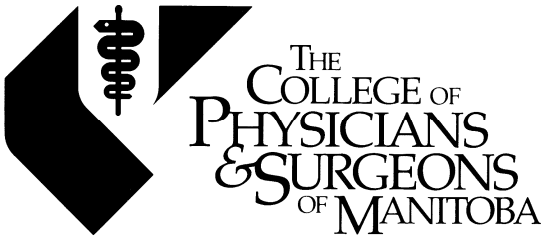


# MANITOBA
# MAMMOGRAPHY STANDARDS

**April 2013**

# INTRODUCTION

These Manitoba Mammography Standards are a subset of the Manitoba Diagnostic Imaging Standards (Version 2), with the exception of 8.0 Mammography; therefore, the numbers are not sequential.

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## 1.0 QUALITY MANAGEMENT PROGRAM

### 1.1 General

1.1.1 A facility must establish and maintain a quality management program[1] that:

1.1.1.1 defines:

1. the organizational structure[2].

### 1.2 Signage

1.2.1 A facility must post in the facility:

1.2.1.1 the facility director's name.

1.2.1.2 only current certificates of accreditation.

### 1.3 Personnel

1.3.1 A facility must:

1.3.1.3 provide personnel with readily available current modality specific reference material, including positioning textbooks and reference books.

### 1.4 Facility Director Reviews

1.4.1 The facility director must:

1.4.1.2 record the changes arising from the annual review and update policies and procedures as required.

1.4.1.3 inform facility personnel of the changes made as a result of the review.

### 1.5 Documentation

1.5.1 All facility policies and procedures must be in writing and available to personnel.

## 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 approval.
3. a historical coversheet.

#### 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 procedure/positioning manual must be available to personnel in hard copy format.

#### 2.1.3 Manual Review

2.1.3.1 A facility director must annually review and update all manuals and maintain a written record of the review and of any changes made. If a facility director delegates all the review, the facility director is responsible to sign off on all revisions and the annual review.

2.1.3.2 A facility must have all personnel sign to confirm review of all manuals and individual job descriptions annually.

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

[2] Organizational Structure defines reporting relationships to include: functional, divisional, and matrix structures.

## 2.2 Required Manuals

A facility must establish and maintain the following manuals:

### 2.2.1 Quality Management Program[3] Manual

2.2.1.1 The Quality Management Program Manual must include:

2. a description of the facility, ownership of the facility, operator of the facility, resources and main duties.
8. policies governing each of the following topics:
   a) compliance with *The Personal Health Information Act*.
   g) exchange of images/reports.
   h) handling of complaints and remedial actions.
   i) internal audits.
   j) client satisfaction.
   k) risk management.
   l) technical support.
   p) image and document retention periods, which must include the following minimum retention periods:

| | | |
|---|---|---|
| (iii) | mammography | 10 years |
| (ix) | request for consultation | 5 years in original transcribed form |
| (x) | quality control/quality assurance | 2 years except for bone density which is 5 years |
| (xi) | repeat/reject | 2 years |
| (xii) | outdated policies/procedures | 10 years |
| (xiii) | accession records | 2 years |
| (xiv) | equipment maintenance | equipment maintenance lifespan plus 2 years |
| (xv) | incident reports | 10 years |

9. 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.

### 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.

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.

[3] See the Quality Management Program Standard.

2.2.2.3 General workplace safety and health policies and procedures must:

2. require use of personal protective equipment where appropriate.
5. prohibit food in technical work areas.
6. 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 visitors in the facility.

2.2.2.4 Routine practices/infection control policies and procedures must include:

8. daily disinfection of work surfaces.
12. infection control, including the following mandatory practices:
    a) using chairs and accessories with a material that may be decontaminated. Cloth chairs are unacceptable.
    b) if pillows are used, changing the pillow covers between each patient.
    c) changing table covers between patients, or disinfecting work surfaces.

2.2.2.5 Waste management policies and procedures must include: decontamination and disposal of contaminated waste, hazardous waste (unwanted lead), chemical waste and sharps.

2.2.2.6 Electrical safety policies and procedures must include:

2. using approved extension cords.

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 personnel.
3. having an evacuation plan which includes a process to assist those who are unable to evacuate without assistance.
4. emergency evacuation route posters visible in all patient and public areas.
5. clear and visible signage to indicate the location of the fire alarm pulls, which must be located at the fire exit.

2.2.2.8 Radiation safety policies and procedures must govern:

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.
4. accidental or unintentional doses to patients.
5. testing all lead shielding integrity initially and annually thereafter.
8. exposure control.
9. examination protocols.
10. thermo luminescent dosimeter badge usage; which must be:
    a) badges specific to the facility.
    b) reports retained for the lifetime of the facility.
    c) badges specific to occupational classifications for issuing dosimeters.

2.2.2.9 Eyewash safety policies and procedures must include:

1. having eyewash stations available.
2. flushing eyewash stations weekly.
3. monitoring wall mounted eyewash stations for expiry dates regularly.

2.2.2.10 Hazardous materials policies and procedures must include:

1. reporting and documenting hazardous material spills.
2. having chemical and biological spill kits readily available and establishing procedures for use of the kits.
3. monitoring expiration dates of chemicals and spill kits.
5. required use of designated labels for Workplace Hazardous Material Information Systems controlled products.
6. having a master inventory list of hazardous materials.
7. maintaining current Material Safety Data Sheets, (i.e. not greater than 3 years old).

### 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.
3. competency based orientation training requirements for each employee.[4]
4. continuing education and maintenance of competence requirements for each employee.
7. annual competence appraisals for each employee.

### 2.2.4 An Operational Policy Manual

2.2.4.1 The Operational Policy Manual must include policies which govern:

1. document[5] control
   a) maintaining a historical coversheet to record major changes, additions or deletions.
   b) requiring all handwritten changes to be signed and dated by the person making the change and approved in writing by the facility director.
   c) ensuring that any posted material, procedural guideline or direction is current and in compliance with manual requirements.
2. management of requests for consultation:
   a) required information must be legible and include:
      (i) the last menstrual period for female patients of child bearing age.
      (ii) a known pregnancy.
      (iii) the weight of the patient.
      (iv) previous imaging examinations.
      (v) history of previous surgeries pertinent to the examination request.
      (vi) the urgency of the examination.
      (vii) the date of referral.
      (x) known or suspected communicable disease.
      (xi) advanced healthcare directives, if known.
   b) criteria for rejection.
3. required patient demographics:
   a) patient first and last name.
   b) personal health identification number (PHIN).
   c) facility health record number or alternate number (e.g. RCMP, Canadian Forces, other provincial health numbers).
   d) date of birth.
   e) date of examination (and time if applicable) and required examination.
   f) facility name

[4] Also found in the Personnel Policy Manual
[5] "Document" includes any information or instructions, including policy statements, text books, examinations, specifications, calibration tables, biological reference intervals and their origins, charts, posters, notices, memoranda, software, drawings, plans and documents of external origin such as regulations, standards, or examination examinations.

4. patient imaging record:
    a) request for consultation.
    b) header for the examination type.
    c) date and time of examination.
    d) technologist initials.
    e) technique used (as required).
    f) reports, which must include:
        (i) addendum reports.
        (ii) corrected reports.
        (iii) preliminary reports.
        (iv) final reports.
        (v) urgent report communication.
5. patient management:
    a) notification of cancelled patient examination.
    b) identifying and correcting patient demographics.
    c) temporary patient identification.
    l) incomplete examinations.
    m) when immediate medical attention is required.
6. report management:
    a) turnaround times and investigating of non-conformities.
    g) criteria for verbal reports, unsigned reports or reports not yet proof-read.
    h) identifying and notifying of critical results and documenting notification.
7. compliance with *The Personal Health Information Act*[6] must include:
    a) correcting of personal health information.
    b) transmitting personal health information via facsimile or other electronic means.
    c) record use and disclosure.
    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.

### 2.2.5 An Equipment and Maintenance Manual

Equipment includes 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:
    d) contingency planning to address failure of equipment.
2. maintenance procedures for:
    a) routine operation of equipment.
    b) minor troubleshooting.
    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. requirements for record keeping must include recording and maintaining the following information respecting equipment:
    b) manufacturer's instructions for equipment operation.
    d) a list of contact personnel and phone numbers for equipment maintenance support.

[6] See also the Quality Management Program Manual.

### 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:

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. quality control procedures used to monitor performance.
2. policies governing:
   a) overriding raw data markers with electronic markers.
   b) image sequencing into PACS.
   c) password protecting logins.
   d) maintaining patient confidentiality on unattended monitors.
   e) performing an electronic repeat/reject analysis.
   f) trouble shooting directions.

### 2.2.8 Radiology Information System (RIS) Manual

2.2.8.1 The Radiology Information System Manual must include:

5. policies governing:
   a) 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) adequate technical support.
   g) a transmission system that has error checking capabilities.
   i) the archive retrieval system, which must include:
      (i) the ability to provide high importance flags, technologist comments and validation of radiologist electronic signature.
      (ii) accurate association of the patient study with the images.
      (iii) consultation request.
      (iv) prior examinations and retrievals.
6. procedures:
   a) respecting scheduled maintenance downtime or electronic failure management, including:
      (i) 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) routine logout of the RIS when not actively working on it.
      (ii) prohibiting use of another personnel member's login to perform work.
   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.

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.
l) governing portable 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.

**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.
4. acquisition requirements:
   a) patient name.
   b) Personal Health Identification Number (PHIN).
   c) facility number/accession number.
   d) date and time of examination.
   e) image markers.
   f) name of facility or institution of origin.
   g) type of examination.
5. intra-facility PACS systems requirements.

**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. each examination beginning on a new page, with the following information at the top of the first page:
   a) facility name.
   b) title of manual.
   c) procedure or policy title.
   d) page number.
   e) authorized/approved by.
   f) date of approval.
5. each examination written in a standard format equivalent to or substantially similar to the following format:
   e) patient preparation.
   g) examination protocols.
   h) deviations from routine positioning views.
   j) appropriate shielding usage.
   p) post-examination care.
   q) patient instructions for each imaging examination offered.

## 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 applicable legislation. Applicable legislation includes:

3.1.1.1 Federal

1. the *Transportation of Dangerous Goods Act* and Transport Canada TDG Regulations.
2. the National Fire Code of Canada, including NFPA 10: "Portable Fire Extinguishers".
3. the Canadian Electrical Code Part 1 and 2.
4. the National Plumbing Code of Canada.
5. the *Canadian Environmental Protection Act.*
6. Health Canada Medical Devices Regulations.
7. Health Canada Safety Code 35: Safety Procedures for the Installation, Use and Control of X-ray Equipment in Large Medical Radiological Facilities.
9. the *Nuclear Safety and Control Act* and Regulations.

3.1.1.2 Provincial

1. *The Workplace Safety and Health Act* and Regulations.
2. Workplace Hazardous Materials Information System (WHMIS).
3. *The Buildings and Mobile Homes Act*, Manitoba Building Code Regulation 127/2006.
4. *The Public Health Act*, Safety Regulations.

3.1.2 A facility must comply with Manitoba's Workplace Safety and Health Act requirements. These requirements include:

3.1.2.1 safety inspections.

3.1.2.2 safe work procedures, which include:

1. having an ergonomic environment to minimize repetitive strain injuries, stress injuries, back injuries and poor posture.
2. having available appropriate patient transfer devices.
3. providing lifting assistance where the workload includes the transfer of heavy or immobile patients or equipment.

### 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 safety[7].
2. WHMIS.
4. handling medical emergencies.

### 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.

### 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.

[7] See the Manuals Standard, Safety Manual, Fire Safety.

## 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 and maintained in good working condition.

### 4.3 Site Specific Equipment (CR/DR)

4.3.3 A facility must:

4.3.3.1 ensure that the primary monitor (i.e. the monitor used by radiologists to interpret images) meets the following specifications:

2. for large-matrix-systems (CR, digitized film, DR): primary monitors with at least 1.6K x 1.2K (1.9 mega pixel) resolution and luminance rating of at least 171 cd/m2.

4.3.3.2 check the performance of all electronic display devices used to view images from digital systems and from scanning of radiographic films:

1. using a test pattern such as the SMPTE or a TG18 test pattern, or if a suitable test pattern is not available, an equivalent test pattern generator.
2. service any monitor which does not pass all tests.

4.3.3.3 annually test all video monitors for:

1. luminance and uniformity.
2. manual brightness and contrast setting.
3. calibration.

## 8.0 MAMMOGRAPHY

Each facility which offers mammography services must hold a valid certificate of accreditation and adhere to the most recent standard requirements set out by the Canadian Association of Radiologists Mammography Accreditation Program. (**As per the Regional Health Authorities Act 28.1**)