



Canadian Association of Radiologists  
L'Association canadienne des radiologistes

CAR PRACTICE GUIDELINES AND  
TECHNICAL STANDARDS FOR

# BREAST IMAGING AND INTERVENTION

APPROVED ON SEPTEMBER 29, 2012

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

Approved on September 29, 2012

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# PREAMBLE

In this document the breast imaging committee intends to present what is considered best breast imaging practice at the time of development. The committee encourages best clinical practice and with the aid of these practice guidelines and consensus statements, hopes to provide radiologists as well as technologists, and other allied staff with a consensus-based approach to include clinical indications and technical standards for performing and interpreting breast imaging, as well as performing breast interventional procedures.

These guidelines are in accordance with those published by the Canadian and American Cancer Societies, the National Comprehensive Cancer Network and the American College of Radiology. Their purpose is to serve as an educational tool and provide minimum requirements to the practitioner; however, they are not intended to be inflexible. It is acknowledged that actions differing from those recommended may be appropriate depending upon resources available to the radiologist, patient factors, changes in technology and knowledge evolving after the publication of these guidelines. Ultimately, the final judgment regarding appropriateness of a given examination or intervention for a particular patient is the responsibility of the supervising radiologist with aid from the medical physicist and technologist.

This version of the Guideline incorporates what were previously the Standards for Breast Imaging, Breast Ultrasound and Breast Interventional. New in this version are Breast MRI and brief discussions of several technologies and therapies which are new since the last Standards. The current Guideline is divided into Breast Imaging and Breast Intervention.

As this version will likely be viewed electronically more than prior versions, we have included several links in a section at the end and also scattered within the document.

# SECTION A: BREAST IMAGING

## I. MAMMOGRAPHY

### I.I. SCREENING MAMMOGRAPHY<sup>1</sup>

Mammography is a proven technique for detecting malignant disease of the breasts, particularly at an early stage. In the presence of breast symptoms, mammography is used not only to further evaluate the breast, but in some cases may be used to allow for a definitive conclusion, as well as detection of other unsuspected neoplasms.

It should be noted that the indications listed below for screening are CAR guidelines. It is acknowledged that there are other jurisdictional and international guidelines and practices in existence that differ from those of the CAR.

While there is periodic controversy<sup>2</sup> around the value of mammography, appropriate screening age groups and screening intervals, population-based trials have shown that periodic screening of asymptomatic women reduces mortality from breast cancer<sup>3</sup>. As is true for other radiological examinations, optimum quality is required at all levels. Important considerations include credentialing and criteria for professionals, equipment specifications, monitoring and maintenance schedules, image quality standards, imaging evaluation standardization, meticulous record keeping, and periodic review and analysis of outcome data.

#### DEFINITION

Screening involves the examination of asymptomatic women to detect abnormalities which can lead to a diagnosis of early stage breast cancer. Small tumour size and negative lymph node status necessitate less extensive surgical treatment, reduced need for chemotherapy and are associated with increased survival<sup>4</sup>. When an abnormality is identified by the screening mammogram, the woman is referred for additional study; therefore the screening examination can be performed without a radiologist in attendance. Despite its sensitivity, however, mammography does not detect all breast cancers; therefore, mammography and clinical examination are complementary procedures, together with breast self-examination or breast awareness<sup>5</sup>. For certain high-risk populations, MRI is also an appropriate screening modality. Please refer to MRI section for further details.

#### INDICATIONS

- a) Asymptomatic women 40–49 years<sup>6</sup> should undergo screening mammography every year<sup>7</sup>
- b) Asymptomatic women aged 50 to 74 should undergo screening mammography every one to two years<sup>8</sup>
- c) Women over the age of 74 should have screening mammography at one to two-year intervals if they are in good general health

Other guidelines<sup>5</sup> and common practice indicate that, while screening mammography is not routinely recommended for women under age 40, it may have a role for selected individuals in the high risk category. Where there is a family history of a first degree relative with pre-menopausal breast cancer, referral for mammography may be advised at an age five to ten years younger than the age of the relative's diagnosis.

MRI is indicated for certain high-risk populations (see, MRI INDICATIONS/CONTRAINDICATIONS below). Other personalized high-risk screening protocols are being developed, some of which employ ultrasound as an adjunct to mammography<sup>9</sup>.

Risk factors for breast cancer include previous biopsy showing cancer or high-risk lesions, strong positive family history, previous exposure to high doses of chest radiation, underlying genetic abnormalities, breast tissue density, early menarche, late childbearing: delivery of first child at age over 30 years, obesity and inactivity, smoking, moderate alcohol consumption (2 drinks per day), and chemical/hormone exposure (estrogen-like e.g. BPA, phthalates). Measures of risk are best defined as a percentage of women expected to develop cancer in a given future interval per year, in the next given number of years, from current age to given future age, as lifetime risk. A number of mathematical models are available to calculate a woman's lifetime risk for developing breast cancer, such as Gail, Claus, BRCAPRO, IBIS (IBIS Breast Cancer Risk evaluator tool: <http://www.ems-trials.org/riskevaluator>) and BOADICEA. The latter three are considered to be the most comprehensive in the assessment of family history of both breast and ovarian carcinoma<sup>10</sup>.

The National Comprehensive Cancer Network (NCCN)<sup>®</sup> has more information on personalized high risk screening. This is available at [www.nccn.org](http://www.nccn.org).

## SELF REFERRAL

In some jurisdictions self referrals are permitted. In these jurisdictions, if a woman within the screening age range wishes to pursue screening outside an organized screening program, she is encouraged to provide the name of the primary health care professional to whom the report will be sent. If the woman is unable to provide the name of a primary health care professional, a name should be chosen from a pool of willing health care providers. This pool should be maintained to take referrals from screening mammography.

The woman should also be directly notified of her screening result.

If the mammogram report is abnormal, both the woman and the selected health care provider should be notified.

A standardized radiology screening results report must be issued for both normal and abnormal results, in a timely fashion. This report must document specific findings and follow up recommendations.

The woman must receive written notification of her mammography results in a timely fashion.

## QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

The personnel standards for education and conduct are determined by the unique demands of mammography practice.

### Radiologist

Radiologists involved in the performance, supervision and interpretation of mammography must have a Fellowship or Certification in Diagnostic Radiology with the Royal College of Physicians and Surgeons of Canada and/or the Collège des médecins du Québec. Equivalent foreign radiologist qualifications are also acceptable if the radiologist is certified by a recognized certifying body and holds a valid provincial license.

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

of Certification Program of the Royal College of Physicians and Surgeons of Canada.

Radiologists interpreting mammography should adhere to the CAR Mammography Accreditation Program (MAP) requirements. For further information, please contact the CAR MAP directly (<http://www.car.ca/en/contact.aspx>).

### Medical Radiation Technologist

Medical radiation technologists (MRTs) performing mammography must have Canadian Association of Medical Radiation Technologist (CAMRT) Certification or be certified by an equivalent recognized licensing body.

Under the overall supervision of the radiologist, the MRT will have the responsibility for patient comfort and safety, examination preparation and performance, image technical evaluation and quality, and applicable quality assurance. The MRT should receive continuous supervision on image quality from the interpreting radiologists. Technologist QA programs, including systematic review, should be encouraged.

The training of MRTs engaged in specialty activities shall meet with the applicable provincial and national specialty qualifications. The MRT shall have training in mammography either in his or her training curriculum or through special courses, and must perform mammography on a regular basis. Where using or converting to digital mammography, training with an application specialist or other trained or experienced personnel is recommended, with attention paid to the artifacts, display and software concerns unique to digital imaging.

Continued professional development in breast imaging is encouraged by the CAMRT and should meet pertinent provincial and CAR MAP requirements.

### Medical Physicist

A medical physicist must take the responsibility for the initial acceptance testing, and for conducting and overseeing quality control testing of the mammographic unit and viewing chain for digital imaging.

The medical physicist shall have a graduate degree and be certified by the Canadian College of Physicists in Medicine (CCPM) in the specialty of Mammography, or its equivalent, or any relevant provincial/territorial license. Please visit [www.ccpm.ca](http://www.ccpm.ca) for further information.

Training and experience shall include knowledge of the physics of mammography, systems components and performance, safety procedures, acceptance testing, quality control and CAR Mammography Accreditation Program (MAP) requirements.

For more specific information about medical physicist responsibilities, please refer to the individual modality sections within this document.

### **Information Systems Specialist**

An Information Systems Specialist (ISS) is required by facilities performing digital imaging. This individual must be either on site or available upon request. He/she must be trained and experienced in installation, maintenance and quality control of information technology software and hardware. The required qualifications of this individual will depend highly on the type of facility and the type of equipment.

The ISS should possess any relevant qualifications required by federal/provincial/territorial regulations and statutes, and should be certified according to a recognized standard such as that of the Society of Imaging Informatics in Medicine or the PACS Administrators Registry and Certification Association.

Training and expertise should include computer and database basics, networking concepts (such as DICOM, HL7, RIS and HIS), security systems, medical imaging terminology, positioning and viewing characteristics, imaging characteristics of various modalities for image acquisition, transmission and storage, and facility workflow. The ISS should also be knowledgeable about federal, provincial, territorial and institutional privacy legislation and policies, such as the Personal Information Protection and Electronic Documents Act (PIPEDA)

Responsibilities include ensuring confidentiality of patient record, understanding policies and procedures in place within the facility, understanding the importance and the requirements for an information systems quality assurance program, and communicating any changes/upgrades to staff, as well as resulting consequences for facility operations.

## **EQUIPMENT**

### **Specifications**

The mammogram must be performed only on dedicated mammography equipment with an adequate

compression device and a removable grid. While there is some evidence of variance between specific digital mammography technologies<sup>11, 12, 13</sup>, digital mammography overall has significant benefits over screen-film mammography<sup>14</sup>, including decoupling of image acquisition and storage. For this reason, digital equipment is recommended when purchasing a mammography unit<sup>15</sup>. All mammography units must be licensed by Health Canada (HC) as class 3 (appropriate for mammography) upon installation. For more specifics on mammography equipment please refer to the Health Canada Canadian Mammography Quality Guidelines website (<http://www.hc-sc.gc.ca/ewh-semt/pubs/radiation/02hecs-sesc267/index-eng.php>). Additionally, a searchable list of all actively licensed medical devices is available at [www.mdall.ca](http://www.mdall.ca).

The mammography unit must be evaluated at the time of equipment installation and before any patients are scheduled for mammography exams. The performance must be verified by a qualified mammographic medical physicist. All corrective actions required on non-compliant tests must be addressed before any mammograms are performed. The unit must then be checked at least annually or more frequently if required by provincial legislation. The physicist report must be approved and signed by a medical physicist certified in mammography by the Canadian College of Physicists in Medicine (CCPM) or its equivalent (see QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL, above). Copies of maintenance and/or service reports should be kept for a minimum of three (3) years. A procedure manual, as well as a properly documented log of the tests performed as part of the quality control (QC) program, must be maintained.

For digital mammography, a review workstation compliant with the standards of Integrating the Healthcare Enterprise (IHE) is necessary. Two (2) 5-megapixel monitors, and appropriate software are required. Information on IHE can be obtained at [www.ihe.net](http://www.ihe.net).

Compression devices should be designed to improve contrast, minimize radiographic scatter, ensure uniform density, and reduce dose and subject motion. Molybdenum target tubes with molybdenum or rhodium filtration are appropriate for film screen mammography. Digital mammography systems may use various anode target materials, including filters of molybdenum, rhodium, aluminum or silver.

For mammography, the focal spot size of the x-ray tube should be 0.3 mm for contact mammography, and 0.1mm for magnification mammography. The focus to receptor distance for contact mammography should be 50 cm or more.

A dedicated film processor with developer time and temperature designed specifically for the single emulsion film being used for film/screen mammography is recommended. As an alternative, mammography film designed for 90 seconds processing is acceptable. The CR reader and laser printer require appropriate parameters and QC.

Please contact the CAR MAP (<http://www.car.ca/en/contact.aspx>) for a list of required QC testing.

### **Radiation dose**

The average glandular dose for the standard breast must be determined at least annually. The average glandular dose cannot exceed 3 mGy for a CC projection. The standard breast is represented by a 4.0 cm thick PMMA phantom which attenuates similarly to a 4.5 cm thick compressed breast consisting of 50% glandular and 50% adipose tissue<sup>16</sup>.

### **Radiation protection**

Aprons and collars are not routinely required (see CAR POSITION STATEMENT ON THE USE OF THYROID SHIELDS: [http://car.ca/en/standards-guidelines/car\\_position\\_papers.aspx](http://car.ca/en/standards-guidelines/car_position_papers.aspx)) as radiation protection for mammography, as the amount of scattered radiation is negligible. At the time of writing, it is recommended that radiation protection be used for patients who are pregnant or who fall outside of the 10 day rule, but require urgent mammographic assessment.

### **SPECIFICATIONS OF THE EXAMINATION**

The examination should ordinarily be limited to a craniocaudal and mediolateral oblique projections of each breast. Occasionally, additional projections may be required to visualize breast tissue adequately. When an abnormality exists which must be investigated further, the woman is referred for additional imaging studies and/or biopsy.

### **Comparison with previous images**

Original images of previous studies should be obtained when practical.

### **Conventional Film Labelling**

Adequate documentation of the study is essential. All radiographic images should be labelled in accordance with the current recommendations of the CAR Mammography Accreditation Program. Film labelling should include an identification label containing:

- a) Facility Name
- b) Acquisition Date
- c) Acquisition Time
- d) Facility Address
- e) Station Name
- f) Operator Initials (or ID number)
- g) Patient's First and Last Names
- h) Patient ID and/or Date of Birth
- i) Cassette (screen) number
- j) Mammography unit identification using roman numerals

The film should also include a standardized radiopaque marker placed on the film near the axilla for identification of laterality and view. This marker must not obscure image information.

### **Digital Image Labelling**

Adequate documentation of the study is essential. It is important to ensure certain key information is automatically transferred from the digital mammography image acquisition system to the stored DICOM image.

Systems must provide all of the information fields listed in the chart below, ideally without additional manual entry by the operator. The DICOM header should contain the following tags:

- a) Facility Name
- b) Acquisition Date
- c) Acquisition Time
- d) Facility Address
- e) Station Name
- f) Operator Initials (or ID number)
- g) Patient's First and Last Names
- h) Patient ID and/or Date of Birth
- i) kV
- j) Exposure Time and X-ray Tube Current (mAs)
- k) Anode Target Material
- l) Filter Material
- m) View Position
- n) Patient Orientation
- o) Image Laterality
- p) Numerical mammography unit identification

### **View boxes and monitors**

View boxes should provide a high luminance level. This is generally higher than that required for viewing conventional radiographs. This should be evaluated by the medical physicist annually. It is essential to mask the area around the mammograms to exclude extraneous light which reduces image contrast and limits maximum densities that can be seen without “bright-lighting” each film. Magnification lenses and bright-light capabilities should be available.

All view boxes should be checked periodically to assure that they are in optimal condition.

In the case of digital mammography, the MRT will use a monitor to ensure that the images are of diagnostic quality prior to image interpretation by a radiologist.

Two (2) 5-megapixel monitors are required for image display and interpretation by the radiologist. The monitors must be checked annually by the medical physicist (see EQUIPMENT, above). One (1) 3-megapixel monitor must be available solely for technologists, at all times. This can include the acquisition station.

### **Viewing conditions**

Contrast is extremely important in the mammographic image and is degraded by extraneous light. View boxes should be positioned to avoid light from windows, other view boxes, and other sources of bright light, either direct or reflected. General lighting should be at a low level and diffuse. Digital monitors should be maintained at adequate luminance, according to manufacturer specifications.

When interpreting digital screening mammograms in a screening setting and utilizing analog screening mammograms films for comparison purposes, the viewbox (for the analog films) should be in close proximity to the digital (reading) monitors.

### **Conventional Film Retention**

Original mammograms should be retained by the facility and made available to the patient for a minimum period of five (5) years. Mammograms must be retained for a statutory period which must be consistent with clinical needs and relevant legal and local health care facility requirements.

### **Digital Image Retention**

Original mammogram data (“for processing”) should be retained by the facility and made available to the patient for a minimum period of five (5) years. Mammograms must be retained for a statutory period which must be consistent with clinical needs and relevant legal and local health care facility requirements.

At this time, as part of the CAR MAP guidelines, digital mammography images must have absolutely no lossy compression. Images sent to other facilities should be sent on media or electronically with non-proprietary lossless compression so that they can be displayed on the consulting physician’s IHE compliant workstation

### **Free standing and mobile settings**

Screening mammography may be performed in non-traditional settings where a radiologist may not be in attendance. This includes digital telemammography.

The examination offered must follow all of the described standards and guidelines cited here as documented protocols.

The MRT should work under the same rules whether in a fixed or mobile setting.

Where practical, the radiologist supervising the facility, or an appropriately qualified delegate, should be available for consultation and should visit the facility at least monthly to observe the performance of mammograms and assure that safe operating procedures are followed.

Quality control documentation should be reviewed by the supervising radiologist, or appropriately qualified delegate, and a log of these visits must be maintained.

### **THE SCREENING MAMMOGRAPHY REPORT**

Most screening mammograms are normal. A small percentage will be reported as abnormal and recommendations will be made for further diagnostic workup. Reporting should be according to the *CAR Standard for Communication of Diagnostic Imaging Findings*, available at [www.car.ca](http://www.car.ca). As well, use of the American College of Radiology (ACR) document *Breast Imaging Reporting Data Systems (BI-RADS®)* is encouraged. This is available on request from the ACR office and excerpted text is available online at [www.acr.org](http://www.acr.org). A description of abnormalities detected at screening and recommendations for diagnostic work up should be included in the report. For abnormalities which are highly suggestive

of malignancy, the report should be directly communicated to the referring health care professional in a manner that ensures receipt and documentation of the reports, such as by telephone, fax or registered mail. Where appropriate, further investigations, such as biopsy, may be expedited by the reporting radiologist.

## QUALITY CONTROL

A documented quality control program with procedure manuals and logs should be maintained in accordance with the CAR Mammography Accreditation Program's quality control specifications. Please contact a CAR MAP coordinator in order to receive a copy of the Quality Control Checklists.

### Radiologist

The radiologist will be responsible for ensuring that medical radiation technologists have adequate training and maintenance of competence. He/she or a designate must ensure that the MRTs and medical physicists perform the appropriate tests on schedule, and that all records are properly maintained and that the quality of clinical images is acceptable. Set up and maintenance of digital viewing equipment may require consultation with an Information Systems Specialist.

### Technologist

The medical radiation technologist will be responsible for routine tests including darkroom cleanliness, processing quality control, screen/digital reader cleanliness, view boxes/monitors and viewing conditions, phantom images, artifact testing, visual checklist, repeat analysis, analysis of fixer retention in film, darkroom fog, screen film contact and compression.

### Medical Physicist

The medical physicist will be responsible for the mammographic unit evaluation, collimation assessment, focal spot size and/or resolution measurements, beam quality assessment (half value layer measurements), automatic exposure control system performance assessment, uniformity of screen speed entrance exposure, average glandular dose and artifact evaluation.

Phantom evaluation of image quality, artifact assessment and appropriate tests should be performed on an annual basis.

The CR readers and laser printers (with specifications for mammography use) should undergo regular preventive maintenance as stipulated by the manufacturer, and the QC activity must be carefully recorded (please refer to the CAR MAP requirements).

Monitor calibration is assisted by ISS personnel and medical physicist annual review. Viewing conditions are assessed solely by a medical physicist during their annual review.

*Practice Guideline for Determinants of Image Quality in Digital Mammography* is available online at [www.acr.org](http://www.acr.org).

## QUALITY ASSURANCE

### Outcome data

Systems for reviewing outcome data from mammography should be established. To enable an assessment of the true and false positive rates, the minimum data to be collected include date range of audit, total number of exams performed, number of BI-RADS<sup>®</sup> 0, 4 and 5 cases and biopsy results of all BI-RADS<sup>®</sup> 4 and 5 cases. Data to be collected should include tumour size, nodal status, histologic type, and grade. Screening data should be distinguished from diagnostic data. Where possible, records of false negative mammograms should be collected and the cases analyzed. Cross references with the provincial cancer registry should be performed if possible.

Performance should be correlated against established benchmarks<sup>15</sup>. Please refer to the Public Health Agency of Canada Performance Measures.

### Comparison with previous mammograms

Original images from previous studies should be made available for consultation and second opinion where practical. Where prior images are digitized, the original images should be available for review upon request. Digitized images must be of high quality and must not be used for diagnosis.

## 1.2. DIAGNOSTIC MAMMOGRAPHY AND PROBLEM SOLVING BREAST EVALUATION<sup>14</sup>

In contrast to screening mammography, diagnostic mammography is intended to evaluate patients with clinically detected or screening detected abnormalities.

### DEFINITION

This is a comprehensive imaging evaluation of a patient with a breast mass, nipple discharge, pain, dimpling, an abnormal or questionable screening mammogram, or other physical finding. Women with augmented or reconstructed breasts will be included for diagnostic evaluation if they are not eligible for a screening program. The mammogram should be correlated with the known physical findings and/or symptoms.

If a woman presents for screening mammography and reports a clinical problem, the patient may be converted to diagnostic and should have her report expedited.

The diagnostic (workup) mammogram is planned and tailored for the needs of the individual patient. It should be done under the direct supervision of a radiologist qualified in mammography.

The diagnostic mammogram may be performed along with additional studies, including but not limited to breast sonography, MRI, imaging guided needle biopsy and/or galactography.

### GOAL

A diagnostic evaluation is performed to assess the patient with an abnormal screening mammogram or clinical finding. During diagnostic workup, consideration should be given to time and cost. Protracted investigations should be avoided wherever possible to allow a definitive diagnosis and avoid the anxiety of prolonged follow-up. After interpretation, there should be a specific conclusion and/or additional recommendation for management.

### INDICATIONS

- a) Any male or female with signs and symptoms suggestive of breast cancer, including, but not limited to a palpable abnormality or thickening localized nodularity, dimpling or contour deformity, a persistent focal area of pain, and spontaneous serous or sanguineous nipple discharge from a single duct. Other types of discharges may not

- reflect pathology, and women with such symptoms would be candidates for screening mammography
- b) Women with abnormal screening mammograms
- c) Follow-up of women with previous breast cancer
- d) Short interval follow-up (less than one year for clinical or radiologic concern)
- e) Suspected complications of breast implants
- f) Any circumstance in which direct involvement of the radiologist is required, for example, monitoring sonography, physical examination and/or consultation

### Special Circumstances

- a) **Pregnancy and Lactation:** Elective mammography should not be performed during pregnancy or during lactation because of increased sensitivity to radiation damage in the proliferating breast. Diagnostic investigation starts with targeted ultrasound. However, mammography should be performed if malignancy is suspected. As gadolinium contrast is not recommended for use in pregnancy, enhanced MRI should not be performed in pregnancy unless assessment with MRI is critical to acute patient care and cannot be avoided. MRI can be performed for suspected malignancy during lactation. It is not necessary to suspend breastfeeding after iodinated contrast or gadolinium administration<sup>17</sup>.
- b) Females under the age of 30 with a palpable abnormality or significant symptoms should undergo targeted ultrasound. Thereafter, mammography should be performed if there is suspicion of malignancy<sup>18</sup>.
- c) If a male presents with a breast lump suspicious for malignancy, mammography and/or breast ultrasound is indicated. If the symptoms and history are typical of gynecomastia, clinical exam and follow-up may be all that are required<sup>19</sup>.

### QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

The same criteria apply as for screening mammography (see QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL, above).

### EQUIPMENT

The same specifications for equipment and its use apply as for screening mammography. However, for diagnostic mammography, current standard detector

equipment must have magnification and spot compression capability with a small focal spot of 0.1mm for magnification imaging.

### **SPECIFICATIONS OF THE EXAMINATION**

The nature and site of clinical or mammographic concern should be documented prior to the examination and acknowledged in the report. The location should be described according to various conventions, including the clock face position, breast quadrant, location within the coronal plane and distance from the nipple.

Areas of clinical concern can be marked using radiopaque devices to confirm that the area of interest was included on the image, and to provide positioning guidance. Additional projections, such as spot compression, spot compression with magnification, tangential projections, projections with markers and other specialized projections may be selected by the radiologist. It is preferable to place the area of concern closest to the image receptor.

Both the MRT and supervising radiologist should be aware of any sites of clinical concern to ensure adequate monitoring during the study.

Implant evaluation should include craniocaudal and mediolateral oblique projections, as well as implant displacement views. If displacement views cannot be performed due to immobility of the implant, 90 degree lateral images should be added to the standard views.

Prior images should be obtained for comparison when possible.

Image labelling should conform to the specifications previously cited for screening mammography.

### **THE DIAGNOSTIC REPORT**

All areas of clinical or radiologic concern should be acknowledged in the report. The report should describe the pertinent observations, establish a level of suspicion based upon the imaging findings, and provide specific recommendations for patient management. The report should also document any other breast imaging studies or procedures which have been performed, and should correlate these results with the mammographic findings. Screening recommendations may be included.

The same criteria for reporting and communication of screening mammography apply. However, ACR BI-RADS® should be used for all diagnostic breast imaging.

### **DOUBLE READING AND COMPUTER ASSISTED DETECTION (CAD)<sup>20</sup>**

Double reading of mammograms is performed using two separate individuals to interpret a single mammogram. It is shown to increase the sensitivity with a mild decrease in specificity although this may be improved with arbitration. It is used in some settings, but is limited by cost and manpower limitations.

Computer-assisted detection or computer-aided diagnosis (CAD) is being developed in order to overcome some of the practical limitations of double reading, but while it may result in a modest increase in detected lesions, to date specificity is significantly compromised.

Both double reading and CAD are proven to increase sensitivity, but CAD is shown to decrease specificity more than double reading. Double reading is encouraged where possible, but readers should be aware of the limitations of CAD at the time of writing.

### **1.3 TOMOSYNTHESIS**

Digital Breast Tomosynthesis (DBT), often referred to as “three-dimensional” (3D) mammography, is a form of serial sectioning created by digital reconstruction of multiple mammographic images into overlapping slices. The slices may be adjusted to variable thicknesses, depending on the vendor and/or software used for display. Images are obtained in the same plane as the original compression plane and are read as planar images. Synthetic views are two-dimensional (2D) projection images reconstructed from the information acquired during DBT data acquisition.

Studies comparing DBT with two-dimensional (2D) Digital Mammography (DM) for the investigation of patients recalled due to a questioned abnormality detected on routine mammography have consistently demonstrated a significantly improved specificity with the potential to decrease false-positive recalls by 30%–40%<sup>21, 22, 23, 24, 25, 26</sup>. DBT diminishes the effects of overlapping tissue by displaying one thin section of tissue at a time, and has proven valuable for the detection and evaluation of focal asymmetries, architectural distortion and some apparent masses. DBT has been found to be equal to, or better than, coned compression views for investigating 2D mammographically detected abnormalities<sup>27, 28, 29</sup>. Reader confidence also improves triage for those patients who will not benefit from ultrasound<sup>27</sup>. The ability of DBT to reliably

demonstrate calcifications is less clear; however, some studies have demonstrated promising results that indicate at least equivalent detection of calcifications when compared with 2D DM<sup>30</sup>.

At the time of writing, the radiation dose for a single DBT projection is similar to, or slightly higher than that of a single conventional mammographic image, but well within acceptable dose limits<sup>31, 32</sup>.

To date, several DBT systems are approved by Health Canada.

### CURRENT CLINICAL INDICATIONS:

- Screening: DBT is currently being introduced as a screening tool worldwide. Results of large prospective and retrospective screening trials have demonstrated improved cancer detection rates, and decreased call back rates. To date, the 2 large prospective European screening trials comparing 2D-DM with DBT and 2D-DM have demonstrated decreased recall rates of 15-17% and improved cancer detection rates of 33-53%. A large randomized control trial is currently underway, intending to enroll 67 000 patients at over 30 sites (T-MIST) comparing 2D-DM + DBT with 2D-DM alone. The study is designed primarily to investigate if 2D-DM+DBT has an effect on the screening population and whether it detects lethal cancers (advanced cancers or small cancers with aggressive markers). Many secondary aims including recall rates are being addressed<sup>33, 34, 35, 36, 37, 38</sup>.
- Diagnostic: DBT is useful in diagnostic workup. Early experience among working group members suggests that when working up 2D screening findings, full view tomosynthesis is superior to spot tomosynthesis<sup>39</sup>. When working up full view tomosynthesis findings, ultrasound may be the first choice, especially for mass-like findings; however spot tomo may be useful for workup of some full view tomo findings, particularly areas of subtle architectural distortion.
- MRI directed “second look”: 2<sup>nd</sup> look ultrasound plus DBT found 75% MRI-detected additional findings (52% and 50% for ultrasound alone and DBT alone, respectively)<sup>40</sup>.

### RECOMMENDATIONS:

- Where synthetic views are used without the addition of 2D imaging<sup>41, 42</sup>, it is mandatory to review the tomosynthesis stack. Synthetic-views must not be used independently<sup>43</sup>.
- Where DBT is employed, both screening and diagnostic, it is essential that there is access to advanced breast imaging, which may include tomosynthesis-guided biopsy, second look ultrasound and/or breast MRI. This is in order to aid biopsy of subtle lesions which may not be visible on standard 2D mammography<sup>44</sup>.
- Keep in mind that at the time of writing, synthetic views may underestimate the suspicious morphology of some calcifications, thus liberal use of 2D magnification spot compression views is recommended for any new or indeterminate calcifications<sup>43</sup>.

### Challenges to implementation of DBT at the time of writing include, but are not limited to<sup>45</sup>:

- Interpretation time is at least double that of routine 2D DM<sup>46,47</sup>.
- Protocols optimizing diagnostic accuracy, quality assurance, radiation dose and workflow have not been fully standardized. In particular, the CAR Mammography Accreditation Program (MAP) has not finalized an accreditation protocol specific to tomosynthesis at the time of writing.
- DBT has large digital storage requirements over and above 2D DM. It is recommended that the tomosynthesis stack be stored in addition to the 2D DM and synthetic images for the required retention time. In the future, advances in data compression, storage costs, synthetic view image quality as well as empiric evidence of safety of synthetic-view-only comparison may modify this recommendation.
- Although screening outcome benchmarks are improved with the use of DBT, longitudinal outcomes are as yet unknown.

### **PERSONNEL REQUIREMENTS:**

In addition to standard mammography requirements (see QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL, above), it is recommended that radiologists get an initial 8 hours of specific tomosynthesis training as per the ACR requirement.

Technologists and medical physicists should obtain appropriate training as available.

### **CONTRAINDICATIONS:**

Similar to mammography (see SPECIAL CIRCUMSTANCES, above). No known contraindications particular to tomosynthesis.

## **2. BREAST ULTRASOUND<sup>48</sup>**

Breast Ultrasound is an established, effective, diagnostic imaging technique which employs the use of high-frequency ultrasound waves for imaging, Doppler assessment, and elastography.

### **INDICATIONS**

Appropriate indications for breast sonography include:

- a) Investigation of palpable abnormalities, skin changes and new dimpling (female or male)
- b) Investigation of serous or sanguineous nipple discharge (see NIPPLE DISCHARGE INVESTIGATION AND INTERVENTION, below)
- c) Investigation of focal, persistent, noncyclical breast pain or tenderness
- d) Further evaluation of ambiguous or abnormal mammographic findings.
- e) Initial imaging technique for evaluation of clinical abnormalities in women under 30 years and in lactating and pregnant women<sup>49</sup>
- f) MRI-directed (second-look) ultrasound
- g) Evaluation of problems associated with breast implants
- h) Treatment planning for post-operative brachytherapy
- i) Screening for high risk patients who cannot or are unwilling to undergo MRI screening<sup>50</sup>
- j) Guidance for intervention
- k) Assessment and biopsy of axillary lymph nodes in initial staging of ipsilateral breast lesions that are (or are likely to be) malignant<sup>51</sup>
- l) Follow-up of probably benign sonographic lesions (BI-RADS® 3) such as probable fibroadenomas, and complicated cysts<sup>52</sup>.

Breast sonography is NOT appropriate for:

1. Screening for the general population<sup>53</sup>
2. Ongoing follow-up of proven simple cysts

### **QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL**

#### **Radiologist Credentials Criteria**

Radiologists involved in the performance, supervision and interpretation of breast ultrasound must have a Fellowship or Certification in Diagnostic Radiology with the Royal College of Physicians and Surgeons of Canada and/or the Collège des médecins du Québec. Equivalent foreign radiologist qualifications are also

acceptable if the radiologist is certified by a recognized certifying body and holds a valid provincial license.

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

### **Sonographer Credentials Criteria**

Technologists performing breast sonography should be graduates of an accredited School of Sonography, or have obtained certification from the American Registry of Diagnostic Medical Sonographers (ARDMS), the Canadian Association of Registered Diagnostic Ultrasound Professionals (CARDUP), the Medical Technology Management Institute (MTMI), or the equivalent. Mammography technologists performing breast sonography must have specific qualifications in breast ultrasound. They should also be members of their national or provincial professional organization. Consistent with the requirements of ARDMS or CARDUP, continuing medical education and minimum volumes should be mandatory.

Sonographers should perform breast ultrasounds regularly in order to maintain high level of quality.

### **Supervision and Interpretation of Ultrasound Examinations**

A radiologist must be available for consultation with the sonographer on a case by case basis. Ideally the radiologist should be on site and available to participate actively in the ultrasound examination.

It is recognized however that the geographic realities in Canada do not permit the presence of an on-site radiologist in all locations. Adequate documentation of each examination is critical. A videotape or video-clip record may be useful as an adjunct to the static images in difficult cases. Despite the geographic isolation of a community the reports must be timely. Furthermore, the radiologist must be available by telephone for consultation with the sonographer and the referring health care professional. Where practical, the radiologist should

visit the facility on a regular basis to provide on-site review of ultrasound procedures and sonographer supervision.

## **SPECIFICATIONS OF THE EXAMINATION**

### **Lesion Characterization and Technical Factors<sup>54</sup>**

- a) Breast ultrasound should be performed with as high a resolution as is practical, allowing for the depth and echogenicity of the breast being imaged (see EQUIPMENT SPECIFICATIONS, below). Gain settings and focal zone selections should be optimized to obtain high quality images. It is acknowledged that mass characterization with sonography is highly dependent upon technical factors. Use of different modes and settings (tissue harmonic imaging, spatial and frequency compounding, colour and power Doppler) is encouraged.
- b) The patient should be positioned to minimize the thickness of the portion of the breast being evaluated. Image depth should be adjusted so that the breast tissue dominates the screen and where the chest wall is seen, it should appear at the posterior margin of the image.
- c) The breast sonogram should be correlated with any prior breast imaging, including mammographic, sonographic and MRI studies.
- d) Any lesion or area of interest should be viewed and recorded in two perpendicular projections. One view is insufficient.
- e) At least one set of images of a lesion should be obtained without calipers. The maximal dimensions of a mass should be recorded in at least two dimensions.
- f) Breast mass characterization should be based on the following features: size, shape, orientation, margin, lesion boundary, echo pattern, posterior acoustic features and surrounding tissue. If a shear-wave elastography pattern is available, it should be noted with the KPa relative to the lesion and its ratio with the surrounding tissue (see ELASTOGRAPHY, below).

## **DOCUMENTATION**

Images of all important findings should be recorded on a retrievable and reviewable image storage format. In the case of interventional procedures, this includes the relationship of the needle to the lesion. Images should also include the skin and the chest wall.

Image labelling should include a permanent identification label that contains:

- a) The facility name and location
- b) Examination date
- c) Patient's first and last name
- d) Identification number and/or date of birth
- e) Anatomic location including: side (left/right), orientation of transducer (radial/antiradial, transverse/longitudinal/oblique), quadrant, clock notation, or labelled diagram of the breast and distance from nipple. Depth (using alphabet) may also be used. If alphabet notation is to be used to describe lesion depth, it is recommended that the referring clinicians are educated as to meaning of the nomenclature.
- f) Sonographer and/or radiologist initials or other identifier

The radiologist's report of the sonographic findings should be placed in the patient's medical record.

Retention of the breast sonographic images should be consistent with the policies for retention of mammograms, and in compliance with federal and provincial regulations, local health care facility procedures, and clinical need.

Reporting should be in accordance with *CAR Standard for Communication of Diagnostic Imaging Findings*. As well, the American College of Radiology (ACR) document *Breast Imaging Reporting Data Systems (BI-RADS®)* should be used and is available on request from the ACR office and online at [www.acr.org](http://www.acr.org). A full version can be purchased from the ACR.

## EQUIPMENT SPECIFICATIONS

Breast ultrasound should be performed with a high-resolution and real-time linear array scanner operating at a center frequency of at least 10 MHz with pulsed, colour and power Doppler. Equipment permitting electronic adjustment of focal zone(s) is recommended. In general, the highest frequency capable of adequate penetration to the depth of interest should be used. For evaluation of superficial lesions, a stand-off device or a thick layer of gel may be helpful.

## QUALITY IMPROVEMENT PROGRAMS

Procedures should be systematically monitored and evaluated as part of the overall quality improvement program of the facility. Monitoring should include evaluation of the accuracy of interpretation as well as the appropriateness of the examination.

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

### 2.1. ELASTOGRAPHY<sup>55</sup>

Elastography is a sonographic method of assessing tissue stiffness, taking advantage of the increased stiffness of most cancer tissue. This has proven useful in improving specificity when assessing solid masses, particularly in BI-RADS® category 3 and 4A lesion assessment. It is also shown to have utility in targeting areas of greatest suspicion within a lesion for the purpose of guiding biopsy.

There are two main techniques, qualitative and quantitative. Qualitative elastography results in greater inter-observer variability. For this reason, quantitative elastography, using shear wave propagation, is considered superior at the time of writing.

Limitations of elastography include, but are not limited to, small invasive malignancies, DCIS, papillary lesions, and mucinous carcinoma. Additionally, at the time of writing elastography has not yet been incorporated into the fee structure.

When including elastography in the sonographic assessment of the breast the radiologist should include KPa relative to the lesion and its ratio with the surrounding tissue and the elastography pattern (i.e. homogeneous, heterogeneous, oval shape, etc.) in his/her report.

Elastography should not replace grey scale ultrasound images, but may be a useful adjunct to breast ultrasound.

## 2.2. AUTOMATED WHOLE BREAST ULTRASOUND (AWBUS)

Automated whole breast ultrasound (AWBUS) allows for mechanized performance and recording of ultrasound scans of the whole breast for later review by the radiologist. Images can be reconstructed in 3 dimensions. Depending on the machine used, either static images or dynamic cine-loops of the whole scan are obtained.

AWBUS has potential advantages over hand-held breast US (HHUS), including standardized reproducible examination, dynamic cine-loop of ultrasound scanning, 3D and multiplanar reconstruction capability, reduced dependence on operator skill, decoupling of acquisition and review, and is being explored as a potential tool for breast screening<sup>56</sup>.

At the time of writing, there is insufficient evidence to support widespread adoption of this technology. The real role of AWBUS in daily practice is not yet established.

Limitations include patients with limited cooperation, limited inclusion of the axillary tail and axilla in some cases, and concern about the nipple area and other artifacts. Furthermore, there is no fee code associated with this practice.

Similar to HHUS, the ability to detect DCIS is also limited. Additionally, the cancer detection performance of AWBUS may not be equivalent to HHUS<sup>57</sup>.

## 3. BREAST MRI<sup>58</sup>

### GENERAL PRINCIPLES

Breast MRI has made many advances in clinical imaging in the past decade. While it was an imaging tool used chiefly to image breast implants when the last set of CAR guidelines was introduced, it has become an essential component of breast imaging. It now performs a vital role in the investigation of breast cancer, as well as in screening women at high risk for developing breast cancer. Whether it is used as a problem-solving tool, a screening test, or for staging patients with breast cancer, it has the highest sensitivity for detecting breast cancer of any clinical breast imaging tool available. These guidelines include the current applications of breast MRI, as well as fundamental requirements for breast MRI imaging in clinical practice.

### INDICATIONS/CONTRAINDICATIONS

#### Indications

- a) Breast implants: to determine presence of silicone implant rupture or other complications
- b) Problem solving: in the case of equivocal mammographic clinical and/or US findings. It should not replace the need for a biopsy.
- c) High risk screening: to screen women at high risk for breast cancer, with estimated lifetime risk of greater than 20–25%. This includes women who are BRCA 1 and 2 gene mutation carriers, women who received chest irradiation for treatment of another malignancy such as lymphoma between the ages of 10–30 years of age, PTEN Li-Fraumeni syndrome, Cowden syndrome, or Bannayan-Riley-Ruvalcaba syndrome, or one of these syndromes in first-degree relatives. Information on risk calculation is included in the Screening Mammography INDICATIONS section.
- d) Neo-adjuvant chemotherapy: to assess response to chemotherapy.
- e) Occult breast cancer: to determine the site of a primary carcinoma in a patient presenting with metastatic breast carcinoma such as axillary lymphadenopathy or other site of bony or body metastases when mammograms and breast ultrasound are negative. Also for patients with suspicious bloody or serous nipple discharge and negative mammograms and breast ultrasound.
- f) Peri-operative evaluation: to assess for residual disease.

- g) Pre-operative staging: to assess extent of disease in the affected breast and to screen for occult contralateral malignancy (expected in 3–6% of patients). Although the evidence for assessing extent of disease has shown that at least 16% of additional tumours are found in the affected breast, there is still insufficient evidence that it changes long-term patient outcome.
- h) Intervention: to guide an MRI interventional procedure such as biopsy or localization

### Contraindications

For Contraindications and Safety Information, please refer to the MRI Safety section of the *CAR Standard for Magnetic Resonance Imaging*.

## QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

### The Radiologist and Appropriately Qualified Medical Personnel

Radiologists involved in the performance, supervision and interpretation of magnetic resonance imaging must have a Fellowship or Certification in Diagnostic Radiology with the Royal College of Physicians and Surgeons of Canada and/or the Collège des médecins du Québec. Equivalent foreign radiologist qualifications are also acceptable if the radiologist is certified by a recognized certifying body and holds a valid provincial license.

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

In order to ensure a safe MRI practice, the supervising radiologist should be familiar with the MRI safety literature including the ACR white paper for safe MRI practice, and policies of appropriate contrast and sedation use.

In addition, the interpreting radiologist should practice and possess knowledge of imaging and diagnosis of breast disease. Breast MRI should be practiced in a facility with the capacity for mammography, ultra-

sound and breast intervention, including MRI-guided biopsy. If MRI-guided biopsy is not offered by the facility, a relationship with a referral centre offering MRI-guided biopsy would be required. The results of biopsies initiated based on MRI findings require radiologic-pathologic correlation regardless of where the biopsy is performed. They should also be tracked by the radiologist recommending the biopsy.

A breast MRI accreditation program is not currently available in Canada. The ACR has established an accreditation program for quality assurance of a breast MRI program that can serve as a guideline for a breast MRI practice. The criteria evaluated in the program include:

- a) Establishment and maintenance by the facility of an outcomes audit program to follow-up positive interpretations and correlate histopathology with the imaging findings
- b) Reporting that uses the BI-RADS® terminology and final assessment codes
- c) Calculation of statistics for each radiologist and facility

The responsibilities of the supervising and interpreting radiologist include:

- a) Review and validation of the clinical indication for the examination
- b) MRI protocol
- c) Use and dose of contrast
- d) Ensuring a physician is available when contrast is given
- e) Interpretation of the imaging, including review of pertinent prior breast imaging studies and clinicopathologic review.
- f) Provision of a report
- g) Quality assurance of the imaging examination and interpretation

The CAR endorses the standard for breast MRI radiologist qualification, as developed by the American College of Radiologists. These are as follows:

- Appropriate qualifications as outlined in the first paragraph AND
- Supervise/interpret/report ≥150 breast MRI examinations in last 36 months OR
- Interpret/report ≥100 breast MRI examinations in the last 36 months in a supervised situation
- 15 hours CME in MRI

## Medical Physicists

An MRI medical physicist should perform initial acceptance testing of the MRI system immediately following installation, and prior to any clinical scanning. The medical physicist is preferably someone on site, but they can also be contracted to perform the testing. The credentials of the medical physicist should include a college certification in MRI physics (or other related MRI technology). Furthermore they should also be accredited by either the Canadian College of Physicists in Medicine (CCPM), or one of the affiliated professional engineering societies in Canada (i.e. P.Eng), and shall have specific training and experience in MRI. Training and experience shall include detailed knowledge of the physics of MRI, system components and performance, safety procedures, acceptance testing, and quality control testing. Acceptance testing may be done by a team of medical physicists as long as at least one of the group members has the aforementioned credentials and takes responsibility for signing the report.

## Medical Radiation Technologists

The medical radiation technologist must be certified by the Canadian Association of Medical Radiation Technologists (CAMRT) in the discipline of magnetic resonance, or be registered with the provincial regulatory body and authorized to work in the discipline of magnetic resonance.

The technologist is primarily responsible for performing the MRI scans and maintaining the overall safety of patients, staff and equipment within the MR environment. This includes careful screening and preparation of patients, ensuring patient comfort, adjustment of protocols (if required) to produce high quality, diagnostic scans, technical and quality evaluation of images and relevant quality assurance. MR technologists are also responsible for the MRI room safety and ensuring that no maintenance staff enters the room without direct supervision. All personnel have to be screened and educated about MRI by the MR technologist. MR technologists, if adequately trained, could also perform intravenous gadolinium injections requested by the responsible radiologist. Continued education of MR technologists is encouraged by the CAMRT, and should meet pertinent provincial regulations.

## DOCUMENTATION

Image labelling should include a permanent identification label that contains:

- The facility name and location
- Examination date
- Patient's first and last name
- Identification number and/or date of birth

The radiologist's report of the MRI findings should be placed in the patient's medical record.

Retention of the breast MRI images should be consistent with the policies for retention of mammograms, in compliance with federal and provincial regulations, local health care facility procedures, and clinical need.

Reporting should be in accordance with the *CAR Standard for Communication of Diagnostic Imaging Findings* and should include:

- All pertinent observations
- Areas of clinical or radiologic concern
- Level of suspicion based on imaging findings
- Specific recommendations for patient management
- Documentation/correlation with of pre-existing breast imaging studies or procedures
- BI-RADS® classification

Images of all important findings should be recorded on a retrievable and reviewable image storage format. Images should also include the skin and the chest wall.

## EQUIPMENT SPECIFICATIONS

The MR equipment specifications and performance shall meet all provincial and federal guidelines, including Health Canada guidelines. Health Canada approval is required prior to the scanning of the first patient. It is recommended a system be purchased that is either already approved or in the process of being 510k approved. The guidelines include, but are not limited to, specifications of maximum static magnetic field strength maximum rate of change of magnetic field gradients (dB/dt), maximum radiofrequency (RF) power deposition (specific absorption rate; SAR), and maximum auditory noise levels.

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

## QUALITY CONTROL PROGRAM

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

Following acceptance testing each MRI site will be required to maintain their level of scan quality through the performance and assessment of weekly quality assurance/quality control (QA/QC) testing where appropriate. Acquisition of the test data can be done by an MRI technologist who has been trained by the MRI medical physicist in the QA/QC acquisition procedure. All MRI technologists should be trained to run and assess basic QA/QC scans. Testing is best done on a routine schedule: first thing in the morning prior to clinical scanning. It is highly recommended the site follow the American College of Radiology (ACR) guidelines for this procedure. This requires an ACR phantom and an MRI medical physicist. In the absence of ACR accreditation, other weekly QA/QC procedures can be followed as recommended by the specific MRI vendor. As with acceptance testing, an MRI medical physicist, certified either through the Canadian College of Physicians in Medicine or one of the Canadian Professional Engineering societies, and having specific training and experience in MRI, is required to analyze and maintain a record of the QA/QC data.

A quality control program with written procedures and logs shall be maintained at the MR site. The ongoing quality control program assesses relative changes in system performance as determined by an MR technologist and medical physicist. It is highly recommended that a qualified MRI medical physicist (see QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL, above) is consulted at least once per year to assess QA/QC results and provide recommendations (if any).

## Quality Control Tests

The following quality control tests shall be performed and documented:

- a) measurement of central frequency
- b) measurement of system signal-to-noise ratio on a standard head or body coil
- c) table positioning
- d) geometric accuracy
- e) high and low contrast resolution
- f) artifact analysis

## Performance Evaluation Tests

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

- review of daily quality control testing records
- measurement of image uniformity
- measurement of spatial linearity
- measurement of high contrast spatial resolution
- measurement of slice thickness, locations and separations
- assessment of image quality and image artifacts
  - eddy current compensation
  - system shim

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

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

## PROTOCOLS

Breast MRI protocols should be used to provide information on high-spatial resolution morphology, functional information on perfusion and capillary leakage, and tissue T1 and T2 relaxation times.

A dedicated breast coil is required for all cases of breast MRI. Only implant assessments do not require the intravenous injection of gadolinium chelates; all other indications for breast MRI currently need an IV injection of gadolinium. The standard dose of 0.1 mg/kg gadolinium is used, and is optimized with a power injector at a rate of 2–3 mls/sec, followed by a 10–20 ml saline flush.

The angiogenic activity of cancers constitutes the basis for breast cancer detection with breast magnetic resonance imaging.

## HIGH-SPATIAL RESOLUTION SEQUENCES

Breast MRI is the most sensitive imaging method currently available for demonstration of invasive breast cancer. However, angiogenic activity is not the only factor responsible for enhancement of the breast. Other conditions such as inflammatory processes in the breast, and increased hormonal activity, may also result in enhancing lesions. Similar to mammographic principles, high spatial resolution images are required to best evaluate the borders of enhancing lesions, and to determine the most likely diagnosis. Higher spatial resolution increases the specificity and sensitivity of the MRI. The sensitivity of Breast MRI is maximized by correlation with the timing of menstrual cycle. When feasible, Breast MRI should be performed between days 7–14 of the menstrual cycle.

Patients should undergo standard mammography prior to breast MRI, and the mammography study and report should be available for review at the time of interpretation of the MRI. The prior mammograms should have been performed six months or less before the MRI examination.

## BASIC REQUIREMENTS FOR BREAST MRI

- a) A dedicated breast coil. There are several available coils on the market.
- b) Temporal resolution of 1–3 minutes or less, ideally 60–90 seconds per acquisition.
- c) Dynamic imaging, acquiring a stack of images temporally at least 3 times, 1 pre and at least 2 post-bolus injection of contrast. The first post-dynamic contrast enhanced sequences (DCES) should be no later than 180 seconds after the contrast injection. The last set of images should be no earlier than 6 to 8 minutes after the contrast injection.
- d) Spatial resolution that uses the largest imaging matrix within the acquisition window. In-plane pixel size of 0.5 X 0.5 to 1.0 X 1.0 mm and through plane pixel size of 1–3 mm.
- e) All DCES requires a T1-weighted gradient echo (GRE) sequence that meets the requirements of adequate temporal resolution. This may be achieved with 2D multi-section or three-dimensional (3D), fast (turbo) or regular, spoiled or nonspoiled. Compared with 2D imaging, 3D imaging has the advantage of stronger T1 contrast, and uses a shorter repetition time than 2D, with a higher signal-to-noise ratio, which allows for thinner (higher spatial resolution) sections to be acquired.
- f) All 3D (2D T1 and T2 requires a certain range of TR to produce the appropriate DCES) should use the shortest possible repetition time and a large flip angle (larger with longer repetition times, usually 90 degrees for 2D and 25–50 degrees for 3D-GRE). Parallel imaging has enabled maximal spatial and temporal resolution.
- g) Current bilateral dynamic protocols use the transverse, sagittal, or coronal planes, and may be vendor-specific to optimise spatial and temporal resolution. If isotropic imaging is used, images can be successfully reformatted in all planes for viewing.
- h) Bilateral breast imaging protocols are required for all women undergoing screening (women at increased risk for breast cancer), and anyone undergoing staging for a known breast cancer. This allows assessment of the contralateral breast, and facilitates comparison to avoid diagnostic errors. There are very few indications where unilateral breast imaging is utilized.
- i) Fat suppression is ideally applied to the dynamic pulse sequences, but should not be used at the expense of temporal or spatial resolution. Fat

suppression may be achieved by a number of methods. This is most commonly achieved through active fat suppression or fat saturation, by eliminating signal from fatty tissue, or by choosing selective water excitation. Active fat suppression requires a very homogeneous field across the entire FOV, which may be difficult to achieve with breast imaging, given the structure of the breasts. Manually choosing a specific region of fat in the breast by which to “shim” the fat signal greatly helps improve the fat saturation. Some of the inhomogeneous fat suppression may also be subtracted out.

- j) Kinetic data is acquired by visual assessment of the enhancement pattern, and by placing a region of interest (ROI) over the enhancing area. No more than 3–4 pixels should be included in the ROI, to minimize inaccurate averaging of the enhancement. The edges or maximally enhancing areas are the best to evaluate. A kinetic curve is generated with dedicated software. It should be recognized that the window widths and levels may vary between sequences and that it is important for accurate visual assessment that the early and delayed contrast enhanced images should be displayed with the same window width and level.
- k) GRE T2 with or without fat saturation for evaluation of fluid, cysts, edema in the breasts.

### Additional Sequences

- GRE T1 without fat saturation- for evaluation of fat, lymph nodes, and architecture of the breast and to see clip placed after previous image guided biopsy
- May use the body coil to evaluate lymph nodes in the axillary and internal mammary nodal stations, cervical and supraclavicular areas
- Axial and sagittal STIR with water saturation sequences may be used to determine the integrity of breast implants

### QUALITY ASSURANCE<sup>59</sup>

Each facility should establish and maintain a medical outcomes audit program to followup positive assessments and to correlate pathology results with the interpreting radiologist’s findings. The audit should include evaluation of the accuracy of interpretation, as well as appropriate clinical indications for the examination. Each center performing breast MRI should be able to obtain the correlative pathology results by

means of correlation with mammographic, sonographic and or MRI guided biopsies Each facility should also adhere to an established quality control program for magnets and coils that includes scanning a phantom. Facilities must use the *Breast Imaging Reporting and Data System (BI-RADS®)* for final assessment codes, and for the terminology used for reporting and tracking outcomes (available at [www.acr.org](http://www.acr.org)).

### 3.1. DIFFUSION WEIGHTED IMAGING<sup>60</sup>

Diffusion-weighted imaging (DWI) is a relatively new and promising technique which may be added to routine Breast MRI in order to potentially improve specificity of the MRI examination. DWI is a modality which relies on the use of MR imaging to depict the diffusivity of water molecules within a lesion. It relies on the principle that water may diffuse more readily in lesions with decreased cellularity or high water content (such as benign lesions) vs. those with increased cellularity or decreased water content (such as carcinomas). DWI may therefore allow differentiation of benign from malignant lesions, although few clinical studies are yet available to confirm this.

Technical requirements for performing DWI include proper breast positioning within the breast coil, and uniform shimming and fat suppression. It should be performed before the administration of a contrast agent to minimize the effect of the contrast material. Spin-echo echoplanar DWI is the most popular clinical technique for generating DW images. Two diffusion-sensitizing gradients are “sandwiched” around a 180 degree radiofrequency (RF) refocusing pulse before echoplanar imaging data collection. The strength of these gradients is often expressed in the b- value of the scan, which determines the strength of the diffusion weighting. The value of the diffusion of water in tissue is called the apparent diffusion coefficient (ADC) value, and is measured in square millimetres per second, and defined by the average area covered by a molecule per unit tissue. It is taken as the measured signal intensities from at least two b- values (e.g. 0 and 1000 s/mm<sup>2</sup>). Both 1.5 and 3.0 T field strength magnets may be used with DWI, with inherent advantages and disadvantages that are beyond the scope of these guidelines. The optimal b-values have yet to be determined, and the b-value exerts great influence on signal intensity and determination of the ADC value. No specific thresholds for ADC

values have been set, but it is recognized that malignant tumours have lower ADC values than benign ones, with some overlap. Early evidence suggests that non-invasive tumours have higher ADC values than invasive tumours. The clinical benefit of DWI still requires more study.

### **3.2. SPECTROSCOPY**

MR Spectroscopy (MRS) has also been used as an adjunct to Contrast-enhanced Breast MRI, as a method of improving the specificity of Breast MRI. It relies on the principle that MRS can measure the amount of a metabolite called choline in suspected breast lesions. In most cases, elevated levels of choline are a strong indicator of malignancy. However, not all breast cancers demonstrate elevated choline levels, and MRS cannot detect small lesions (<1 cm). The first and most studied application for Breast MRS is to distinguish benign from malignant lesions before biopsy. An overall sensitivity of 83% and specificity of 85% have been reported in several studies. A second and perhaps more promising application is the use of Breast MRS for predicting response to cancer treatment. 1.5 T magnets have been used with MRS, but the higher signal-to-noise ratio of higher field strength magnets (e.g. 3T) is helpful to maximizing the benefit of MRS.

## **4. ALTERNATIVE IMAGING METHODS**

### **4.1. THERMOGRAPHY<sup>61</sup>**

Breast Thermography is thermal imaging using an infrared camera to produce a map of the patterns of heat and blood flow near the surface of the breast. Thermography is an unproven modality in breast cancer detection. It is not an alternative to mammography and there is no evidence to support its clinical use.

## **5. EMERGING TECHNOLOGIES**

Emerging technologies carry some promise, but have not as yet been statistically proven effective in screening or diagnosis of breast disease, and should be considered experimental. These include, but are not limited to: Digital Optical Breast Imaging (DOBI), electrical impedance studies, CT laser mammography, and transillumination.

# SECTION B: BREAST INTERVENTION

## I. GENERAL PRINCIPLES<sup>62</sup>

Breast interventional procedures may be diagnostic, therapeutic, or both. Diagnostic procedures include, but are not limited to pre-surgical wire localization, fine needle aspiration (FNAB) biopsy, spring-loaded core needle biopsy (CNB) and vacuum-assisted breast biopsy (VAB). Diagnostic/therapeutic procedures include cyst aspiration and abscess drainage. There are also some emerging image-guided therapeutic procedures which are detailed near the end of the guideline.

Image guidance should be used for biopsy of both palpable and impalpable masses provided that the mass is visualized. Palpation guidance is only necessary if the lesion is not seen by any imaging method.

The shortest distance from the skin to the lesion should be used when possible.

Image guided percutaneous biopsy is superior to open surgical biopsy for several reasons, including increased accuracy, decreased cost and wait times, and decreased surgical morbidity and cosmetic deformity<sup>63</sup>.

In this guideline biopsy and non-biopsy procedures are separated due to the need for discussion of points specific to pathology and follow-up. Stereotactic and ultrasound-guided biopsies are discussed together while MRI guided procedures are treated separately because of significant differences from the other guidance modalities, including the indications and use of contrast. These separations are somewhat arbitrary and some crossover exists.

## 2. BIOPSIES

### 2.1. SELECTION OF IMAGE GUIDANCE MODALITY

The percutaneous intervention guidance modality should be the modality with which the salient lesion is best visualized. In some cases, the lesion is visualized equally by more than one modality. For these lesions, other deciding factors should be considered, including accessibility/wait times, cost, patient comfort, operator preference and radiation exposure.

#### MAMMOGRAPHIC GUIDANCE

The use of mammography images for intervention procedures is now reserved almost exclusively to galactography (ductography) and pre-operative localization with an alpha numeric grid.

#### STEREOTACTIC GUIDANCE

Stereotactic guidance is a method of localizing a lesion in 3 dimensions using 2 angled mammographic images and computerized calculation of the depth (or Z-axis) using parallax. When available, stereotactic guidance is preferred over grid-type mammographic guidance because it is more accurate for the calculation of the Z position of a lesion, is faster, and requires less radiation. Stereotactic guidance may be used for any lesion which is mammographically visible. Stereotactic guidance can be used for lesions which are visible on one projection only. Both add-on units and prone tables are acceptable for stereotactic guidance.

#### ULTRASOUND GUIDANCE

Ultrasound guidance can be used when a lesion (usually a mass or lymph node) is visualized sonographically. Prior to the performance of any ultrasound-guided percutaneous procedure, the finding should be assessed sonographically.

#### MRI GUIDANCE

MRI guided intervention is required when a lesion that looks suspicious on Breast MRI (BI-RADS® 4 or 5) does not have a sonographic correlate on MRI-directed US, or mammographic correlate. The incidence of malignancy of such lesions is in the order of 25–30%<sup>64</sup>, similar to the

PPV of mammographic detected lesions. A suspicious lesion on MRI with no ultrasound or mammographic correlate requires tissue diagnosis. All centers providing Breast MRI service are required to provide MRI-guided biopsies, or to have an established referral pattern with a center providing this service.

## 2.2. PERFORMANCE OF BREAST BIOPSY

### STEREOTACTIC AND ULTRASOUND GUIDED BIOPSIES

#### I. INDICATIONS/CONTRAINDICATIONS FOR BIOPSY UNDER STEREOTACTIC AND ULTRASOUND GUIDANCE

##### Indications

###### Cysts

Including complicated cysts, defined as having an imperceptible wall, acoustic enhancement, and low-level echoes

- If a lesion is proven cystic, intervention is not indicated unless patient is symptomatic, although patient preference or distress may also prompt aspiration
- If an infection/abscess is suspected, the procedure may be both diagnostic and therapeutic

###### Masses

Including complex cysts, defined as having a thick (perceptible) wall and/or thick ( $\geq 0.5$  mm) septations, intracystic or mixed cystic and solid masses (at least 50% cystic), or predominantly solid masses with eccentric cystic foci<sup>65</sup>.

Image-guided percutaneous biopsy is indicated for:

- a) BI-RADS<sup>®</sup> 4 and 5 lesions
- b) Targeted suspicious mammographic- or ultrasound-detected lesions following MRI
- c) BI-RADS<sup>®</sup> 3 lesions at patient request
- d) Repeat biopsy, as an alternative to open surgical biopsy (preferably with a larger gauge needle than the original biopsy)

Multiple lesions may require multiple biopsies if multifocal or multicentric malignancy is suspected.

##### Axillary Nodes

Axillary node biopsy is performed under ultrasound guidance. It may be required as part of pre-operative staging for the patient with a suspicious lesion or known breast cancer if nodes have suspicious features<sup>66</sup>. These include, but are not limited to:

- Cortical thickening and/or eccentric bulging ( $>2.5$  mm or more than half the width of the node)
- Small, deformed or absent hilum
- Abnormal flow (hyperemia in hilum and central cortex and/or non-hilar flow)<sup>67</sup>

The abnormal cortex should be targeted, and a smaller gauge (i.e.  $< 14$  gauge) core or FNAB may be used (see BIOPSY NEEDLE SELECTION, below). Caution is required due to the proximity of large nerves and vessels in the axilla.

Node biopsy may be performed at the time of core biopsy of the index lesion.

##### Contraindications

- Inability to visualize lesion (absolute)
- Significant allergy to local anesthetic agent (relative)

The risks of reversing anticoagulation often outweigh the potential complications of local hemorrhage in anticoagulated patients. Discussion with the referring physician on a case by case basis is recommended if reversal of anticoagulation is considered. For further guidance, please refer to the Society of Interventional Radiology document, *Consensus Guidelines for Periprocedural Management of Coagulation Status and Hemostasis Risk in Percutaneous Image-guided Interventions*. ([http://www.sirweb.org/clinical/cpg/Consensus\\_Guidelines\\_for\\_Periprocedural\\_Management\\_of\\_Coagulation\\_Malloy.pdf](http://www.sirweb.org/clinical/cpg/Consensus_Guidelines_for_Periprocedural_Management_of_Coagulation_Malloy.pdf))

#### II. BIOPSY NEEDLE SELECTION

Biopsy needle selection is based on several factors, including:

- a) **Accuracy of sampling:** In general, the larger the needle (and the contiguous sample size), the more likely that the preoperative diagnosis will be accurate and that there will be a lower likelihood of false negative biopsy or upgrading to a higher degree of malignancy at surgery<sup>68</sup>. A lower upgrade rate is desirable, as it decreases the

number of operations a patient may need to achieve definitive treatment.

- b) **Lesion type:** Certain lesions may be preferentially sampled with VAB in order to avoid underestimation, for example complex cystic lesions<sup>69</sup>, and clustered calcifications. Conversely, FNAB is accepted for axillary node biopsy.
- c) **Ease of use:** For some lesions, the choice of needle may be influenced by challenges in penetration of the lesion. For example, very scirrhous or sclerotic lesions may be difficult to penetrate with a large gauge core needle, or may result in bending of the needle. In this scenario, existing options include: dissection of tissues with anesthetics, firing the core needle in the projected path, use of a manual trocar to create a tunnel leading to the lesion, or vacuum assisted biopsy as VAB may ease penetration of dense fibrous tissue. Using a smaller gauge needle may be a last resort, but if using a needle smaller than 14 gauge, dialogue with the pathologist is recommended and careful radiologic-pathologic correlation is required to determine if the sample is adequate. If there is suspicion of undersampling or radiologic-pathologic discordance, repeat biopsy with a larger gauge needle is recommended (see RADIOLOGIC-PATHOLOGIC CORRELATION, below).
- d) **Safety:** In the case of lesions located very close to vital structures, including axillary structures, initial biopsy may be performed with a small gauge or non-advancing core needle. A fine needle may also be a last resort in order to avoid trauma to surrounding structures and FNAB is widely used for axillary lymph node biopsy. This may vary with operator preference, but choice of a needle smaller than 14 gauge increases the risk of undersampling/upgrading if used for assessment of the index lesion (see SPRING-LOADED 14 GAUGE NEEDLE, below).
- e) **Cost:** In general, needle cost increases as needle caliber increases, with fine needles being least expensive and vacuum assisted needles most costly. However, this cost must be weighed against the cost of increased frequency of repeat or two-stage surgery to achieve definitive treatment if lesions are undersampled or upgraded.
- f) **Access:** The availability of equipment and expertise may vary in remote or rural locations.

- g) **Imaging modality:** MRI guided biopsy is almost exclusively VAB, whereas all types of needle are used for ultrasound guided procedures. Stereotactic biopsies can be performed with spring-loaded and vacuum-assisted needles.

### Fine Needle Aspiration Biopsy

Fine Needle Aspiration Biopsy (FNAB) is defined as using a fine needle to obtain cells for cytology examination.

#### Indications

- Axillary node biopsy when staging a known or suspected ipsilateral breast malignancy<sup>70</sup>
- Expediting the investigation and surgical referral of a very suspicious mass in the setting of a dedicated rapid diagnosis clinic or remote location prior to definitive large core biopsy. FNAB should not be used to exclude malignancy.
- Investigation of suspected multicentric/multifocal malignancy when the index lesion has undergone definitive biopsy, although this should preferably be performed in collaboration with the surgeon and with on-site cytopathologist support.
- Diagnosis of a solid mass when spring-loaded core or VAB is not feasible due to patient factors.

#### Caveats

- Unless there is strong, preferably on-site cytopathologist support, 14 gauge spring-loaded core or VAB should be performed instead of FNAB for diagnosis of the index lesion.
- Cytology (FNAB) is not the preferred method of obtaining a pre-operative diagnosis of breast lesion<sup>71</sup>.
- FNAB is NOT appropriate for assessment of calcifications without a focal solid mass lesion.
- Tumour biomarker assessment cannot be performed with FNAB samples.

### Spring-loaded 14 Gauge Needle

Biopsy of any breast lesion should be performed with a core biopsy needle, either spring-loaded or vacuum assisted. When using an automated spring-loaded biopsy device, 14 gauge needle (or larger) is recommended<sup>72</sup>. If there is suspicion of radiologic-pathologic discordance, repeat biopsy with a larger needle is required (see RADIOLOGIC-PATHOLOGIC CORRELATION, below). A minimum of four (4) 14 gauge cores is recommended for

solid masses<sup>73</sup> and a minimum of ten (10) 14 gauge cores is recommended for calcifications<sup>74</sup> to minimize the risk of undersampling. If using a needle smaller than 14 gauge, the number of cores may have to be further increased to achieve an adequate sample and very careful radiologic-pathologic correlation and follow-up/audit are required. Maintaining a dialogue with the pathologist helps to ensure quality diagnosis.

### **Vacuum-assisted Needles**

Vacuum-assisted needles (14-7 gauge) are used to obtain a larger sample than either 14 gauge spring-loaded core or fine needles can provide. A larger contiguous sample size results in improved ability to make an accurate pre-operative diagnosis, significantly reducing the upgrade rate at subsequent surgery and thus decreasing the need for two-stage surgical procedures<sup>75</sup>.

Vacuum assisted biopsy (VAB) is commonly used with stereotactic guidance to sample clustered calcifications and is associated with decreased upgrading at surgery<sup>76</sup>. MRI-guided biopsies are almost exclusively performed using VAB.

VAB may also be used as a next step for further assessment following spring-loaded core biopsy when there is discordant pathology or insufficient sampling.

### **MRI GUIDED BIOPSY**

For MRI-guided biopsies, vacuum assistance is preferable<sup>77</sup> as ample evidence has shown that the MRI-detected lesions are small, with a high incidence of atypia, and have a higher underestimation rate than with stereotactic biopsies<sup>78</sup>. 14 gauge spring-loaded core biopsy often yields insufficient samples for diagnosis and requires extreme precision in targeting. This degree of precision, which is often challenging when conducting MRI biopsies and when targeting a lesion, is dependent on its relative position to the overlying grid.

The breast is stabilized with light to moderate compression between grid plates. Excessive compression has been shown to interfere with lesion enhancement. A pre-contrast image may be obtained to confirm that the breast is adequately positioned so that the targeted lesion lies within the area of accessibility. If necessary, the patient can be repositioned (for example, if the lesion is posterior to the area of accessibility). A post-contrast sequence is obtained to confirm

presence of the lesion. Approximately 10% of lesions will not persist<sup>79</sup>. If not seen on MRI, a six month follow-up is recommended for confirmation. Targeting can be performed with computer software assistance or calculation of the x, y, and z coordinates from the images. x, y are determined from counting over on the grid and referencing a marker placed on the grid such as a vitamin E capsule, or other fiducial. The z coordinate is determined based on the slice thickness used. Imaging in the sagittal and axial planes with the co-axial sheath and imaging obturator is required to confirm accurate placement. Post biopsy imaging is then required, to demonstrate adequate sampling of the lesion. It is recommended to perform a 6 month follow-up MRI after a concordant benign pathology result is obtained, as post-biopsy changes make it difficult to confirm accurate sampling based on MR images at the time of biopsy.

When a marker is placed, post-procedure mammography should be performed in two orthogonal views to document tissue marker position, and the report should state the position in relation to the biopsy site (see BIOPSY MARKERS later in document).

The physician's report of MRI-guided breast intervention should include:

- a) Procedure performed
- b) Designation of left or right breast
- c) Description and location of the lesion
- d) Approach used
- e) Type and amount of contrast material
- f) Type of local anesthesia
- g) Skin incision, if made
- h) Gauge of needle and type of device (spring-loaded, vacuum-assisted, etc.)
- i) Number of specimen cores or samples, if applicable
- j) Tissue marker placement, if performed, with specification of name and shape of metallic localization clip
- k) Complications and treatment, if any
- l) Post-procedure mammogram, if obtained, documenting tissue marker placement and location of the marker with respect to the biopsied lesion

For any lesion that is benign and concordant, a follow-up breast MRI is recommended in 6 months to document stability.

### 2.3. NIPPLE DISCHARGE INVESTIGATION AND INTERVENTION<sup>80</sup>

Nipple discharge is a common symptom, but investigation depends on the characteristics of the secretion.

Low risk secretion is defined as expressible only, bilateral, arising from multiple duct orifices, and greenish or milky. Low risk secretions are most likely the result of hyperprolactinemia, duct ectasia, and/or fibrocystic change with or without identifiable communicating cysts. Low risk secretion does not require imaging work-up.

High risk nipple discharge is defined as spontaneous, unilateral and arising from a single duct orifice. This discharge may be clear, serous, serosanguineous, or frankly bloody. High risk discharge is more likely to be caused by carcinoma or papillary lesions and necessitates further investigation. Fluid cytology may be performed, but is only useful when positive<sup>81</sup>. In the case of single duct nipple discharge, incidence of malignant or high-risk pathology is reported to be as high as 15%.

Ultrasound is the initial investigation. If the cause for nipple discharge is a suspected papillary lesion, biopsy should be performed. FNAB is strongly discouraged (see BIOPSY NEEDLE SELECTION, above).

Ultrasound may fail to show lesions that are not associated with abnormally ectatic ducts or lesions that lie too far peripherally. If ultrasound shows no cause, or a nonspecific cause such as duct ectasia, galactography may be performed. Emerging evidence suggests that Breast MRI is a useful tool in the assessment of suspicious nipple discharge<sup>82</sup>, and may be performed in patients with negative mammograms and US, often demonstrating unexpected pathology. Additionally, MRI may be more widely accessible than galactography.

For papillary lesions that are palpable or symptomatic, the use of VAB alone, without further surgical excision, is not recommended even when the pathology report indicates that the papillary lesion has been completely removed at the time of VAB (see RADIOLOGIC-PATHOLOGIC CORRELATION, below).

### 2.4. COMPLICATIONS OF BREAST INTERVENTION

- allergy to local anesthetic
- lidocaine toxicity
- infection
- hematoma (most common with VAB)
- trauma to chest wall/pneumothorax
- trauma to neurovascular structures in axilla
- implant perforation
- milk fistula (during lactation)

### 2.5. SUBMISSION OF PATHOLOGY SPECIMEN(S)

Submitting a specimen for histopathology is a request for a consultant opinion. For this opinion to be effective, accurate identification and good preservation of the specimen are essential. Providing good clinical details is vital as the histopathological findings are interpreted in the clinical context.

The requisition should be properly filled out with the following information:

- patient complete name, age, date of birth, and collection date
- clinical history
- side and source of tissue
- number of needle core biopsies submitted

Specimen containers should be labelled completely with patient information, collection site, date and physician's name. When multiple specimens are to be examined and diagnosed individually, each specimen must be submitted in a separate container completely labelled as indicated above

As a general rule, specimens should be placed in buffered formalin within approximately ten minutes of their removal from the patient. Increased cold ischemic time will interfere with the assessment and staining of the tissues. The volume of formalin is ideally twenty times that of the specimen, but for very large specimens this may be reduced to ten times the volume of the specimen. Very small specimens should be placed in formalin almost immediately (within one or two minutes depending on the size); otherwise marked drying artifacts will occur. Larger specimens with a high fat content, which float, may be covered within a few layers of paper towels to allow formalin to reach the upper surface of the specimen.

The container obviously must be able to accommodate the specimen plus many times its volume in formalin. The specimens should fit through the opening of the container with ease.

## **2.6. RADIOLOGIC-PATHOLOGIC CORRELATION<sup>83</sup>**

Following receipt of the pathology report, an addendum to the biopsy report should be produced by the radiologist in charge of the biopsy or by his/her assigned proxy when required to expedite results. This addendum should include the radiologist's opinion on radiologic-pathologic concordance or discordance as well as a suggestion for the appropriate management follow-up, such as the need for further imaging, imaging follow-up, repeat biopsy or surgical consultation. Discussion with the pathologist is encouraged when determining appropriate management.

For concordant lesions with a definitive benign diagnosis (e.g. lymph node, fibroadenoma), follow-up should be considered at a year. For lesions with concordant benign diagnosis that is nonspecific (e.g., fibrocystic change, apocrine metaplasia, benign/fibrous breast tissue) a six-month assessment as well as longer term follow-up may be prudent in order to decrease the chance of missed diagnosis<sup>84</sup>.

In cases of insufficient sampling, repeat biopsy should be recommended, preferably using a method that achieves a larger sample size than that of the original biopsy.

For some lesions, excision may be required due to a high rate of underestimation/upgrading. These lesions include, but are not limited to: atypia (including ADH, ALH, and FEA) LCIS, papillary lesions, radial scar, mucinous lesions, spindle cell lesions, phyllodes tumour, microcalcifications not associated with a specific pathology, but suspicious of origin in DCIS and recurrent residual malignancy following radiotherapy.

Where possible, correlation with final surgical pathology is encouraged based on clinical grounds and multidisciplinary consultation.

## **2.7. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL INVOLVED IN BREAST BIOPSY**

### **Radiologist and Technologist**

#### **Credentials Criteria**

Radiologist, technologist, sonographer, and MR technologist credentials are discussed in the Breast Imaging section of this document.

For MRI guided breast interventions there are specific additional requirements: the radiologist must be qualified to interpret Breast MRI, have a minimum of 3 hours of CME in breast MRI intervention and experience in performing percutaneous breast biopsies. Maintenance of certification requires performing 6 breast MRIs every 2 years, alone or with supervision from another radiologist, 3 hours of Breast MRI biopsy CME every 3 years, and radiologic-pathologic correlation of all biopsies.

### **SPECIFICATIONS OF THE EXAMINATION**

The decision to perform an interventional procedure should conform to the general principles noted above. If ultrasound guidance is used, a complete planning ultrasound examination should be performed, including the mass and, particularly if there is suspicion of malignancy, axillary regions. If stereotactic guidance is used, pre-procedure images should be obtained, ensuring that the area of concern is located within the region of the paddle fenestration.

Benefits, limitations, and risks of the procedure as well as alternative procedures should be discussed with the patient. Informed consent should be obtained and documented.

The breast, the probe or stereotactic equipment, and the field in which the procedure is to be performed should be prepared in conformity with the principles of cleanliness to minimize the risk of infection.

For ultrasound-guided biopsy, the skin entry site and region of needle sampling should be evaluated with colour Doppler before biopsy. Any sizeable artery should be avoided. Using a high-frequency transducer, continuous visualization of the needle is possible and desirable. The length of the needle, particularly the tip,

should be visible during the examination, particularly immediately prior to and during deployment of a spring-loaded device. The needle axis should be kept as parallel to the chest wall as possible.

For stereotactic biopsy, the operating radiologist must perform or supervise lesion targeting. Needle position should be imaged during targeting and sampling.

Documentation of needle position during sampling should be retained as part of the medical record.

If using ultrasound guidance, compression may be applied after each needle pass. Hemostasis should be achieved, using direct compression, after the procedure has been completed.

Post-procedure imaging should be performed. Mammographic images should be performed if calcifications have been sampled or if there has been placement of a radiopaque marker. Calcifications should be confirmed on a specimen radiograph. If calcifications are not present on specimen radiography the risk of insufficient sampling is greater than if there is calcification retrieval<sup>85</sup>.

If there is a reason to suspect that the patient may be a candidate for neoadjuvant chemotherapy, a radiopaque marker should be placed. Also, consider requesting biomarker assessment. The latter cannot be performed with FNAB specimens.

## **2.8. DOCUMENTATION**

A permanent record of interventional procedures should be documented on a retrievable image storage format.

Images showing the biopsy needle within the lesion on at least one pass are required. If there is concern that partial volume averaging has simulated traversing a very small lesion, a transverse image with the needle within the lesion is recommended to document the position of the biopsy needle within the lesion. For VAB an image of the lesion in the aperture of the needle is required.

### **Imaging labelling should include permanent identification containing:**

- a) Facility name and location
- b) Examination date
- c) Patient's first and last names
- d) Identification number and/or date of birth
- e) Right or Left breast
- f) Measurement of lesion in three planes
- g) Location of the lesion in the breast using diagram, clock, or other consistent notation
- h) Distance from the nipple
- i) Image of the needle within the lesion (Two orthogonal projections may be required for small lesion)

### **The radiologist's report of ultrasound-guided interventional procedures of the breast should include:**

- a) Procedure performed
- b) Right or Left breast
- c) Gauge of biopsy needle
- d) Number of passes/cores
- e) Type and amount of local anesthesia
- f) Location of the lesion in the breast using diagrammatic, clock, or other consistent notation
- g) Immediate complications and treatment, if any
- h) Specimen radiograph or sonogram and results, if performed
- i) Clip placement, if performed
- j) Post-procedure mammography and/or sonography, if performed

### **Post-procedure patient follow-up should include:**

- Identification of delayed complications and required treatment, if any
- Record of communications with the patient and/or referring health care professional
- Radiologic-pathologic correlation report/addendum including follow-up recommendations

Retention of biopsy and specimen images should be compliant with federal and state policies, local health care facility procedures, and clinical need.

The radiologist who performs the procedure is responsible for obtaining pathology results and must determine if the lesion has been adequately biopsied. An addendum to the biopsy report should be produced by the radiologist in charge of the biopsy or by his/her assigned proxy when required to expedite results. (See RADIOLOGIC-PATHOLOGIC CORRELATION, above). These results should be communicated to the referring health care professional or to the patient, as appropriate. These communications should be documented in accordance with the *CAR Standard for Communication of Diagnostic Imaging Findings*.

## **2.9. EQUIPMENT SPECIFICATIONS**

Breast ultrasound should be performed with a high-resolution real-time linear array scanner operating at a center frequency of at least 10 MHz with pulsed, colour and power Doppler. Equipment permitting electronic adjustment of focal zone(s) is recommended. In general, the highest frequency capable of adequate penetration to the depth of interest should be used.

Stereotactic biopsy may be performed with a dedicated prone setup or with an add-on device and adjustable chair. All equipment must be calibrated as per the manufacturer guidelines.

MRI equipment specifications are discussed in the Breast Imaging MRI EQUIPMENT SPECIFICATIONS section.

## **2.10. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION CONCERNS**

Results of all imaging-guided percutaneous breast interventional procedures should be systematically monitored and evaluated. Performance should be correlated against established benchmarks. Please refer to the Public Health Agency of Canada *Report from the Evaluation Indicators Working Group: Guidelines for Monitoring Breast Screening Program Performance – Second Edition*.

The number and type(s) of procedures, numbers of cancers and benign lesions and the number of repeat biopsies (including information on the reason and type of needle) should be recorded for each facility and individual radiologist. Additionally, the numbers of inconclusive or discordant results, inadequate samples, and recommendations for re-biopsy or complete excision of a lesion should be recorded.

Imaging findings and pathologic interpretations should be correlated in every instance and provisions for review of these findings should be made. Biopsy follow-up should be performed to detect and record false-negative and false-positive results.

As with all interventional procedures, the procedure should be fully described and the relative risks, limitations, benefits, and alternatives should be explained to the patient. Informed consent should be recorded. Incidence of complications and adverse reactions, where known, should be recorded and periodically reviewed in order to identify opportunities to improve patient care.

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

## 3. NON-BIOPSY INTERVENTION

### 3.1. PERIOPERATIVE LOCALIZATION AND IMAGING

#### HOOK WIRE<sup>86</sup>

Wire localization is performed in order to guide excision of an impalpable breast lesion. It should be performed using a flexible wire specifically designed for breast localization. As wire localization is a multidisciplinary procedure, there should be ongoing communication between the surgical team and the radiological team regarding preferences for documentation and needle type.

Localization can be performed under either mammographic, ultrasound or MRI guidance. Mammographic guidance can be either stereotactic or grid-based. Wire placement should be performed the same day as the surgical excision and as close as possible to the time of surgery, in order to minimize the risk of wire migration.

The localization wire should be placed with the intent to traverse the lesion and extend a short distance beyond the lesion. The shortest distance from the skin to the lesion should be used when possible. For large lesions, particularly large clusters of calcifications, bracketing wire localization can be performed in order to roughly outline the extent of the lesion with 2 or more wires.

Orthogonal (CC and 90 degree mediolateral) mammographic images should be gently performed immediately after wire placement.

Documentation of the localization should be forwarded to the surgeon along with pre- and post-localization breast images. Documentation may include a simple diagrammatic representation of the localization, as well as pertinent measurements, including, but not limited to:

- a) Identifying patient data and side of lesion
- b) Relationship between wire, lesion and breast anatomic landmarks, such as:
  - size of lesion
  - Total length of wire
  - Length of wire below the skin
  - Distance from lesion to skin
  - Length of wire beyond lesion

- c) Contact info/pager # of radiologist performing localization

The radiologist should be available for discussion at the time of surgery.

#### SURGICAL SPECIMEN IMAGING

Surgical specimen radiography should be performed for lesions which have been localized with image guidance. If a lesion is visible sonographically, specimen sonography can be performed. The pertinent imaging studies should be available for review at the time of the specimen image review, and this may require several days notice if prior images must be acquired. The radiologist placing the wire and/or his proxy interpreting the specimen images are responsible for the complete knowledge of all pertinent imaging. If the patient is being reviewed while under general anaesthetic, consideration should be given to the timeliness of the specimen review and the surgical team should coordinate with the radiology team so that the radiologist is available at short notice to review the images. The specimen should be appropriately identified and marked for orientation by the surgical team. The lesion should be identified, and the closest margins between the lesion and the edge of the specimen should be reported, acknowledging the limitations resulting from the fact that specimen radiography imaging is often 2 dimensional. The specimen images should be compared with the preoperative images in order to determine if the entire lesion has been excised. If there is a localizing device/clip in place, this should be noted, along with any pertinent details of placement.

If it is felt that the lesion has not been fully excised, this should be communicated to the surgeon immediately.

The pathologist should have access to the specimen images in order to identify areas of interest.

#### RADIOACTIVE SEED LOCALIZATION<sup>87</sup>

RSL was developed to overcome some of the drawbacks of conventional wire localization, specifically, the potential for transaction of the guide wire, the conflict between ideal skin entry sites for radiologists and surgeons and scheduling difficulties. Overall, RSL facilitates breast surgery for the patient and makes lead up procedures more comfortable.

Radioactive seed localization (RSL) is performed to guide excision of an impalpable breast lesion. RSL utilizes a titanium seed containing a small amount of radioactive material that serves to allow localization of a breast lesion during surgery. Radiation exposure due to RSL has been determined to comply with radiation exposure regulations.

Localization can be performed under either ultrasound or mammographic guidance. The seed should be placed within the lesion, and its position should be confirmed with mammography after the localization procedure. Placement may be performed up to five days prior to surgery. During surgery, a hand-held Geiger counter is used to detect the specific location of the seed. As RSL is a multidisciplinary procedure, there should be ongoing communication between the surgical team and the radiological team regarding preferences for documentation, equipment, etc.

Documentation of the localization should be forwarded to the surgeon along with pre- and post-localization breast images. Documentation should include a simple diagrammatic representation of the localization as well as pertinent measurements, including, but not limited to:

- a) Identifying patient data
- b) Size of lesion
- c) Distance from lesion to skin
- d) Contact info/pager # of radiologist performing localization
- e) The radiologist should be available for discussion at the time of surgery

### BIOPSY MARKERS

Placement of a radiologically and/or ultrasound visible clip/marker or, alternatively, carbon-marking of the track is indicated in the following situations:

- a) Any lesion which may be difficult to identify at follow up or subsequent localization
- b) Complete or near-complete removal at sampling
- c) Modification of the lesion after biopsy to an extent that the lesion is no longer recognizable with imaging (e.g., small, solid intracystic lesions or clusters of microcalcifications)
- d) Lesion for which the distribution or morphology may create ambiguity in the event that a wire-localization is needed (e.g., multiple lesions, microcalcifications superimposing with other microcalcifications or asymmetric density/

architectural distortion seen and biopsied under ultrasound guidance)

- e) Lesions that may fulfill criteria for neo-adjuvant chemotherapy
- f) All lesions biopsied under MRI guidance
- g) Any lesion which may be confused with similar adjacent lesions

Note that purposely leaving behind suspicious microcalcifications as a “natural” marker is not recommended as this may result in under-sampling of the lesion.

Where there is more than one clip placed in the same breast, different shaped clips should be used at the biopsy site(s).

Post-biopsy mammograms are mandatory when a marker has been left in place during the biopsy. Comments on the positioning of the marker, in relation to the location of the lesion biopsied should be included in the report.

Radiopaque marker migration and misplacement may occur following biopsy and can be troublesome if there has been complete excision of the visible portion of the lesion at biopsy<sup>88</sup>.

### 3.2. ABSCESS DRAINAGE AND CYST ASPIRATION<sup>89</sup>

Suspected abscess should be imaged with ultrasound. Percutaneous ultrasound drainage should be performed if the cavity is less than 3 cm in size. Cavities greater than 3 cm in size may require catheter drainage and occasional surgical incision and drainage. An 18 gauge or larger needle may be required<sup>90</sup>.

Percutaneous aspiration of a cyst may be performed in the following situations:

- a) Diagnostic uncertainty – complicated cyst vs. a solid mass if the solid mass would otherwise need biopsy
- b) Painful cysts
- c) Cyst recurrence after a previous aspiration
- d) Patient anxiety

The fluid aspirated from cysts can be discarded without pathology assessment if the fluid is non-bloody<sup>91</sup>. If there are any suspicious features such as sanguineous fluid or a non-collapsing lesion, a clip can be placed to localize the lesion and the fluid should be sent to cytology.

Following abscess drainage, the patient and specimen should be dealt with in a manner consistent with the protocol for abscess drainage care at the institution at which the procedure was performed.

### **3.3. IMAGE-GUIDED BREAST THERAPY**

The following technologies are a selection of breast imaging and/or treatment options that are currently active areas of research. Though widely investigated and reported upon, these technologies are not widespread in use and require additional investigations before they can be incorporated into common practice. This guide serves simply as an introduction to these techniques.

#### **HIGH INTENSITY FOCUSED ULTRASOUND<sup>92</sup>**

High intensity focused ultrasound (HIFU) is a non-invasive therapy option that has recently been developed. HIFU provides an alternative to surgical interventions by using external high intensity ultrasound beams to create heat and selectively cause cell death without compromising any external tissue. Magnetic Resonance Imaging (MRI) is used to guide and monitor the therapy. This non-invasive technique is thought to be more psychologically and cosmetically acceptable to patients, and more suitable for treating patients who are not (ideal) surgical candidates.

Research has shown that HIFU has the potential to provide a non-invasive replacement for lumpectomy. It has not however, been conclusively shown that the destruction of malignant breast tissue using HIFU is equivalent to conventional surgery outcomes. A HIFU treatment method has recently gained FDA approval for treating uterine fibroids, a promising development for breast HIFU.

#### **LASER INTERSTITIAL THERAPY<sup>93</sup>**

Laser interstitial therapy (LITT) is a minimally-invasive therapy option that uses laser energy to hyperthermally cause cell death to a target tissue volume [1]. LITT in breast is commonly administered using stereotactic guidance but is also performed using magnetic resonance imaging (MRI) as well as stereotactically. To date a considerable amount of research surrounding LITT methods has involved theoretical or animal models.

#### **RADIOFREQUENCY ABLATION<sup>94</sup>**

Radiofrequency ablation (RFA) is an upcoming technology that has been developed as a minimally invasive option for the treatment of breast masses. The treatment utilizes frictional heat generated by an electrode placed within a mass. Radiofrequency ablation is performed under real-time ultrasound guidance and monitoring.

RFA has demonstrated promising results in tumours within liver, brain, kidney, pancreas and prostate tissue. Initial trials using RFA for the treatment of breast cancer have yielded high rates of tumour destruction and low complication rates, however more research is needed.

#### **CRYOSURGERY<sup>95</sup>**

Cryosurgery is an ablation procedure that uses freezing to destroy diseased tissue. Cryoablation treatment is minimally invasive and locally destroys target tissue without requiring resection. Cryoablation surgery can also be used to encompass a non-palpable tumour in order to provide a palpable marker for surgeons before resection. Cryoablation surgery is advantageous over other ablation techniques as the phase change that occurs during ice formation can be visualized on ultrasound, the modality most commonly used to undertake and monitor the treatment.

Cryoablation surgery has been used extensively to treat benign breast abnormalities and is currently being explored as a potential therapy option for malignant tumours.

### **3.4. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL FOR BREAST INTERVENTION**

Radiologist, technologist, sonographer, and MR technologist credentials are discussed in the Breast Imaging section of this document.

For MRI guided breast interventions there are specific additional requirements: the radiologist must be qualified to interpret Breast MRI, have a minimum of 3 hours of CME in breast MRI intervention and experience in performing percutaneous breast biopsies. Maintenance of certification requires performing 6 breast MRIs every 2 years, alone or with supervision from another radiologist, 3 hours of Breast MRI biopsy CME every 3 years, and radiologic-pathologic correlation of all biopsies.

### **3.5. SPECIFICATIONS OF THE EXAMINATION**

The decision to perform an interventional procedure should conform to the general principles noted above. If ultrasound guidance is used, a pre-procedure planning ultrasound examination should be performed, including the area of concern and, particularly if there is suspicion of malignancy, the axillary regions. If stereotactic guidance is used, pre-procedure images should be obtained, ensuring that the area of concern is located within the region of the paddle fenestration.

Benefits, limitations, and risks of the procedure as well as alternative procedures should be discussed with the patient. Informed consent should be obtained and documented.

The breast, the probe or stereotactic equipment, and the field in which the procedure is to be performed should be prepared in conformity with the principles of cleanliness to minimize the risk of infection.

For ultrasound-guided intervention, the skin entry site and projected needle path should be evaluated with colour Doppler before biopsy. Any sizeable artery should be avoided. Using a high-frequency transducer, continuous visualization of the needle is possible and desirable. The length of the needle, particularly the tip, should be visible during the examination, particularly immediately prior to and during deployment of a spring-loaded device. The needle axis should be kept as parallel to the chest wall as possible.

For stereotactic intervention, the operating radiologist must perform or supervise lesion targeting. Needle/wire position should be imaged during targeting and sampling.

Documentation of needle/wire position during the procedure or after localization should be retained as part of the medical record.

If using ultrasound guidance, compression should be applied after each needle pass. Hemostasis should be achieved, using direct compression, after the procedure has been completed.

Post-procedure imaging should be performed. Mammographic images should be performed if calcifications are within the area of interest or if there has been placement of a radiopaque marker or wire.

### **3.6. DOCUMENTATION**

A permanent record of interventional procedures should be documented on a retrievable image storage format. Specific details of documentation vary with the type of procedure performed. Retention of procedure imaging should be compliant with federal and provincial policies, with local health care facility procedures, and with clinical need.

The radiologist who performs the procedure is responsible for obtaining any pathology results and must determine if the lesion has been adequately aspirated, biopsied, localized or ablated.

These communications should be documented in accordance with the *CAR Standard for Communication of Diagnostic Imaging Findings*.

### **3.7. EQUIPMENT SPECIFICATIONS**

Breast ultrasound should be performed with a high-resolution and real-time linear array scanner operating at a center frequency of at least 10 MHz with pulsed, colour and power Doppler. Equipment permitting electronic adjustment of focal zone(s) is recommended. In general, the highest frequency capable of adequate penetration to the depth of interest should be used.

Stereotactic localization may be performed with a dedicated prone setup or with an add-on device and adjustable chair. All equipment must be calibrated by the manufacturer and must also undergo calibration and acceptance testing by the medical physicist.

MRI equipment specifications are discussed in the Breast Imaging MRI EQUIPMENT SPECIFICATIONS section.

### **3.8. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION CONCERNS**

Results of all imaging-guided percutaneous breast interventional procedures should be systematically monitored and evaluated. Performance should be correlated against established benchmarks. Please refer to the Public Health Agency of Canada *Report from the Evaluation Indicators Working Group: Guidelines for Monitoring Breast Screening Program Performance – Second Edition*.

The numbers of procedures should be kept for each institution and each radiologist. Where possible, follow-up should include any instances of failed procedure and/or post-procedure infection.

As with all interventional procedures, the procedure should be fully described and the relative risks, limitations, benefits, and alternatives should be explained to the patient. Informed consent should be recorded. Incidence of complications and adverse reactions, where known, should be recorded and periodically reviewed in order to identify opportunities to improve patient care.

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

# APPENDIX A – BI-RADS® AND OTHER REPORTING AND DATA RESOURCES

The American College of Radiology developed BI-RADS® as a means of standardizing terminology, reporting and assessment for mammography, ultrasound and MRI. Details on data collection and auditing of results as well as peer review and quality assurance are included in this document. The complete BI-RADS® Atlas includes details and explanations beyond the scope of this document and referral to excerpted text from that document ([www.acr.org](http://www.acr.org)) is recommended. Links are included at the end of this document. A full version of the BI-RADS® Atlas is available for purchase from the ACR.

All Breast Imaging reports should use the lexicon and assessment categories as outlined in the BI-RADS® Atlas.

The Canadian Breast Cancer Screening Initiative and the Quality Determinants Working Group through the Public Health Agency of Canada have developed several relevant documents, including *Quality Determinants of Organized Screening Programs in Canada* and *Guidelines for Monitoring Breast Screening Program Performance*. These documents also include details on auditing as well as core indicators relevant to screening programs and diagnostic breast imaging. These documents are regularly updated to reflect current practice and standards. In addition to following the links above, these can be accessed at the Public Health Agency of Canada website (<http://www.phac-aspc.gc.ca>).

## RELEVANT LINKS

Canadian Association of Radiologists ([www.car.ca](http://www.car.ca))

Canadian Association of Radiologists Mammography Accreditation Program  
(<http://www.car.ca/en/accreditation/map.aspx>)

American College of Radiology ([www.acr.org](http://www.acr.org))

ACR BI-RADS® Atlas Mammography Fourth edition  
(<http://www.acr.org/Quality-Safety/Resources/BIRADS/Mammography>)

ACR BI-RADS® Atlas Ultrasound First edition  
(<http://www.acr.org/Quality-Safety/Resources/BIRADS/Ultrasound>)

ACR BI-RADS® Atlas MRI First edition  
(<http://www.acr.org/Quality-Safety/Resources/BIRADS/MRI>)

ACR Breast MRI Accreditation Requirements  
(<http://www.acr.org/Quality-Safety/Accreditation/BreastMRI>)

ACR Breast Imaging and Intervention Practice Guidelines and Technical Standards  
(<http://www.acr.org/Quality-Safety/Standards-Guidelines>)

ACR Appropriateness Criteria®  
(<http://www.acr.org/Quality-Safety/Appropriateness-Criteria>)

ACR, SBI Statement on ACRIN Breast Ultrasound Trial Results and Role of Ultrasound in Breast Imaging Care  
(<http://www.acr.org/About-Us/Media-Center/Position-Statements/Position-Statements-Folder/ACR-Statement-Regarding-the-Digital-Mammographic-Imaging-Screening-Trial-DMIST-Results>)

AIUM Practice Guideline for the Performance of a Breast Ultrasound Examination  
([http://www.acr.org/~media/ACR/Documents/PGTS/guidelines/US\\_Breast.pdf](http://www.acr.org/~media/ACR/Documents/PGTS/guidelines/US_Breast.pdf))

Public Health Agency of Canada. Program Performance Measures  
([http://www.phac-aspc.gc.ca/publicat/2007/gmbspp-ldsppdcs/pdf/gmbspp-ldsppdcs\\_e.pdf](http://www.phac-aspc.gc.ca/publicat/2007/gmbspp-ldsppdcs/pdf/gmbspp-ldsppdcs_e.pdf))

Health Canada Canadian Mammography Quality Guidelines  
(<http://www.hc-sc.gc.ca/ewh-semt/pubs/radiation/02hecs-sesc267/index-eng.php>)

MDALL – Your reference tool for licensed medical devices in Canada  
([www.mdall.ca](http://www.mdall.ca))

Integrating the Healthcare Enterprise  
([www.ihe.net](http://www.ihe.net))

IBIS Breast Cancer risk evaluation tool  
(<http://www.ems-trials.org/riskevaluator/>)

The National Comprehensive Cancer Network (NCCN)®  
([www.nccn.org](http://www.nccn.org))

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