



MANITOBA DIAGNOSTIC IMAGING STANDARDS

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INTRODUCTION

Pursuant to By-Law No. 3 of the College of Physicians and Surgeons of Manitoba, Council has established standards governing diagnostic imaging facilities, as follows:

Diagnostic Imaging:

1. Quality Management Program
2. Manuals
3. Safety
4. Equipment
5. Computed Tomography (CT)
6. Fluoroscopy
7. Magnetic Resonance Imaging (MRI)
8. Mammography
9. Radiography
10. Mobile Radiography/Mammography
11. Vehicular Facility
12. Ultrasound

Certain standards, namely Quality Management Program, Manuals, Safety and Equipment apply to all diagnostic imaging facilities. Whether the remaining standards are applicable to a facility depends on the type of work done in the facility.

TABLE OF CONTENTS

1.0 QUALITY MANAGEMENT PROGRAM 5

 1.1 General 5

 1.2 Signage..... 5

 1.3 Personnel 5

 1.5 Documentation..... 5

2.0 MANUALS 6

 2.1 General 6

 2.1.1 Format of Manuals 6

 2.1.2 Manual Availability..... 6

 2.1.3 Manual Review 6

 2.2 Required Manuals..... 6

 2.2.1 Quality Management Program Manual 6

 2.2.2 A Safety Manual 8

 2.2.3 A Personnel Policy Manual 11

 2.2.4 An Operational Policy Manual 11

 2.2.5 An Equipment and Maintenance Manual..... 14

 2.2.6 Procedure Positioning Manual 15

 2.2.7 Computer Radiography and Digital Radiography Manual 15

 2.2.8 Radiology Information System (RIS) Manual 16

 2.2.9 A Picture Archiving and Communications Systems (PACS) Manual..... 17

 2.2.10 A Site Specific Ward Manual 17

 2.2.11 A Modality Specific Manual..... 17

 2.2.12 Contrast Media Manual..... 18

3.0 SAFETY 18

 3.1 Legislation..... 18

 3.2 Personnel Training 18

 3.3 Physical Space..... 18

 3.4 Site Specific Safety Risks 19

 3.5 Safety Documentation 19

4.0 EQUIPMENT 19

 4.1 General 19

 4.2 Emergency Power..... 19

 4.3 Site Specific Equipment..... 20

5.0 COMPUTED TOMOGRAPHY 20

 5.1 CT Technologist Qualifications 20

 5.2 General 21

 5.3 Policies and Procedure 21

 5.4 Radiation Dose Management..... 22

 5.5 Quality Control Program 22

 5.6 Additional Requirements for Remote Computed Tomography Facilities 23

MANITOBA DIAGNOSTIC IMAGING STANDARDS

6.0	FLUOROSCOPY/C-ARM	23
6.1	General	23
6.2	Policies and Procedures	23
6.3	Additional Requirements for Non-Radiologist Operated Fluoroscopy	24
7.0	MAGNETIC RESONANCE IMAGING (MRI)	25
7.1	Technologist Qualifications.....	25
7.2	General	25
7.3	Safety.....	25
7.4	Quality Control Program	26
7.5	Policies and Procedures	26
7.6	Additional Requirements for Remote MRI Facilities.....	27
8.0	MAMMOGRAPHY	28
9.0	RADIOGRAPHY	28
9.1	Technologist Qualifications.....	28
9.1	General	28
9.2	Policies and Procedures	28
10.0	MOBILE RADIOGRAPHY/MAMMOGRAPHY	29
10.1	General	29
10.2	Policies and Procedures	29
11.0	VEHICULAR FACILITY	30
12.0	ULTRASOUND	30
12.1	Sonographer Qualifications.....	30
12.2	General	31
12.3	Policies and Procedures	31
12.4	Quality Control Program	32
12.5	Additional Requirements for Remote Ultrasound Facilities	32
12.6	Ultrasound Equipment	33

MANITOBA DIAGNOSTIC IMAGING STANDARDS

1.0 QUALITY MANAGEMENT PROGRAM

1.1 General

1.1.1 A facility must establish and maintain a documented quality management program¹ that:

1.1.1.1 defines:

1. the accountability of the facility director² to meet the requirements of the College of Physicians and Surgeons of Manitoba By-law 3 "Accredited Facilities".
2. policies³.
3. procedures⁴.
4. resources⁵.
5. the monitoring required for the quality management program.

1.1.1.2 at minimum, meets the requirements of *Health Canada Safety Code 35: Radiation Protection in Radiology – Large Facilities Safety Procedures for the Installation, Use and Control of X-ray Equipment in Large Medical Radiological Facilities*.

1.1.2 A facility must establish and maintain a documented organizational structure that defines reporting relationships that includes: functional, division, and matrix systems.

1.2 Signage

1.2.1 A facility must post in the facility's waiting room or reception area:

1.2.1.1 the responsible facility director's name.

1.2.1.2 the current certificates of accreditation (outdated or invalid certificates must be removed).

1.3 Personnel

1.3.1 The facility director must:

1.3.1.1 ensure that the facility only employs personnel with registration and/or licensure where registration and/or licensure is required by law for the individual's scope of practice.

1.3.1.2 employ only personnel with the education, training, competence and experience to perform procedures within the individual's job description.

1.3.1.3 ensure personnel have access to modality specific reference material, including positioning and reference material.

1.3.1.4 establish and maintain a program for the maintenance of personnel competency which includes:

1. a quarterly image quality assessment. The facility director or their appointed quality personnel must annually review the quality image assessment reports. Documentation is required.
2. a performance appraisal of technologists/sonographers at least once every two years. The facility director must review the performance appraisals and provide feedback as required; date and signature are required.
3. a performance appraisal at least every year for cross-trained medical laboratory technologists.

1.3.1.5 have a process in place to monitor and maintain competency when examinations required in the scope of practice are performed infrequently.

1.3.1.6 indicate when there is a need to provide refresher training.

1.3.1.7 have a mechanism in place for personnel to request refresher training.

1.4 Documentation

1.4.1 All facility policies and procedures must be documented and available to personnel.

¹ A Quality Management Program Manual is required by the Manuals Standard.

² Facility director means a physician appointed as director of a facility in accordance with By-law 3 "Accredited Facilities".

³ Policy: A policy is a pre-determined course of action that establishes the rules and directives around core processes of the facility. A policy restricts negotiation and legitimizes decision making and actions. A policy is not intended to communicate operating procedures and is not a reiteration of laws and regulations.

⁴ Procedure: A procedure is an informative process that provides protocols, routines, guidelines and methodologies.

⁵ Resources include but are not limited to equipment, space, human resources, etc.

MANITOBA DIAGNOSTIC IMAGING STANDARDS

2.0 MANUALS

2.1 General

2.1.1 Format of Manuals

2.1.1.1 A facility must format manuals to include:

1. a table of contents.
2. page headers with the following information:
 - a) facility name.
 - b) policy/procedure title.
 - c) edition, effective and revision date.
 - d) author.
 - e) facility director name.

2.1.2 Manual Availability

2.1.2.1 A facility must make each manual available to all personnel.

2.1.2.2 The safety manual and all procedure/positioning protocol assignments (including technical factors) must be available to personnel in hard copy format.

2.1.3 Manual Review

2.1.3.1 A facility director must review and update all manuals and maintain a written record of the review and of any changes made through a document control process at least once every two years.

2.1.3.2 Manuals must have a coversheet to indicate approval of manual content and must include:

1. the date of approval and the facility director's signature.
2. the facility director's signature indicating that the revisions, additions and deletions in the manual have been reviewed, and the date of the review.
3. signatures of personnel who are required to review the document, indicating that they have reviewed the manual, at least once every two years and the date of the review.
4. signatures of personnel who are required to review the document, indicating review of manual revisions, additions and deletions, and the date of the review.

2.2 Required Manuals

A facility must establish and maintain the following manuals:

2.2.1 Quality Management Program⁶ Manual

2.2.1.1 The Quality Management Program Manual must include:

1. a table of contents.
2. a description of the quality management program, including a master list of quality control tests/procedures.
3. the requirement for an appointment of a quality assurance technologist/sonographer.
4. a radiology technologist/sonographer designated by the facility director to oversee the quality management program; documentation is required.
5. the requirements for the physical facilities.
6. the requirements for personnel education.
7. policies governing each of the following topics:
 - a) compliance with *The Personal Health Information Act*.
 - b) delegation of function to comply with the requirements of the College of Physicians and Surgeons of Manitoba.
 - c) standing orders.
 - d) the exchange of images/reports.
 - e) handling of complaints and the remediation procedures.
 - f) requirements to perform internal audits (e.g. turnaround times, wait times, report delivery).
 - g) a patient/client satisfaction process. Complaints must be brought forward to the facility director and designate as soon as possible.

⁶ See the Quality Management Program Standard.

MANITOBA DIAGNOSTIC IMAGING STANDARDS

- h) a risk management process for managing errors (e.g. incorrect marker used, incorrect patient information, incorrect information provided on consultation requests, patient unable to provide PHIN).
- i) the contact information for technical support.
- j) a process for reporting/documenting technical support repairs/remediations.
- k) a repeat/reject image analysis, which must include:
 - (i) specific anatomical areas and specific views along with the reason for rejection.
 - (ii) capture of all images.
 - (iii) monthly review of the repeat analysis data.
 - (iv) personnel education sessions to review deficiency trends.
 - (v) a process to manage non-conformances.
- l) maintaining image and document retention periods, which must include the following minimum retention periods:

(i) medical images adults	5 years
(ii) medical images pediatrics	until 23 years of age
(iii) mammography	10 years
(iv) PACS archive adults	5 years
(v) PACS archive pediatrics	until 23 years of age
(vi) bone density	DXA studies 10 years
(vii) reports adults	5 years (original and verified final report)
(viii) reports pediatrics	until 23 years of age (original and verified report)
(ix) request for consultation	5 years in original transcribed form (it is acceptable to maintain a scanned copy of the original consultation request).
(x) quality control/quality assurance	2 years except for bone density which is 5 years
(xi) repeat/reject	2 years
(xii) outdated policies/procedures	as required by the College of Physicians and Surgeons of Manitoba
(xiii) accession records	2 years
(xiv) equipment maintenance	equipment maintenance lifespan plus 2 years
(xv) incident reports	10 years
(xvi) Material Safety Data Sheets (MSDS)	30 years
(xvii) Workplace Health and Safety documents	5 years
- 8. an emergency preparedness plan. The emergency preparedness plan must include:
 - a) definitions of all emergency codes.
 - b) emergency contact information (e.g. fan out call list).
 - c) directives for personnel regarding emergency preparedness, including any additional precautions required.
- 9. a qualitative and quantitative image review process to include:
 - a) at least quarterly performance reviews are performed.
 - b) a random selection of examinations.
 - c) all examinations are reviewed at least once annually (exception: a selection of extremity examinations is appropriate).
 - d) for radiology: demographics, identification of the technologists, positioning, technical factors, raw-data marker usage, annotations, the As Low As Reasonably Achievable principle (ALARA) requirements (e.g. coning, shielding, pregnancy screening), artifacts, equipment malfunctions.
 - e) for ultrasound: demographics, identification of the sonographer, adequate number of images, adequate ciné capture, mechanical index/thermal index (MI/TI), quality of grayscale, color Doppler and pulsed Doppler, protocol is met.

MANITOBA DIAGNOSTIC IMAGING STANDARDS

- f) for computed tomography (CT): demographics, identification of the technologist, Field of View (FOV), Auto mA, technical factor used, the As Low As Reasonably Achievable principle (ALARA) requirements, estimated dose captured, anatomy inclusion, protocol is met, retro-reconstruction, dose capture and CT/DI range established.
- g) for magnetic resonance imaging (MRI): demographics, identification of the technologists, FOV, parameters set, image quality met, anatomy inclusion and protocols are met.
- h) an avenue to remediate non-conformances as required.
- i) examinations that are performed infrequently are reviewed at least quarterly.
- j) a process to maintain competency for examinations that are not frequently performed.

2.2.2 A Safety Manual

- 2.2.2.1 The Safety Manual must be site specific. For all facilities, the Safety Manual must establish and maintain policies and procedures governing:
 - 1. general workplace safety and health.
 - 2. routine practices.
 - 3. waste management.
 - 4. electrical safety.
 - 5. fire safety.
 - 6. radiation safety.
 - 7. Workplace Hazardous Materials Information System (WHMIS).
 - 8. fire extinguishers meeting NFPA 10 "Portable Fire Extinguishers" requirements; which includes:
 - a) that monthly inspections are performed by a trained and competent individual. The inspection dates must be documented.
 - b) that annual maintenance is performed by trained and competent individuals. The equipment must be tagged with the last date of maintenance.
- 2.2.2.2 If these topics are applicable to the specific facility, the Safety Manual must also have policies and procedures governing safety for:
 - 1. eyewash stations.
 - 2. hazardous materials.
 - 3. carcinogens.
 - 4. chemical hazards.
 - 5. compressed gases.
 - 6. flammables.
- 2.2.2.3 General workplace safety and health policies and procedures must:
 - 1. require a job hazard analysis that is modality and job specific.
 - 2. require competency based orientation training⁷.
 - 3. require use of personal protective equipment where appropriate.
 - 4. define when it is necessary to have personnel secure hair.
 - 5. identify suitable facility apparel.
 - 6. prohibit food and beverages in areas where patients have access.
 - 7. include processes:
 - a) to identify and resolve safety hazards.
 - b) to document and investigate any incidents, accidents and adverse events.
 - c) regarding incidents and work related injuries.
 - d) regarding incidents involving visitors in the facility.
- 2.2.2.4 Routine practices/infection control policies and procedures must include:
 - 1. the use of personal protective equipment, when handling blood and body fluids.
 - 2. the prevention of blood and body fluid exposure.
 - 3. a follow-up process for potential exposure to communicable pathogens including, but not limited to, tuberculosis.
 - 4. requirements for hand hygiene.
 - 5. the appropriate utilization of alcohol based (minimum 70% alcohol) hand rubs.

⁷ See also the Personnel Policy Manual.

MANITOBA DIAGNOSTIC IMAGING STANDARDS

6. the requirements for FIT masks.
 7. the requirements for sterile techniques.
 8. the daily disinfection of work surfaces.
 9. the type and strength of decontamination solution must be expressed in percentage (bleach) or relative concentration (precept).
 10. that biohazard sign posting requirements are provided.
 11. infection control, including the following mandatory practices:
 - a) using chairs and accessories with a material that may be decontaminated. Cloth chairs are unacceptable.
 - b) acceptable decontamination of pillows, bolsters, positioning aides, etc.
 - c) changing table covers or disinfecting work surfaces between patients.
 - d) daily disinfection of work surfaces must be documented, initialled and dated by personnel.
 - e) disinfection of work areas, after examinations when special precautions are necessary, must be documented, initialled and dated by personnel.
 - f) designating areas where personal protective equipment is required.
- 2.2.2.5 Waste management policies and procedures must include decontamination and disposal of contaminated waste, hazardous waste, chemical waste and sharps (note: lead is considered to be a hazardous waste).
- 2.2.2.6 Electrical safety policies and procedures must include:
1. using approved extension cords
 2. ensuring the safety of electrical cords and receptacles.
 3. that new, modified or repaired equipment is not put into use until a qualified person is satisfied that it is safe to use.
 4. locating all electrical receptacles, switches, and controls so that they are not subject to liquid spills.
- 2.2.2.7 Fire safety policies and procedures must include:
1. having appropriate fire extinguishers, including non-magnetic fire extinguishers for MRI rooms.
 2. having annual documented fire safety, fire extinguisher, fire drill and evacuation training for personnel.
 3. having an evacuation plan which includes a process to assist those who are unable to evacuate without assistance.
 4. that emergency evacuation route posters are visible, easily understood, and securely mounted in all patient and public areas.
 5. that emergency lights are provided when back-up generated emergency lights are not available in the work area.
- 2.2.2.8 Radiation safety policies and procedures to manage:
1. pregnancy, which must include:
 - a) pregnant female patients.
 - b) female patients who may be pregnant.
 - c) female patients of childbearing age.
 - d) pregnant personnel.
 2. pediatric imaging protocols, which must include:
 - a) that strict shielding protocols are practiced.
 - b) that appropriate essential investigations are defined in protocols.
 - c) that scoliosis investigations reflect best practice.
 3. the reporting and documentation of accidental or unintentional doses to patients which includes reporting through an investigation process.
 4. that testing of all lead shielding integrity is performed initially and annually thereafter.
 5. annual inspections by Radiation Protection Services, CancerCare Manitoba and compliance with Radiation Protection Service report/recommendations.
 6. the notification of excessive exposure (i.e. more than one gray) which must include notification of:

MANITOBA DIAGNOSTIC IMAGING STANDARDS

- a) the x-ray equipment operator.
 - b) a Radiation Protection Services officer.
 - c) the facility director.
 - d) the patient.
7. that exposure controls (technical factors) are available in hard copy format and are not handwritten.
 8. that examination protocols include ALARA practices for each examination.
 9. dosimeter badge usage; which must ensure that:
 - a) badges are specific to the facility.
 - b) reports are retained for the lifetime of the facility.
 - c) badges are specific to occupational classifications for issuing dosimeters.
- 2.2.2.9 Eyewash safety policies and procedures (as applicable) must include:
1. that eyewash stations are available.
 2. that eyewash stations are flushed weekly, documentation is required.
 3. that monitoring wall mounted eyewash stations for expiry dates on a regular basis; documentation is required.
- 2.2.2.10 Hazardous materials policies and procedures must include:
1. the reporting and documenting of hazardous material spills.
 2. having chemical and biological spill kits readily available and establishing procedures for use of the kits. There must be signs posted to indicate the location of the spill kit.
 3. the expiry date on spill kits is documented.
 4. requiring personnel to certify in the transport of dangerous goods training, if applicable.
 5. the required use of designated labels for Workplace Hazardous Material Information Systems controlled products.
 6. having a master inventory list of hazardous materials available in the department.
 7. maintaining current Material Safety Data Sheets (i.e. not greater than 3 years old).
- 2.2.2.11 Carcinogen safety policies and procedures must include:
1. the storage and usage of known carcinogens in a safe manner.
 2. using only designated labels for all carcinogenic agents.
 3. specifying:
 - a) the precautions to be taken to reduce risk of exposure.
 - b) the steps to be taken should accidental exposure to carcinogens occur to patients, staff, or visitors.
- 2.2.2.12 Chemical hazard policies and procedures must include:
1. a process for educating personnel.
 2. identifying precautions to be taken and instructions if an accident does occur.
 3. storing strong acids in Workplace Hazardous Material Information System approved containers in a secure location, and below counter level.
 4. having acid spill kits readily available and establishing procedures for use of the kits, if applicable.
 5. using acid/solvent bottle carriers for transportation of hazardous chemicals in excess of 500 millilitres (ml).
 6. transporting all chemicals in accordance with the *Transportation of Dangerous Goods Act* and Regulations.
 7. having Occupational Health and Safety monitor air for potentially harmful fumes (fixer, developer) at least annually. If safety limits are exceeded, extraction systems must be used.
 8. providing a fume hood or chemical filtration unit for when using volatile chemicals.
 9. adhering to the manufacturer's recommendations to maintain efficiency of ventilation systems (e.g. ultrasound probe soaking stations).

MANITOBA DIAGNOSTIC IMAGING STANDARDS

2.2.2.13 Compressed gas policies and procedures must include a requirement to:

1. identify the contents of compressed gas cylinders.
2. use appropriate storage and transportation of compressed gas cylinders.
3. equip compressed gas cylinders with an approved functional valve system.
4. appropriately secure cylinders.

2.2.3 A Personnel Policy Manual

2.2.3.1 The Personnel Policy Manual must include policies governing:

1. a job description for each employee. The job description must be signed and dated by the facility director, personnel, and administrators.
2. a documented review of the job description must be performed at least once every two years, the facility director is required to sign and date revisions to job descriptions.
3. the competency based orientation training requirements for each employee.⁸
4. the continuing education requirements, as applicable.
5. the maintenance of competence requirements for the scope of practice (the scope of practice must be approved by the facility director).
6. the records of personnel qualifications, registration and licensure.
7. the competence appraisals for each employee (see 1.3.1.4).
8. working alone, if applicable.
9. documentation of incidents, work related injuries (e.g. compensation documentation)
10. a signed Personal Health Information Act (PHIA) accountability agreement.

2.2.4 An Operational Policy Manual

2.2.4.1 The Operational Policy Manual must include policies which govern:

1. document⁹ control:
 - a) all handwritten changes to be signed and dated by the person making the change and approved in writing by the facility director.
 - b) all posted material, procedural guideline or direction is current and in compliance with manual requirements.
 - c) a process to implement handwritten changes into a controlled document in a timely manner.
2. management of requests for consultation:
 - a) requires that information is legible and includes:
 - (i) the signature and printed name of the referring healthcare professional (individuals authorized to complete consultation requests).
 - (ii) the emergency contact information of the referring healthcare professional for communicating a critical result.
 - (iii) the mailing address of the referring healthcare professional.
 - (iv) the last menstrual period for female patients of child bearing age.
 - (v) a known pregnancy.
 - (vi) the weight of the patient when applicable.
 - (vii) previous imaging examinations.
 - (viii) history of previous surgeries pertinent to the examination request.
 - (ix) the urgency of the examination.
 - (x) the date of referral.
 - (xi) the most appropriate patient telephone number for urgent delivery of results.
 - (xii) identification of patients at high risk for contrast media injections and documentation of previous reactions to contrast media.
 - (xiii) a history of all allergies.
 - (xiv) a known or suspected communicable disease.

⁸ Also found in the Personnel Policy Manual

⁹ "Document" includes any information or instructions, including policy statements, text books, examinations, specifications, calibration tables, charts, posters, notices, memoranda, software, drawings, plans and documents of external origin such as regulations, standards, or examination examinations.

MANITOBA DIAGNOSTIC IMAGING STANDARDS

- b) a policy that contains the criteria for rejecting a consultation request (e.g. the consultation request does not contain the patient demographics and information defined as requirements in these standards).
 - c) the address of the patient must be available to the interpreting radiologist.
3. compliance with the College of Physicians and Surgeons of Manitoba by-laws, statements and guidelines for electronic medical records (including consultation requests).
4. the required patient demographics and information on the image must include:
 - a) the patient's first and last name.
 - b) the personal health identification number (PHIN).
 - c) the facility health record number or alternate number (e.g. Canadian Forces, other provincial health numbers).
 - d) the date of birth.
 - e) the date of examination (and time if applicable) and required examination.
 - f) the facility name.
 - g) the accession number or master file number
 - h) the vendor quality exposure index number for computed and direct radiography images.
5. the patient imaging record must include:
 - a) the request for consultation.
 - b) the final report.
 - c) the technologist/sonographer identification.
 - d) technique used (as required).
 - e) technical notes of explanation when protocols are not met.
 - f) last menstrual period or pregnancy status (as required).
 - g) lead shielding usage (when used and is not seen on the image).
6. the final report, which must include:
 - a) the patient's first and last name.
 - b) the personal health identification number (PHIN).
 - c) the facility health record number or alternate number (e.g. Canadian Forces or other provincial health numbers).
 - d) the date of birth.
 - e) the date of examination (and time, if applicable) and required examination.
 - f) the facility name.
 - g) examination header.
 - h) the name of the interpreting radiologist.
 - i) evidence that a radiologist has verified the report.
 - j) the date the examination was dictated.
 - k) the date the examination was transcribed.
 - l) the date the report was delivered to the intended recipient(s).
7. reporting policies, including labelling, disclosure and retention are required for:
 - a) addendum reports.
 - b) corrected reports.
 - c) preliminary reports
 - d) verbal reports
 - e) unsigned reports or reports not yet proof-read.
 - f) disclosing test results to patients.
 - g) critical report communication which includes notifying a physician immediately of a critical result and documenting the date, time, staff member, person notified, results conveyed, and any difficulty in notification.

MANITOBA DIAGNOSTIC IMAGING STANDARDS

8. that patient management includes:
 - a) the notification of cancelled patient examinations.
 - b) identifying and correcting patient demographics.
 - c) temporary patient identification.
 - d) examinations with no patient clinical information available.
 - e) record management for neonates who have not yet been issued a personal health identification number including at least gender and the following demographics:
 - (i) facility health record number (if out of province, provincial health number).
 - (ii) date and time of birth.
 - f) instructions if required and pertinent documentation in the patient's chart.
 - g) that consent/patient information document issues include:
 - (i) that an informed consent or patient information document is completed for all invasive examinations (must include explanation, benefits, risks and alternatives).
 - (ii) a process for obtaining consent by telephone.
 - (iii) access to interpreters for patients who do not speak English (whenever possible).
 - (iv) a process for authorized substitute decision makers.
 - (v) management of emergent situations, no substitute decision maker.
 - (vi) a process for refusal of examination.
 - h) sedation, which must include requirements for:
 - (i) available emergency drugs and supplies.
 - (ii) administering sedation.
 - (iii) monitoring patients.
 - (iv) patient recovery management.
 - (v) discharging patient.
 - (vi) medical record keeping.
 - i) chaperone requirements are identified.
 - j) management of incomplete examinations.
 - k) when immediate medical attention is required.
 - l) when immediate transfer of patient is required.
9. report management, which includes:
 - a) turnaround times audits to include:
 - (i) date the examination was ordered.
 - (ii) date the examination was performed.
 - (iii) date the examination was dictated by a radiologist and verified, if not verified at time of dictation.
 - (iv) date transcribed.
 - (v) date the report was delivered.
 - (vi) traceability of the report to the patient.
 - b) turnaround processes for:
 - (i) investigating turnaround time audit non-conformances.
 - (ii) implementing remediations for non-conformances.
 - (iii) establishing best practices to maintain the best turnaround time outcomes.
 - c) call-back service examination requests; a list of examinations offered for a call-back service must be provided.
 - d) identifying any statutory reporting requirements (e.g. Public Health or child abuse or sexual activity in patients 13 years of age or younger).

MANITOBA DIAGNOSTIC IMAGING STANDARDS

10. compliance with *The Personal Health Information Act*¹⁰, including:
 - a) correcting personal health information errors.
 - b) transmitting personal health information via facsimile or other electronic means.
 - c) maintaining records.
 - d) disposing of confidential information, including personal health information.
 - e) security measures for electronic databases and transferring of personal health information.
 - f) reporting of security breaches and corrective procedures.
11. incident management which must include reporting and management of critical clinical incidents.
12. documentation of incidents, work related injuries (e.g. compensation documentation)
13. that the facility director has a process in place to ensure that all emergency equipment and pharmaceuticals are operational and in date. The documentation of regular safety checks must be maintained and available for review.
14. that the medical grade accessories are available for use whenever possible as homemade accessories are not acceptable.

2.2.5 An Equipment and Maintenance Manual

Equipment includes, but is not limited to, processing equipment/machines, computer hardware and software, primary display work stations, information systems, analytical systems, generators, imaging machines, phantoms and injectors.

The Equipment and Maintenance Manual must be site specific and must include policies and procedures governing equipment maintenance, monitoring and records.

2.2.5.1 The Equipment and Maintenance Manual must include:

1. procedures:
 - a) for safe handling, transporting, storing and use of equipment.
 - b) for removing equipment from service when it is found to be defective or no longer used. Defective equipment that is taken out of service must be clearly labelled "do not use, out of service" until it has been repaired.
 - c) for decontaminating equipment prior to it being serviced or removed from the facility.
 - d) for a contingency plan to address failure of equipment.
 - e) for repairing equipment in a suitable location.
2. maintenance procedures for:
 - a) routine operation of equipment.
 - b) minor troubleshooting management.
 - c) equipment maintenance to be scheduled and performed at least annually and more frequently if recommended by the manufacturer or required by the quality management program.
3. the requirements for record keeping which must include recording and maintaining the following information respecting equipment:
 - a) the name, model, serial number and date of purchase.
 - b) the manufacturer's instructions for equipment operation.
 - c) the equipment maintenance requirements which include maintenance procedures, documenting troubleshooting, breakdowns and repairs.
 - d) that a list of contact personnel and phone numbers for equipment maintenance support is readily available.

¹⁰ See also the Quality Management Program Manual.

MANITOBA DIAGNOSTIC IMAGING STANDARDS

4. retention of the following records for the lifespan of the equipment plus two years, which includes:
 - a) the manufacturer's name, type of equipment, identification and serial number.
 - b) the manufacturer's contact information.
 - c) the date of receipt and date of commencement of service.
 - d) the condition when received.
 - e) the acceptance testing reports.
 - f) the location of the equipment.
 - g) manufacturer's manuals are readily available.
 - h) equipment performance records.
 - i) maintenance records/equipment history log.
5. primary display work station¹¹ policies and procedures, which must require:
 - a) accurate reproduction of the original examination.
 - b) minimal technical capabilities as follows:
 - (i) image sequence identification.
 - (ii) accurate association of the patient and study demographic data with the images.
 - (iii) adjustable brightness and contrast.
 - (iv) interactive window and level function.
 - (v) invert the gray-scale values of the displayed image.
 - (vi) zoom (magnification) function.
 - (vii) rotating and flipping the displayed images with preservation of orientation of patient labelling.
 - (viii) calculating and displaying accurate linear measurements and pixel value determinations in values appropriate for the modality (e.g. Hounsfield values for CT images).
 - (ix) displaying prior image compression ratio, processing or cropping.

2.2.6 Procedure Positioning Manual

2.2.6.1 The Procedure Positioning Manual must use a standard format for header information equivalent or substantially similar format to the following:

1. facility name.
2. title of examination.
3. date/revision date.
4. facility director signature.

2.2.6.2 Policies and procedures governing:

1. a description of each view required for examination type.
2. positioning regimes to include lead shielding and lowest technical factors while maintaining image quality.

2.2.7 Computer Radiography and Digital Radiography Manual

2.2.7.1 The Computer Radiography and Digital Radiography Manual must include:

1. the quality control procedures used to monitor performance.
2. policies are required for governing:
 - a) a process for overriding raw data markers with electronic markers.
 - b) the preference hanging protocols as required by the facility director.
 - c) that password protecting logins are required.
 - d) a process to maintain patient confidentiality on unattended monitors.
 - e) a requirement to have an electronic repeat/reject analysis when available by the vendor.
 - f) trouble shooting directions.
 - g) management of workflow when there is an equipment failure.

¹¹ Primary display workstations are stations where a radiologist interprets images to provide a final interpretive report.

MANITOBA DIAGNOSTIC IMAGING STANDARDS

2.2.8 Radiology Information System (RIS) Manual

2.2.8.1 The Radiology Information System Manual must have policies that include:

1. how to get assistance from the information technology experts when assistance is required (e.g. Health Helpline).
2. a list of contact personnel and phone numbers for system maintenance support.
3. a schedule for and location of back-up disks.
4. a backup system for computer failure is in place.
5. policies are required for governing:
 - a) the requirements for RIS competency, training, orientation and evaluation for new personnel who will be required to use RIS. Training is required when updates or new versions are implemented.
 - b) providing adequate technical support.
 - c) validating alterations to the RIS hardware or software by authorized personnel.
 - d) having controls in place to protect computer applications from unauthorized adjustments or tampering or destruction.
 - e) changing of passwords at least quarterly and confidentiality of passwords.
 - f) who may use the RIS, and who may access or change patient information or application/configuration of data.
 - g) a requirement to have a transmission system that has error checking capabilities.
 - h) that the archive retrieval system includes:
 - (i) the ability to provide high importance flags, technologist comments and validation of radiologist electronic signature.
 - (ii) the accurate association of the patient study with the images.
 - (iii) the consultation request.
 - (iv) that prior examinations are available to be retained.
 - (v) online retrieval of patient results and images.
6. procedures for:
 - a) respecting scheduled maintenance downtime or electronic failure management, including:
 - (i) the recovery of the RIS.
 - (ii) replacing or updating data files.
 - (iii) notifying users of interruption and restoration of service.
 - (iv) maintaining written records of scheduled downtime, unscheduled downtime, the reasons for any failure and particulars of corrective action taken.
 - b) specifying requirements for protecting confidentiality of patient results.
 - c) governing personnel use of RIS, including:
 - (i) a requirement to logout of the RIS when not actively working on it.
 - (ii) prohibiting use of another personnel member's login to perform work.
 - d) verifying and validating the RIS when first installed and after any alterations are made.
 - e) comparing original input with all types of end user reports to detect errors in data transmission, processing or storage, whenever there has been a change to the RIS.
 - f) verifying transfer of Digital Imaging and Communications in Medicine (DICOM) transfer.
 - g) verifying DICOM modality work list and RIS.
 - h) validating measurement tool accuracy.
 - i) approving any auto-verification of radiologist signoff on final reports.
 - j) maintaining controls to ensure that data storage media is properly labelled, stored and protected from damage and unauthorized use.
 - k) governing documentation of other significant events that could affect clinical care.
 - l) governing media process when exchanging images/reports on portable media, which must include:
 - (i) the media must be labelled with required patient demographics.
 - (ii) the appropriate program to open the images must be included.
 - (iii) the media must be delivered in a secure manner.

MANITOBA DIAGNOSTIC IMAGING STANDARDS

2.2.9 A Picture Archiving and Communications Systems (PACS) Manual

2.2.9.1 The Picture Archiving and Communications Systems Manual must have policies governing:

1. retrieving prior examinations in a timely manner to be available for comparison at the time of interpretation.
2. uniform collection of patient demographics.
3. monthly test image capture, transmission, archival, retrieval and display.
4. degree of compression (if any).

2.2.10 A Site Specific Ward Manual

2.2.10.1 The Site Specific Ward Manual must include:

1. list of examinations performed on-site.
2. instructions for filling out consultation requests.
3. a process for ordering STAT examinations.
4. the requirements for patient transport.
5. the requirements for consent/patient information.
6. a process for telephone consultation requests.
7. patient preparation instructions.
8. the laboratory results required.
9. sedation requirements.
10. a requirement to have a post-procedure chart review as required.
11. post-procedure care requirements.
12. examinations offered during non-core hours.
13. call-back arrangements.

2.2.11 A Modality Specific Manual

2.2.11.1 The Modality Specific Manual must set out procedures for each examination performed in the facility. The Modality Specific Manual must include:

1. a list of examinations included in the manual.
2. patient instructions as required.
3. each examination written in a standard format equivalent to or substantially similar to the following format:
 - a) title of examination.
 - b) author.
 - c) principle/purpose of the examination.
 - d) booking examination.
 - e) patient preparation.
 - f) positioning regimes.
 - g) examination protocols.
 - h) deviations from routine positioning views.
 - i) deviations from coded protocols.
 - j) appropriate shielding usage.
 - k) pre-examination screening.
 - l) consent/patient information sheet requirements.
 - m) equipment/supplies needed.
 - n) special equipment cleaning/sterilizing.
 - o) special precautions (when applicable).
 - p) post-examination care.
 - q) patient instructions for each imaging examination offered.

MANITOBA DIAGNOSTIC IMAGING STANDARDS

2.2.12 Contrast Media Manual

2.2.12.1 The Contrast Media Manual must include policies governing:

1. patient screening.
2. managing high risk patients.
3. consent/patient information documents.
4. venipuncture competencies.
5. post-examination patient care.
6. medical emergencies/adverse reactions.
7. extravasations of contrast media.
8. reporting severe reactions to the Canadian Adverse Drug Reaction Monitoring Organization Program.
9. documenting reactions in the final report.
10. requirements for a physician on-site to oversee the contrast media injection if a radiologist is not available.
11. multi-dosing.
12. patient charting requirements.
13. emergency preparedness:
 - a) having oxygen and suction available and checked weekly.
 - b) having emergency drugs and resuscitation equipment and checking drug expiration dates monthly.
 - c) inspecting battery operated emergency devices weekly.
14. a requirement to train personnel in CPR when an on-site emergency response team (which includes an on-site physician) is not available.
15. instructions for personnel regarding directives to handle medical emergencies.

3.0 SAFETY

3.1 Legislation

3.1.1 A facility must establish and maintain workplace health and safety policies and procedures that adhere to the *Manitoba Workplace Safety and Health Act* and Regulations requirements.

3.1.2 A facility must meet applicable federal and provincial legislation, acts, and regulations requirements; the facility director will be required to sign documentation annually that indicates conformance with these requirements.

3.2 Personnel Training

3.2.1 A facility must:

- 3.2.1.1 provide competency based safety training for all new employees as part of the orientation process.
- 3.2.1.2 have documented orientation and annual updates in training for facility personnel in:
 1. general safety.
 2. fire safety¹².
 3. WHMIS as required.
 4. handling medical emergencies.
 5. routine practices.

3.3 Physical Space

3.3.1 A facility must:

- 3.3.1.1 post clear signage to direct patients and indicate areas of restricted access.
- 3.3.1.2 provide a secure and private location for personnel to change clothing and store personal items.
- 3.3.1.3 provide separate storage space for patient consumables.
- 3.3.1.4 provide sufficient work space for functionality of examinations.

¹² See the Manuals Standard, Safety Manual, Fire Safety.

MANITOBA DIAGNOSTIC IMAGING STANDARDS

3.4 Site Specific Safety Risks¹³

3.4.1 A facility must establish and maintain policies and procedures governing the following risks:

- 3.4.1.1 General Workplace Safety and Health.
- 3.4.1.2 Routine Practices.
- 3.4.1.3 Waste Management and Disposal.
- 3.4.1.4 Electrical Safety.
- 3.4.1.5 Eyewash Safety.
- 3.4.1.6 Fire Safety.

3.4.2 A facility must establish and maintain policies and procedures governing the following risks, as applicable to the specific site:

- 3.4.2.1 Hazardous Materials.
- 3.4.2.2 Carcinogens Safety.
- 3.4.2.3 Chemical Hazards.
- 3.4.2.4 Compressed Gas.
- 3.4.2.5 Contrast Media Safety.
- 3.4.2.6 Radiation Safety.
- 3.4.2.7 Nuclear Medicine Safety.

3.5 Safety Documentation

3.5.1 The Safety Manual must be available to personnel in hard copy format.

3.5.2 All safety records, including records of monitoring and quarterly checks, must be retained for at least 5 years.

4.0 EQUIPMENT

“Equipment” includes processing equipment/machines, computer hardware and software, information and analytical systems, generators, imaging machines, phantoms and injectors.

4.1 General

4.1.1 A facility must:

- 4.1.1.1 have the equipment necessary to perform the scope of testing and examinations offered by the facility and suitable for that purpose.
- 4.1.1.2 keep equipment clean.
- 4.1.1.3 maintain equipment in good working condition.
- 4.1.1.4 maintain equipment to function as intended by the vendor.
- 4.1.1.5 remediate deficiencies noted on Radiation Protection Survey Reports, as required.
- 4.1.1.6 operate equipment only as intended by the manufacturer.
- 4.1.1.7 safeguard equipment from unauthorized adjustments or tampering.
- 4.1.1.8 permit only authorized and trained personnel to operate equipment.
- 4.1.1.9 situate equipment as required for safe operation.
- 4.1.1.10 only utilize equipment that is in good working condition.
- 4.1.1.11 report equipment issues to the facility director whenever equipment is not able to function as intended by the vendor.
- 4.1.1.12 uniquely identify equipment.
- 4.1.1.13 schedule quality control testing and maintenance as specified by the manufacturer and the quality management program.
- 4.1.1.14 protect wires and cables that are located in traffic areas.

4.2 Emergency Power

4.2.1 A facility must maintain critical equipment:

- 4.2.1.1 on an emergency power system, if available.
- 4.2.1.2 on a robust uninterrupted power supply (UPS), if an emergency power system is not available.

¹³ Requirements in relation to specific types of risks are found in the Manuals Standard, Safety Manual.

MANITOBA DIAGNOSTIC IMAGING STANDARDS

4.3 Site Specific Equipment

- 4.3.1 A facility must establish and maintain policies and procedures governing equipment:
 - 4.3.1.1 maintenance.
 - 4.3.1.2 monitoring.
 - 4.3.1.3 record creation and retention.
 - 4.3.1.4 quality control/quality assurance.
- 4.3.2 A facility must establish and maintain policies and procedures governing the following equipment, as applicable to the specific site:
 - 4.3.2.1 CT.
 - 4.3.2.2 MRI.
 - 4.3.2.3 fluoroscopy/C-arm.
 - 4.3.2.4 radiography/mobile radiography.
 - 4.3.2.5 ultrasound.
 - 4.3.2.6 electronic display devices.
- 4.3.3 A facility must ensure that monitors used by radiologists to report on images are medical grade primary diagnostic monitors which provide sufficient resolution and luminance for the modalities for which they are used and meet the recommendation of the ACR-AAPM-SIIM Technical Standard for Electronic Practice of Medical Imaging (2012 or successor documents).

5.0 COMPUTED TOMOGRAPHY

5.1 Technologist Qualifications

A CT technologist must be a member in good standing with the Canadian Association of Medical Radiology Technologists (CAMRT) and have successfully completed the didactic component of Computed Tomography Imaging Certificate Program (i.e. CT Imaging 1, CT Imaging 2 and CT Imaging 3) or an equivalent nationally recognized CT certificate course or the CT technologist successfully completes the CAMRT Certificate Program within three years of hire.

A facility director may exempt a CT Technologist from the foregoing requirement if the facility director performs a competency assessment and is satisfied that the CT technologist has the core competencies of one who has successfully completed the didactic components of the Computed Tomography Imaging Certificate Program, and that competency will be maintained.

- 5.1.1 A facility director may allow general duty technologists to perform non-contrast CT examinations for a limited scope of practice provided:
 - 5.1.1.1 the scope of practice is defined.
 - 5.1.1.2 appropriate training is provided.
 - 5.1.1.3 competency is achieved; facility director signature is required.
 - 5.1.1.4 the frequency of examinations performed maintain competency.
 - 5.1.1.5 refresher training is available.
 - 5.1.1.6 dose reduction strategies.
 - 5.1.1.7 appropriate shielding is used.
 - 5.1.1.8 protocol assignments are provided.
 - 5.1.1.9 image assessments are performed for each study to monitor image quality, reference slice selection, gantry angle, technical parameters, and pathology inclusion. Non-conformances must be documented and remediated.
 - 5.1.1.10 a reassessment of competency is performed if any examination does not meet quality standards.

MANITOBA DIAGNOSTIC IMAGING STANDARDS

5.2 General

5.2.1 A facility must:

5.2.1.1 establish and maintain:

1. a list of procedures which may be done during non-core hours.
2. for referring physicians, a list of procedures performed at the facility.

5.2.1.2 require a radiologist to:

1. screen CT consultation requests for appropriateness, contrast media usage, and priority.
2. code the requisition with the required protocol, including the appropriate use of radiation shielding, before performing the examination.
3. review images after each examination.
4. provide directives when the examination is to be reviewed prior to removing the patient from the table.

5.2.1.3 transmit images to a radiologist after each examination.

5.3 Policies and Procedures

5.3.1 A facility must establish policies and procedures governing:

5.3.1.1 adherence to Health Canada Safety Code 35: Safety Procedures for the Installation, Use and Control of X-ray Equipment in Large Medical Radiological Facilities.

5.3.1.2 control booth monitoring which must include:

1. a direct view of the patient or a television monitor.
2. communication with the patient.

5.3.1.3 a process for patients who exceed the table weight limit.

5.3.1.4 a process for alternate imaging or diagnostic testing.

5.3.1.5 a process for postponing examinations.

5.3.1.6 providing a definition policy for threshold volumes for Hounsfield units.

5.3.1.7 requesting for additional information.

5.3.1.8 using dose reduction technology whenever possible.

5.3.1.9 a process for technologists performing venipuncture.

5.3.1.10 a process for repeating an image or select images.

5.3.1.11 a process for managing pregnant patients.

5.3.1.12 biopsies requirements.

5.3.1.13 interventional examination instructions.

5.3.1.14 documenting CT dose-length product in the patient record.

5.3.1.15 image display in a Picture Archiving and Communications System (PACS).

5.3.1.16 management of potential artifacts, which must include:

1. piercings.
2. dental appliances.
3. surgical hardware.
4. metallic foreign bodies.

5.3.1.17 radiologist availability; the facility director must define when a radiologist must be:

1. on-site to code consultation requests, supervise CT examinations and provide interpretations during core hours of operation.
2. available to the technologist when CT examinations are performed during non-core hours of operation.
3. available for consultation for remotely supervised facilities as required; see additional requirements for remote CT Facilities¹⁴.

¹⁴ Remote facilities are facilities that do not have an on-site radiologist and which involves the electronic acquisition, storage and transmission of examinations from one location to another for the purpose of consultation and interpretation.

MANITOBA DIAGNOSTIC IMAGING STANDARDS

5.3.1.18 examination protocols for each examination to include:

1. appropriateness of the clinical history relative to the examination ordered.
2. detector configuration.
3. field of view (FOV).
4. technique parameters.
5. cranial-caudal extent.
6. table speed.
7. phase of respiration.
8. cross-reference images.
9. cross-sectional anatomy requirements.
10. window width and window length.
11. slice thickness.
12. reconstruction interval.
13. reconstruction algorithm.
14. appropriate shielding.
15. assessing clinical history.
16. appropriate contrast media utilization.
17. intravenous contrast media injection rate and scan delay.
18. positioning and set scan parameters.
19. repeat images.
20. post-processing for reconstructions and retrospective image manipulation.
21. dose reduction strategies, which must evaluate the associated risks regarding long-term radiation effects.
22. technique parameters.
23. pathology variances.
24. necessity for preliminary non-contrast scans.
25. post-processing image generation.
26. when a radiologist review of examination prior to ending the patient examination is required.

5.4 Radiation Dose Management

5.4.1 A facility must:

- 5.4.1.1 collect the dose length product (DLP) data to establish a dose average for routinely performed examinations on average sized patients.
- 5.4.1.2 adopt dose reduction strategies to minimize patient dose, which must include:
 1. the "As Low As Reasonably Achievable" (ALARA) principle.
 2. providing radiation shielding to all vulnerable body areas that are not included in the examination as per protocol assignments.
 3. utilizing dose reduction technologies appropriately.
 4. examination protocols which take into account body habitus, body mass index or lateral width.

5.5 Quality Control Program

5.5.1 A facility must:

- 5.5.1.1 establish a quality control program under the oversight of a medical physicist certified by the Canadian College of Physicists in Medicine.
- 5.5.1.2 perform acceptance testing upon installation of CT equipment.
- 5.5.1.3 frequently review the quality assurance test results to an established benchmark and remediate non-conformances.
- 5.5.1.4 notify the medical physicist and the facility director when remediation avenues fail to solve non-conformances.
- 5.5.1.5 require an annual quality assurance review document from the medical physicist who oversees the quality control program.
- 5.5.1.6 meet the recommendations as required in the physicist's annual quality assurance review document.

MANITOBA DIAGNOSTIC IMAGING STANDARDS

5.6 Additional Requirements for Remote Computed Tomography Facilities

5.6.1 A facility must:

- 5.6.1.1 limit procedures to the competency of the CT technologist.
- 5.6.1.2 stipulate when additional requirements to procedure protocols are required.
- 5.6.1.3 make the radiologist's contact information available to the CT technologist and referring physician.
- 5.6.1.4 use a digitization and display system with a minimum of a 0.5K x 0.5K x 8 bit array to transmit direct capture images after each examination to a radiologist.
- 5.6.1.5 provide each CT technologist with direct training at least annually and more frequently if required by the facility director; a documented competency assessment is required.
- 5.6.1.6 monitor report turnaround times at least monthly and more frequently as required.
- 5.6.1.7 establish and maintain policies for governing:
 - 1. weekly test image process evaluation.
 - 2. delivery of urgent results.
 - 3. the scope of emergent examinations and the mechanism to convey emergency results.
 - 4. referral of complex or out of scope examinations.
- 5.6.1.8 establish policies and procedures governing radiologist availability; the radiologist must be:
 - 1. available to code consultation requests, supervise CT examinations and provide interpretations during core hours of operation.
 - 2. available to the technologist when emergent/urgent CT examinations are performed during non-core hours of operation.

6.0 FLUOROSCOPY

6.1 General

6.1.1 A facility must:

- 6.1.1.1 limit the performance of fluoroscopy procedures to:
 - 1. a radiologist.
 - 2. a radiology technologist (see the Technologist Qualifications Section 9.1).
 - 3. a radiology technologist student or medical student under the supervision of an on-site radiologist.
 - 4. a radiology resident physician approved by the facility director.
 - 5. a physician who has satisfactorily completed didactic training by Radiation Protection and Imaging Physics Division of Manitoba.
 - 6. a radiology technologist delegated by the facility director.
- 6.1.1.2 establish and maintain:
 - 1. a list of procedures which may be done during non-core hours.
 - 2. a list of procedures performed at the facility for referring physicians.
- 6.1.1.3 provide protective lead aprons to all persons present in the fluoroscopy room during exposure.
- 6.1.1.4 use lead curtains on a stationary radiosopic unit during fluoroscopy.
- 6.1.1.5 provide a radiologist interpretive report on all fluoroscopic examinations.
- 6.1.1.6 provide the operator with a clear line of sight to the output display at all times.

6.2 Policies and Procedures

6.2.1 A facility must establish and maintain policies and procedures governing:

- 6.2.1.1 examination protocols, which must include:
 - 1. positioning regimes for general duty radiography.
 - 2. technical factors for positioning regimes.
 - 3. lead shielding, dose reduction initiatives and coning requirements.
 - 4. intravascular contrast media examinations.
 - 5. contrast media examinations.

MANITOBA DIAGNOSTIC IMAGING STANDARDS

- 6.2.1.2 technique parameters.
- 6.2.1.3 required overhead views.
- 6.2.1.4 barium preparation/contrast preparation.
- 6.2.1.5 barium enemas:
 - 1. rectal.
 - 2. colostomy.
- 6.2.1.6 private access to washroom facilities for barium enema patients.
- 6.2.1.7 oral contrast media.
- 6.2.1.8 non-intravascular contrast media.
- 6.2.1.9 intravascular contrast media.
- 6.2.1.10 intra-arterial contrast media.
- 6.2.1.11 swallowing difficulties.
- 6.2.1.12 operating room examinations.
- 6.2.1.13 sterile field examinations.
- 6.2.1.14 required examination accessories.
- 6.2.1.15 lead shielding, which must include required use of:
 - 1. thyroid protectors fluoroscopy if near the intensifier.
 - 2. gauntlets during palpation.
 - 3. lead glasses when the lenses of the eyes could receive a dose of 150 mSv.
- 6.2.1.16 documenting technical factors, fluoroscopy time and technologist initials in the patient record.
- 6.2.1.17 capture at least one fluoroscopic image in the patient record.

6.3 Quality Control Program

- 6.3.1 A facility must:
 - 6.3.1.1 establish a quality control program under the oversight of a medical physicist certified by the Canadian College of Physicists in Medicine.
 - 6.3.1.2 perform acceptance testing upon installation of fluoroscopy equipment.
 - 6.3.1.3 frequently review the quality assurance test results to an established benchmark and remediate non-conformances.
 - 6.3.1.4 notify the medical physicist and the facility director when remediation avenues fail to solve non-conformances.
 - 6.3.1.5 require an annual quality assurance review document from the medical physicist who oversees the quality control program.
 - 6.3.1.6 meet the recommendations as required in the physicist's annual quality assurance review document.

6.4 Additional Requirements for Non-Radiologist Operated Fluoroscopy

- 6.4.1 These standards are for circumstances when a radiologist interpretive report of images is not required. The following criteria must be met:
 - 6.4.1.1 The consultation request meets standard requirements, including documentation of the last menstrual period, when applicable. Pregnancy screening takes place on the day of the examination when the last menstrual period is not indicated on the consultation request or when the last menstrual period provided is considered to be out of date; the pregnancy status is documented in the patient's medical record. The consultation request must be stored in RIS if achievable, or in the patient's medical record.
 - 6.4.1.2 All images acquired are retained and accessible for review. Images are to be stored in PACS if achievable, or retained in the patient's record.
 - 6.4.1.3 At least one image captured is maintained in the patient's record (PACS) or patient's medical record for hard copy images. In keeping with the As Low As Reasonably Achievable Principle, the patient does not need to receive an exposure to attain a final image, a screen save image will suffice to meet the image capture requirement.
 - 6.4.1.4 A record of the physician's report is maintained in the patient's medical record and/or is stored in RIS if achievable (may be scanned in), and accompanies the images.

MANITOBA DIAGNOSTIC IMAGING STANDARDS

- 6.4.1.5 The facility director provides equipment operators with a policy for minimizing patient doses to the lowest practical level, consistent with optimal quality of diagnostic information, by implementing the following practices whenever possible:
 - 1. pulsed control.
 - 2. the smallest practicable x-ray file size.
 - 3. appropriate x-ray beam filtration.
 - 4. the greatest focal spot to skin distance and limiting the focal spot to skin distance to 30 cm.
 - 5. lead shielding to provide the required protection.
- 6.4.1.6 The facility director has a policy in place to ensure the dose of the patient is recorded and maintained in the patient's medical record or in RIS/PACS. For equipment that does not capture the actual dose, the technical factors set and the fluoroscopy time is required.
- 6.4.1.7 The facility director has a policy in place to monitor radiation exposure and address excessive exposures concerns.

7.0 MAGNETIC RESONANCE IMAGING (MRI)

7.1 Technologist Qualifications

An MRI technologist must be a member in good standing with the Canadian Association of Medical Radiology Technologists (CAMRT) and have successfully completed the MRI and Spectroscopy course in order to perform an MRI examination.

A facility director may exempt an MRI technologist from the foregoing requirement only if the MRI technologist was performing MRI examinations in Manitoba before 1996 and if the facility director is satisfied that the MRI technologist is competent to perform MRI examinations.

7.2 General

7.2.1 A facility must provide three magnet zones defined as:

- 7.2.1.1 Zone A: Zone A is uncontrolled and outside the MRI environment. Zone A must have a magnetic field caution sign (e.g. reception, waiting room).
- 7.2.1.2 Zone B: Zone B is the interface between the Zone A and Zone C, and must be strictly controlled to prohibit entry into Zone C. In Zone B, patients are screened and prepped for their MRI procedure. Zone B must have a magnetic field warning sign.
- 7.2.1.3 Zone C: Zone C is the MRI scanner room. All access to Zone C must be strictly restricted and controlled by trained MRI personnel or securely locked when not in use. The doors entering Zone C must have a magnetic field danger sign.

7.3 Safety

7.3.1 A facility must have equipment that:

- 7.3.1.1 complies with Health Canada Safety Code 6: Limits of Human Exposure to Radiofrequency Electromagnetic Energy in the Frequency Range from 3 kHz to 300 GHz (including Errata Section 2.3, page 19).
- 7.3.1.2 complies with the Health Canada's Technical Guide for Interpretation and Compliance Assessment of Health Canada's Radiofrequency Exposure Guidelines.
- 7.3.1.3 has a warning and abort scan alert when radiofrequency power deposition limits are exceeded.

MANITOBA DIAGNOSTIC IMAGING STANDARDS

7.4 Quality Control Program

7.4.1 A facility must:

- 7.4.1.1 establish a quality control program under the oversight of a medical physicist certified by the Canadian College of Physicists in Medicine.
- 7.4.1.2 perform acceptance testing upon installation of MRI equipment.
- 7.4.1.3 frequently review the quality assurance test results to an established benchmark and remediate non-conformances.
- 7.4.1.4 notify the medical physicist and the facility director when remediation avenues fail to solve non-conformances.
- 7.4.1.5 require an annual quality assurance review document from the medical physicist who oversees the quality control program.
- 7.4.1.6 meet the recommendations as required in the physicist's annual quality assurance review document.

7.5 Policies and Procedures

7.5.1 A facility must establish and maintain policies and procedures:

- 7.5.1.1 establishing a screening process by a radiologist to:
 - 1. determine if an MRI examination is the best option for the patient.
 - 2. assess patients for safe access to Zone C.
 - 3. establish priority of the consultation.
- 7.5.1.2 establishing protocol assignments for each examination offered which includes:
 - 1. radiologist approval.
 - 2. appropriate scanning sequences.
 - 3. imaging parameters.
 - 4. the use of appropriate coils and techniques for optimal SNR as well as spatial contrast and temporal resolution.
- 7.5.1.3 governing access to the MRI room, which includes screening for patients who cannot complete the MRI screening form.
- 7.5.1.4 governing patients who are claustrophobic.
- 7.5.1.5 taking into account the restrictions of the fringe field (5 Gauss line).
- 7.5.1.6 complying with vendor directives.
- 7.5.1.7 immediate access to current reference manuals.
- 7.5.1.8 identifying MRI safe equipment and accessories.
- 7.5.1.9 providing appropriate hearing protection.
- 7.5.1.10 requiring monitoring of patients who are sedated or unable to communicate.
- 7.5.1.11 requiring emergency call systems in all patient areas, including the magnet.
- 7.5.1.12 addressing emergencies including:
 - 1. evacuating patients from the MRI scanner room to a pre-determined magnetic safe zone where cardiac or respiration intervention is required.
 - 2. if safe, quick evacuation cannot occur, the magnet room is monitored to ensure that only pre-screened personnel are allowed access into the room.
 - 3. only MRI compatible emergency response equipment may enter the magnet room.
 - 4. MRI personnel training in cardiopulmonary resuscitation.
- 7.5.1.13 requiring the MRI technologist operator be able to visibly and verbally monitor the patient from the control booth.
- 7.5.1.14 governing procedures to be followed when screening detects a high risk patient (e.g. implants).
- 7.5.1.15 to manage pregnant patients.

MANITOBA DIAGNOSTIC IMAGING STANDARDS

- 7.5.1.16 governing pre-examination screening for ferromagnetic objects, or other foreign objects, which must include:
 - 1. acquiring scout radiograph(s), if required.
 - 2. a mandatory requirement to acquire orbit radiographs or computed tomography whenever there is a risk of an orbital foreign body.
 - 3. a radiologist interpretation.
 - 4. acquiring previous imaging.
- 7.5.1.17 removing a patient from the MRI scanner when an unanticipated implant or foreign body is discovered.
- 7.5.1.18 establishing a protocol for quenching the magnet, which must include:
 - 1. a clearly marked magnetic field emergency rundown switch.
 - 2. evacuation procedures for patients and personnel.
 - 3. a fail-safe ventilation path for vented helium.
 - 4. an immediate restricted access.
 - 5. training the MRI technologist.
- 7.5.1.19 establishing a protocol for cryogenic gasses.
- 7.5.1.20 governing image display DICOM header or image display in a Picture Archiving and Communications System (PACS), which includes (whenever possible):
 - 1. sequence name/orientation.
 - 2. image series number.
 - 3. slice thickness.
 - 4. FOV (field of view).
 - 5. matrix size.
 - 6. phase encode direction.
 - 7. band width.
 - 8. acquisition time.
 - 9. coil.
 - 10. TR.
 - 11. TE.
 - 12. TI.
 - 13. flip angle.
- 7.5.1.21 radiologist availability; the facility director must define when a radiologist must be:
 - 1. on-site to code consultation requests, supervise MRI examinations and provide interpretations during core hours of operation.
 - 2. available to the technologist when MRI examinations are performed during non-core hours of operation.
 - 3. available for consultation for remotely supervised facilities as required; see additional requirements for remote MRI facilities.

7.6 Additional Requirements for Remote MRI Facilities

7.6.1 A facility must:

- 7.6.1.1 limit procedures to the competency of the MRI technologist.
- 7.6.1.2 stipulate when additional requirements to procedure protocols are required.
- 7.6.1.3 make the radiologist's contact information available to the MRI technologist and referring physician.
- 7.6.1.4 provide each MRI technologist with direct training at least annually and more frequently if required by the facility director; a documented competency assessment is required.
- 7.6.1.5 monitor report turnaround times at least monthly and more frequently as required.
- 7.6.1.6 establish and maintain policies for governing:
 - 1. weekly test image process evaluation.
 - 2. delivery of urgent results.
 - 3. the scope of emergent examinations and the mechanism to convey emergency results.
 - 4. the referral of complex or out of scope examinations.

MANITOBA DIAGNOSTIC IMAGING STANDARDS

- 7.6.1.7 establish policies and procedures governing radiologist availability; the radiologist must be:
1. available to code consultation requests, supervise MRI examinations and provide interpretations during core hours of operation.
 2. available to the technologist when emergent/urgent MRI examinations are performed during non-core hours of operation.

8.0 MAMMOGRAPHY

Please refer to the College of Physicians and Surgeons of Manitoba Mammography Standards.

9.0 RADIOGRAPHY

9.1 Technologist Qualifications

A radiography technologist must be a member in good standing with the Canadian Association of Medical Radiology Technologists (CAMRT).

9.2 General

9.2.1 A facility must:

- 9.2.1.1 comply with recommendations made in Radiation Protection Services reports.
- 9.2.1.2 provide calipers for patient measurements.
- 9.2.1.3 provide the following immobilizers:
 1. infant immobilizers, if infant x-rays are performed.
 2. upright bucky stabilizers.
 3. pediatric skull immobilizers.
- 9.2.1.4 provide lead shielded walls for stationary control booths.
- 9.2.1.5 provide radiology rooms with stationary x-ray equipment.
- 9.2.1.6 not use mobile machines as a fixed installation.

9.3 Policies and Procedures

9.3.1 A facility must establish and maintain policies governing:

- 9.3.1.1 adherence to Health Canada Safety Code 35: Safety Procedures for the Installation, Use and Control of X-ray Equipment in Large Medical Radiological Facilities.
- 9.3.1.2 a list of routine views provided for each examination.
- 9.3.1.3 positioning regimes.
- 9.3.1.4 lowest achievable technical factors while maintaining image quality, which must include:
 1. caliper measurement variations.
 2. each view.
 3. ionization chamber selection.
 4. body habitus selection.
 5. backup times.
 6. documentation of variation from routine.
 7. appropriate focal spot.
 8. carrying out radioscopy examinations with the smallest x-ray field size.
 9. a focal spot-to-skin distance that is as large as possible.

MANITOBA DIAGNOSTIC IMAGING STANDARDS

- 9.3.1.5 exposure control, which must include:
 1. only a radiology technologist or other approved x-ray equipment operator (as per these standards) may take an exposure.
 2. an irradiation exposure may only be taken:
 - a) for diagnostic purposes when requested by a physician or other approved referrers.
 - b) for quality purposes.
 - c) for testing purposes.
 3. holding patients during exposure.
 4. presence of individuals in the room during exposure.
- 9.3.1.6 technologist initials in the patient examination record.
- 9.3.1.7 the use of markers; changing electronic markers or lead markers on images must include technologist initials.
- 9.3.1.8 lead shielding, dose reduction initiatives and coning requirements.
- 9.3.1.9 intravascular contrast media examinations.
- 9.3.1.10 operating room radiology examinations.
- 9.3.1.11 sterile field examinations.

9.4 Quality Control Program

- 9.4.1 A facility must:
 - 9.4.1.1 establish a quality control program under the oversight of a medical physicist certified by the Canadian College of Physicists in Medicine.
 - 9.4.1.2 perform acceptance testing upon installation of radiography equipment.
 - 9.4.1.3 frequently review the quality assurance test results to an established benchmark and remediate non-conformances.
 - 9.4.1.4 notify the medical physicist and the facility director when remediation avenues fail to solve non-conformances.
 - 9.4.1.5 require an annual quality assurance review document from the medical physicist who oversees the quality control program.
 - 9.4.1.6 meet the recommendations as required in the physicist's annual quality assurance review document.

10.0 MOBILE RADIOGRAPHY/MAMMOGRAPHY

10.1 General

- 10.1.1 A facility must limit use of mobile equipment to cases where the condition of the patient makes it inadvisable for the examination to be carried out with a stationary unit in the x-ray department.

10.2 Policies and Procedures

- 10.2.1 The facility must establish and maintain policies governing:
 - 10.2.1.1 a technical factor list for routine mobile examinations must accompany the mobile equipment.
 - 10.2.1.2 document technical factors for each examination.
 - 10.2.1.3 technologist initials in the patient record for each examination performed.
 - 10.2.1.4 mobile exposures:
 1. provide a verbal warning that an exposure will be taken.
 2. provide lead shielding for individuals who are present during exposure.
 - 10.2.1.5 an operating room.
 - 10.2.1.6 sterile field examinations.

MANITOBA DIAGNOSTIC IMAGING STANDARDS

10.3 Quality Control Program

10.3.1 A facility must:

- 10.3.1.1 establish a quality control program under the oversight of a medical physicist certified by the Canadian College of Physicists in Medicine.
- 10.3.1.2 perform acceptance testing of mobile equipment.
- 10.3.1.3 frequently review the quality assurance test results to an established benchmark and remediate non-conformances.
- 10.3.1.4 notify the medical physicist and the facility director when remediation avenues fail to solve non-conformances.
- 10.3.1.5 require an annual quality assurance review document from the medical physicist who oversees the quality control program.
- 10.3.1.6 meet the recommendations as required in the physicist's annual quality assurance review document.

11.0 VEHICULAR FACILITY

A vehicular facility is considered to be a re-locatable diagnostic imaging facility and as such, must adhere to the Manitoba Diagnostic Imaging Standards that apply to a diagnostic facility.

- 11.1 The facility director must have a documented scope of practice suitable to meet the needs of the vehicular diagnostic imaging service.
- 11.2 The facility director must establish a quality control program under the oversight of a medical physicist certified by the Canadian College of Physicists in Medicine; an annual report issued by the medical physicist is required.
- 11.3 When a vehicular facility is relocated, the safety and functionality of the equipment must be re-established prior to use. To maintain best practices, as referenced in Health Canada Safety Code 35, a facility must, at minimum, perform the following quality assurance tests:
 - 11.3.1 meters operations.
 - 11.3.2 system movements.
 - 11.3.3 processor function/laser film printer operation.
 - 11.3.4 visual assessment of electronic display devices.
 - 11.3.5 sensitometry/densitometry.
 - 11.3.6 test pattern image.
 - 11.3.7 collimator operation.
 - 11.3.8 interlocks.
 - 11.3.9 x-ray field and light field alignment.
 - 11.3.10 automatic exposure control (AEC) system.
- 11.4 Non-conformances identified in the above quality assurance tests must be reported to the medical physicist who oversees the quality control program and the facility director.

12.0 ULTRASOUND

12.1 Sonographer¹⁵ Qualifications

A sonographer must hold an active registration status with Sonography Canada in the appropriate practitioner category. An exemption may be granted for sonographers who hold active registration status with the American Registry for Diagnostic Medical Sonographers (ARDMS) in the appropriate speciality provided that the facility director has determined that the competency of the sonographer is compliant with the competency requirements of Sonography Canada.

¹⁵ A sonographer is an ultrasound technologist.

MANITOBA DIAGNOSTIC IMAGING STANDARDS

12.2 General

12.2.1 A facility must:

12.2.1.1 establish and maintain:

1. a list of procedures which may be done during non-core hours.
2. a list of procedures performed at the facility for referring physicians.

12.2.1.2 have a process to:

1. screen consultation requests for appropriateness and priority of examination.
2. promptly review each examination image taken.

12.3 Policies and Procedures

12.3.1 A facility must establish and maintain policies governing:

12.3.1.1 demographic requirements which must include:

1. the name of the sonographer performing the examination.
2. the date and time of examination.
3. relevant clinical information.
4. a record of the quantity of data (e.g. number of images or clips).

12.3.1.2 ergonomic requirements for personnel, which must include:

1. properly designed scanning chairs.
2. height adjustable stretchers/scanning beds.
3. support cushions.
4. adjustable footrests.

12.3.1.3 use of Doppler ultrasound in obstetrics.

12.3.1.4 biopsies.

12.3.1.5 interventional procedures.

12.3.1.6 gel usage meeting Health Canada Safety Guidelines¹⁶.

12.3.1.7 contrast media, if used.

12.3.1.8 sonographer modification of the examination due to relevant findings, which must include sonographer documentation of rationale for any deviations from the required protocol.

12.3.1.9 documentation of structures not well visualized.

12.3.1.10 availability of spill kits when endocavity transducers are used.

12.3.1.11 transducer cleaning.

12.3.1.12 transducer cover usage.

12.3.1.13 endocavity transducer disinfection.

12.3.1.14 transducer disinfection with high-level disinfectants requiring fume hoods.

12.3.1.15 transducer usage in a sterile field.

12.3.1.16 annual competency evaluations of sonographers, which must include:

1. scan skills.
2. interpretative skills.
3. appropriateness of technical impressions.
4. image quality and annotation.
5. appropriate acoustic output levels (patient exposure).
6. DICOM header or image display information must include (whenever possible) the appropriate MI, TI.

12.3.1.17 sonologist availability; the facility director must define when a sonologist must be:

1. on-site for consultation, interpretation and supervision of ultrasound examinations.
2. available for consultation, interpretation and supervision of ultrasound examinations.
3. available for consultation for remotely supervised facilities as required; see additional requirements for remote ultrasound facilities.

¹⁶ Health Canada Health Products and Food Branch NOTICE TO HOSPITALS Important Safety Information on Ultrasound and Medical Gels. Retrievable from http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/_2004/ultrasound_nth-ah-eng.php

MANITOBA DIAGNOSTIC IMAGING STANDARDS

- 12.3.1.18 procedure protocols for each examination, which must include:
1. providing a list of required images (including ciné-loops number and type).
 2. optimizing the image.
 3. monitoring output display indices and adjust power output in accordance with the As Low As Reasonably Achievable Principle.
 4. the anatomic region examined with the patient positioned as appropriate.
 5. measuring structures as required.
 6. documenting a summary of sonographic findings as required.

12.4 Quality Control Program

12.4.1 A facility must:

- 12.4.1.1 establish a quality control program under the oversight of a medical physicist certified by the Canadian College of Physicists in Medicine.
- 12.4.1.2 perform acceptance testing upon installation of ultrasound equipment.
- 12.4.1.3 frequently review the quality assurance test results to an established benchmark and remediate non-conformances.
- 12.4.1.4 notify the medical physicist and the facility director when remediation avenues fail to solve non-conformances.
- 12.4.1.5 require an annual quality assurance review document from the medical physicist who oversees the quality control program.
- 12.4.1.6 meet the recommendations as required in the physicist's annual quality assurance review document.
- 12.4.1.7 provide appropriate quality control phantom and test tools.

12.5 Additional Requirements for Remote Ultrasound Facilities

12.5.1 A facility must:

- 12.5.1.1 limit procedures to the competency of the sonographer (as per Sonography Canada competency requirements).
- 12.5.1.2 stipulate when additional requirements to procedure protocols are required.
- 12.5.1.3 make the sonologist's contact information available to the sonographer and referring physician.
- 12.5.1.4 provide each sonographer with direct training at least annually and more frequently if required by the facility director; a documented competency assessment is required.
- 12.5.1.5 monitor report turnaround times at least monthly and more frequently if required.
- 12.5.1.6 establish and maintain policies governing:
 1. weekly test image process.
 2. delivery of urgent results.
 3. emergent examinations.
 4. referral of complex or out of scope examinations.
- 12.5.1.7 establish policies and procedures governing sonologist availability; the sonologist must be:
 1. available to the sonographer to code emergent/urgent requests and provide interpretation during core hours of operation.
 2. available to the sonographer to code emergent/urgent requests and provide interpretations during non-core hours of operation.

MANITOBA DIAGNOSTIC IMAGING STANDARDS

12.6 Ultrasound Equipment

12.6.1 A facility must operate, maintain and monitor ultrasound equipment in accordance with the manufacturer performance requirements. The equipment must, at a minimum, have the following:

- 12.6.1.1 real-time, 2D gray-scale imaging.
- 12.6.1.2 M-mode imaging.
- 12.6.1.3 color, pulsed, and power Doppler.
- 12.6.1.4 harmonic imaging.
- 12.6.1.5 a range of transducer frequencies appropriate for the patient population.
- 12.6.1.6 an endocavity transducer for prostate or rectal imaging.
- 12.6.1.7 an endovaginal transducer with a frequency of ≥ 7 MHz for early obstetric and gynecologic imaging as required by the examinations offered..
- 12.6.1.8 a linear transducer with a frequency of ≥ 7.5 MHz for superficial structures.
- 12.6.1.9 a curved array transducer as required by the examinations offered.
- 12.6.1.10 operator adjustable acoustic power output.