). *Burkholderia cepacia* Infections Associated.
8. Jacobson, M., Wray R., Kovach, D., Henry, D., Speert, D., Matlow, A, (2006). Sustained Endemicity of *Burkholderia Cepacia* Complex in a Pediatric Institution, Associated with Contaminated Ultrasound Gel: Infection Control and Hospital Epidemiology (ICHE). 2006, April 27. 362-6.
9. Hutchinson, J., Runge W, Mulvey, M, Norris G, Yetman, M., Valkova, N, Villemur, R, Lepine, F. *Burkholderia cepacia* infections Associated with Intrinsically Contaminated Ultrasound Gel: The Role of Microbial Degradation of Parabens. Infection Control and Hospital Epidemiology (ICHE), (2004) April 25(4); 291-6
10. CDC: Clinician Outreach and Communication Activity (COCA) Safety Communication: Bacteria Found in Other-Sonic Generic Ultrasound Transmission Gel Poses Risk of Infection. CDC April 20,2012
11. Oleszkowicz, S.C., Chittick, P., Russo, V., Keller, M.S., Sims, M., Band, J. Infections Associated with Use of Ultrasound Transmission Gel (2012):33 (12): 1235-1237
12. Clinical Outreach and Communication Activity (COCA) CDC Emergency Communication System. Safety Communication: Bacteria Found in Other-Sonic Generic Ultrasound Transmission Gel Poses Risk of Infection. April 20,2012
13. Spratt, H.G., Levine, D., Tillman, L. (2014). Physical therapy clinic therapeutic ultrasound equipment as a source for bacterial contamination. *Physiother Theory Pract*, 2014; 30(7):507–511

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

Fetal Ultrasound for Non-Medical Reasons – CPSO Policy Statement #4-10

Approved by Council:	May 2004
Reviewed and Updated:	May 2010
Publication Date:	<i>Dialogue</i> , Issue 2, 2010
Key Words:	Ultrasound, Diagnostic Imaging, Entertainment, 3D, 4D, Gender selection
Related Topics:	Practice Guide
Reference Materials:	Health Canada; Ontario Association of Radiologists; Canadian Association of Radiologists; Society of Obstetricians and Gynecologists of Canada; Canadian Society of Diagnostic Medical Sonographers; Food and Drug Administration; American College of Obstetricians and Gynecologists; American Institute of Ultrasound in Medicine.
College Contact:	Public and Physician Advisory Service

Purpose

Physicians routinely order or perform diagnostic fetal ultrasounds during the course of a patient's pregnancy. At times, physicians may be asked by expectant mothers and their families to order or perform a fetal ultrasound for non-medical reasons.

The purpose of this policy is to outline the College's expectations of physicians with respect to ordering and performing fetal ultrasounds.

Principles

1. The physician's responsibility is to act in the best interest of the patient.
2. Acting in the patient's best interest includes maintaining the medical knowledge and clinical skills necessary to provide quality care to patients.

Background

Diagnostic fetal ultrasound is an essential component of prenatal care.¹ Fetal ultrasound, in conjunction with other appropriate diagnostic tests, provides important medical information, such as the size, age and state of health of the fetus.²

Fetal ultrasound technology is used by others for non-medical reasons, such as for entertainment or gender identification:

1) Entertainment

As more advanced ultrasound technologies are becoming available such as 3D/4D ultrasound, expectant mothers and their families are requesting fetal keepsake videos and portraits.

2) Gender Identification

Requests are sometimes made for the performance of an ultrasound to determine the sex of the baby for gender selection purposes.

There are a number of organizations that have formal statements that provide that the use of ultrasound for entertainment or fetal gender determination purposes is inappropriate.³ The College of Physicians and Surgeons of Ontario's Independent Health Facilities Program refers to these statements, along with this policy, when inspections are carried out in facilities where fetal ultrasounds are performed.

College Policy

Physicians must ensure that all diagnostic fetal ultrasounds are ordered and conducted for appropriate clinical indications, in accordance with relevant statements and guidelines.

The purpose of an imaging examination should always be to obtain information relevant to the diagnosis or treatment of a patient. Therefore, when ordering the diagnostic fetal ultrasound, the physician should specify the clinical indications.

If a physician orders or performs a diagnostic fetal ultrasound for medical reasons, they may provide their patients with any picture or video of the fetus that is created as a result of that imaging examination.

However, it is inappropriate and contrary to good medical practice to use ultrasound only to view the fetus to obtain a picture or video of the fetus or to determine gender of the fetus.

Endnotes

¹ Experts in Canada recommend that all women have a diagnostic ultrasound when they are pregnant. The Society of Obstetricians and Gynaecologists of Canada has clinical guidelines with respect to diagnostic fetal ultrasound.

² Health Canada, “Fetal Ultrasound for Keepsake Videos”, November 2003, available at <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/med/ultrasound-eochographie-eng.php>.

³ Health Canada, the Ontario Association of Radiologists, the Canadian Association of Radiologists, the Society of Obstetricians and Gynaecologists of Canada, the Canadian Society of Diagnostic Medical Sonographers, the Food and Drug Administration, the American College of Obstetricians and Gynecologists, and the American Institute of Ultrasound in Medicine are just some of the organizations that oppose the use of ultrasound for these purposes.

Appendix VI Endocavity Transducer Reprocessing

Reprocessing must be in a separate designated area than scanning and include a sink.
All transducers should be labelled as "HIGH LEVEL DISINFECTION."

Sterile one-time use transducer covers and gel must be used for all endocavity exams.
Non-latex covers and gloves should be available for latex sensitive patients.

Gloves, masks and goggles should be worn as per SDS during reprocessing. An eye wash station must be available as per IPAC clinical office practice parameters.
Verify if the HLD requires venting and/or a spill kit.

After completion of the exam, the sonographer uses gloved hand to dispose of the transducer cover and their glove. (Careful not to contaminate the transducer with the patient's secretions.)

The transducer and cable is wiped with a dry cloth/tissue to remove excess gel and disconnect from the system

The transducer is wiped with a hospital grade low level disinfectant and/or washed in an enzymatic detergent in the reprocessing area. A medical instrument brush may be required to clean crevices. (All solutions/brushes should be approved by manufacturer)

The transducers must be soaked in an approved high level disinfectant solution as per the manufacture's guidelines. Care to ensure that the integrity of the transducer is intact, so that the solution does not enter the device or connector.

Once the soaking time has completed, the transducer must be thoroughly rinsed with potable water and wiped dry. DO NOT let air dry.

Perform Hand Hygiene in another area as reprocessing sink stations cannot be used for hand hygiene and return the transducer to its clean location.

Go To: DOCUMENTATION OF REPROCESSING

Integrity of Transducers

- Endocavity transducers should be examined regularly for any damage. If damage is evident, discontinue use.

Non Endocavity Transducers:

- Transducers and cords should be wiped clean of gel with a dry wipe and then a hospital grade low level disinfectant wipe after each examination. (Approved by manufacturer)

****DO NOT** use any alcohol, bleach, ammonium chloride or hydrogen peroxide on transducers.
All endocavity transducers must be cleaned according to the manufacturer's instructions.

Documentation of Reprocessing

Record the following:

- Patient's ID number
- Transducer Identifier
- Soaking Time, Date
- Name of the Person who cleaned the transducer



Testing of HLD: Record the following:

- Test strips specific to the HLD be done daily before use (record lot #)
- Test strip testing be done after solution change



HLD solution change: Change either at:

- Manufacturer's suggested time i.e. every 2 weeks
- Fails test strip testing

Solution must be discarded as per manufacture's instruction as some may require a neutralizing substance to be added before it can be poured down the drain.



Record Keeping:

All written documentation must be maintained on site for 6 years



To Ensure Compliance:

The written policy and procedure on reprocessing techniques be reviewed and updated annually by all staff.

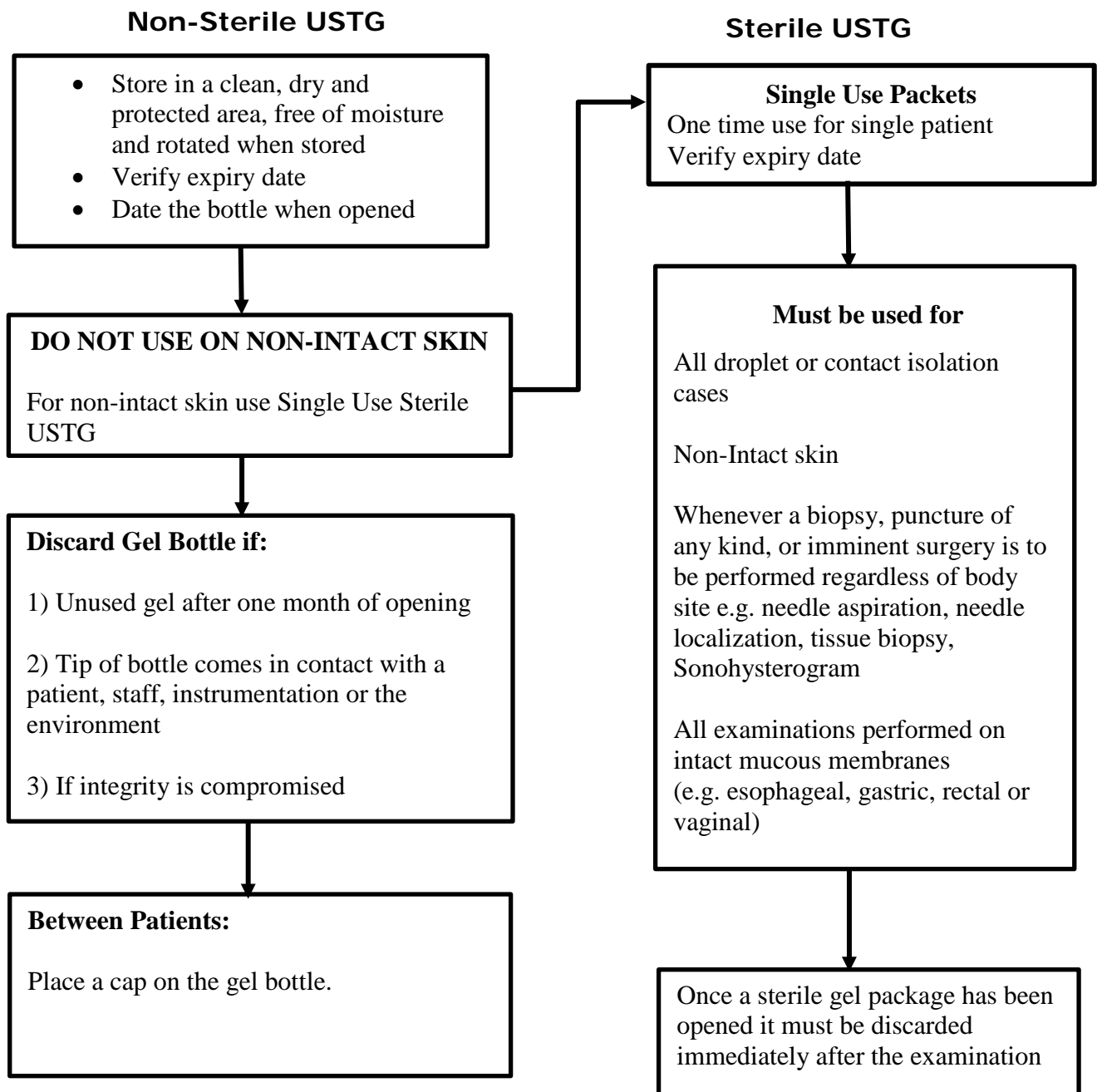
Appendix VII Ultrasound Transmission Gel (USTG) Recommendations

Ultrasound Transmission Gel (USTG) Recommendations: Referred to as “Gel”

***DO NOT WARM GEL**

****Gel Bottles are one time use only!**

IPAC Canada position statement on medical gels “Containers of gel should never be washed and refilled for use but should be discarded when empty.”



Appendix VIII 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, once your patient is seen?		1	2	3	4	5
to get an oral report from this facility when it is required because of an urgent or emergency situation, once your patient is seen?	0	1	2	3	4	5

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 IX 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.

<i>Please rate each by circling the number that best describes your opinion</i>	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

<i>Please answer the following questions by circling 1 for Yes or 2 for No.</i>	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
<i>Please rate this item by circling the number that best describes your opinion</i>	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!

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 in compliance 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 (www.car.ca) to ensure that they have obtained and are in compliance with the most current standards of practice for the profession.

Practice Guidelines

Please refer to the link: <http://car.ca/en/standards-guidelines/standards.aspx>

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 (<https://www.acr.org/>) 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. For more information, please refer

to: <https://www.cancercare.on.ca/pcs/screening/breastscreening/OBSP/affiliatingobsp/>

Referral Guidelines

Diagnostic Imaging Referral Guidelines – A Guide for Physicians 2012

<http://www.car.ca/en/standards-guidelines/guidelines.aspx>

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

<http://www.ncbi.nlm.nih.gov/pubmed/15516621>

Source

Departments of Radiology, Internal Medicine, and Pulmonary Medicine, Emory Clinic, Bldg. A, 1365 Clifton Rd NE, Atlanta, GA 30322, USA. stefan_tigges@emoryhealthcare.org.

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.

Comment in

- [Radiology. 2005 Jul;236\(1\):368; author reply 368.](#)

[Tigges S, Roberts DL, Vydareny KH, Schulman DA](#)

Independent Health Facilities: Clinical Practice Parameters and Facility Standards

Diagnostic Imaging

VOLUME 3 TELERADIOLOGY (PACS)

OAR Teleradiology Practice Standard

June 2007

OAR TELERADIOLOGY PRACTICE STANDARD

Definition

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

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

Preface

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

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

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

Role of a Diagnostic Radiologist

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

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

1. Diagnostic radiology is an integrated medical service required in every modern health care system.
2. Referring physicians are dependent upon the local availability of diagnostic imaging physicians to assist them to manage the health of their patients.
3. Only fully qualified diagnostic radiologists should provide the teleradiology service. They must be properly accredited, registered, and licenced in Ontario. The radiologist should be subject to licensing and quality assurance requirements of the provincial health authority; legislative and professional requirements of the facility providing the service; the provincial College of Physicians and Surgeons, accreditation and be in good standing with the Royal College of Physicians and Surgeons of Canada.
4. A definitive report is mandatory with the signature of the reporting radiologist. Electronic signatures are acceptable as long as they can be authenticated.
5. In a public hospital the members of the radiology department must be credentialed and be part of the recognized medical staff.
6. The department head via the Medical Advisory Committee (MAC) and Board is responsible for the medical service.
7. In an Independent Health Facility (IHF), the off-site radiologist must be approved by the radiologist Quality Advisor who is legislatively responsible for Quality Control/Quality Assurance (QC/QA) at the IHF.
8. All radiologists providing teleradiology services must be covered by the Canadian Medical Protective Association (CMPA) for medical liability issues and ensure they are compliant with current CMPA guidelines and policies covering diagnostic imaging physicians to safeguard patient interests.
9. Ensure that all radiologists and their staff involved in the delivery of teleradiology services are in full compliance with relevant privacy legislation and facility policies to protect patient confidentiality.
10. Ensure that the information received for a primary read is the full data set and that the reading radiologist should have all of the functionality of the PACS at his/her disposal to do an interpretation.

Key Management Issues

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

- a. The clinical evaluation and data is provided with the request for the examination.
- b. The requirements of the Healing Arts Radiation Protection Act (HARP) (including justification, appropriate techniques, optimization, and good procedure) are fulfilled.
- c. The report of the teleradiology service can be reviewed with clinicians and where applicable, in multi-disciplinary meetings and integrated with patients' notes and previous studies.
- d. The reporting radiologist of the teleradiology service is able to communicate directly with the referring radiology department and clinicians in order to discuss the clinical background and unexpected diagnosis, which may be relevant to the timely management of the patient.
- e. Teleradiology services that are developed to meet the needs of rural, remote and small community areas must be linked to the nearest substantive radiology department and the service is managed by that department. The radiologists involved in providing the service must have a close connection and knowledge of referring clinicians, and technologists, and should understand any particular local disease and cultural factors.

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

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

Real and Potential Problems

Clinico-Radiological Communication

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

Team Working

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

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

Communication

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

Wording of Report and Clinical Impact

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

Modern imaging commonly demonstrates an abundance of reportable findings, some of which are clinically relevant and some of which are incidental findings/pseudo-disease. Multiple pathologies can exist in the same patient. The clarity and certainty conveyed in the text is particularly important in converting a report that is merely 'diagnostically accurate' into one that has a diagnostic outcome and potentially a therapeutic outcome for the patient. Clinicians are more likely to act on the nuances intended in a report generated by a radiologist with whom they regularly liaise compared with a report generated by a third party teleradiology service from someone they never met. Specific wording of reports for general family doctors may be necessary, which is different from the reports to specialists

within their sphere of interest. Familiarity with the referring doctors can make specific reports more appropriate and useful. Knowledge of referring doctors can make specific reports more appropriate. Health care delivery varies between different jurisdictions. Recommendations for further imaging/specialist referral, which might be appropriate in the locale where a teleradiology service is provided, may be inappropriate in the area where the patient is located.

Access to Previous Examinations/Interpretations

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

Downstream Costs

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

Quality Control and Quality Assurance

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

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

Legal Issues

There are a number of potential legal issues.

- a. The registration of the reporting doctors must be accredited by the regulatory body of the local jurisdiction of a hospital/facility or the health authority purchasing the service. This is an essential requirement in order to maintain proper standards of practice. The reporting radiologists must

demonstrate that they undergo appropriate CME and are properly trained in the tasks to be undertaken.

- b. The providers of the service must abide by the jurisdiction's health and safety legislation.
- c. The use of radiology also creates difficulties in terms of the medico-legal issues and the medico-legal responsibilities of the referring hospital/facility and that of the reporting teleradiology services must be identified. Any radiologist that reviews images has a responsibility. Liability may also reside with the purchasers of the radiology service and/or the employers of the "radiologist". It must be clear who maintains responsibility for the patient. It is clear that the "radiologist" has a direct responsibility for the patients whose study they interpret. Teleradiology providers would have to comply with any statutory duty of candor to inform the hospital/facility and patient(s) when they become aware of a negligent act or omission. At present, the legal status of teleradiology remains to be clearly established.
- d. Consent. It is not clear whether the patients will be required to give explicit consent for their images to be transferred to another country or different provincial jurisdiction for reporting.
- e. Jurisdiction. An individual has the right to sue a company providing electronic services within another country and the suit would be heard in the patient's own country or provincial jurisdiction.
- f. Patient confidentiality. The teleradiology service must ensure patient confidentiality and be of adequate technical specification. It must comply with the data protection legislation in the transmitting and receiving provincial jurisdiction.
- g. There is increasing awareness of the need to reduce the radiation dose that many patients receive, particularly CT scanning. When creating teleradiology contracts, it must be made clear who has responsibility for defining the protocol of an individual imaging study, e.g. high or low dose depending on clinical indication. Teleradiology providers need to comply with pertinent directives mandated in the provincial jurisdiction.

Guidelines for the Development and Appropriate Use of Teleradiology

- 1. The principle that the patient is best served by a close liaison between the patient, the clinicians and the clinical radiology department should be paramount.
- 2. The radiologist's expected duty of care to the patient must not be compromised, lowered, or altered in any way by the use of teleradiology.
- 3. Teleradiology referrals should, be in the majority of cases, organized between clinical radiologists and the teleradiology provider. It is important that the radiologists act as practitioners under the statutes, regulations, directives, policies, bulletins, bylaws issued by provincial and local hospital/clinic authorities in order to ensure that appropriate investigations are performed and to justify any further investigations suggested by the reporting radiologist.
- 4. The full agreement of radiologists should be obtained in order for the development of teleradiology services to be implemented.
- 5. Teleradiology services developed for rural, remote and/or under-serviced areas should be linked to other facilities in the province of Ontario and the service should be managed by the receiving department/clinic unless there is a radiologist at the originating centre who may elect to assume that responsibility or share it with the receiving centre radiologist. The radiologists involved in providing the service should have close communication with the referring clinicians and patients and should understand any particular local disease and cultural factors.

6. The radiologists providing the service must be properly accredited and registered within the provincial jurisdiction where the patient receives the service. They should also be registered and subject to quality and revalidation requirements, where applicable.
7. Under no circumstances should teleradiology reports be made by radiologists in training without supervision and the implementation of teleradiology should not be to the detriment of the training in the originating centre.
8. The use of subspecialty services should be for the benefit of a second opinion or for the immediate transfer of patients to specialist centres and not for the centralization of subspecialty reporting away from general hospitals/clinics.
9. The reporting radiologist of the teleradiology service must be able to communicate directly with the referring radiology department and clinicians in order to discuss the clinical background and unexpected diagnosis which may be relevant to the timely management of the patient. The equipment used to undertake the whole process of teleradiology must be of a quality and standard that provides diagnostic quality images at all times.
10. Proper audit procedures should be in place in order to check the quality of the teleradiology service, the accuracy of the radiological reports and the overall therapeutic and clinical impact of the service. This must include user/clinician feedback.
11. The teleradiology service must comply with all national and provincial data protection standards. Transfer of images outside the province could pose significant problems of data protection. It is essential that the privacy and the integrity of patient information must be preserved at all times.
12. There needs to be clearly defined agreement with the teleradiology service with regard to confidentiality of the images which should allow retention for comparison, proper defense against litigation or other clinically appropriate reason.
13. The legal arrangements must be clearly defined between the user and the provider so that proper restitution may be made to patients, if errors are made. If the service is less than optimal, patients should not be required to litigate in the foreign country in the event of a complaint unless they have consented formally to the transfer of their rights for local litigation in addition to initial image transfer.
14. At all times the provision of teleradiology must be primarily developed in the best interest of the patient care and not as a cost cutting measure which may jeopardize patient safety and standards of health care.

References

1. HOU SH, BUSHINSKY DA, WISH JB, COHEN JJ, HARRINGTON JT. Hospital-acquired renal insufficiency: a prospective study. *Am J Med* 1983;74:243-8.
2. NASH K, HAFEEZ A, HOU S. Hospital-acquired renal insufficiency. *Am J Kidney Dis* 2002; 39:930-6.
3. MCCULLOUGH PA, WOLYN R, ROCHER LL, LEVIN RN, O'NEILL WW. Acute renal failure after coronary intervention: incidence, risk factors, and relationship to mortality. *Am J Med* 1997;103:368-75.
4. RIHAL CS, TEXTOR SC, GRILL DE, et al. Incidence and prognostic importance of acute renal failure after percutaneous coronary intervention. *Circulation* 2002;105:2259-64.
5. LEVY EM, VISCOLI CM, HORWITZ RI. The effect of acute renal failure on mortality. A cohort analysis. *Jama* 1996;275:1489-94.
6. DAWSON P. Patient dose in multislice CT: why is it increasing and does it matter? *Br J Radiol* 2004;77 Spec No 1:S10-3.
7. MORCOS SK. Contrast medium-induced nephrotoxicity. In: Dawson P, ed. *Textbook of Contrast Media*. Oxford: Isis Medical Media Ltd., 1999.
8. MORCOS SK, THOMSEN HS, WEBB JA. Contrast-media-induced nephrotoxicity: a consensus report. Contrast Media Safety Committee, European Society of Urogenital Radiology (ESUR). *Eur Radiol* 1999;9:1602-13.

9. WAYBILL MM, WAYBILL PN. Contrast media-induced nephrotoxicity: identification of patients at risk and algorithms for prevention. *J Vasc Interv Radiol* 2001;12:3-9.
10. GAULT MH, LONGERICH LL, HARNETT JD, WESOLOWSKI C. Predicting glomerular function from adjusted serum creatinine. *Nephron* 1992;62:249-56.
11. FOUNDATION NK. K/DOQI Clinical Practice Guidelines for Chronic Kidney Disease: Evaluation, classification, and Stratification.
12. DANGAS G, IAKOVOU I, NIKOLSKY E, et al. Contrast-induced nephropathy after percutaneous coronary interventions in relation to chronic kidney disease and hemodynamic variables. *Am J Cardiol* 2005;95:13-9.
13. BEST PJ, LENNON R, TING HH, et al. The impact of renal insufficiency on clinical outcomes in patients undergoing percutaneous coronary interventions. *J Am Coll Cardiol* 2002;39:1113-9.
14. RUDNICK MR, GOLDFARB S, WEXLER L, et al. Nephrotoxicity of ionic and nonionic contrast media in 1196 patients: a randomized trial. The Iohexol Cooperative Study. *Kidney Int* 1995;47:254-61.
15. MANSKE CL, SPRAFKA JM, STRONG JT, WANG Y. Contrast nephropathy in azotemic diabetic patients undergoing coronary angiography. *Am J Med* 1990;89:615-20.
16. COCHRAN ST. Determination of serum creatinine level prior to administration of radiographic contrast media. *Jama* 1997;277:517-8.
17. TIPPINS RB, TORRES WE, BAUMGARTNER BR, BAUMGARTEN DA. Are screening serum creatinine levels necessary prior to outpatient CT examinations? *Radiology* 2000;216:481-4.
18. BARTHOLOMEW BA, HARJAI KJ, DUKKIPATI S, et al. Impact of nephropathy after percutaneous coronary intervention and a method for risk stratification. *Am J Cardiol* 2004;93:1515-9.
19. MEHRAN R, AYMONG ED, NIKOLSKY E, et al. A simple risk score for prediction of contrast-induced nephropathy after percutaneous coronary intervention: development and initial validation. *J Am Coll Cardiol* 2004;44:1393-9.
20. RICH MW, CRECELIUS CA. Incidence, risk factors, and clinical course of acute renal insufficiency after cardiac catheterization in patients 70 years of age or older. A prospective study. *Arch Intern Med* 1990;150:1237-42.
21. THOMSEN HS, MORCOS SK. In which patients should serum creatinine be measured before iodinated contrast medium administration? *Eur Radiol* 2005;15:749-54.
22. CHOYKE PL, CADY J, DEPOLAR SL, AUSTIN H. Determination of serum creatinine prior to iodinated contrast media: is it necessary in all patients? *Tech Urol* 1998;4:65-9.
23. THOMSEN HS. How to avoid CIN: guidelines from the European Society of Urogenital Radiology. *Nephrol Dial Transplant* 2005;20 Suppl 1:i18-22.
24. BARRETT BJ, PARFREY PS. Clinical practice. Preventing nephropathy induced by contrast medium. *N Engl J Med* 2006;354:379-86.
25. OLSEN JC, SALOMON B. Utility of the creatinine prior to intravenous contrast studies in the emergency department. *J Emerg Med* 1996;14:543-6.
26. BLAUFox MD, AURELL M, BUBECK B, et al. Report of the Radionuclides in Nephrourology Committee on renal clearance. *J Nucl Med* 1996;37:1883-90.
27. MORCOS SK, THOMSEN HS. European Society of Urogenital Radiology guidelines on administering contrast media. *Abdom Imaging* 2003;28:187-90.
28. TRIVEDI HS, MOORE H, NASR S, et al. A randomized prospective trial to assess the role of saline hydration on the development of contrast nephrotoxicity. *Nephron Clin Pract* 2003;93:C29-34.
29. MUELLER C, BUERKLE G, BUETTNER HJ, et al. Prevention of contrast media-associated nephropathy: randomized comparison of 2 hydration regimens in 1620 patients undergoing coronary angioplasty. *Arch Intern Med* 2002;162:329-36.
30. MERTEN GJ, BURGESS WP, GRAY LV, et al. Prevention of contrast-induced nephropathy with sodium bicarbonate: a randomized controlled trial. *Jama* 2004;291:2328-34.
31. MCCULLOUGH PA, SOMAN SS. Contrast-induced nephropathy. *Crit Care Clin* 2005;21:261-80.
32. TAYLOR AJ, HOTCHKISS D, MORSE RW, MCCABE J. PREPARED: Preparation for Angiography in Renal Dysfunction: a randomized trial of inpatient vs outpatient hydration protocols for cardiac catheterization in mild-to-moderate renal dysfunction. *Chest* 1998;114:1570-4.
33. FREEMAN RV, O'DONNELL M, SHARE D, et al. Nephropathy requiring dialysis after percutaneous coronary intervention and the critical role of an adjusted contrast dose. *Am J Cardiol* 2002;90:1068-73.

34. Compendium of Pharmaceuticals and Specialties – The Drug Reference for Health Professionals: Canadian Pharmaceutical Association, 2005.
35. BUSH WA. Update on Metformin (Glucophage®) Therapy and the Risk of Lactic Acidosis: Change in FDA-approved Package Insert. ACR Bulletin 1998;54.
36. THOMSEN HS. Guidelines for contrast media from the European Society of Urogenital Radiology. AJR Am J Roentgenol 2003;181:1463-71.
37. RADIOLOGISTS TRAANZCO. Guidelines for Metformin Hydrochloride and Intravascular Contrast Media, 2003 (vol 2006).
38. MARENZI G, MARANA I, LAURI G, et al. The prevention of radiocontrast-agent-induced nephropathy by hemofiltration. N Engl J Med 2003;349:1333-40.
39. ASPELIN P, AUBRY P, FRANSSON SG, STRASSER R, WILLENBROCK R, BERG KJ. Nephrotoxic effects in high-risk patients undergoing angiography. N Engl J Med 2003;348:491-9.
40. NYMAN U, ELMSTAHL B, LEANDER P, NILSSON M, GOLMAN K, ALMEN T. Are gadolinium-based contrast media really safer than iodinated media for digital subtraction angiography in patients with azotemia? Radiology 2002;223:311-8; discussion 328-9.
41. NALLAMOTHU BK, SHOJANIA KG, SAINT S, et al. Is acetylcysteine effective in preventing contrast-related nephropathy? A meta-analysis. Am J Med 2004;117:938-47.
42. BAKER CS, WRAGG A, KUMAR S, DE PALMA R, BAKER LR, KNIGHT CJ. A rapid protocol for the prevention of contrast-induced renal dysfunction: the RAPPID study. J Am Coll Cardiol 2003;41:2114-8.
43. MCCULLOUGH PA, SANDBERG KR. Epidemiology of contrast-induced nephropathy. Rev Cardiovasc Med 2003;4 Suppl 5:S3-9.
44. BAKER CS, WRAGG A, KUMAR S, DE PALMA R, BAKER LR, KNIGHT CJ. A rapid protocol for the prevention of contrast-induced renal dysfunction: the RAPPID study. J Am Coll Cardiol 2003;41:2114-8.
45. MCCULLOUGH PA, SANDBERG KR. Epidemiology of contrast-induced nephropathy. Rev Cardiovasc Med 2003;4 Suppl 5:S3-9.
46. Solomon R. The role of osmolality in the incidence of contrast-induced nephropathy: A systematic review of angiographic contrast media in high risk patients. Kidney International. 2005;68:2256-2263.

CAR Standards for Teleradiology

It is the position of the IHF Diagnostic Imaging Task Force that studies must be physically performed in Ontario and that the reporting radiologist must be in the province at the time of reviewing and reporting.

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

Approved: May 2008

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

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

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

I. DEFINITION

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

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

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

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

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

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Radiologists

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

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

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

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

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

The radiologist workload for teleradiology and on site should be at a level that quality of care and interpretation accuracy are not compromised. The local, or if unavailable, reporting radiologist should therefore be involved in decisions involving teleradiology. If there is no local radiologist, then the reporting radiologist or another radiologist must regularly visit the department for quality control.

B. Technologists

The Medical Radiation technologist must meet the certification requirements for the province in which they are practising. For most provinces, for MRT this would be certification by either the CAMRT or the Ordre des technologues en radiologie du Québec. For Sonographers, this would be certification by ARDMS or CARDUP.

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

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

C. Others

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

III. EQUIPMENT STANDARDS

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

A. Specific Standards

Specifications for equipment used in teleradiology will vary depending on the individual facility's needs, but in all cases it should provide image quality and availability appropriate to the clinical need. Compliance with the current DICOM and Canadian IHE standard is required for all new equipment acquisitions, and consideration of periodic

upgrades incorporating the enhancements recommended in that standard should be part of the continuing quality improvement program.

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

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

B. Acquisition or Digitization

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

1. Direct image capture

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

2. Secondary image capture

- a. Small-matrix images: Each image should be digitized to a matrix size as large as or larger than that of the original image by the imaging modality. The images should be digitized to a minimum of 8 bits pixel depth. Film digitization or video frame grab systems conforming to the above specifications are acceptable.
- b. Large-matrix images: These images should be digitized to a matrix size corresponding to 2.5 lp/mm or greater, measured in the original detector plane. These images should be digitized to a minimum of 10 bits pixel depth.

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

C. Mammography and Fluoroscopy and Ultrasound

i) Mammography:

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

ii) Fluoroscopy:

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

iii) Tele-Ultrasound

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

D. General Standards

1. Image Management

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

- a. Capability for the selection of the image sequence for transmission and display at all the reviewing sites.
- b. The patient must be identified accurately and unambiguously. This may include patient name, identification number, date and time of examination, film markers, institution of origin, type of examination, degree of compression (if used) and a brief patient history. This information should be bundled with the image file but may also be transmitted by other secure means e.g. fax.
- c. Capacity to obtain prior examinations and reports.
- d. The issue of compression is currently under investigation by members of the CAR PACS /Teleradiology committee who hope to define and recommend compression levels for varying modalities. In the interim compression should be used judiciously.
- e. Image storage at either the acquisition or reviewing site as well as transmission must be arranged such that patient confidentiality is maintained and that the system is secure.
- f. The provider must ensure that the image quality is the same at the acquisition site and reviewing site(s).

E. Transmission of Images and Patient Data

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

F. Display Capabilities

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

- 1. Luminance of the gray-scale monitors of at least 50 foot-lamberts.
- 2. Display stations must accurately reproduce the original study and must include:
 - a. brightness and contrast and/or interactive window and level function
 - b. a magnification function
 - c. the capability of rotating and flipping the displayed images
 - d. the capability of accurate linear measurements and CT Hounsfield units
 - e. the capability of inverting the gray-scale values of the displayed image
 - f. the capability to display clinically relevant parameters

G. Patient Database

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

- 1. patient name, identification number and date
- 2. type of examination e.g. Chest
- 3. modality e.g. CT, MRI etc.

4. number of images
5. image acquisition site
6. date and time of acquisition and availability for review

H. Security

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

I. Reliability and Redundancy

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

IV. STORAGE OF RECORDS

The legal requirements for the storage and retention of images and reports will vary from province to province and the providers of the teleradiology service are responsible for adhering to these requirements.

Images stored at either the acquisition or reviewing site shall meet the jurisdictional requirements of the acquisition site. Images interpreted off-site need not be stored at the reviewing facility provided that they are stored at the acquisition site. The policy on record retention should be in writing and may in part reflect the accreditation requirements of the two facilities involved.

V. DOCUMENTATION

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

VI. QUALITY CONTROL FOR TELERADIOLOGY

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

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

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

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

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

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

VII. QUALITY IMPROVEMENT

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

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

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

VIII. LICENSING, CREDENTIALING AND LIABILITY

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

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

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

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

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

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

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

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

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

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

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

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

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

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

PACS – Picture Archival and Communication System

Resolution - the ability of an imaging system to differentiate between objects.

Sonographer - a technologist approved by the regional licensing body to perform diagnostic ultrasound services.

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

Ezequiel Silva III, MD (Chair)^{a,b}, Jonathan Breslau, MD^c, Robert M. Barr, MD^d,
Lawrence A. Liebscher, MD^e, Michael Bohl, RT, MHA^f, Thomas Hoffman, JD, CAE^g,
Giles W. L. Boland, MD^h, Cynthia Sherry, MDⁱ, Woojin Kim, MD^j,
Samir S. Shah, MD, MMM^k, Mike Tilkin^g

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

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

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

BACKGROUND

Introduction and Definitions

The rapid evolution of the corporate business model and the absence of a public ACR statement on acceptable practices and quality standards for teleradiology companies impelled John A. Patti, MD, chairman of the ACR Board of Chancellors, to establish the ACR Task Force on Teleradiology Practice in January 2012. The outcome of our work is this white paper. Its goals are neither to

commend nor to condemn the practice of teleradiology but to comment on the current status of domestic teleradiology, propose guidelines for best practice, and recommend possible actions to the ACR.

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

Prior ACR Comments on Teleradiology

Several extant ACR documents address the topic of teleradiology. In 1994, the ACR Council adopted a resolution concluding that state licensing boards should require licensure of

out-of-state physicians who provide official, authenticated written radiological interpretations of examinations that are performed on patients in the licensing state but interpreted in another jurisdiction, provided that such law or regulation does not restrict the ability of

^aSouth Texas Radiology Group, San Antonio, Texas.

^bDepartment of Radiology, University of Texas Health Science Center at San Antonio, San Antonio, Texas.

^cRadiological Associates of Sacramento Medical Group, Inc, Sacramento, California.

^dMecklenburg Radiology Associates, PA, Charlotte, North Carolina.

^eCedar Valley Medical Specialists, PC, Waterloo, Iowa.

^fRadiology Group, PC, SC, Davenport, Iowa.

^gAmerican College of Radiology, Reston, Virginia.

^hMassachusetts General Hospital, Boston, Massachusetts.

ⁱTexas Health Presbyterian Hospital, Dallas, Texas.

^jDepartment of Radiology, Perelman School of Medicine at the University of Pennsylvania, Philadelphia, Pennsylvania, USA.

^kVirtual Radiologic, Eden Prairie, Minnesota.

Corresponding author and reprints: Ezequiel Silva III, MD, South Texas Radiology Group, 8401 Datapoint, Suite 600, San Antonio, TX 78229; e-mail: zekesilva3@gmail.com.

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

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

Current State of Teleradiology

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

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

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

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

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

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

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

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

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

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

TASK FORCE RECOMMENDATIONS

The Teleradiologist

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

Licensure. States mandate and enforce medical licensure through legislation and regulation by the states' medical boards. To ensure that the full resources of a state are available for the protection of patients, medical practice is considered to occur at the location of the patient [17]. The task force endorses the ACR's 2012 Technical Standard for Electronic Practice of Medical Imaging [3] requirement that radiologists be familiar with the licensure requirements for providing teleradiology services at

both the transmitting and receiving sites and obtain licensure as appropriate. Under current law, that would typically involve licensure in the transmitting state, but not necessarily the receiving state.^{1,2}

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

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

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

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

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

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

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

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

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

The Teleradiologist's Work Environment

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

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

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

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

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

ties that have applied for FDA [27] approval did so with 5-megapixel monitors.

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

Interpretive

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

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

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

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

Services

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

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

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

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

The communication of critical test results, a Joint Commission National Patient Safety Goal, is important to the practice of radiology because failures in this process can lead to patient morbidity and mortality. It is also one of the major contributors to malpractice claims in radiology [32,33]. Different levels of acuity and criticality should be predefined and should include the time frame during which critical test results should be communicated. Some results may require synchronous (usually via telephone) physician-to-physician communication.

Given the potential for delays and the importance of the information, teleradiologists should escalate their efforts to communicate when a provider cannot be reached immediately. The parameters for escalation should be predetermined and the process terminated only when the appropriate provider acknowledges receipt of the report.

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

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

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

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

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

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

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

Payment and Regulatory Considerations

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

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

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

Medical Directors' Duties. MIPPA-accredited facilities must have medical directors whose roles are supervisory and who serve to fulfill a number of regulatory, professional, administrative, educational, and quality initiatives. Medical directorship is required for optimal imaging facility functionality, whether the facility is part

of a hospital network, a physician-owned practice, or an independent diagnostic testing facility (IDTF) [38].⁴

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

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

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

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

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

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

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

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

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

⁵ In 2008, CMS imposed an antimarkup limitation on the PC of diagnostic tests provided to IDTFs [41]. The antimarkup limitation is triggered when the facility bills and collects for the PC on behalf of the physician providing the PC service and then pays the physician for having performed the service. For services subject to the antimarkup limitation, “the payment from the facility to the physician who provided the PC may not exceed the lowest of the following amounts: [1] The performing supplier’s net charge to the physician or other supplier; [2] The billing physician or other supplier’s actual charge; or [3] The fee schedule amount for the test that would be allowed if the performing

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

Technology-Specific Considerations

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

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

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

supplier billed directly.” In 2009, CMS extended the antimarkup payment limitation on the PC of diagnostic tests to those that are performed under the in-office ancillary services exception of the Stark law [40,42]. This rule applies to the PC of diagnostic tests that are ordered by the billing physician or other supplier if the PC is outright purchased or if the PC is not performed in the office of the billing physician or other supplier.

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

PRACTICAL CONSIDERATIONS FOR RADIOLOGY PRACTICES

Contract Considerations

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

- Definitions of examinations and interpretations: There should be a clear statement of what constitutes a study or examination. Interpretations may be preliminary reports, with subsequent final interpretations provided by the contracting local radiologists, who will ultimately bill for the service. Alternatively, the teleradiology provider may issue a final or official interpretation and directly bill the insurer or patient. There may be different performance expectations for reporting time, completeness of the interpretation, and comparison with historical examinations for preliminary versus final interpretations.
- Hours of coverage.
- Minimum and maximum volumes of examinations: Teleradiology companies may seek to negotiate additional fees if minimum volumes are not met.
- Response time: There should be a defined time for most reports to be available. There may be different times for emergency examinations and routine studies or for preliminary reports versus final reports. Care should be taken in defining what starts the clock and what determines the end point. There should be provisions for rapid evaluation and communication of findings in emergent life-threatening situations. Critical results reporting should meet established institutional policies.
- Modalities covered: The specific modalities to be covered should be specified. There may be agreement for different response times and qualifications of the interpreting physician for different modalities, especially for specialized examinations such as coronary CT angiography and CT colonography.
- Subspecialty interpretations: A clear definition of what constitutes a subspecialist should be agreed upon. The specific examinations requiring interpretation by subspecialists should be defined. It is important that all parties have a clear understanding of how examinations are assigned. For examinations that require special attention, there should be a defined process for informing the teleradiology provider and routing the examinations to appropriate interpreting radiologists.

- Credentialing: Processing credentialing applications for a teleradiology provider can be a lengthy and costly process because there are advantages to obtaining privileges for a large number of providers. How many teleradiologists will be granted privileges and who is responsible for any associated fees should be understood.
- Quality assurance: The teleradiology provider should have an established quality assurance program including formal peer review. There should be a defined process for resolving discrepancies between preliminary and final interpretations. The interpreting physician should be available for consultation with the ordering clinician and with local radiologists. A process should be in place to provide additional review upon presenting new historical images or clinical information, as well as for dictating appropriate addenda to the final report. There should be a means to request second opinions in cases in which clinicians or local radiologists have questions or concerns regarding the initial interpretations.
- Malpractice coverage: The teleradiology provider should meet all local requirements for malpractice coverage.
- Accreditation: The teleradiology provider should meet all requirements for the facility's accreditation processes, including ACR accreditation.
- Records: The contract should define who owns records and is responsible for storage and HIPPA compliance.
- IT requirements: Responsibility for network connections, how issues are reported and resolved, and hours of tech support should be defined. Emergency downtime processes should be understood.
- Standard contractual issues: There should be delineation of typical requirements for contracts, such as the term of the contract, termination, warranties and covenants, indemnification, and confidentiality. Many contracts will include clauses for exclusivity on behalf of one or both parties.

COMPETITIVE MARKET FORCES

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

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

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

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

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

communication that occurs directly between the hospital and teleradiology company, regardless of whether that communication was initiated by the provider or the hospital.

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

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

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

RECOMMENDATIONS TO THE ACR

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

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

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

ACKNOWLEDGMENTS

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

REFERENCES

1. American College of Radiology. Off-site radiology. In: Digest of Council Actions 2012-2013. Available at: <http://amclcr.acr.org/digest2012-2013.pdf>. Accessed April 17, 2013.
2. Moore AV, Allen B, Campbell S, et al. Report of the ACR Task Force on International Teleradiology. *J Am Coll Radiol* 2005;2:121-5.
3. American College of Radiology. ACR-AAPM-SIIM Technical Standard for Electronic Practice of Medical Imaging. Revised 2012. Available at: <http://www.acr.org/media/AF1480B0F95842E7B163F09F1CE00977.pdf>. Accessed December 11, 2012.
4. Muroff LR. National entrepreneurial radiology initiatives: what are they, and what can they do to and for you? *J Am Coll Radiol* 2013;10:247-52.
5. Levin DC, Rao VM. Outsourcing for teleradiology companies: bad for radiology, bad for radiologists. *J Am Coll Radiol* 2011;8:104-8.
6. Harolds JA, Duszak R, Strax R, Short B, Kaye AD. Preventing another group from displacing your practice: perspectives from the 2010 AMCLC. *J Am Coll Radiol* 2011;8:99-103.
7. Radisphere. How to run a successful radiology RFP process. Available at: <http://www.radspheregroup.com/resources/tools/webcast-rfp-process>. Accessed June 17, 2012.
8. Radiologists employed with vRad face pay cuts in 2013. Imaging Economics. Available at: <http://www.imagingeconomics.com/all-news/19561-radiologists-employed-with-vrad-face-pay-cuts-in-2013>. Accessed December 11, 2012.
9. Neurostar announces new brand name. Imaging Economics. Available at: <http://www.imagingeconomics.com/all-news/19053>. Accessed January 2, 2013.
10. OptimalIMX becomes optimal radiology. Imaging Economics. Available at: <http://www.imagingeconomics.com/all-news/19538-optimal-imx-becomes-optimal-radiology>. Accessed December 12, 2012.
11. Virtual radiologic and nighthawk radiology complete merger. PR Newswire. Available at: <http://www.prnewswire.com/news-releases/virtual-radiologic-and-nighthawk-radiology-complete-merger-112322579.html>. Accessed February 22, 2013.
12. Larson PA, Janower ML. The nighthawk: bird of paradise or albatross? *J Am Coll Radiol* 2005;12:967-70.
13. Johnson AJ, Easterling D, Nelson R, Chen MY, Frankel RM. Access to radiologic reports via a patient portal: clinical simulations to investigate patient preferences. *J Am Coll Radiol* 2012;7:256-63.
14. Advanced Radiology Consultants. Home page. Available at: <https://www.adrad.com>. Accessed February 25, 2013.
15. Institute of Medicine. Core metrics for better care, lower costs, and better health. Available at: http://iom.edu/media/Files/Activity%20Files/Quality/VSR/TC/Core%20Metrics%20Workshop/Core%20Metrics_1paper_13Mar12.pdf. Accessed February 8, 2013.
16. Patti JA, Berlin JW, Blumber AL, Bryan RN. ACR white paper: the value added that radiologists provide to the health care enterprise. *J Am Coll Radiol* 2008;5:1041-53.
17. Report of the Council on Medical Education: Telemedicine and medical licensure. CME Report 6-A-10. Available at: <http://www.ama-assn.org/resources/doc/council-on-med-ed/cme-rep6-a10.pdf>. Accessed December 10, 2012.
18. Federation of State Medical Boards. Telemedicine overview: board-by-board approach. Available at: http://www.fsmb.org/pdf/GRPOL_Telemedicine_Licensure.pdf. Accessed June 8, 2012.
19. American College of Radiology. Practice guidelines and technical standards. Available at: <http://www.acr.org/Quality-Safety/Standards-Guidelines>. Accessed January 2, 2013.
20. Steele JR. The role of RADPEER in the Joint Commission ongoing practice performance evaluation. *J Am Coll Radiol* 2011;8:6-7.
21. Harisinghani MG, Blake MA, Saksena M, et al. Importance and effects of altered workplace ergonomics in modern radiology suites. *Radiographics* 2004;24:615-27.

22. Goyal N, Jain N, Rachapalli V. Ergonomics in radiology. *Clin Radiol* 2009;64:119-26.
23. Ong CN. Musculoskeletal disorders in operators of visual display terminals. *World Health Forum* 1994;15:161-4.
24. Burgess-Limerick R, Plooy A, Ankrum DR. The effect of imposed and self-selected computer monitor height on posture and gaze angle. *Clin Biomech* 1998;13:584-92.
25. Siddiqui KM, Chia S, Knight N, et al. Design and ergonomic considerations for the filmless environment. *J Am Coll Radiol* 2006;3:456-67.
26. US Department of Health and Human Services. Mammography Quality Standards Act regulations. Available at: <http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/Regulations/ucm110906.htm>. Accessed February 21, 2013.
27. 3MP display FDA-cleared for digital mammography. *Imaging Technology News*. Available at: <http://www.itnonline.com/article/3mp-display-fda-cleared-digital-mammography>. Accessed January 7, 2013.
28. US Department of Health and Human Services. Summary of the HIPAA privacy rule. Revised May 2003. Available at: <http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/privacysummary.pdf>. Accessed December 11, 2012.
29. American College of Radiology. Revised statement on the interpretation of radiology images outside the United States. In: *Digest of Council Actions* 2012-2013. Available at: <http://amclc.acr.org/digest2012-2013.pdf>. Accessed April 17, 2013.
30. US Department of Justice, The United States Attorney's Office, Northern District of Georgia. Atlanta radiologist sentenced to prison. December 9, 2011. Available at: <http://www.justice.gov/usao/gan/press/2011/12-09-11b.html>. Accessed February 8, 2013.
31. American College of Radiology. ACR practice guideline for communication of diagnostic imaging findings. Available at: <http://www.acr.org/Quality-Safety/Standards-Guidelines/Practice-Guidelines-by-Modality/General-Diagnostic>. Accessed February 19, 2013.
32. The Joint Commission. National Patient Safety Goals effective January 1, 2013. Available at: http://www.jointcommission.org/assets/1/18/NPSG_Chapter_Jan2013_HAP.pdf. Accessed February 21, 2013.
33. Gale BD, Bissett-Siegel DP, Davidson SJ, Juran David C. Failure to notify reportable test results: significance in medical malpractice. *J Am Coll Radiol* 2011;8:776-9.
34. American Registry of Radiologic Technologists. ARRT® standards of ethics. Revised September 1, 2012. Available at: <https://www.arrt.org/pdfs/Governing-Documents/Standards-of-Ethics.pdf>. Accessed January 4, 2013.
35. US Government Printing Office. Medicare Improvement for Patients and Providers Act of 2008, 122 Stat. 2494, 110th Cong. Available at: <http://www.gpo.gov/fdsys/pkg/PLAW-110publ275/pdf/PLAW-110publ275.pdf>. Accessed February 25, 2013.
36. Centers for Medicare and Medicaid Services. Chapter 13—radiology services and other diagnostic procedures. In: *Medicare claims processing manual*. Available at: <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c13.pdf>. Accessed February 22, 2013.
37. Centers for Medicare and Medicaid Services. Chapter 36—competitive bidding. In: *Medicare claims processing manual*. Available at: <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c36.pdf>. Accessed February 22, 2013.
38. US Department of Health and Human Services. Excerpts of the code of federal regulations 42 CFR § 410.33(b). Available at: <http://www.gpo.gov/fdsys/pkg/CFR-2010-title42-vol2/pdf/CFR-2010-title42-vol2-sec410-33.pdf>. Accessed May 3, 2013.
39. US Department of Health and Human Services, Centers for Medicare and Medicaid Services. Pub 100-04 Medicare claims processing: Transmittal 2613. Available at: <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2613CP.pdf>. Accessed April 17, 2013.
40. US Department of Health and Human Services. Code of federal regulations. 42 CFR [CMS-1403-FC] [CMS-1270-F2] 411.355(b). Accessed December 20, 2012.
41. US Department of Health and Human Services. 42 CFR 414.50. Federal Register. November 27 2007:66222, 66401.
42. StarkLaw.org. Home page. Available at: <http://starklaw.org>. Accessed December 20, 2012.
43. Institute of Medicine. Health IT and patient safety: building safer systems for better care. Washington, District of Columbia: National Academies Press; 2012.
44. Kuzmak PM, Dayhoff RE. Minimizing Digital Imaging and Communications in Medicine (DICOM) modality worklist patient/study selection errors. *J Digit Imaging* 2001;14(suppl):153-7.
45. Siegel E, Bruce R. Work flow redesign: the key to success when using PACS. *AJR Am J Roentgenol* 2002;178:563-6.
46. Smith JJ, Berlin L. Picture archiving and communication systems (PACS) and the loss of patient examination records. *AJR Am J Roentgenol* 2001;176:1381-4.
47. Thrall JH. Teleradiology: two-edged sword or friend of radiology practice? *J Am Coll Radiol* 2009;2:73-5.
48. Mook J. Beware predatory practices in teleradiology. *Healthcare Finance News*. June 16, 2011. Available at: <http://www.healthcarefinancenews.com/blog/beware-predatory-practices-teleradiology>. Accessed December 14, 2012.
49. Patti JA. Is quality good enough? *J Am Coll Radiol* 2012;9:88.

CPSO Telemedicine Policy

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

APPROVED BY COUNCIL: April 2007

REVIEWED AND UPDATED: December 2014

TO BE REVIEWED BY: December 2019

PUBLICATION DATE: Issue 4, 2014

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

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

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

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

COLLEGE CONTACT: Public and Physician Advisory Service

CPSO TELEMEDICINE POLICY

Introduction

Telemedicine is both the practice of medicine and a way to provide or assist in the provision of patient care at a distance¹ using information and communication technologies² (hereinafter “telemedicine”).

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

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

Principles

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

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

Purpose & Scope

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

This policy applies to all physicians who are members of the CPSO, regardless of where the physician or patient is physically located when telemedicine is practised. Expectations are provided in relation to providing or assisting in the provision of patient care via telemedicine, which includes consulting with and referring patients to other health-care providers, and practising telemedicine across borders. This policy applies broadly to the practice of telemedicine, regardless of the specific area of practice or practice setting in which telemedicine is used.

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

Policy

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

1. General Expectations for Telemedicine

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

Physicians must use their professional judgment to determine whether telemedicine is appropriate in a particular circumstance each and every time its use is contemplated for patient care, consultations and referrals.⁴ In doing so, physicians must consider whether practising telemedicine will enable physicians to satisfy all relevant and applicable legal⁵ and professional⁶ obligations, and meet the standard of care.

Physicians must:

- Consider the patient's existing health status, specific health-care needs and specific circumstances, and only use telemedicine if the risks do not outweigh the potential benefits and it is in the patient's best interest.
- Identify what resources (e.g., information and communication technology, equipment, support staff, etc.) are required, and only proceed if those resources are available and can be used effectively.
- Ensure the reliability, quality⁷ and timeliness of the patient information obtained via telemedicine is sufficient, and the patient is accurately identified.
- Protect the privacy and confidentiality of the patient's personal health information.

More specifically,

- Evaluate whether the information and communication technology and physical setting being used by the physician has reasonable security protocols^{8,9,10} in place to ensure compliance with physicians' legal¹¹ and professional¹² obligations to protect the privacy and confidentiality of the patient's personal health information.

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

2. Specific Expectations for Practising Telemedicine Across Borders

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

a) Expectations for CPSO Members

Physicians are reminded that the CPSO maintains jurisdiction over its members¹⁴ regardless of where (i.e., physical location) or how (i.e., in-person or via telemedicine) they practise medicine. In keeping with its statutory obligations as a medical regulatory authority, the CPSO will investigate any complaints made about a member,¹⁵ regardless of whether the member or patient is physically located in Ontario.

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

Out-of-province consultations and referrals

There may be circumstances when physicians consult with out-of-province physicians regarding their patients¹⁶ or refer patients to out-of-province physicians for care via telemedicine.

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

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

b) Expectations for Non-CPSO Members

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

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

Endnotes

- ¹ Patients, patient information and/or physicians may be separated by space (e.g., not in same physical location) and/or time (e.g., not in real-time).
- ² The specific technology that can be used is constantly evolving. Some current examples include, but are not limited to, the use of telephones (e.g., land lines and mobile phones), email, video and audio conferencing, remote monitoring and telerobotics.
- ³ The existence of a physician-patient relationship will be established having regard to the nature and frequency of the treatment provided, whether there is a medical record, whether the physician bills for the services provided, and any other relevant factors.
- ⁴ Physicians must make this determination when using telemedicine for the first time for a particular patient and each subsequent time its use is contemplated to ensure using telemedicine is still appropriate for that patient.
- ⁵ Including, for example, legal obligations with respect to privacy and confidentiality as set out in the *Personal Health Information Protection Act, 2004, S.O. 2004, c. 3, Schedule A* (hereinafter *PHIPA*), and mandatory liability coverage as set out in Section 50.02 of the *General By-Law*, enacted under Section 94(1) of the *Health Professions Procedural Code*, Schedule 2 of the *Regulated Health Professions Act, 1991, S.O. 1001, c.18* (hereinafter *HPPC*).
- ⁶ Professional expectations set out in the CPSO's *Practice Guide* and *policies*.
- ⁷ For example, diagnostic images must be of sufficient quality.
- ⁸ The security standards for information and communication technology are constantly evolving, so physicians may want to contact the Office of the Information and Privacy Commissioner of Ontario and/or the Canadian Medical Protective Association for the most up-to-date advice. Physicians can also refer to the following resources: Ann Cavoukian, Stuart Shapiro & R. Jason Cronk, Esq., *Privacy Engineering: Proactively Embedding Privacy, by Design* (Toronto: Information and Privacy Commissioner of Ontario, MITRE Corporation and Enterprivacy Consulting Group, 2014); Ann Cavoukian, *Encryption by Default and Circles of Trust: Strategies to Secure Personal Information in High-Availability Environments* (Toronto: Information and Privacy Commissioner of Ontario, Sunnybrook Health Sciences and CryptoMill

Technologies Ltd., 2012); Canadian Medical Protective Association, Telemedicine – Challenges and obligations (Ottawa: CMPA, 2013).

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

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

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

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

¹³. Section 3(2) of the HPPC.

¹⁴. Sections 13 and 14 of the HPPC.

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

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