## **Independent Health Facilities**

# Clinical Practice Parameters and Facility Standards

#### **Magnetic Resonance Imaging**



THE
COLLEGE
OF
PHYSICIANS
AND
SURGEONS
OF
ONTARIO

#### The College of Physicians and Surgeons of Ontario

#### **Vision Statement**

The best quality care for the people of Ontario by the doctors of Ontario.

#### **Mission Statement**

The College of Physicians and Surgeons of Ontario merits the trust and respect of the public and the profession by:

- 1. Maintaining a rigorous and efficient regulatory process,
- 2. Focusing on the ongoing improvement of quality,
- 3. Being open and accountable,
- 4. Communicating clearly and effectively,
- 5. Promoting excellence in health care,
- **6.** Working with others to achieve our vision.

We demand of ourselves the same exacting standards that we expect of the profession.

#### Goals

The vision of Council will be implemented by:

- 1. Advocating for quality health care in partnership with other stakeholders,
- 2. Integrating the roles of clinical education, evidence-based clinical practice and regulatory responsibilities to improve patient care at the individual and system level,
- 3. Evaluating and improving the effectiveness and efficiency of the current investigative and disciplinary processes and identifying potential alternatives,
- 4. Accelerating efforts to find creative ways to address physician resource needs without compromising registration standards,
- 5. Providing publicly accessible regulatory information about physicians
- 6. Engaging stakeholders in a public debate about the limits of medicine and focusing on what patients can expect from their physicians,
- 7. Establishing a comprehensive and effective communication plan to improve recognition of the CPSO by its stakeholders,
- 8. Establishing an effective and transparent governance model for the College.

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# Contents Clinical Practice Parameters and Facility Standards: Magnetic Resonance Imaging

**Preface** 

Role of the Responsib Updating t	Clinical Practice Parameters i College of Physicians and Surgeons i lities of the College	v v v
Volume 1	Facility Standards	
Overview Qualification MRI Direct Medical Phedical Range Continue Charge	Staffing a Facility  ns of Physicians or/Quality Advisor ysicist diation Technologists ing Medical Education Technologist Qualifications Technologist Responsibilities	3 5 7 8 8
Overview Facilities, I Safety Cor Major I Equipn Minor I	Facilities, Equipment and Supplies	1 3 4 5
	Developing Policies and Procedures	
Requesting	Requesting and Reporting Mechanisms	2
Providing (	Providing Quality Care           Quality Care         25           Quality of Care         26	5

#### **Volume 2** Clinical Practice Parameters

## CAR Standards for Magnetic Resonance Imaging Approved: June 1999

Appendix I	Independent Health Facilities Act - Ontario Regulation 57/92 - Amended to O. Reg. 14/95
Quality Adv Standards Records of Patient Rec Books and Notices	49         visor and Advisory Committee       49         50         Employees       51         cords       52         Accounts       55         56       56         bus       56
Appendix II	Sample Latex Allergy Questionnaire
	57
· ·	gy Questionnaire59
	Factor Assessment
	tact Dermatitis Assessment
	tact Dermatitis Assessment cont'd
	ntact Urticaria (Hives) Assessment
	ory of Reactions Suggestive of Latex Allergy60
Appendix III	Sample Patient Survey: Quality of Care
Appendix IV	Sample Referring Physician Survey- Independent Health Facilities Program
Appendix V	MR Safety
Appendix VI	Sample MRI Requisition
Index	

#### **Preface**

The Independent Health Facilities Act (IHFA), proclaimed in April 1990, and 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 out-of-hospital facilities may provide some of the following insured services:

- in diagnostic facilities: radiology, ultrasound, magnetic resonance imaging, computed tomography, 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, contribute to the College achieving its goals as stated in the College's Mission Statement. An important goal of the College is to promote activities which will improve the level of quality of care by the majority of physicians. The Independent Health Facilities program helps reach this goal by developing and implementing explicit clinical practice parameters and facility standards for the delivery of medical services in Ontario, assessing the quality of care provided to patients, and as a result, promotes continuous quality improvement.

#### **Purpose of Clinical Practice Parameters**

The Independent Health Facilities clinical practice parameters and facility standards are designed to assist physicians in their clinical decision-making by providing a framework for assessing and treating clinical conditions commonly cared for by a variety of 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 judgement or to establish a protocol for all patients with a particular condition. It is understood that some patients will not fit the clinical conditions contemplated by certain parameters and that a particular parameter will rarely be the only appropriate approach to a patient's condition.

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

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

At the beginning of this process, the College adopted the role of a facilitator for the development of clinical practice parameters and facility standards. Representatives of national specialty societies and sections of the Ontario Medical Association, and individuals with acknowledged skill, experience and expertise formed specialty-specific Task Forces.

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

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

The Task Forces continue to adhere to the following principles:

- clinical practice parameters must be based on the appropriate mix of current, scientifically-reliable information from research literature, clinical experience and professional consensus.
- any parameter-setting exercise must be done exclusively from the quality perspective. That may well mean that some of the conclusions reached could add to medical care costs.
- parameters have to be flexible enough to allow for a range of appropriate options and need to take into account the variations in practice realities from urban to rural areas.
- parameters need to be developed by consensus and consultation with the profession at large.
- parameters should provide support and assistance to physicians without boxing them in with "cookbook formulas."
- parameters will need to be regularly updated based on appropriate research studies.

- parameters should reduce uncertainty for physicians and improve their clinical decision-making.
- information on practice parameters must be widely distributed to ensure that all physicians benefit from this knowledge.

#### Responsibilities of the College

Responsibilities of the College include:

- assessing the quality of care when requested by the Ministry. The College will maintain a roster of physicians, nurses, technologists and others to serve as inspectors and assessors as required.
- inspecting the illegal charging of facility fees by unlicensed facilities when requested by the Ministry.
- monitoring service results in facilities. The College's information system
  will monitor individual and facility outcome performance. This is a unique
  feature of the legislation, which for the first time in North America, requires
  facility operators to establish and maintain a system to ensure the
  monitoring of the results of the service or services provided in a facility.
- providing education and assisting facilities so that they may continually
  improve the services they provide to patients. The College will work with
  and assist physicians in these facilities so that they can develop their own
  quality management programs based on the parameters and standards,
  monitor facility performance by conducting quality assessments, work with
  facilities to continually improve patient services, assist in resolving issues
  and conducting reassessments as necessary.

#### **Updating this Document**

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

- pre-examination evaluation by a referring physician.
- a request for radiologic consultation. The requisition includes pertinent clinical findings, a working diagnosis, and signature of referring physician or other qualified professional.
- a safe patient environment in which the radiologist supervises a 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, diagnostic data, 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: Magnetic Resonance Imaging

Volume 1

Facility Standards

#### **Chapter 1** Staffing a Facility

#### **Overview**

Diagnostic imaging services are provided by qualified imaging physicians and technologists.

There is a current written plan describing the organization of the facility and its services.

There are sufficient numbers of qualified physicians, technologists, and clerical personnel available to meet the stated goals and objectives. Duties and responsibilities of all diagnostic imaging services staff are specified in job descriptions.

Staff are educated in Workplace Hazardous Materials Information System (WHMIS) and this is documented.

At least one staff member with current Basic Cardiac Life Support (BCLS) certification is on site at all times during hours of scanner operation. Documentation regarding BCLS certification is maintained on site.

#### **Qualifications of Physicians**

All physicians must maintain and document current Advanced Cardiac Life Support (ACLS) certification.

Physicians performing or interpreting Magnetic Resonance Imaging (MRI) examinations are:

 certified in Diagnostic Radiology with the Royal College of Physicians and Surgeons of Canada and have a certificate of registration to practice in Ontario

#### **AND**

 have demonstrated competence (6 months of MRI training, 1500 reported cases) in an appropriate facility and under the full-time supervision of a radiologist fully trained in MRI as per the description of an MRI Director.

Appropriate training centres for radiologists seeking to obtain the required MRI credentials are:

an academic centre with a diagnostic radiology residency program

#### OR

 a hospital MRI facility in Ontario under the supervision of the MRI Director.

**Note:** Where training occurs at a hospital MRI centre not associated with a University centre, the training should also include at least 160 hours of training through ACCME, RCPSC-recognized CME courses or equivalent (a full range of MRI clinical applications as well as MRI physics, instrumentation, QA and safety) within 2 years prior to start of practice.

In addition, the MRI Radiologist should have at least two years experience interpreting Computed Tomography (CT).

A letter signed by the MRI Director attesting to the training of all MRI Radiologists, including the Director, will be required. This letter should be kept on file at the facility.

Note: For the following, "MRI Radiologist" means a radiologist satisfying the above criteria.

MRI Radiologists who have not been in active practice of MRI (i.e. performing less than 100 patient cases/year) or who have not actively provided MRI services for two years or more but were fully trained in the past will require re-training at an appropriate MRI facility as described earlier in this section. A minimum of one month of re-training at an appropriate MRI facility will include reporting a minimum 300 patient cases, with an appropriate case mix, under the direct supervision of a qualified MRI Director-level radiologist. A letter shall be provided from the preceptor, attesting to competence, and must be presented to the MRI Director and kept on file by the licensed facility.

MRI Radiologists who have not been in active practice of CT (i.e. performing less than 100 patient cases/year) or who have not actively provided CT services for two years or more but were fully trained in the past will require re-training. A minimum of one month re-training at an appropriate CT facility will include reporting a minimum 300 patient cases, with an appropriate case mix, under the direct supervision of a qualified CT Director-level radiologist. Re-training is documented.

All physicians attend Continuing Medical Education (CME) programs relevant to their practice, which comply with their Royal College requirements for maintenance of certification. Documentation of annual

CME in MRI-related courses taken by every radiologist providing MRI medical services must be submitted to the MRI Director no later than the end of each calendar year.

#### **MRI Director/Quality Advisor**

Each licensed facility has an MRI Radiologist who is appointed as both the MRI Director and Quality Advisor. The MRI Director/Quality Advisor shall have demonstrated competence (one year of MRI training) and would be qualified to provide additional on-site training to the other MRI radiologists in the licensed facility.

As outlined in the IHF Regulations "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."

#### Every MRI Director/Quality Advisor shall:

- be responsible for the development and maintenance of a procedure to ensure that only services which are indicated and medically appropriate are provided (see Preface: Radiology Guiding Principles).
- be physically present at the Independent Health Facility on a regular basis, on average at least 8 hours per week. The MRI Director or a designated MRI Radiologist should be available by phone for consultation at any time when services are provided and documented.
- seek advice from other health professionals where necessary to ensure that
  all aspects of the services provided through the independent health facility
  are provided in accordance with generally accepted professional and quality
  standards.
- consult with the Quality Advisory Committee at least quarterly if the independent health facility has more than six full-time staff equivalents even if there is another Quality Advisor for other imaging modalities, otherwise at least semi-annually, and to document the substance of the discussion, the actions agreed upon, and the completion date for any actions agreed upon.
- ensure that safe MR practice guidelines are established and maintained as current and appropriate for the facility.
- consult with the facility staff after any serious MR safety incidents and, as a minimum, update the MR safety guidelines on a yearly basis.
- approve and review all MR imaging protocols performed by the licensed facility at least annually, or as often as may be deemed necessary by the MRI Director. All requisitions will be assigned a specific protocol by an MRI radiologist associated with the facility prior to the study being performed. Changes to the assigned protocol can only be modified by the MRI Director or another designated MRI Radiologist.

The MRI Director/Quality Advisor shall advise the facility licensee and document this advice concerning the following:

- qualifications, selection and ongoing education of the professional and technical staff working in the independent health facility.
- performance of any professional or technical staff who do not have sufficient qualifications for the procedures being performed but who are being permitted to practise because of special circumstances.
- whether adequate and appropriate staffing, equipment and procedures are available to ensure patient and staff safety in the independent health facility, particularly with respect to the use of equipment containing ferrous materials and/or electronics in the vicinity of the MRI scanner.
- whether a physician or other practitioner should be physically present for the performance of any category of procedure.
- testing being performed on a periodic basis to ensure the accuracy and reliability of the independent health facility's equipment.
- implementation and adherence to the facility's safe MR practice guidelines.
- proper design of consultation requests, performance protocols (including, where appropriate, reference values for procedures), documentation and reports used at the independent health facility.
- facility's policies regarding the maintenance of all appropriate clinical records, including their maintenance for the required length of time.
- facility policies that are consistent with government regulations regarding the confidentiality and handling of patient information particularly if the information is being shared and stored in an electronic format.
- quality and the maintenance of the imaging equipment and the related technology for the electronic viewing, archiving, and communication of imaging information produced or in the responsible possession of the facility.
- development and maintenance of a quality assurance program for the facility.
- other such matters as deemed by the MRI Director/Quality Advisor to be important to the maintenance of quality assurance practices that are consistent with those observed in hospital MRI facilities as well as with quality standards and international accreditation guidelines by recognized bodies such as the Canadian Association of Radiologists and the American College of Radiologists.

Every licensee shall have a written agreement with the MRI Director/Quality Advisor requiring and authorizing the MRI Director/Quality Advisor to fulfill the requirements as set out above.

Whenever the MRI Director/Quality Advisor has reasonable grounds to believe the conduct of the diagnostic imaging services might jeopardize the safety of patients or the proper performance and interpretation of diagnostic imaging services and where, in the judgment of the MRI Director/Quality Advisor, he or she is constrained from correcting the perceived deficiencies by actions taken or not taken by the licensee, then the MRI Director/Quality Advisor reports those concerns in writing to the Director, Independent Health Facilities as required by the Regulations under the Independent Health Facilities Act.

It is understood that the sections above do not in any manner remove from the licensee or impose upon the MRI Director/Quality Advisor the obligation or responsibility for operating the facility; it being understood that the MRI Director/Quality Advisor's sole responsibility is to provide advice to the licensee on the matters specified.

#### **Medical Physicist**

A medical physicist has the responsibility for the initial acceptance testing of equipment and related systems/components and for implementing and overseeing quality control testing of the MRI scanner. The medical physicist repeats the acceptance test on at least an annual basis and after any major hardware upgrades (see Chapter 2, Quality Control).

The medical physicist must either be board certified in Diagnostic Radiology by the Canadian College of Physicists in Medicine, the American Board of Radiology, or the American Board of Medical Physics and have specific training and experience in MRI; or have a PhD in Nuclear Magnetic Resonance/Magnetic Resonance Imaging plus 3 years clinical MR experience. Training and experience includes detailed knowledge of MRI physics, system components and performance, safety procedures, acceptance testing, and quality control testing.

The medical physicist acquires Continuing Medical Education (CME) credits on a yearly basis relevant to their practice that complies with Board requirements for continued certification.

#### **Medical Radiation Technologists**

Medical Radiation Technologists have a current and valid certificate of registration with the College of Medical Radiation Technologists of Ontario. Certification in MRI must be documented.

All technologists must maintain and document current Basic Cardiac Life Support (BCLS) certification.

#### Continuing Medical Education

Medical Radiation Technologists attend and document their attendance at relevant continuing medical education programs, as mandated by the CMRTO, or as identified by the MRI Director. This documentation must be provided to the MRI Director annually no later than at the end of the calendar year.

#### Charge Technologist Qualifications

The designation of a Charge Technologist is mandatory. Their qualifications must include:

- current and valid certificate of registration with the College of Medical Radiation Technologists of Ontario (CMRTO).
- certificate in MRI and should have 4 years full-time MRI experience.
- certificate in BCLS with recertification yearly.

Charge Technologists have completed an injection course and are certified by a Radiologist as per facility policy.

#### Charge Technologist Responsibilities

The Charge Technologist is current with changing technical trends in MRI by attending conferences, meetings, or other CME, and reading current relevant literature. Documentation of CME is maintained.

Charge Technologists are responsible for the day-to-day operation of the MRI suite, including:

- training of technologists to include Quality Control, safety, injections, policies and procedures
- reporting to/advising the MRI Director/Quality Advisor
- ensuring that all technologists remain current with all qualifications and CME requirements
- ensuring that all support staff receive and implement MRI safety guidelines
- inputting site-specific protocols into the MRI unit
- writing and updating MRI policy and procedure manual on at least an annual basis
- ensuring implementation of policies and procedures

- maintaining records of equipment calibration, maintenance, and repair procedures
- maintaining copies of test observations and reports
- ensuring that safety policies and the equipment and facilities necessary for their implementation are in place and in working order
- implementing infection control measures
- maintaining all necessary facility supplies
- performing and documenting Quality Control procedures.

#### **Injection Certification**

The Charge Technologist is responsible for supervising the technologists for injection certification. The MRI Director/Quality Advisor certifies the technologist.

Certification includes the following:

- Successful completion of a certified program for the injection of contrast media.
- Review of all policies with the candidate regarding the injection of contrast media (patient consent, contraindications, contrast reaction protocol, premedication, radiologist availability, sterile technique, contrast protocols and facility standards).
- Successful performance of 20 intravenous injections under the direct supervision of the MRI Charge Technologist. These will be logged and initialed by the MRI Charge Technologist.
- Observation and recommendation of the candidate's competence to inject contrast media under specific conditions by the MRI Director.
- Presentation of certificate of competence to the candidate after certification by the Radiologist. This certificate is signed by the MRI Director/Quality Advisor. This certificate is kept along with a copy of proof of certification and a copy of the course curriculum.
- Annual recertification for contrast injections at the discretion of the MRI Director.

#### **Chapter 2** Facilities, Equipment and Supplies

#### **Overview**

All resuscitations are performed outside the scanner room. The biggest danger is the introduction of ferromagnetic objects into the magnet room by the responding staff and the resulting projectile motion of the ferromagnetic objects toward the centre of the magnet causing injury/death to anyone intersecting the projectile trajectory.

Although it is possible to set up a complete emergency response trolley and equipment which is non-magnetic, it is almost impossible to ensure that all staff who may respond to the emergency will not carry any ferromagnetic objects into the magnet room.

Ambulance, fire or police crews who respond to an emergency call will be carrying ferromagnetic objects. For these reasons, it is imperative that the first response to a patient code inside the magnet is for the MRI technologist(s) to remove the patient from the magnet room.

Oral or sublingual anxiolytic medications may be administered in an IHF, but intravenous sedation or parenteral (e.g. intramuscular) sedation must be referred to a hospital. Patients who have received or taken any sedation or anxiolytics must be provided with safety instructions (i.e. should not drive home) prior to leaving the facility. Patients under the age of 18 requiring sedation are not examined in an IHF.

A metal detector similar to security detectors at airports is <u>not</u> recommended. They give a false sense of security, are ignored after a few months, cannot distinguish non-magnetic from magnetic materials, and will not detect most of the metal contraindications inside patients such as metal filings in the eye and aneurysm clips.

#### Facilities, Equipment and Supplies

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

If headphones are available to patients, they must be disinfected after each use, otherwise disposable ear plugs should be offered.

An area must be provided for patients' valuables/personal belongings to be secured/locked during procedures.

The minimum strength of the primary magnet must be 1.5 Tesla. If a second MR system is installed, the second magnet can be a whole-body open magnet. The MR system should be equipped with the appropriate gradient hardware, radio frequency hardware (receiver channels), phased array coils, and software packages for the case mix. A power injector is strongly recommended.

For patient imaging, the MR system meets or exceeds the following specifications:

- New when installed in the facility and manufactured within 12 months prior to installation with current technology.
- A clear upgrade pathway, defined to keep the technology current, will be implemented by the facility.
  - In recognition of changing technology standards, machines need to be upgradeable to future state-of-the-art requirements.
- The MRI scanner must pass all quality assurance tests at the time of installation as outlined by organizations such as the American Association of Physicists in Medicine (AAPM) or the American College of Radiology (ACR).

Facility monitoring equipment and procedures are appropriate to the documented patient mix and procedures.

The MR facility layout must give the MRI technologist an unimpeded view of the magnet room entrance door when seated at the operating console. Access is restricted to all areas within the 5 gauss magnetic field line of the MRI magnet. The magnet room itself usually encompasses this area.

Ideally the MRI technologist has a direct view of the patient down the bore of the magnet when seated at the operating console. If this is not the case then a closed television camera/monitor is installed to provide this view of the patient to the MRI technologist.

The following non-magnetic equipment is available:

- stretcher (if scanner table is not detachable)
- wheelchair
- IV poles
- laundry hamper
- step stool

If a parent is expected to accompany and stay inside the magnet room with their child, then a non-magnetic chair is provided for inside the magnet room.

All facility fire extinguishers that may be brought into the magnet room during a fire emergency are non-magnetic. The fire alarm must be audible inside the magnet room.

There should be a small, portable, strong (usually rare earth) magnet available to the MRI technologist to test whether objects are ferromagnetic. [For example, Lee Valley, product number 50K02.01]

A non-magnetic step ladder (usually aluminum) should be provided for changing light bulbs inside the MRI magnet room. This task should be performed by an individual trained in MR safety.

*Note:* The MRI magnet room usually appears intimidating to the patient. A facility design with daylight entering the magnet room decreases patients' fears.

#### **Safety Concerns and Resuscitation Equipment**

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

Facilities performing contrast-enhanced studies require the presence of a physician who is trained and experienced in the recognition and management of adverse effects of these agents (ACLS) and other life threatening events. If this physician is not the MRI Radiologist, then he/she must also have appropriate training and experience in MR safety. Technologists are trained in resuscitation (BCLS). The IHF is very different from hospital-based MRI units where experienced teams manage codes of differing severity, therefore the IHF must have an emergency protocol in place to deal with these types of emergencies.

If pediatric patients are to receive contrast then specific pediatric doses/drugs and pediatric resuscitation equipment should be clearly labelled and colour coded for age groups.

Facilities provide a means of moving patients in difficulty outside the magnet room to an area equipped to handle any adverse reactions up to and including respiratory and cardiac arrest.

Any interventions and resuscitative procedures MUST take place outside the magnet room.

No additional personnel or equipment will enter the magnet room.

#### Major Resuscitative and Monitoring Equipment Required

Excellent guidelines, such as the Manual on Contrast Media (*Contrast Media 4th Edition American College of Radiology 1998*) are published, however, it is recommended that for each site a plan of action and formulary be developed in consultation with local anaesthetists and internal medicine specialists responsible for their hospital arrest teams.

- ECG monitor
- defibrillator
- oxygen source with mask
  - All oxygen tanks *must* be non-magnetic
- oxygen & suction
- MR compatible oxygen saturation monitor
- humidifier and sterile distilled water
- resuscitation drugs
  - Basic treatment medication (atropine, epinephrine, Beta 2-agonist inhaler) is kept in the area outside the magnet room designated for patient resuscitation. An emergency kit is available consisting of the following drugs essential for Contrast Reaction:
    - •Atropine sulfate 0.1 mg/ml (pre-filled syringe)
    - •Lidocaine
    - •Corticosteroids for intravenous administration (Hydrocortisone sod succ 500 mg)
    - •Anti-convulsive drugs (i.e. Diazepam 5 mg/ml)
    - •Dopamine infusion 200 mg
    - •Epinephrine 1:1,000 (pre-filled syringe)
    - •Epinephrine 1:10,000 (pre-filled syringe)
    - •Sterile water for injection (30ml)
    - •Dextrose 5% in water (mini-bags for medication infusion)
    - •Beta 2-agonist metered dose inhaler
    - •I.V. Fluids—normal saline or Ringers solution
    - Alcohol skin prep
    - •Antihistamine H1—suitable for injection
    - •Antihistamine H2 (e.g. Cimitidine/Rantidine)
    - •Anti-emetic parenteral
    - •Appropriate IV needles and syringes

The contents of the resuscitation tray are checked monthly for expiry dates on all drugs and sterile equipment. These activities are documented and kept with the resuscitation equipment.

#### Minor Equipment

- stethoscope
- sphygmomanometer
- laryngoscope and endotracheal tubes (sized for adults and paediatrics)
- oropharyngeal airways (sized for adults and paediatrics)
- ambu bag or equivalent (sized for adults and paediatrics)

#### **Quality Control**

All equipment is properly maintained and calibrated during the monthly preventive maintenance period. Written records of preventive maintenance, repairs, and unscheduled down time are maintained. A daily record of both the MRI magnet room and equipment room temperature, humidity, primary chilled water temperature, secondary water temperature, and the magnet helium level (where appropriate) are documented. The following Quality Control schedule is recommended:

- Daily: a phantom scan should be done before the first patient is scanned. A different MR coil is used every day with the appropriate manufacturer's supplied MR phantom for that particular coil. Depending on number of days of operation per week, the most commonly used set of 5 to 7 coils should be rotated through for the daily Quality Control each week. Signal to Noise, Ghosting, and Geometric Distortion is measured and recorded. If available, the transmitter amplitude, receiver gain, and the MRI centre frequency is recorded.
- Weekly: On the day that the head coil is tested, image uniformity is measured and recorded. As well, the diffusion weighted stroke protocol used by the facility is run on the head coil phantom and the ghosting and image distortion is measured and recorded. If a hard copy camera is used a test film is printed and the optical densities of the test step pattern measured and recorded. This requires that the site have a small film densitometer. The camera internally generates the test film pattern.
- Monthly: depending on phantom availability, the slice profile and slice position is measured and recorded. If an appropriate phantom is not available, the accuracy of the laser beam couch positioning is checked with a MRI marker such as a vitamin E pill taped to the head coil phantom. The Radio Frequency (RF) cabin should be checked for RF leaks with an FM radio.

- **Quarterly:** the medical physicist reviews the daily Quality Control data and the system repairs log.
- **Annually:** a qualified medical MRI physicist performs the complete system acceptance test with the ACR Test Phantom.

After any service work/repairs the service engineer runs the calibrations/ service tests as appropriate for the specific hardware serviced.

#### **Chapter 3** Developing Policies and Procedures

#### **Overview**

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

#### **Developing Policies and Procedures**

The procedure manual is available for consultation by all diagnostic imaging personnel. The manual is reviewed 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, technologists, and other staff.

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

- imaging protocols detailing the sequences involved in examining a target organ for both adult and paediatric patients.
- instructions regarding routine preparation of patients.
- safety of patients who have taken oral or sublingual anxiolytics
  - •particularly for patients departing the facility
- techniques for managing patients with claustrophobia, anxiety and emotional distress.
- managing patients with possible or definite ferrous/metallic foreign bodies (particularly intracranial and intraoccular locations).
- screening just prior to patient entering the magnet room.
- response to fire alarm and fire within the magnet room
  - •when personnel are present in the facility
  - •when personnel are not present in the facility
- working with local emergency response teams
- initiating a magnet quench.
- inadvertent magnet quenches.
- maintenance work inside the magnet room.
- pregnancy of patients/facility staff.
- adult sedation.

- delegated acts.
- scope and limitations of diagnostic imaging services provided by the facility.
- patient-booking systems.
- certification for administration of contrast injections.
- patient consent, written or verbal, based on the scope of practice in the facility.
- infection control.
- contraindications for performing tests.
- latex anaphylaxis
  - there are many areas of latex allergy which are important for the IHF to know about -from knowing the symptoms of the allergy (urticaria, dermatitis, rhinitis and asthma) to the management of anaphylactic reactions. The following represents some basic guidelines to use when developing a policy for the facility:
    - All patients at risk for latex allergy should have a careful history for questions of possible latex allergy. A latex allergy questionnaire may be helpful. (See Appendix II, Sample Questionnaire)
  - procedures on all patients with latex specific IgE antibody should be done in a latex-safe environment which is defined as one in which there is no latex glove use by any personnel. In addition, no direct patient contact should occur with other latex devices (catheters, condoms, adhesives, tourniquets and anaesthetic equipment)
- specific first aid measures to be followed in the event of an adverse health effect, including a description of the arrangements for transferring patients to an acute care facility when required.
- documentation of and method for receiving written referrals for consultation.
- methods for preliminary interpretations and/or telephone calls of reports, and for the subsequent written interpretation of images by qualified diagnostic imaging physicians.
- maintenance of requisitions, imaging media and interpretation reports (See Appendix I, Independent Health Facilities Act- Ontario Regulation 57/92 Amended to O.Reg. 14/95).
- · confidentiality.
- safety training for medical and non-medical staff.
- emergency resuscitation both inside and outside the MRI suite.

#### •emergency resuscitation only to occur outside the magnet room

• Material Safety Data Sheets (MSDS) for all chemicals maintained in the facility.

- routine maintenance and calibration of equipment.
- performance of additional views and examinations.

•any additional views or examinations are identified in the imaging report with reasons.

# Chapter 4 Requesting and Reporting Mechanisms

#### **Overview**

The content of this overview has been extracted from the CAR Guidelines on Communication (approved in June 1997; reviewed in September 2001. www.car.ca).

Communication is a critical component of the art and science of medicine and is especially important in Diagnostic Radiology. Diagnostic Radiology is one of the most important consultative services in medicine.

The final product of any consultation is the submission of a report on the results of the consultation. In addition, the diagnostic radiologist and the referring physician have many opportunities to communicate directly with each other during the course of a patient's case management. Such communication should be encouraged because it leads to more effective and appropriate utilization of Diagnostic Radiology in addressing clinical problems and focuses attention on such concerns as radiation exposure, appropriate imaging studies, clinical efficacy, and cost-effective examinations.

These principles apply to all radiology consultations irrespective of the technology used including Picture Archiving & Communication Systems (PACS) or an equivalent electronic work station with an archival system.

In order to afford optimal care to the patient and enhance the cost-effectiveness of each diagnostic examination, radiological consultations ought to 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.

Teleradiology should not be used for primary reporting until the College of Physicians and Surgeons of Ontario has a policy in place. The interpreting radiologist should be based in Ontario in close geographic proximity to the IHF MRI facility.

#### **Requesting Procedures**

Written requisitions and forms to screen the patient for MRI compatibility must be completed by the referring physician. All MRI requests must be approved by a radiologist prior to booking the test. The technologist rescreens just prior to the patient entering the magnet room. (for sample screening forms, see Appendix V)

An appropriate request for all radiological consultations specifies:

- the basic demographic information of the patient such as name, health number, date of birth, and sex.
- the name of the referring physician and the names of any other physicians who are to receive copies of the report.
- the type of procedure requested for the patient including any special instructions where applicable.
- pertinent clinical information including indications, pertinent history, and provisional diagnosis.
- whether a "stat report" is required.

This is the responsibility of the referring physician. If a patient arrives with requisitions and screening form containing incomplete information, the diagnostic imaging physician contacts the referring physician.

It is recommended that patients be provided written information about magnetic resonance imaging procedures prior to an appointment. (See Appendix V under Patient Instructions)

#### **Reporting Procedures**

Previous diagnostic images and ultrasound scans are available for the interpreting physician.

Reports of the interpretation of imaging procedures include the following:

- name of the patient and another identifier such as birth date, pertinent identification number.
- name of the ordering physician, most responsible physician and/or other physicians.
- name or type of examination.
- dates of examination, dictation, and transcription.
- limitations, technical factors, or patient anatomy.
- reasons for additional views or examinations if deemed necessary.

- findings using precise anatomical and radiological terminology to describe
  the findings accurately and a description of the procedures performed and
  any contrast media (agent, concentration, volume and reaction, if any),
  medications, catheters, devices, if not reported elsewhere.
- any pertinent clinical issues raised in the request for the imaging examination.
- comparative information with previous examinations.
- a "conclusion" section unless the study is being compared with other recent studies and no changes have occurred during the interval, or the body of the report is brief. The report should also contain:
  - a precise diagnosis whenever possible
  - a differential diagnosis when appropriate
  - recommendations, when appropriate
  - follow-up and additional diagnostic radiological studies to clarify or confirm the conclusion.

The final report is proofread carefully to avoid typographical errors, deleted words, confusing or conflicting statements.

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

The report is authenticated by a radiologist, whenever possible. Electronic or rubber-stamp signature devices, instead of a written signature, are acceptable if access to them is secure.

- if this is not possible, the name of the radiologist who dictated the report should appear on the report.

Reports of the interpretation of diagnostic imaging examinations are transmitted to the referring physician within 24 hours if possible.

Unusual, unexpected, or urgent findings which may require immediate case management decisions are communicated to the referring physician by the interpreting physician, or as directed by the interpreting physician.

Direct or attempted direct communication is documented.

Any discrepancy between a preliminary report and the final written report is directly communicated to the referring physician or representative.

A copy of the diagnostic image is retained as the permanent record. It is recommended that either a PACS system (or an equivalent electronic work station with an archival system) be utilized if MRAs are done routinely. If film is being utilized, it is recommended that 20 images be the maximum per film.

All images must be 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 facility must have the ability to retrieve and/or produce a copy of the image(s), within 24 hours of the request as required.

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

Unusual and interesting examinations are maintained for educational purposes.

# **Chapter 5** Providing Quality Care

### **Overview**

A Quality Advisory Committee is established as per the IHF Act. The advisory committee shall consist of health professionals who provide health services in or in connection with the independent health facility. Regular meetings are held and minutes maintained (IHF Act Regulation 57/92 amended to 14/95- see Appendix I).

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

Facility staff should have meetings at least quarterly and maintain minutes.

# **Providing Quality Care**

The performance of MRI examinations complies with standards accepted by the College of Physicians and Surgeons of Ontario as described in the Clinical Practice Parameters section.

A designated MRI Radiologist is available for consultation with the technologist on a case-by-case basis. For cases requiring monitoring, ideally, the MRI Radiologist is on-site and available to participate in the examination when required.

Although optimally a designated MRI Radiologist is present for all cases this is not always possible. For cases that do not require monitoring a designated MRI Radiologist should always be available by phone to consult with the technologist and referring physician.

Whenever contrast is administered, a designated physician must be personally and immediately available. There must be adequate equipment/medications available to treat an adverse reaction.

An MRI-trained radiologist should visit the facility on a regular basis to review imaging procedures and provide technologist supervision. Ideally there should be an MRI radiologist present at the facility on a daily basis. Even in remote sites, an MRI-trained radiologist should be on site at least one day per week. A daily log of visits to the facility by the radiologist should be maintained.

Diagnostic imaging procedures are carried out in a manner in which patient privacy is respected.

## **Monitoring Quality of Care**

The facility establishes and maintains a system to 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.

Each facility has written goals and objectives as part of their Quality Management Program.

Components of quality management include a review of:

- goals and objectives.
- policies and procedures.
- incidents, adverse drug reactions, complications.
- clinical data, for example, assessing the accuracy of interpretations and the appropriateness of procedures.
- Quality Control activities.
- staff performance appraisals.
- in-service education using recent patient records
- patient/referring physician surveys.

Staff receive the results of such reviews.

Staff participate in planning strategies to overcome any deficiencies and to continually improve the services provided to patients.

# Independent Health Facilities: Clinical Practice Parameters and Facility Standards: Magnetic Resonance Imaging

Volume 2

Clinical Practice Parameters

The following Clinical Practice Parameters have been developed by the Canadian Association of Radiologists and have been adopted by the IHF MRI & CT Task Force, College of Physicians and Surgeons of Ontario.

All Clinical Practice Parameters contained within this document should be read in conjunction with the Facility Standards (Volume 1) developed by the IHF Task Force.

### CAR Standards for Magnetic Resonance Imaging

Approved: June 1999

These Standards were reviewed by the Magnetic Resonance Imaging Expert Advisory Panel: Pierre Bourgouin, MD, Chair, John Mayo, MD, Blake McCarthy, MD, Pierre Milette, MD, Peter Poon, MD

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 high-quality 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.

CAR Website Url: www.car.ca

### I. INTRODUCTION AND DEFINITION

Magnetic resonance imaging (MRI) is a cross sectional imaging method based on an interaction between radiofrequency (RF) electromagnetic fields and certain nuclei in the body (usually hydrogen nuclei) after the body has been placed in a strong magnetic field. MRI provides excellent differentiation of normal tissues and exceptional sensitivity to disease. This sensitivity is based on the high degree of inherent contrast due to variations in the magnetic relaxation properties of different tissues, both normal and diseased, and the dependence of the MR signal on these tissue properties.

Magnetic resonance angiography (MRA) involves the use of selected MRI pulse sequences in order to visualize blood vessels. Functional magnetic resonance imaging (fMRI) uses powerful gradients in order to study diffusion (diffusion weighted MRI), perfusion (perfusion weighted MRI), and brain activation during pre-defined tasks (brain mapping).

This document is an updated version of the standards (first published in 1994) for the use of MRI, for the qualifications of personnel involved in the clinical application of MRI, and for quality assurance practices in MRI. The CAR Subcommittee on MRI Standards, of the CAR Task force on Radiology Standards was formed to recommend standards for the utilization of MRI for clinical diagnosis in fixed and mobile sites. It is recognized that by circumstance the available technology at individual

MRI sites in Canada will vary and that the submitted standards act a guidelines for MRI practice, to which individual centers should attempt to aspire.

#### II. QUALIFICATIONS OF PERSONNEL

# A. The Radiologist (for Ontario guidelines, see Volume I, Chapter 1, Staffing a Facility)

That physicians involved in the performance, supervision and interpretation of magnetic resonance imaging should be Diagnostic Radiologists and must have a Fellowship or Certification in Diagnostic Radiology with the Royal College of Physicians of Canada and/or the Collège des médecins du Québec. Also acceptable are foreign Specialist qualification if the Radiologist so qualified holds an appointment in Radiology with a Canadian University.

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.

# <u>B. Medical Physicists</u> (for Ontario guidelines, seeVolume I, Chapter 1, Staffing a Facility)

A medical physicist (on-site or contracted part-time) shall have the responsibility for the initial acceptance testing and for conducting and overseeing quality control testing of the MR scanner.

The medical physicist shall be certified by the Canadian College of Physicists in Medicine and shall have specific training and experience in MRI. Training and experience shall include detailed knowledge of the physics of MRI, system components and performance, safety procedures, acceptance testing, and quality control testing.

# <u>C. MR Technologists</u> (for Ontario guidelines, see Volume I, Chapter 1, Staffing a Facility)

The medical radiation technologist must have Canadian Association of Medical Radiation Technologists (CAMRT) certification in magnetic resonance (RTMR) or be certified by an equivalent licensing body recognized by the CAMRT.

Under the overall supervision of the radiologists, the technologist is responsible for patient comfort and safety, examination and

preparation of patients, performing the MRI scans, technical and quality evaluation of images and relevant quality assurance.

Continued education of technologists is encouraged by the C.A.M.R.T. and should meet pertinent provincial regulations.

### **D. Service Engineers**

The service engineer shall be responsible for system installation, calibration, and preventive maintenance at regularly scheduled intervals. The service engineer's qualification will be ensured by the corporation responsible for service and the manufacturer of the MR equipment used at the site.

#### III. CONTRAINDICATIONS

Contraindications include, but are not limited to, the presence of cardiac pacemakers, ferromagnetic heart valves, ferromagnetic intracranial aneurysm clips, neuro stimulators, certain otic implants and ferromagnetic foreign bodies in critical locations, e.g., the eye. Relative contraindications include claustrophobia and obesity.

The safety of MR scanning during pregnancy has not been established. The decision to scan during pregnancy should be made on an individual basis after consideration of medical necessity and alternate imaging methods. This particularly applies to scanning during the first trimester.

#### **IV. TECHNIQUES**

The committee has attempted to enumerate the currently accepted techniques for MRI based on clinical experience, as summarized in peer-reviewed literature'. Because the clinical application of MRI is still under development, it is not intended that the enumerated techniques (and indications in the reference document) be all-inclusive. It is very important that each site offering MRI have documented procedures for the indications and technical factors for each anatomic site.

These procedures will need to be reviewed frequently. The final judgment regarding appropriateness of a given examination for a particular patient is the responsibility of the radiologist.

The indications for scanning could include any part of the human body, depending on the MR software and hardware available and the efficacy and availability of competing imaging methods.

To accomplish its clinical purposes, MRI must be performed with adequate attention to technical abilities of the MR scanner.

Spatial resolution, slice thickness, signal-to-noise (SNR), and acquisition

time are all inter-related sequence parameters which have a major influence on the detect-ability of disease. In the performance of any MR examination, major decisions have to be made regarding the appropriate coil, the imaging plane(s), the field of view (FOV), the slice thickness and slice gap, the imaging matrix, the number of excitations, the requirement for ECG gating and respiratory compensation, band width selection, the pulse sequence parameters which maximize signal and contrast to noise and contrast needs.

The purpose of these guidelines is not to prescribe the details of individual techniques, but rather to address the spectrum of recognized MR applications and to outline the minimum requirements necessary to undertake these, and to which the radiologist, in conjunction with ancillary staff should aspire.

Techniques and references are presented by anatomic site.

### V. CHOICE OF AN MR SYSTEM

Many systems are available on the market with different field and gradient strengths. In addition, closed and open configuration are offered. Purchase of a system is subject to financial and site considerations. Knowledge of the referral base and clinical needs is also necessary and will help choose the appropriate system. Before purchasing a system, it is recommended that a team be set up which will include a radiologist with previous MR experience, a medical physicist with previous MR experience, technologists and administrators. [Please refer to the Facilities, Equipment and Supplies section in the Facility Standards]

#### VI. PRINCIPLES OF CONTRAST AGENT USE

There are many potential indications for injection of contrast agents:

- <u>A</u>. When breakdown of the blood-brain barrier is suspected, the intravenous administration of gadolinium chelates may increase the sensitivity of magnetic resonance imaging in the central nervous system.
- **<u>B</u>**. When characterizing the vascularity of pathology outside of the central nervous system, or when improved lesion conspicuity is achievable due to differential vascularity and subsequent enhancement.
- **C**. For visualizing vessels both in the central nervous system and outside the central nervous system.
- **<u>D</u>**. For performing perfusion studies.
- **E**. New contrast agents for use in the liver, pancreas or bowel loops

or for blood pool are or will be available in the next few years.

In general, with many applications (gadolinium chelates), it is desirable to acquire Tl-weighted images (either spin echo (SE) or gradient echo (GE)) using the same technique both before and after the administration of gadolinium chelates. (When images are acquired only after administration of gadolinium chelates, it may be difficult to distinguish other causes of high signal intensity, i.e., extracellular methemoglobin from subacute hemorrhage, flow related enhancement from inflowing blood or CSF, or fatty lesions, from gadolinium-enhancement.) In practice, a pre-injection Tl-weighted image in a single plane is generally adequate for comparison. It is often useful to obtain fat saturated Tl-Weighted images to better visualize gadolinium enhancement at sites where there is a lot of fat (e.g. orbits, base of skull, pelvis, etc.).

Gadolinium chelates should not be administered to patients with known or suspected hypersensitivity to the product or with severe hepatic insufficiency.

### VII. RECOGNIZED CLINICAL APPLICATIONS OF MR

- **<u>A</u>**. Adult and Pediatric Brain
- **B**. Adult and Pediatric Spine
- C. Head and Neck
- **<u>D</u>**. Abdomen and Pelvis (Male and Female Genitourinary System)
- **E**. Musculoskeletal System
- **F**. Cardiac
- G. Chest
- **<u>H.</u>** Vascular and Magnetic Resonance Angiography
- I. Breast Imaging

### A. Brain

In both the adult and pediatric brain, magnetic resonance imaging is more sensitive than x-ray computed tomography for the detection of parenchymal abnormalities in the brain (1). This is particularly true in the posterior fossa (2,3) where CT is degraded by beam-hardening, Hounsfield artifact. The advantage of MRI is based on the greater sensitivity of long TR, short TE ('proton density (PD) weighted'

images) and long TR, long TE 'T2-weighted images (T2WI) to alterations of water content compared to the differences in electron density seen by CT.

In infants, the water content of the brain is much higher than in adults. The excess water present in the newborn is gradually lost from both the grey and white matter during the first two years of life. In order to optimally visualize pathology and differentiate grey and white matter on T2W images during this time period it is often useful to prolong the TE and TR values. TR times of 3000 msec or more and TE times of 120 msec or more are useful. It is also useful to obtain axial TIW sequences. This may be helpful to more fully evaluate for possible congenital disorders of migration which demonstrate abnormalities of the sulci and gyri and to be used in conjunction with T2W images to evaluate myelin deposition.

The minimum standard MR technique for scanning the brain should endeavour to maximization SNR and spatial resolution and should include the following:

- 1. A dedicated head coil should be used for imaging.
- 2. Imaging in at least two separate planes.
- 3. T1-weighted images are usually obtained in the sagittal plane together with axial T2-weighted images in the axial plane. In addition, routine examinations might include axial T1-weighted, proton density-weighted or flair images. Conventional or fast spin echo pulse sequences can be used. The choice of pulse sequences should be tailored to the clinical indication of the study (e.g. multiple sclerosis, IAC's, pituitary fossa).
- **4**.Slice thickness of no greater than 5 mm provided that current technology with user-defined bandwidth selection is available. With older technology, slice thickness of at most 6 mm can be tolerated.
- 5. Slice gap between 20 and 50%.
- **6**. Matrix and slice profile selection resulting in an in plane spatial resolution in the order of I mm.
- **7.** Maximum use of motion and flow artifact reduction techniques; i.e. first order flow compensation.
- **8**. Gadolinium-enhanced studies are performed when lesion diagnosis and improved conspicuity are required. If flow compensation is available, it has been found to be useful in the

evaluation of gadolinium-enhanced images in the posterior fossa which are otherwise degraded by flow artifacts arising from the transverse and sigmoid sinuses.

The exact combination of repetition time TR and echo delay time TE to produce the desired contrast depends on field strength since TI increases with increasing field. For example, when the field strength is increased from .35 Tesla to 1.5 Tesla. the TI of the brain increases by 62%. Thus to have comparable amounts of Tl-weighting (short TR) or T2 or proton density weighting (long TR), TR must be scaled to T1 at different field strengths.

New pulse sequences are now available for imaging in the brain. These include:

- **1**. Fluid attenuated inversion recovery (FLAIR) which produces T2-weighted images with dark CSF. It is particularly useful for detection of multiple sclerosis lesions.
- **2.** Diffusion weighted pulse sequences which enable study of proton motion with the use of powerful gradients. The most common clinical indication is for detection of acute ischemic stroke.
- **3**. Perfusion studies using bolus injection of gadolinium and rapid acquisition of multiple brain volumes. Perfusion studies are usually done to determine regional cerebral blood flow and blood volume in patients presenting with acute ischemic stroke.

### **B.** Spine

The role of MRI in the spine has been well established by comparative studies with conventional imaging methods using surgical correlation as an objective measure of accuracy. The areas of greatest proven value include degenerative diseases involving both the cervical and lumbar spine, vertebral inflammatory lesions, congenital malformations and intramedullary lesions such as syringomyelia and neoplasms. Equally useful are the applications of MRI in evaluating extradural, intradural and extramedullary neoplasms, trauma, and patients with signs and symptoms of cord compression.

The minimum standard MR technique for imaging the spine includes the following:

1. A dedicated neck coil (either posterior alone or in combination with an anterior neck coil) for the cervical spine and a dedicated spine surface coil or phased-array surface coils for the thoracic and lumbar spines.

- **2**. A combination of sagittal Tl-weighted and T2-weighted images might be obtained. Again, protocols should be tailored to answer specific clinical questions. For example, when evaluating nerve roots, axial T1- or T2-weighted images should be added.
- **3**. A maximum slice thickness of between 3-5 mm and 1.5-2 mm for cervical spine and corresponding nerve roots.
- **4.** Slice gap between 20-30% for TI-weighted images, and 30-50% for T2-weighted images.
- **5**. Matrix and slice profile selection resulting is an in plane spatial resolution in the order of 1-2 mm.
- 6. Depending on the indication, either the combination of gradient moment nulling, cardiac gating, and saturation pulses for spin echo imaging (conventional or fast spin echo), or gradient moment nulling, with or without cardiac gating and saturation pulses for gradient echo imaging, should be used. Sagittal or axial gradient echo proton density-weighted sequences may be used as substitutes for T2-weighted sequences, especially for cervical and thoracic spinal bio-mechanical clinical problems.
- **7.** Gadolinium chelates should be used in evaluation of intramedullary and leptomeningeal diseases especially in tumor involvement. Contrast should also be routinely utilized in the differentiation of scar from disk, especially in the post-operative failed back.

### C. Head and Neck

The major strengths of magnetic resonance imaging (MRI) in the head and neck region include the outstanding soft tissue contrast, the multiplanar capabilities, the noninvasiveness (except for injection of gadolinium chelates). MR techniques include combination of SE, 2D and 3D GRE sequences, fat suppression or fat saturation sequences, and magnetic resonance angiography (MRA). The drawbacks include the insensitivity to calcification, degradation of the images caused by motion artifacts or by the presence of metallic dental appliances in the mouth.

Patients in whom neurological findings are present, in addition to the head and neck symptoms, require a complete examination of the brain.

The minimum standard MR technique for scanning the head and neck should endeavour to maximization SNR and spatial resolution and should include the following:

- 1. A dedicated head coil should be used in suprahyoid applications, a dedicated neck coil for infrahyoid applications and dedicated surface coils for the temporomandibular joint (TMJ) and globe.
- **2**. A combination of Tl-weighted and T2-weighted images in sagittal, axial and coronal planes are needed. Depending upon the pathology being evaluated, fat saturation and T2 GRE sequences should be used in addition.
- **3**. Slice thickness of between 5-7 mm is suitable for most applications. For TMJ's and optic nerves a slice thickness of 3-4 mm should be used.
- 4. Slice gap between 20-30%, preferably 20%.
- **5**. Matrix and slice profile selection resulting in an in-plane spatial resolution in the order of 3 mm.
- **6**. Maximum use of motion and flow artifact reduction techniques; i.e. respiratory compensation and in flow presaturation.
- **7.** Gadolinium-enhancement studies are performed when lesion diagnosis and improved conspicuity are required, i.e. tumor characterization, aggressive inflammatory process or vascular anomalies. Fat saturation or TlWl GRE sequences are desirable in order to optimize the additional contrast afforded whenever gadolinium chelates are utilized.

#### **D.** Abdomen and Pelvis

Adequate images of the abdomen may generally be obtained in high, mid, and low field strength systems. The precise technical factors employed may, however, vary depending on the instrument, its field strength, and the range of motion compensation techniques which are available. The points pertaining to field strength alluded to above will equally apply.

The minimum standard technique should include:

1. The body coil is suitable for most applications but when available, a phase array surface coil is preferable. However, when high spatial resolution is required specific configurations of phased-array surface coils and/or intraluminal surface coils can be used. FOV should be appropriate to the size of the abdominal or pelvic cavity.

- 2. TI-weighted and T2-weighted images through the upper abdomen generally should be acquired axially. Examinations in other planes may be useful to evaluate anatomy and pathology. Depending upon the pathology being evaluated fat saturation and T2 GRE sequences should be used in addition. Fast GRE breath hold techniques are useful for evaluation of hepatobiliary ducts and the arterial phase of some organs such as the pancreas. In the evaluation of the pelvis a combination of sagittal and axial sequences is often the most helpful for evaluation of lesions involving midline structure whereas a combination of coronal and axial sequences may be more helpful in fully assessing lesions of the bony structures, pelvis side walls and ovaries. For imaging the uterus, ideal planes are along the long and short axis of the corpus.
- **3**. Slice thickness of between 7-10 mm is suitable for most applications in which the body coil is used. If phased-array coils or intraluminal coils are used, slice thickness in the order of 2-5 mm can be used.
- **4**. Slice gap between 20-30%, preferably 20%.
- **5**. Matrix and slice profile selection resulting in an in-plane spatial resolution in the order of 3-5 mm.
- 6. Maximum use of motion reduction techniques such as signal averaging techniques, respiratory ordered phase encoding, and gradient moment nulling techniques, selective fat saturation, and short T I inversion recovery (STIR) are examples of techniques which may be used in isolation or in combination to reduce motion related artifacts on abdominal MR imaging. Breath hold techniques should be used when available. In addition, a bowel movement reducing agent such as buscopan or glucagon should be used for all examinations except liver evaluation.
- 7. Gadolinium-enhanced studies are performed when lesion detection, characterization and improved conspicuity are required. Fat saturation or TIW GRE sequences are desirable in order to optimize the additional contrast afforded whenever gadolinium chelates are utilized. Gadolinium enhancement is specifically important for detection and characterization of liver, pancreatic and renal lesions. It is also useful for staging endometrial and cervical carcinoma. Imaging of bile and pancreatic ducts (MRCP) should be achieved with heavily T2-Weighted sequences either with a thick slab 3D technique or with a thin multislice sequence followed by reconstruction, without or with breath hold.

### E. Musculoskeletal

The minimum standard MR technique for scanning musculoskeletal system should endeavour to maximization of SNR and spatial resolution and should include the following:

- 1. Dedicated volumetric coils should be used for as many joint and non-joint applications as possible to obtain ideal, uniform image contrast and spatial resolution and evaluation of the region of interest.
- 2. A combination of TIWI and T2WI images and multiple planes of section will be required in many instances. Depending upon the pathology being evaluated, fat saturation, 3D TI, T2 GRE and, fat suppressed proton density and STIR sequences are useful. The evaluation of cartilage surface will require a combination of 3D GRE and Fast 3D GRE. Use of intra-articular contrast injection is being investigated for that purpose.
- **3**. Slice thickness of between 3-10 mm is suitable for most applications. 3D GRE images afford slice thickness of 0.7-3 mm for the evaluation of intra-articular pathology.
- 4. Slice gap between 0-20%, preferably contiguous.
- **5**. Matrix and slice profile selection resulting in an in-plane spatial resolution in the order of 0.53 mm.
- **6**. In peripheral musculoskeletal applications use of motion and flow artifact reduction techniques are dependent upon the anatomic region being evaluated; i.e. respiratory compensation in shoulder imaging.
- 7. The use of gadolinium chelates for enhancement permits more specific detection, characterization, and staging of musculoskeletal masses, and their recurrence. Gadolinium also has a role in the evaluation of inflammatory disorders. Finally intraarticular injection is being investigated, particularly following previous surgery, in the presence of joint instability, and in the assessment of certain types of joint derangement.
- **8**. Use of vitamin E capsules is recommended to locate subtle soft tissue masses in order to confirm that the examination has included the relevant area of clinical concern.

#### F. Cardiovascular

There are a variety of techniques now available for MRI of the cardiovascular system. These are used in varied combinations depending upon the indication for the scan. MR studies of the heart

and great vessels have usually required either prospective or retrospective cardiac gating. Evaluation of the heart may include the following techniques:

### Routine applications:

- **1**. Multislice ECG gated technique for routine evaluation of the heart.
- **2**. Multiphasic multislice technique for the evaluation of cardiac dimensions and function.
- **3**. The biphasic technique is performed by acquiring images at multiple anatomical locations at end diastole and end systole.
- **4**. Fast GRE sequences ('turbo-GRE") have made it possible to acquire images of the heart without gating, and for some special sequences (segmental turbo GRE) during a single breath-hold. The value of this technique is currently limited but it may have increasing value as a method to evaluate myocardial perfusion by monitoring the first pass distribution of MR contrast media.
- **5**. Echoplanar (EPI) imaging provides multiple images during a single cycle without the necessity for ECG gating in an acquisition tie of 30 to 50 msec. It is expected that the fast MR techniques will undergo considerable development in the next few years.
- **6**. Cine MR imaging can be accomplished by ECG referencing of repetitive GRE sequences. These images are laced together in a cinematic display so wall motion of the ventricles, valve motion, and blood flow patterns in the heart and great vessels can be visualized.
- **7.** Flow-sensitive imaging techniques now permit the measurement of blood flow expressed either as velocity or volume flow per unit time. See H. Vascular/Magnetic Resonance Angiography (MRA).

The minimum standard MR technique for scanning the central cardiovascular system should endeavour to maximization SNR and fidelity of anatomic registration and should include the following:

1. In adult cardiac applications the body coil is suitable. The selected FOV should be appropriate to the size of the thoracic cavity. For pediatric applications, volumetric coils appropriate to the child size and age should be used.

- 2. The relative weighting in a given image is governed by the RR interval. Relatively TIWI or PD images in a combination of transverse, axial and coronal planes and oblique planes are suitable when evaluating cardiac anatomy, i.e. congenital heart disease.
- **3**. When alternate cardiac and pericardial pathologies are under evaluation TIWI and T2WI in a combination of transverse, axial and coronal planes are acquired. Additional planes may be required in certain instances.
- **4**. Slice thickness of between 5-10 mm is suitable for most applications.
- 5. Slice gap between 20-30%, preferably 20%.
- **6**. Matrix and slice profile selection resulting in an in-plane spatial resolution in the order of 3-5 mm.
- 7. Optimized cardiac gating and respiratory ordered phase encoding motion reduction techniques should be employed.
- **8**. The role of gadolinium chelates for the evaluation of ischemic heart disease has yet to be determined.

### G. Chest

MRI is presently used as a problem solving modality. The principle applications are evaluation of the chest wall, mediastinal and hilar structure. All other pertinent imaging studies should be reviewed before MRI imaging is undertaken.

The minimum standard MR technique for scanning the chest should endeavour to maximization of SNR and fidelity of anatomic registration and should include the following:

- 1. In adults the body coil is suitable. The selected FOV should be appropriate to the size of the thoracic cavity. For pediatric applications, volumetric coils appropriate to the child size and age should be used.
- 2. For the evaluation of mediastinal and hilar structure adjacent to the heart cardiac gating is always required, with the relative weighting in a given image governed by required RR interval. Relatively Tl-weighted or PD-weighted images in a combination of transverse, axial and coronal planes and oblique planes are suitable when evaluating anatomy. For evaluation of the superior mediastinum, cardiac gating is not always required, providing greater flexibility over TI and T2 weighting.

- **3**. When alternate mediastinal, hilar and chest wall pathologies are under evaluation Tl-weighted and T2-weighted (2 RR and 3 RR) images in a combination of transverse, axial and coronal planes; additional planes may be required in certain instances. Additional sequences (e.g. STIR) maybe of value in specific instances.
- **4**. Slice thickness of between 7-10 mm is suitable for most applications.
- 5. Slice gap between 20-30%, preferably 20%.
- **6**. Matrix and slice profile selection resulting in an in-plane spatial resolution in the order of 3-5 mm. Vascular conspicuity is improved with 2 averages (2 NEX).
- 7. Optimized cardiac gating, respiratory ordered phase encoding motion reduction techniques and spatial pre-saturation should be employed.
- **8**. Gadolinium chelates should be utilized in the evaluation of recurrent or post-therapy residual chest wall and mediastinal tumors.

### H. Vascular/Magnetic Resonance Angiography (MRA)

One of the remarkable features of magnetic resonance imaging is the sensitivity of amplitude and phase of its signal to moving spins, a situation that applies to flowing blood. There are three major families of MRA techniques: time of flight (TOF) or inflow angiography, phase contrast (PC) angiography (related to the phase shift of the flowing proton spins) and dynamic gadolinium-enhanced (DGE) MRA. High field MR unit (1.5 Tesla) with high-speed gradient will give the best results especially for breath-hold DGE MRA.

### 1. TOF methods

TOF MRA imaging methods provide vascular contrast based on tagging of the longitudinal magnetization of spins flowing into a region of interest. The more common approach is the creation of vascular contrast during a single scan acquisition followed by removal of stationary tissue by image processing.

If the arterial system is to be examined, an inferior (lower limb angiography) or superior (carotid angiography) saturation band must be used to eliminate venous signal. To get an adequate signal slice, acquisition must be perpendicular to flow direction.

Inflow-enhancement-based TOF angiography can be performed

using a sequential two-dimensional (2D-TOF) or a three-dimensional (3D-TOF) Fourier transform. Coverage of larger anatomic area and better signal especially for low flow are obtained with 2D-TOF techniques. Better spatial resolution are given with 3D TOF techniques but signal loss at the distal portion of the volume of interest can be observed. If 2D TOF sequence are used, an overlap of 20 to 25 % within slices must be obtained to allow quality MIP reconstruction.

### 2. Phase contrast

2D or 3D PC angiograms are obtained using phase difference and encoding for velocity, which will avoid flow aliasing. This technique gives a good signal especially in case of low flow (venous flow) with excellent background suppression. Flow can be analyzed in all three directions.

Limitations of this technique are:

- •Use of long TE for signal sampling which will give other T2 effects that may degrade image quality,
- •Image degradation from pulsatile flow,
- Signal flow aliasing if encoding is inappropriate.

### 3. Breath Hold DGE MRA

This technique involves the administration of a large (0.2 mmole/kg) dose of a gadolinium-chelated contrast agent during a breath-hold 3D gradient echo acquisition (20-30 secondes). This technique provides an excellent signal without motion artefact related to respiratory motion. Adequate timing of the bolus is critical to get adequate signal without venous enhancement. Better signal to noise ratio can be obtained with substraction.

### 4. Clinical applications

Cervical carotid artery: Neck coil, 3D TOF or 2D TOF. Effective slice thickness 1.5-2.5mm.

Intracranial carotid artery and circle of Willis: Head coil, 1.5-2.5 mm, 3D TOF or 3D PC.

Cerebral veins: Head coil, slice thickness 2-4mm, 2D or 3D PC.

Aortic arch and carotid arteries: Body coil or body phased array, DGE MRA, effective thickness 1-2mm, short acquisition time is required to avoid jugular enhancement.

Thoracic aorta: Body coil or body phased array. Slice thickness 3-5mm. Anatomic studies are best achieved with conventional cardiac gated spin-echo sequences. Angiography can be performed using gated 2D TOF techniques or DGE MRA. The latter gives better visualisation of slow flow dissection and aortic ulceration.

Abdominal aorta: Body coil or body phased array. Slice thickness 3-5mm (aneurysm) or 1-2mm (renal artery). Best results are obtained with breath hold DGE MRA, especially for renal arteries. Cine-phase contrast sequence can be used for quantification of flow in renal arteries.

Iliac arteries: Body coil or body phased array. Slice thickness (2-4mm). Best results are obtained with breath hold DGE MRA. 2D TOF gated sequences can be used, but images can be limited by ghost artefact and signal loss due to tortuosity.

Femoral arteries: Body coil or body phased array. Slice thickness 2-4 mm. 2D TOF with or without cardiac gating (required if no proximal stenosis). Better results can be obtained with DGE MRA.

Infra popliteal arteries: Head or knee coil. Separate study of each side is preferred. 2D TOF. Slice thickness 2mm. Cardiac gating not required

Entire bilateral lower limb angiogram using DGE MRA with dedicated coil are under investigation. Preliminary data are promising.

### I. Breast Imaging

MRI is useful in investigating patients with breast prosthesis, for excluding implant rupture. Research is currently underway to define other indications.

# VIII. EQUIPMENT SPECIFICATIONS (for Ontario guidelines, see Volume I, Chapter 2, Facilities, Equipment and Supplies)

The MR equipment specifications and performance shall meet all provincial and federal guidelines, including HPB guidelines. The guidelines include, but are not limited to, specifications of maximum static magnetic field strength, maximum rate of change of magnetic field strength (dB/dt), maximum radiofrequency power deposition (specific absorption rate), and maximum auditory noise levels.

It is recommended that purchase and upgrade specifications be written by the medical physicist in consultation with the supervising physician and MR technologist.

# IX. SPECIFICATIONS OF THE EXAMINATION (for Ontario guidelines, see Volume I, Chapter 2, Facilities, Equipment and Supplies)

The examination shall be performed within current HPB guidelines. When necessary, contrast and sedation shall be administered in accordance with institutional policy and provincial and federal law by a physician, who has trained in cardiopulmonary resuscitation. An appropriately equipped emergency cart must be immediately available to treat serious adverse reactions.

MR compatible ventilators, and appropriate patient monitoring should be available at those sites undertaking general anesthesia and sedation studies.

# X. SAFETY GUIDELINES (for Ontario guidelines, see Volume I, Chapter 2, Facilities, Equipment and Supplies)

Safety guidelines, practices, and policies shall be written, enforced, documented, and reviewed at least annually by the supervising radiologist and the MR charge technologist. These guidelines take into consideration potential interactions of the magnetic field with ferromagnetic objects in the environment of the scanner. They also consider potential hazards engendered by objects implanted within the patient as well as within personnel in the area.

# **XI. QUALITY CONTROL PROGRAM** (for Ontario guidelines, see Volume I, Chapter 2, Facilities, Equipment and Supplies)

The objective of an MR quality control (QC) program is to provide a series of tests and measurements which may be performed on a regular basis to determine if the MR system is performing in a reproducible and predictable manner. Protocols for routine system performance testing are still evolving. Quality control test should be conducted under the supervision of the medical physicist (if present on site), with review at least every six months by the supervising radiologist. A preventive maintenance program is recommended as a mean to minimize unscheduled down time.

A quality control program with written procedures and logs shall be maintained at the MR site.

The ongoing quality control program assesses relative changes in system performance as determined by a technologist and medical physicist (if present on site).

### A. Technologist Quality Control Tests

The following quality control tests shall be performed and documented by an MR technologist knowledgeable in quality control procedures at the frequencies indicated in parenthesis:

- 1. measurement of central frequency (daily)
- 2. measurement of system signal-to-noise ratio on a standard head or body coil (weekly)
- **3**. processor sensitometric testing (daily) unless automatic sensitometry is not available

# <u>B. Medical Physicist Quality Control Tests</u> (for Ontario guidelines, see Volume I, Chapter 2, Facilities, Equipment and Supplies--Quality Control)

The following quality control tests shall be reviewed by the medical physicist annually, and after any major upgrade or major change in equipment:

- 1. review of daily quality control testing records
- 2. measurement of image uniformity
- 3. measurement of spatial linearity
- 4. measurement of high contrast spatial resolution
- **5**. measurement of slice thickness, locations and separations
- 6. assessment of image quality and image artifacts
- 7. eddy current compensation
- **8**. system shim

All quality control testing shall be carried out in accordance with specific procedures and methods.

Preventive maintenance shall be scheduled, performed and documented by a qualified service engineer on a regular basis. Service performed to correct system deficiencies shall also be documented and service records maintained by the MR site.

#### XII. ACCEPTANCE TESTING

Acceptance testing is intended to measure quantifiable system parameters which may then be compared to the manufacturer's specifications. A complete evaluation of the system performance shall be conducted by a medical physicist after completion of installation and prior to regular patient imaging.

Preventive maintenance shall be scheduled, performed and documented by a qualified service engineer on a regular basis. Service performed to correct system deficiencies shall also be documented and service records maintained by the MR site.

#### XIII. QUALITY IMPROVEMENT PROGRAM

A documented, systematic quality improvement program shall be established under the direction of the supervising physician in order to monitor and evaluate such problems as claustrophobia, sedation, administration of contrast agents, equipment malfunctions and accidents (such as metallic objects entering the scan room) endangering patients or workers. Monitoring should include the evaluation of the accuracy of radiologic interpretations as well as the appropriateness of examinations. Incidence of complications and adverse events should be recorded and periodically reviewed in order to identify opportunities to improve patient care.

Data should be collected in a manner that complies with statutory and regulatory peer review procedures in order to protect the confidentiality of the peer review data.

#### **Notes**

For specific details on techniques and indications, as a model, see ACR Reference Document MRI Indications and Techniques - 1992 for examples of.- Brain; Head and Neck; Spine; Abdomen and pelvis, Musculoskeletal; Pediatric; Cardiovascular, Vascular/MRA; Safety and Sedation; and Quality Assurance. See also ACR Glossary of Terms, Third Edition, 1991.

A suggested protocol for acceptance testing is contained in "Acceptance Testing of magnetic Resonance Imaging Systems. Report of American Association of Physicists in Medicine (AAPM) Nuclear Magnetic Resonance Task Group No. 6, Medical Physics. 1992;19(1):217-219".

# **Appendix 1** Independent Health Facilities Act - Ontario Regulation 57/92 -Amended to O. Reg. 14/95

### General

# **Quality Advisor and Advisory Committee**

- 1 (1)Every licensee shall appoint a quality advisor to advise the licensee with respect to the quality and standards of services provided in the independent health facility.
  - (2)If the quality advisor dies or ceases to be the quality advisor, the licensee shall appoint a new quality advisor forthwith.
  - (3)The quality advisor must be a health professional who ordinarily provides insured services in or in connection with the independent health facility and whose training enables him or her to advise the licensee with respect to the quality and standards of services provided in the facility.
  - (4)It is a condition of a licence that the quality advisor be a physician if all the insured services provided in the independent health facility that support the facility fees that the licensee may charge are provided by physicians.
  - (5)In subsection (4), an insured service supports a facility fee if the facility fee is for or in respect of a service or operating cost that supports, assists or is a necessary adjunct to the insured service.
  - (6)A licensee who is qualified under subsection (3) may appoint himself or herself as the quality advisor only if there is no other health professional who is qualified to be the quality advisor who will consent to be the quality advisor. O Reg 57/92, s.1.
- **2** (1)Every licencee shall appoint an advisory committee to advise the quality advisor.
  - (2) The advisory committee shall consist of health professionals who provide health services in or in connection with the independent health facility.
  - (3)The quality advisor shall be the chair of the advisory committee.

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

### **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

- (1) any consents; and
- (m) any diagnoses of the patient.
- (3)A patients 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 only such services.
- (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.
- 12 (1)No licensee shall allow any person to examine a patient's health record or give any person any information, copy or thing from a patient's health record except as required by any Act or regulation made under an Act or as required or allowed by this section. O. Reg. 57/92, s.12(1).
  - (2)Every licensee shall provide copies from a patient's health record to any of the following persons on request:
    - 1. The patient.
    - 2. A personal representative who is authorized by the patient to obtain copies from the record.
    - 3. If the patient is dead, the patient's legal representative

- 4. If the patient is incapable of giving an authorization described in paragraph 2,
  - i. a lawfully authorized substitute decision maker
  - ii. a person to whom the patient is married
  - iii. a person of the opposite or same sex, with whom the patient is living in a conjugal relationship outside marriage if the patient and the person:
    - A. Have cohabited for at least one year
    - B. Are together the parents of a child, or
    - C. Have together entered into a cohabitation agreement under section 53 of the *Family Law Act*
    - iv. the patient's child if the child is sixteen years old or older
    - v. the patient's parent. O. Reg. 57/92, s. 12(2); O. Reg. 14/95, s.1
- (3)A licensee may provide copies from a patient's health record to any person authorized by a person to whom the licensee is required to provide copies under subsection(2).
- (4)A licensee may, for the purpose of providing health care, or assisting in the provision of health care, to a patient, allow a health professional to examine the patient's health record or give a health professional any information, copy or thing from the health record.
- (5)A licensee may provide to the person described in subsection (6) information or copies from a patient health record if anything which could identify the patient is removed from the information or copies.

### (6)Subsection (5) applies to:

- 1. Any person if the information or copies are 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. The Ontario Cancer Treatment and Research Foundation.
- (7)A licensee may charge a reasonable fee for any information, copies or thing provided under this section. O. Reg. 57/92, s.12(3-7).

### **Books and Accounts**

- **12.1**(1) This section applies to licensees of independent health facilities that are funded under section 24 of the Act, other than independent health facilities whose funding is based solely on the Ministry of Health publication titled "Schedule of Facility Fees".
- (2)Every licensee shall keep the following records in relation to the independent health facility:
  - 1. Current financial records showing:
    - i. the amounts paid by the Minister to the licensee under section 24 of the Act.
    - ii. the revenue earned by the licensee from facility fees charged by the licensee for or in respect of services or operating costs that support, assist or are a necessary adjunct to the primary insured services set out in the licensee's licence, and
    - iii. the expenditures, assets and liabilities of the facility that relate to the costs paid by the Minister under section 24 of the Act.
  - 2. A reporting record listing each service provided in the facility that is a primary insured service set out in the licensee's licence and each service provided in the facility that is a funded service under section 24 of the Act and showing how many of each of such services are provided.
  - 3. An annual income and expense statement showing the income received and the expenses incurred by the licensee in connection with the services mentioned in paragraph 2.
  - 4. An annual inventory of the assets of the facility that have an acquisition cost exceeding \$3,500 and that relate to the costs paid by the Minister under section 24 of the Act.
- (3)Every licensee shall ensure that the records required under section (2):
  - (a) are kept in the independent health facility; and
  - (b) are kept in a bound or looseleaf book or are recorded by a system of mechanical or electronic data processing or any other information storage device.
- (4)Every licensee shall ensure that any part of a record required under subsection (2) that relates to a period of time is retained for at least six years following the end of the period.

- (5)Every licensee shall ensure that the accounts of the independent health facility are audited by a person licensed under the *Public Accountancy Act.* O. Reg. 283/94, s.1, *part*.
- **12.2**Every licensee of an independent health facility shall furnish such information and accounts as the Director may require. O. Reg. 283/94, s.1, *part*.

### **Notices**

- 13. Every licensee of an independent health facility,
  - (a) who decides to cease operating the facility at a future date shall give the Director, as soon as possible, written notice of the date; and
  - (b) who ceases operate the facility shall give the Director, within seven days after the date the licensee ceases to operate the facility, written notice of the date. O. Reg. 57/92, s.13.
- **14.** Every licensee of an independent health facility shall give the Director:
  - (a) if the licensee is a corporation, written notice of any change in the location of the licensee's head office within ten days after the change; and
  - (b) written notice of any change in the name under which the licensee carries on business within ten days after the change. O. Reg. 57/92, s.14.

## **Miscellaneous**

- **15**.It is a condition of a licence that the licensee post the first page of the licence in a conspicuous place in the independent health facility. O. Reg. 57/92, s.15.
- **16** (1) The fee for a licence is \$100.
  - (2) The fee for the transfer of a licence is \$100.
  - (3) The fee for the renewal of a licence is \$100. O. Reg. 57/92, s.16.
- **17**. The administrative charge for the purposes of section 36 of the Act is \$50. O. Reg. 57/92, s.17.

# Appendix II Sample Latex Allergy Questionnaire

### **Overview**

A sample Latex Allergy Questionnaire is provided on the following pages.

# **Latex Allergy Questionnaire**

### I. Risk Factor Assessment

### Please circle Y or N to answer the following questions

### **Exposure History:**

Are you a health care worker?	Y	N
Do you wear latex gloves regularly or are you otherwise exposed to latex regularly?	Y	N
Do you have a history of eczema or other rashes on your hands?	Y	N
Do you have a medical history of frequent surgeries or invasive medical procedures?	Y	N
Did these take place when you were an infant?	Y	N
Do you have a history of "hay fever" or other common allergies?	Y	N
Do your fellow workers wear latex gloves regularly?	Y	N
Do you take beta-blocker medication?	Y	N

List any foods below that cause hives, itching of the lips or throat, or more severe symptoms when you eat or handle them:

### II. Contact Dermatitis Assessment

### For patients who wear latex gloves frequently

Do you have rash, itching, cracking,		
chapping, scaling, or weeping of the skin from latex glove use?	Y	N
Have these symptoms recently changed or worsened?	Y	N
Have you used different brands of latex gloves?	Y	N

11	Contact Dermatitis	Assassment	cont'd
11.	Contact Dennatius	ASSESSIIIEIII	COIIL a

If so, have your symptoms persisted?	Y	N
Have you used non-latex gloves?	Y	N
If so, have you had the same or similar symptoms as with latex gloves?	Y	N
Do these symptoms persist when you stop wearing all gloves?	Y	N

### III. Contact Urticaria (Hives) Assessment

### For patients who wear latex gloves frequently

When you wear or are around others wearing latex gloves do you get hives, red itchy swollen hands within 30 minutes or, "water blisters" on your hands within a day?

### IV. Aerosol Reaction Assessment

When you wear or are around others wearing latex gloves, have you noted any of the following:

Y

N

Itchy, red eyes, fits of sneezing, runny or stuffy nose, itching of the nose or palate? Y N

Shortness of breath, wheezing, chest tightness or difficulty breathing? Y N

Other acute reactions, including generalized or severe swelling or shock? Y N

### V. History of Reactions Suggestive of Latex Allergy

Do you have a history of anaphylaxis or of intra-operative shock? Y N Have you had itching, swelling or other symptoms following dental, Y rectal or pelvic exams? N Do condoms, diaphragms or latex sexual aids cause itching or swelling? Y N Do rubber handles, rubber bands or elastic bands or clothing cause any discomfort? Y N

## **Appendix III** Sample Patient Survey: Quality of Care

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

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

#### PLEASE TURN OVER THIS PAGE

Please answer the following questions l	YES	NO				
10. Were you told to leave the clinic before	1	2				
11. Did you have to visit a physician, wa urgent care centre or hospital in the day because your health got worse as a resuthe clinic?	1	2				
12. Would you recommend the clinic to a they needed services that it provides?	1	2				
Please rate this item by circling the number that best decribes your opinion	Excellent	Not Applicable No Opinion				
13. Overall quality fo care: how you evaluate the services you received and the way you were treated	5	8				
14. If there were some things you could	change a	about th	is visit to	o improv	e it, what wo	uld 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!

# **Appendix IV** Sample Referring Physician Survey-Independent Health Facilities Program

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 decsribes your answer.
1. How long have you referred patients to this facility?
years ormonths
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: ( <i>Please rate</i>

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 <u>before</u> your patient receives a diagnostic work-up?

Never	Rarely	Occasionally	Sometimes	Often	Almost all the time
1	2	3	4	5	6
		mately how many	•	•	rred to this facility in s referred)

- 5. Do you refer your patients to more than one facility of this type?
  - 1 No (if you circled No, please skip to Question number 7)
  - 2 Yes
- 6. What are the reasons you refer patients to this particular facility? (*Please circle all that apply.*)
  - 1 Nearer Patient's home
  - 2 Has specialized equipment needed for test requested
  - 3 Turn around time to receive the results is shortest
  - 4 Has staff that speak other languages, and thus can better understand my patients
  - 5 Is able to quickly see patients when feedback is urgently required
  - 6 Has convenient hours of operation
  - 7 Quality of the services provided
  - 8 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.*)
  - 1 Only facility of its type in this community
  - 2 Our group has a service contract with this facility
  - 3 Facility is located near this practice and is thus convenient for patients
  - 4 Has staff that speak other languages and thus can better understand my patients
  - 5 Has specialized equipment needed for tests requested
  - 6 Turn-around time to receive results is short
  - 7 Nearest patients' homes
  - 8 Is able to quickly see patients when feedback is urgently required
  - 9 Quality of the services provided
  - 10 Has convenient hours of operation
  - 11 Other, please describe

8. 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

<sup>9.</sup> Have you been dissatisfied with a consult you received from this facility in the past six months? 1 No 2 Yes

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	Dissatisfied	Neutral	Satisfied	Very Satisfied
1	2	3	4	5

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

Our address is:

# **AppendixV** MR Safety

The following safety forms are taken from the ACR White Paper on MR Safety and are used as examples of basic screening tools.

## **Safety Screening Form for MR Procedures**

Reprinted with permission of the American Roengten Ray Society, Leesburg, Virginia

Date:	Name:(first/r	middle/last):			
Female [] N	Male [ ] Age:	_ Date of Birth:	Height:	Weight:	
1. Why are	you having this	examination (medic	cal problem?)		
				Yes	No
problem?			n before and had a		
=		surgical operation	or procedure of ar	y kind?	
bullet, BE	3, shrapnel)?		object/foreign bod	y (e.g.	
,	ease describe:				
-			tal object in your ey	ye?	
		rings, other metal	objects?		
	d you seek med				
Describe	what was foun	a:			
	ı have a history ry disease?	of kidney disease	e, asthma, or other a	allergic	
7. Do you	ı have any drug	g allergies?			
If yes, ple	ease list drugs:				
	ou ever receive ner x-ray or stu		nt/x-ray dye used fo	or MRI,	
	ou ever had ar		gnetic resonance Im	naging	
If Yes, ple	ease describe:				
10. Are y	ou pregnant or	suspect you may	be pregnant?		
•	ou breast feedi		. •		
=	of last menstru	_	Post-menopaus	sal?	

#### **MR Hazard Checklist**

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The following items may be harmful to you during your MR scan or may interfere with the MR examination. Please mark on the chart below the location of any metal inside your body or site of surgical operation.

You must provide a Yes or No for every item. Please indicate if you have ever had any of the following:

Yes	NO	
		Any type of electronic, mechanical, or magnetic implant (Type:)
		Cardiac pacemaker
		Aneurysm clip(s)
		Implanted cardiac defibrillator
		Neurostimulator
		Biostimulator (Type:)
		Any type of internal electrode(s) or wire(s)
		Cochlear implant
		Hearing aid
		Implanted drug pump (e.g. insulin, Baclofen, chemotherapy, pain medicine)
		Halo vest
		Spinal fixation device
		Spinal fusion procedure
		Any type of coil, filter, or stent (Type:)
		Any type of metal object (e.g. shrapnel, bullet, BB)
		Artificial heart valve
		Any type of ear implant
		Penile implant
		Artificial eye
		Eyelid spring
		Any type of implant held in place by a magnet (Type:)
		Any type of surgical clip or staple
		Any IV access port (e.g. Broviac, Port-a-Cath, Hickman, Picc line)
		Medication patch (e.g. Nitroglycerine., nicotine)
		Shunt

Yes	NO	_
		Artificial limb or joint (What and where:
		/ Tissue expander (e.g. breast)
		Removable dentures, false teeth or partial plate
		Diaphragm, IUD, Pessary (Type:)
		Surgical mesh (Location:)
		Body piercing (Location:)
		Wig, hair implants
		Tattoos or tattooed eyeliner
		Radiation seeds (e.g. cancer treatment)
		Any implanted items (e.g. pins, rods, screws, nails, plates, wires)
		Any hair accessories (e.g. bobby pins, barrettes, clips)
		Jewelry
		Any other type of implanted item (Type:)
I have re	ead and u ortunity t	bove information is correct to the best of my knowledge understood the entire contents of this form and I have has a sk questions regarding the information on this form.
MD/RN	/RT sign	nature: Date:

#### **Patient Instructions**

## Reprinted with permission of the American Roengten Ray Society, Leesburg, Virginia

Print name of MD/RN/RT\_\_\_\_\_

- 1. You are urged to use the ear plugs or headphones that we supply for use during your MRI examination since some patients may find the noise levels unacceptable and the noise levels may affect your hearing.
- 2. Remove all jewelry (e.g. necklaces, pins, rings)
- 3. Remove all hairpins, bobby pins, barrettes, clips etc.
- 4. Remove all dentures, false teeth, partial plates
- 5. Remove all hearing aids
- 6. Remove eyeglasses
- 7. Remove your watch, pager, cell phone, credit and bank cards, and all other card with a magnetic strip

- 8. Remove body piercing objects
- 9. Use gown, if provided, or remove all clothing with metal fasteners, zippers

#### **Hazard checklist for MRI Personnel**

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For MR	I Office	e Use only
Patient 1	Name_	
Patient 1	ID Nun	nber Referring Physician
Procedu	re	
Clinical	Histor	y
	_	ist for MRI Personnel:
V		
Yes	NO	
res	NO	Endotracheal tube
res	NO	Endotracheal tube Swan-Ganz catheter
Yes	NO	=
	NO	Swan-Ganz catheter
Yes	NO	Swan-Ganz catheter  Extraventricular device
Yes	NO	Swan-Ganz catheter  Extraventricular device  Arterial line transducer  Foley catheter with temperature sensor and/or
Yes	NO	Swan-Ganz catheter  Extraventricular device  Arterial line transducer  Foley catheter with temperature sensor and/or metal clamp
Yes	NO	Swan-Ganz catheter  Extraventricular device  Arterial line transducer  Foley catheter with temperature sensor and/or metal clamp  Rectal probe

# **Appendix VI** Sample MRI Requisition

The following requisition is a sample, copied with permission from the Rouge Valley Health System in Scarborough, Ontario.

Patient Information	Area to be examined (please be specific):
Name:(first/last)	
Address:	Clinical Information
Postal Code:	
DOB (D/M/Y):	
Room #: Male [] Female []	
Outpatient [] or Inpatient []	
Inpatient from other hospital []	Working Diagnosis:
Other Hospital:	
Health Card #	Referring Physician Information
version:	Name:
Telephone - Home ()	Address:
-work ()	
	Postal Code:
Mode of transport:	Phone Number: ()
walking []	Copies sent to:
wheelchair []	
stretcher []	Other Tests and Results to Date
Is this a WSIB examination? Yes [] No []	MRI:
Claim #:	CT:
Imaging Protocol (radiologist Use)	X-Ray:
Priority Code 1 2 3 4	US:
Monitor: Yes [] or No []	Myelogram:
Protocol Code	Angiogram:
Protocol Details	Nuclear Medicine:
	Arthrography:
	Does the Patient require sedation (to
Gadolinium: Yes [ ] or No [ ]	be provided by the referring
Dose:	physician)?
	Yes [ ] or No [ ]
	See other side for Patient Screening section to be completed by a referring physician

Patient Screening (must be completed by a referring physician) Please check Yes or No	Yes	No
Have you ever worked with metal?		
2. Has metal ever gone into your eye?		
3. Could you be pregnant?		
4. Do you have any of the following?		
-cardiac pacemaker/leads		
-artificial cardiac valve		
-aneurysm clips		
-neurostimulator		
-Cochlear implants		
-shrapnel/bullets		
-Porta Cath		
-dentures/braces		
-other implanted devices		
5. Have you ever had surgery on your:		
-head?		
-neck?		
-spine?		
-chest?		
-abdomen?		
-arms/legs?		
6. What is your current weight		
(maximum allowable weight: 350 lbs/159 kg)		
-Referring Physicians: If the answer is YES to questions 1 or 2,	please o	rder
x-ray of the Orbits on the patient and submit the report with this	s requisi	tion.
If Yes to any part of section 4 or 5, please provide details below:		
Referring MD Signature:		

## Index

#### anaesthetists 14 AAPM (American Association of annually, Quality Control 16 Physicists in Medicine) 12 anxiolytics 11, 17 ACCME 4 appropriate care vi, 5 ACLS (see Advanced Cardiac Life archival system 21 Support) 3, 13 В ACR 16 Basic Cardiac Life Support (see ACR (see American College of BCLS) 3,8 Radiology) 12 BCLS (see Basic Cardiac Life administration, contrast 25 Support) 3, 8, 13 Advanced Cardiac Life Support beta-blockers 59 (ACLS) 3 allergies 13, 18 ambu bag 15 calibration 19 American Association of Physicists in Canadian Association of Radiologists Medicine (AAPM) 12 (CAR) 6, 21 American Board of Medical Physics 7 Canadian College of Physicists in American Board of Radiology 7 Medicine 7 American College of Radiologists 6 Canadian Council on Health Facilities American College of Radiology Accreditation iv (ACR) 12 American Medical Association iv

Canadian Council on Health Services	College of Physicians and Surgeons of
Accreditation iv	Ontario, responsibilities v
Canadian Medical Association iv	communication 21, 23
CAR (see Canadian Association of	computed tomography, experience 4
Radiologists) 21, 29	computed tomography, re-training 4
CAR, website 29	confidentiality 6, 18
case mix 12	consent, patient 18
Charge Technologist, CME 8	consultation 18, 21, 22
Charge Technologist, qualifications 8	consultations 21
Charge Technologist,	consultative services 21
responsibilities 8, 9	contraindications 18
clerical personnel 3	contrast 13, 14
clinical data 21	contrast injection 18
clinical practice parameters iv, 25, 29	Contrast Injection for Radiographers 8
clinical practice parameters and facility	contrast injections 9
standards iii, iv	contrast media 9
clinical practice parameters and	contrast reaction, drugs 14
Facility Standards, principals	contrast, administration 25
used to develop iii	
clinical practice parameters and facility	D
standards, purpose iii	daily log 25
clinical practice parameters, principals	daily, Quality Control 15
used to develop iv	defibrillator 14
clinical practice parameters, purpose	delegated acts 18
of iii	development, policies 17
clinical practice parameters, updates v	development, procedures 17
CME 4, 5	diagnosis vi, 23
CME, Charge Technologist 8	diagnostic facilities iii
CME, Medical Physicist 7	diagnostic images, copy 23, 24
CME, Medical Radiation	diagnostic images, filing 24
Technologists 8	diagnostic images, reports vi, 18, 22,
CME, physcians 4	23, 24
CMRTO 8	diagnostic imaging practice 18, 26
codes 11, 13, 24	diagnostic imaging services 3, 17, 18,
coding system 24	25
College of Medical Radiation	diagnostic imaging, elements vi
Technologists of Ontario 7, 8	diagnostic imaging, films vi, 22, 24
College of Nurses of Ontario iv	diagnostic imaging, requisitions 18, 22
College of Physicians and Surgeons of	dictation 22
Ontario iii, 21, 25	Director, Independent Health
College of Physicians and Surgeons of	Facilities 7
Ontario, Mission	documentation 3, 4, 9, 12, 15, 18, 23
Statement iii	documentation, permanent record 23
College of Physicians and Surgeons of	documentation, policies 17
Ontario, mission statement iii	documentation, telephone referrals 18

documentation, written referrals 18	filing 24
drug reactions 26	film 23
drugs 15	films vi, 24
drugs, contrast reaction 14	fire alarm 13, 17
drugs, emergency kit 14	first aid 18
drugs, equipment 25	
drugs, resuscitation 14	G
-	geography 21, 26
E	goals and objectives 26
ECG monitor 14	gradient hardware 12
education, college responsibilities v	
educational material 24, 26	Н
electronic signature 23	hygiene 11
emergency kit 14	
emergency reports 23	I
emergency response teams 17	IHF (see Independent Health
emergency, equipment 11	Facilities) 18
emergency, protocol 13	IHF Task Force 21
emergency, response 11, 17	IHFA (see Independent Health
emergency, resuscitation 18	Facilities Act) iii
endotracheal tubes 15	images 21, 22
equipment 9, 15	imaging protocols 5, 17
equipment, drugs 25	imaging reports vi, 18, 22, 24
equipment, facility 6	imaging, patient 12
equipment, maintenance 9, 19	Independent Health Facilities Act 7
equipment, monitoring 12	Independent Health Facilities Act
equipment, non-magnetic 12, 13	(IHFA) iii, 18, 49
equipment, Quality Control 15	Independent Health Facilities, clinical
equipment, repair procedures 9	pratice parameters iii
equipment, repairs 16	Independent Health Facilities, facility
equipment, resuscitation 13, 14, 15	standards iii
	Independent Health Facilities, goals
F	and objectives iii
facility layout 12, 13	independent health facilities.
facility standards iii, iv	organization 25
facility, equipment 6, 12	infection control 9, 18
facility, policies 6	injection certificate 8
facility, policy 18	injection certification 9
facility, procedures 12	injections 8
facility, quality management 26	injector 12
facility, quality of care 26	interpretating 18
facility, services provided v, 18, 26, 50	- <del>-</del>
facility, supplies 9	J
field strength 12	job descriptions 3
field, magnet 12	-
,	

L	Ontario Medical Association
laryngoscope 15	(OMA) iv
layout, facility 12, 13	oropharyngeal airways 15
light bulbs 13	oxygen 14
	oxygen saturation monitor 14
M	7.0
magnet quench 17	Р
magnet room, view 12	PACS (see Picture Archiving &
magnet, primary 12	Communication Systems) 21,
magnet, second 12	23
maintenance 6, 18, 19	paediatrics 11, 12, 13, 15, 17
maintenance, equipment 9, 19	patient care, clinical information 21
Material Safety Data Sheets 18	patient care, latex allergy 13, 18
Material Safety Data Sheets	patient care, patient privacy 11, 26
(MSDS) 18	patient care, policies and
Medical Physicist 7	procedures 17
Medical Physicist, CME 7	patient care, quality of service iii
Medical Radiation Technologists 7	patient care, transferring patients to
Medical Radiation Technologists,	acute care 18
CME 8	patient case preparation 17
Medical Radiation Technologists,	patient consent 18
qualifications 7	patient mix 12
Medical Radiation Technologists,	patient privacy 26
training 7	patient records 26, 52
meetings, facility 25	patient, imaging 12
metal detector 11	patient, screening 17
Ministry of Health and Long-Term	patient, services provided vi
Care iii	patient, view 12
monitoring equipment 12	patient-booking systems 18
monthly, Quality Control 15	phased array coils 12
MRA 23	physicians, consultation 21
MRI Director/Quality Advisor 5, 6, 7,	physicians, diagnostic imaging 3
8, 9	physicians, interpreting reports 18
MRI Director/Quality Advisor,	physicians, policies and procedures 17
responsibilities 9	physicians, qualifications 3
MRI Radiologist, definition 4	physicians, qualified 3, 18
MSDS (see Material Safety Data	Picture Archiving & Communication
Sheets) 18	Systems (PACS) 21
,	plan, written 3
N	planning strategies 26
non-magnetic, equipment 13	policies 8
	policies and procedures 17, 26
0	policies and procedures, quality
Ontario Chapter, College of Family	care 26
Physicians of Canada iv	policies, development 17
	1 , I

policies, facility 6	Quality Control, quarterly 16
power injector 12	Quality Control, testing 7
pregnancy 17	Quality Control, weekly 15
preliminary reports 18, 23	quality management 26
primary magnet 12	quality management progam, clinical
procedure manual 17	data 26
procedure manual, availability 17	quality management program iii, v, 26
procedure manual, contents 17	quality management program,
procedure manual, review 17	evaluating diagnostic
procedures 8	efficacy 26
procedures, development 17	quality management program, goals
procedures, facility 12	and objectives 26
procedures, reporting 22	quality management program, policies
	and procedures 26
Q	quality management program, staff
qualifications, Charge Technologist 8	performance appraisals 26
qualifications, Medical Physicist 7	quarterly, meetings 25
qualifications, Medical Radiation	quarterly, Quality Control 16
Technologists 7	quench, magnet 17
qualifications, MRI Director/Quality	1
Advisor 5, 6	R
qualifications, physicians 3	radio frequency 12
qualifications, technologists 8	radiological consultations 21
Quality Advisor 5	radiologists, third party 24
Quality Advisor (see MRI Director/	RCPSC (see Royal College of
Quality Advisor) 6	Physicians and Surgeons of
Quality Advisor, availability 5	Canada) 4
Quality Advisor, IHFA 49	reactions, drugs 26
Quality Advisor, patient safety 6	receiver channels 12
Quality Advisor, regulations 5	recommendations 23, 26
Quality Advisor, reporting 7	record, permanent 23
Quality Advisor, responsibilities 5	records 6, 26
Quality Advisory Committee 25	records, patient 26, 52
quality assurance 12	referring physician vi, 21, 22, 23, 26
quality assurance program 6	referring physician, responsibilities 22
quality assurance tests 12	referring physician, surveys 26
quality care 25	repairs, equipment 16
quality care, monitoring 26	report, emergency 23
Quality Control 7, 8, 15, 26	report, written 23
quality control 15	reporting 21
Quality Control, annually 16	reporting, procedures 22
Quality Control, daily 15	reports 9
Quality Control, documentation 9	reports, concerns 7
Quality Control, equipment 15	reports, emergency 23
Quality Control, monthly 15	reports, filing vi, 24

reports, interpretation 18, 22, 23	staff, documenting staff supervision 17
reports, preliminary 18	staff, job descriptions 3
reports, proper design of 6	staff, staffing facilities 3
reports, stat 22	staff, standards 17
reports, telephone 18	stat report 22
reports, urgent 23	stat reports 22
requesting 21, 22	sac reports 22
requesting procedures 22	Т
requesting procedures 22	Task Force iv
requisition vi, 18, 22	Task Forces iv
requisition, written 22	Technologists, training 8
	telephone, reports 18
responsibilities, Charge	teleradiology 21
Technologist 8, 9	
responsibilities, Medical Physicist 7	training, Medical Physicist 7
responsibilities, MRI Director/Quality	training, Medical Radiation
Advisor 5, 9	Technologists 7
responsibilities, referring physician 22	training, physicians 3, 4
resuscitation, drugs 14	training, safety 18
resuscitation, emergency 11, 18	transcription 22
resuscitation, equipment 13, 14, 15	transferring patients 18
resuscitation, procedures 13	tray, resuscitation 15
resuscitation, tray 15	treatment facilities iii
Royal College of Physicians and	treatment medication 14
Surgeons of Canada 3	
rubber-stamp signature 23	U
	upgrade pathway 12
S	urticaria 60
safety 5, 7, 8, 13, 18, 67	
safety guidelines 5, 8	V
safety precautions 18	view, magnet room 12
safety, instructions 11	view, patient 12
safety, patient 17	
safety, policies 9	W
safety, training 18	weekly, Quality Control 15
scanner 12	WHMIS (see Workplace Hazardous
screening 21, 22	Materials Information
screening, patient 17	System) 3
secondary magnet 12	Workplace Hazardous Materials
sedation 11, 17	Information System
services, written plan 3	(WHMIS) 3
signature, electronic 23	written report 23
software packages 12	•
sphygmomanometer 15	
staff performance appraisals 26	
staff safety 6	